

ASSESSMENT CENTERSM

USER MANUAL

Version 9.6

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What Is Assessment Center?

Assessment Center is a free, online research management tool. It enables researchers to create study-specific websites for capturing participant data securely. Studies can include measures within the Assessment Center library as well as custom instruments created or entered by the researcher. PROMIS instruments (short forms, CATs, profiles) are a central feature of the instrument library within Assessment Center. Any PROMIS measure can be downloaded for administration on paper or be included in an online study. Detailed statistical information and development history about PROMIS items and instruments is available for review.

Assessment Center enables customization of item or instruments (e.g., format, randomization, skip patterns), real-time scoring of CATs, storage of protected health information in a separate, secure database, automated accrual reports, real-time data export, graphing of individual PROMIS CAT or Profile scores, and ability to capture endorsement of online consent forms among many other features.

SPONSORS

<u>PROMIS</u>	<u>Neuro-QOL</u>	<u>NIH TOOLBOX</u>
http://www.nihpromis.org	http://www.neuroqol.org	http://www.nihtoolbox.org

Registration

How do I register?

Before you can work within the Assessment Center, you must register. This includes setting up a Login and password, as well as providing other information regarding your institution, how to contact you, etc. and agreeing to Assessment Center Terms and Conditions.

To register yourself as a new user, click on the Register New User link on the Assessment Center homepage: <http://assessmentcenter.net/>. Your password must be at least six characters. You may use any combination of letters, numbers, or special characters to create a password.

To complete the registration process, you must log into Assessment Center. Once you have created a registration record, enter your Login and password on the homepage and click Continue. After you have logged in at least once, your name will appear on the Assessment Center user list and you may be included as a team member on any applicable Assessment Center study.

Register New User

1. Click Register New User Link
2. Complete all required registration fields
3. Click Register button.
4. Navigate to Assessment Center homepage
5. Enter Login and password
6. Click Continue

[Register New User](#)
[Forgot Password](#)

Resources

- [Instrument Library](#)
- [Scoring Manuals](#)
- [Workshops](#)
- [Publications](#)
- [Presentations](#)
- [User Manuals](#)
- [Glossary](#)
- [Terms and Conditions](#)
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- [Release History](#)
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WHAT IS ASSESSMENT CENTERSM

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- Patient-Reported Outcomes Measurement Information System (PROMIS)
- Quality of Life in Neurological Diseases (Neuro-QOL)
- NIH Toolbox

Among other important features, Assessment Center also enables:

- Downloading library instruments for administration on paper
- Customization of items or instruments (e.g., format, randomization, skip patterns)
- Real-time scoring of CATs and short forms
- Storage of protected health information (PHI) in a separate, secure database
- Automated accrual reports
- Real-time data export
- Ability to capture endorsement of online consent forms

ANNOUNCEMENTS

- **Additional PROMIS Instruments now available in Spanish:** See the Instrument Library link at left to see what PROMIS instruments are available in Spanish.
- **New PROMIS Computer Adaptive Tests for Upper Extremity Function and Mobility:** Physical Function can now be assessed specifically for upper or lower body function. The full Physical Function CAT remains available.
- **Updated versions of some PROMIS Instruments:** Some PROMIS item banks have had minor modifications (typically removal of 1-2 items).

Demonstration CAT

Try out a PROMIS Computerized Adaptive Test and get an instant score report. CATs include Emotional, Physical, and Social Health. Click here to begin.



[Request PDFs of PROMIS Short Forms](#)

Sponsors

- [PROMIS](#)
- [Neuro-QOL](#)
- [NIH Toolbox](#)

Studies of Interest

[PROsetta Stone](#)

Assessment Center reserves the right to have regular scheduled maintenance windows. Weekly maintenance may be performed on Sunday mornings from 7am to 9am CST. During this time, Assessment Center may be unavailable. We apologize for any inconvenience this may have. If you have any questions, please contact us at help@assessmentcenter.net

Contact Us
help@assessmentcenter.net
Help Line: 877-283-0596

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Required Fields

Any field with an asterisk (*) means it's required and you must enter valid information.

Several registration elements are required to be unique across Assessment Center, i.e., the registration elements cannot already exist in Assessment Center. These elements include Login and the combination of last name, first name and institution. If another user has already registered with the same combination of last name, first name and institution, you must change at least one of these three registration elements.

Registration step 1: Please complete fields below.

Login*	<input type="text"/>	<input type="button" value="Save"/> <input type="button" value="Cancel"/>
Password*	<input type="password"/>	
Re-enter Password*	<input type="password"/>	
Title	<input type="text"/>	
First Name*	<input type="text"/>	
Last Name*	<input type="text"/>	
Institution*	<input type="text"/>	
Email*	<input type="text"/>	
Re-enter Email*	<input type="text"/>	
Phone	<input type="text"/>	
Mailing Address	<input type="text"/>	
City	<input type="text"/>	
State/Province	Please Select <input type="text"/>	
Country	<input type="text"/>	
Postal Code	<input type="text"/>	
Single Sign On ID	<input type="text"/>	

Assessment CenterSM

You are required to agree to the Assessment Center Terms and Conditions. The terms and conditions will appear in a pop-up window once you have clicked Save on the User Registration page. You will want to review the entire document and then click on the Accept button to move forward. The Assessment Center Terms and Conditions address issues related to software security, use and copyrights. You will also be required to accept study specific terms and conditions within the application as they relate to certain publicly available instruments.

The screenshot shows the Assessment Center User Registration page. A pop-up window titled "ASSESSMENT CENTER TERMS AND CONDITIONS" is displayed over the registration form. The pop-up window includes the following text:

ASSESSMENT CENTER TERMS AND CONDITIONS
Last Updated 1/21/2011

You understand and agree that the services that Northwestern University - Department of Medical Social Sciences (NU-MSS) provides to you through the Assessment Center websites are subject to the following Terms and Conditions (TAC). NU-MSS reserves the right to update the TAC at any time. Changes in the TAC will apply to new users and to new projects created by existing users after these changes are posted. The most current version of the TAC can be reviewed by clicking on the "Terms and Conditions" hypertext link located on the Assessment Center Home page.

DESCRIPTION OF SERVICES.

Assessment Center provides you with access to a variety of resources, including survey measures, study administration, data management, and storage of statistical analysis results (collectively, the "Services"). The Services, including any updates, enhancements, and/or new features are subject to the TAC, and your use of the Services constitutes acceptance of all terms and conditions set forth in the TAC.

PRIVACY AND PROTECTION OF PERSONAL INFORMATION.

At the bottom of the pop-up window, there are two buttons: "Accept" (highlighted with a red box) and "Cancel".

The background registration form includes fields for: User ID*, Password*, Re-enter Password*, Title, First Name*, Last Name*, Institution*, Email*, Phone, Mailing Address, City, and State/Province (with a dropdown menu showing "Please Select").

What if I do not have a Login?

If you are a first-time visitor to Assessment Center and do not have a Login, click on the Register New User link on the Assessment Center homepage found at www.assessmentcenter.net. Then, complete required information.

What if I forgot my Login?

If you have a Login but cannot remember it, contact the Assessment Center Administrator:

Email: help@assessmentcenter.net

Assessment Center support line: 1-877-283-0596

What if I forgot my password?

If you remember your Login but not your password, enter your Login and click on the Forgot Password link.

Assessment Center will automatically email your password to you at the address currently on file in your Login.

[Register New User](#)[Forgot Password](#)

Resources

- [Instrument Library](#)
- [Scoring Manuals](#)
- [Workshops](#)
- [Publications](#)
- [Presentations](#)
- [User Manual](#)
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help@assessmentcenter.net
Help Line: 877-283-0596

Support Hours:
9:00am - 5:00pm CST
Monday - Friday

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ANNOUNCEMENTS

PROMIS and Assessment Center Workshop in Chicago, February 17, 2012

Learn more about PROMIS, item response theory, computerized adaptive testing, and Assessment Center at a full day workshop in downtown Chicago on Friday, February 17, 2012. For more information, click on the Workshop hyperlink to the left.

New Feature: Setup and administer assessments in English and Spanish

Assessment Center can now administer the same study in English and Spanish. A researcher can create a study and allow a participant to choose to view instruments in English or Spanish. The researcher is responsible for uploading Spanish versions of instruments. Additional features (consent, registration) will be enabled in Spanish in the next release. Future development will enable data collection in other languages.

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Sponsors

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- [Neuro-QOL](#)
- [NIH Toolbox](#)

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How could I quickly access instrument PDFs?

A subset of PROMIS instrument PDFs are available from a button on the Assessment Center homepage. Click the Request PROMIS PDFs button to initiate the process of downloading PDFs. A short registration and acceptance of PROMIS Terms & Conditions is required prior to obtaining the PDFs. An email will be sent to the address provided containing a link to a zip file from which the instrument PDFs may be accessed.

[Register New User](#)[Forgot Password](#)

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Alternatively, you may log into Assessment Center zip files of PROMIS Instrument PDFs are available from the PDF link in the upper right hand corner of the application. This provides quick access to PROMIS instruments without having to navigate further into Assessment Center. You must agree to the terms and conditions in order to access the PROMIS instrument zip files.

PROMIS PDFs

Below are PROMIS Instruments in PDF format. Prior to downloading, you must accept the terms of use. Click on ©, read the terms of use, and click agree to accept.

Study	Document	Date Published	Terms of Use	
PROMIS	PROMIS Adult Item Banks	02/13/2011	©	Endorsed 01/10/2013
PROMIS	PROMIS Adult Short Forms	02/13/2011	©	Endorsed 01/10/2013
PROMIS	PROMIS Cancer Item Banks	03/22/2012	©	Endorsed 01/10/2013
PROMIS	PROMIS Adult Profile 29, 43, 57	04/16/2009	©	Endorsed 01/10/2013
PROMIS	PROMIS Pediatric Profile 25, 37, 49	04/16/2011	©	Endorsed 01/10/2013
PROMIS	PROMIS Pediatric Short Forms	06/12/2009	©	Endorsed 01/10/2013
PROMIS	PROMIS Sexual Function Profiles	06/20/2012	©	Endorsed 01/10/2013
PROMIS	PROMIS Parent Proxy Item Banks and Short Forms	07/07/2011	©	Endorsed 01/10/2013
PROMIS	PROMIS Pediatric Item Banks	09/09/2011	©	Endorsed 01/10/2013
PROMIS	PROMIS Adult Profile Short Forms Investigator	09/26/2010	©	Endorsed 01/10/2013
PROMIS	PROMIS Adult Profile Short Forms Participant	09/26/2010	©	Endorsed 01/10/2013
PROMIS	PROMIS Sexual Function User Manual	10/19/2011	©	Endorsed 01/10/2013

Studies

MyStudies List

The first screen you access in Assessment Center will be the Study List page within the Studies tab. Note that you may have multiple studies and name them whatever you wish. In the MyStudies list, you will see studies which you have created and studies in which you have been identified as a team member. The MyStudies list first organizes your studies by the most recently accessed, and then in alphabetical order. Select any study from this list by clicking the study name hyperlink. The system will default the current study to the last study you worked on in Assessment Center.

- **Name:** name of the study
- **Created By:** who created the study and when
- **Properties:** Name, Description and Study Status
- **Team:** Other users you designate as part of your study

Create a Study

Why do I need to create a Study?

The structure of Assessment Center is based around studies. All research activities conducted within Assessment Center are nested under a study. This enables users to keep research activities separate and move from the various stages of research easily, i.e. instrument selection to data collection.

To create a new Study, you must click on the Create New Study button and fill out the Study Properties page. Study Names must be unique across Assessment Center.

Assessment CenterSM

Create New Study

1. Click Create New Study button to generate a blank Study Properties page
2. Complete Study Properties criteria
3. Click Save button
4. Confirm new study has been established

The screenshot shows the Assessment Center web application interface. At the top, there is a navigation bar with tabs for 'Studies', 'Instruments', 'Set-up', 'Assemble', and 'Administration'. On the right side of the navigation bar, there are links for 'PDFs', 'Admin', 'My Account', 'Help', and 'Logout'. Below the navigation bar, the current study is identified as 'Current Study: PROMIS'. The main content area is titled 'Study List (PROMIS)' and contains a 'Study List' section. Below this section, there is a 'Create New Study' button highlighted with a red box. Below the button, there is a text prompt 'To select, click on study name:' and a 'Hide Archived Studies' checkbox. A table titled 'My Studies' is displayed below the text prompt. The table has columns for 'Name', 'Created By', 'Properties', and 'Team'. The table contains four rows of study data.

Name	Created By	Properties	Team
PROMIS	Hanrahan, Rachel (7/3/2007)	Properties	Team
1st time Practice	ALDERSON, JETTIE (7/17/2009)	Properties	Team
6723 Sat with Social Roles_Profile_29	Hanrahan, Rachel (7/17/2013)	Properties	Team
6916_ProxyDepSansLocal	Hanrahan, Rachel (7/19/2013)	Properties	Team

How many studies should I create?

Assessment Center will allow you to administer instruments from its library as well as create your own instruments. If you have a number of instruments to create, we suggest making a “master” study in which you will create and manage all of your custom study instruments. This study will not be launched as it is not intended to be used in data collection. Instead, it is a workspace within Assessment Center to maintain instruments, create new instruments and modify existing instruments.

When your custom instruments are finalized and you wish to add instruments from the master study to other studies access the Instrument Properties page and change the Status field from Under Development to Administered. Then, you can add these custom instruments to any other study.

Why would I need to break up my project into multiple studies within Assessment Center?

You may find that you need to have multiple data collection websites (and therefore Assessment Center studies) for your research plan. This happens if you need to administer different consent forms to different participants. For example, you may have one Assessment Center study with a Lombardi Cancer Center consent form and a second Assessment Center study that is identical in content except that it has a Fred Hutchinson Cancer Center consent form.

You may also want different URLs if participants are self-registering, but need to receive different instruments. For example, one Assessment Center URL may be advertised on a breast cancer support website for a study that includes both global and breast cancer-specific measures but a different Assessment Center URL may be advertised on a prostate cancer website for a study that contains the global and prostate cancer-specific instruments.

What should I do when I have completed a study?

If your data collection and export are complete, you have the option to Archive a study. You should only select this status if all work within Assessment Center is complete. Archived studies remain in Assessment Center for historical review, although you do have the option to hide Archived studies.

Archive Study

1. Find existing study
2. Select Properties link
3. Mark Study Status to Archived

Assessment CenterSM

Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Current Study: AC User Manual_Example

[Study List \(AC User Manual_Example\)](#) >> Study Properties

Study Properties

Name of Study* AC User Manual_Exan Save Back

Description* AC User Manual_Example

Study Status* Active Archived

(*) fields are required.

Study Team

How do I determine my study team?

You may want to add other Assessment Center users to your study team. Adding others to a study team will enable these users to view your study and, depending on the roles you assign them, conduct various study-related tasks, e.g. pick instruments or export data. It is important to carefully consider who should be added to your study and what roles, i.e. permissions, these users should be assigned. All team members will need to have registered and logged into Assessment Center at least once before they may be added to your team.

Designate which team members you want to be part of your study, as well as their roles, by first selecting the Team hyperlink from the Studies page. The All Users list box on the left of the Study Team page lists the names of all users across all institutions registered in Assessment Center. To add one of these users to your study, click on that person's name, then click the right arrow button. The user will be moved from the All Users box to the Team Members for Current Study box.

Assign Team Members to Study

1. Click Team link
2. Highlight desired team member's name
3. Use arrows to add member to Team
4. Assign member appropriate permissions by checking role boxes, repeat if necessary

Assessment CenterSM

Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Current Study: AC User Manual_Example

Study List (AC User Manual_Example)

Study List

To get started, please select an existing study or create a new one. Then continue work in the system by selecting from the tabs above.

[Create New Study](#)

To select, click on study name: Hide Archived Studies

My Studies			
Name	Created By	Properties	Team
AC User Manual_Example	Hanrahan, Rachel (4/7/2014)	Properties	Team
6723_Sat_with_Social_Roles_Profile_29		Properties	Team
6916_ProxyDepSansLocal	Hanrahan, Rachel (7/19/2013)	Properties	Team
6916_Score_Ver_AnxPeds_DepPeds_Proxy	Hanrahan, Rachel (7/19/2013)	Properties	Team

Who can see my work on this study, in particular participants' data?

Team members will be able to view information in your study, based on their roles. Assessment Center users that are not part of the study team will not have access to any study information or participant data. You may want to click on the Team feature to ensure the team role assignments are appropriate. New team members are automatically assigned the role of Associate; this role has read-only access to study elements. To reassign roles, select a team member's name, and then check the Role box(s) that best identifies their responsibilities within the study.

The only roles that will be able to view participants' data and personal health information (PHI) are Study Administrator, Study Participant Administrator, Study Data Entry Administrator, and Data & Statistics Administrator. It is important to be very thoughtful when assigning these roles. Only the Study Data Entry Administrator may edit participant data while only the Data & Statistics Administrator may export raw data files.

You can check more than one Role box for your team members, in any combination that is useful to you. Each role has very specific rights. For example, some roles allow a team member to modify items whereas some roles allow a team member to manage participant data. It is likely that you will assign team members to multiple roles unless you have a very large team with individuals holding narrow responsibilities.

Team Roles

- **Study Administrator:** Creates studies and manages the team; may view participant data
- **Instrument/Item Administrator:** Creates instruments; adds instruments to study; enters set-up elements
- **Study Participant Administrator:** Recruits participants; manages study; may view participant data
- **Study Data Entry Administrator:** Enters and/or edits study participant responses
- **Data + Statistics Administrator:** Exports data for statistical analysis
- **Associate:** Read-only access (no read access to participant data and PHI)

What is my role as the creator of a study?

The creator of a study is defaulted to the role of Study Administrator. This role may not enter or edit participant-level data and export datasets. If the Study Administrator needs all permissions within AC, click on the Team hyperlink, highlight the name and check all boxes under Roles.

How do I remove people from my study team?

To remove a team member from your study, click the person's name, and then click the left arrow button. Assessment Center removes the name from the Team Members for Current Study box.

The screenshot shows the 'Study Team' management page in the Assessment Center. At the top, there is a navigation bar with tabs for 'Studies', 'Instruments', 'Set-up', 'Assemble', and 'Administration'. On the right, there are links for 'PDFs', 'Admin', 'My Account', 'Help', and 'Logout'. The current study is identified as 'AC User Manual_Example'. Below the navigation, there is a breadcrumb trail: 'Study List (AC User Manual_Example) >> Study Team'. The main heading is 'Study Team', with 'Save' and 'Cancel' buttons to the right. Two instructions are provided: 1. Identify team members by selecting names and moving them to the 'Team Members for Current Study' box. 2. Highlight a team member's name from the list, then select their role(s) other than Associate (read only). The interface is divided into three sections: 'All Users' (a list of names with a scroll bar), 'Team Members for Current Study' (a box containing 'Hanrahan, Rachel - Northwestern University' and a red box around the arrow keys), and 'Roles' (a list of roles with checkboxes, where 'Study Administrator' is selected).

Instruments

How do I view my study Instruments?

All instruments selected for use in a study are displayed on the Study Content page, the default page in the Instruments tab. From the Study Content page, users can add instruments to their study from the Instrument Library and initiate the creation of new instruments.

Add an Instrument/Battery

How do I add an existing instrument to my study?

Access the instrument library by clicking the Add button on the Study Content page. You will be navigated to the Add an Instrument page. The page defaults to display all instruments designated as public in the Assessment Center library. You may review and select instruments from this list or you may use the search criteria to target results. Assessment Center houses instruments (e.g., a depression short form) and batteries (collection of instruments). NIH Toolbox has batteries for Emotion, Motor, Cognition, and Sensation. On the Add an Instrument page, you will first need to decide if you want to search for instruments (default) or batteries. At the top of the page are three drop lists that enable you to customize a search. Make a selection and click on the Show Results button to view your search results. Instruments with a status of Administered or Public are eligible for inclusion. Instruments with a status of Under Development or Locked will not appear in the search results. If you would like to use NIH Toolbox batteries or instruments in a study, you must request access via nihtoolbox.org.

Assessment CenterSM

Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Current Study: AC User Manual_Example

[Study Content \(AC User Manual_Example\)](#) >> Add an Instrument

Add an Instrument

First, select instrument or battery (a fixed set of instruments). Use search criteria to find and add instruments / batteries to your study.

Instrument
 Battery

Study: Type: Domain:

Search Results

Select	Name	Administration Study	Type	Domain	Terms of Use
<input type="checkbox"/>	<input checked="" type="checkbox"/> Neuro-QOL Bank v1.0 - Ability to Part. in SRA	Neuro-QOL	Item Bank/CAT (Computerized Adaptive Testing)	Social Function, Ability to Participate in Social Roles/Activities	Statistics
<input type="checkbox"/>	<input checked="" type="checkbox"/> Neuro-QOL Bank v1.0 - AC - Executive Function	Neuro-QOL	Item Bank/CAT (Computerized Adaptive Testing)	Applied Cognition, Executive Function	Statistics

Instrument Search Drop lists

- **Study:** The default is All Public instruments. You can also search studies in which you are team member.
- **Type:** Choose from Item Bank/CAT (Computer Adaptive Testing), Short Form, or All (default).
- **Domain:** Choose from instrument domains (e.g. Fatigue, Pain). To search multiple domains use default (All).

To select an instrument/battery for inclusion in your study, check the box next to each applicable instrument/battery. You may select multiple instruments/batteries. After you have made your selections, click on the Add to Study button at the top or bottom of the results list. A confirmation message indicating that your selections have been added to your study will appear at the top of the screen. The Select box is disabled for all instruments/batteries already included in your study so that it cannot be added a second time. A single instrument/battery may, however, be administered at multiple time points within a given study.

Add an Instrument to Study Content

1. Select Instrument or Battery
2. Select Study, Type & Domain from drop lists
3. Click Show Results button
4. Select an Instrument/Battery by checking box
5. Click Add to Study button

How will I know which Instruments to select?

Review the search results to determine which instrument(s) would suit your study. The search results have information relating to the instrument and its items that will help you determine if you would like to include the instrument in your study.

Instrument Elements in Search Results

- Instrument name
- Original study from which the instrument was created
- Instrument type classification
- Instrument domain classification
- Instrument Statistics page hyperlink
- Instrument Terms of Use, where applicable
- Instrument PDF, where applicable

Are additional instruments required when using NIH Toolbox instruments/batteries?

All NIH Toolbox instruments were normed by level of education. Therefore, when any NIH Toolbox battery or instrument is added to your study, an education instrument will automatically be included. The education instrument **MUST** be administered prior to the NIH Toolbox instruments in order for accurate scoring to occur. For example, in language tests, education level determines where to begin the presentation of items. For children under the age of 18, a second education instrument about parental education is included. Parental education was used in norming for this age group.

Additionally, some instruments (Cognition, Motor) were normed for use of one's dominant hand. Depending on the battery or instrument, a handedness instrument may be included automatically. This instrument includes a series of questions (e.g., what hand is used to write, to throw a ball) if the respondent doesn't know the dominant hand. The handedness instrument should be administered prior to the NIH Toolbox instruments. If you are selecting individual NIH Toolbox instruments rather than using an entire battery, Assessment Center will automatically include the education and handedness instruments where needed.

Finally, a couple registration questions (e.g. Age) are also added to your study when you opt to use certain Toolbox instrument. These fields can be reviewed from the Registration tab within Set-up.

How can I learn more about an item?

After reviewing instrument information, it may be useful to review the items within an instrument. To view the items within an instrument, click on the plus sign next to the instrument name; the screen will expand to display all items. To hide the items, click on the minus sign.

Assessment CenterSM

Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Current Study: AC User Manual_Example

[Study Content \(AC User Manual_Example\)](#) >> Add an Instrument

Add an Instrument

First, select instrument or battery (a fixed set of instruments). Use search criteria to find and add instruments / batteries to your study.

Instrument
 Battery

Study: Type: Domain:

Search Results

Select	Name	Administration Study	Type	Domain	Terms of Use
<input type="checkbox"/>	<input checked="" type="checkbox"/> Neuro-QOL Bank v1.0 - Ability to Part. in SRA	Neuro-QOL	Item Bank/CAT (Computerized Adaptive Testing)	Social Function, Ability to Participate in Social Roles/Activities	Statistics
<input type="checkbox"/>	<input checked="" type="checkbox"/> Neuro-QOL Bank v1.0 - AC - Executive Function	Neuro-QOL	Item Bank/CAT (Computerized Adaptive Testing)	Applied Cognition, Executive Function	Statistics
	NQCOG16	How much DIFFICULTY do you currently have... checking the accuracy of financial documents, (e.g., bills, checkbook, or bank statements)?	<input type="text" value="None"/>	Statistics	
	NQCOG17	How much DIFFICULTY do you currently have... counting the correct amount of money when making purchases?	<input type="text" value="None"/>	Statistics	

Item components (e.g., stem, responses, and instrument of origin) can be reviewed on the Item Detail page. To access the Item Detail page, click on the item ID hyperlink.

Assessment CenterSM

Assessment CenterSM

Studies Instruments Set-up Assemble Administration

PDFs Admin My Account Help Logout

Current Study: AC User Manual_Example

[Study Content \(AC User Manual_Example\)](#) >> Add an Instrument

Add an Instrument

First, select instrument or battery (a fixed set of instruments). Use search criteria to find and add instruments / batteries to your study.

- Instrument
 Battery

Study: Type: Domain:

Show Results

Search Results

Select	Name	Administration Study	Type	Domain	Terms of Use
<input type="checkbox"/>	<input checked="" type="checkbox"/> Neuro-QOL Bank v1.0 - Ability to Part. in SRA	Neuro-QOL	Item Bank/CAT (Computerized Adaptive Testing)	Social Function, Ability to Participate in Social Roles/Activities	Statistics  
<input type="checkbox"/>	<input checked="" type="checkbox"/> Neuro-QOL Bank v1.0 - AC - Executive Function	Neuro-QOL	Item Bank/CAT (Computerized Adaptive Testing)	Applied Cognition, Executive Function	Statistics  
	NQCOG16	How much DIFFICULTY do you currently have... checking the accuracy of financial documents, (e.g., bills, checkbook, or bank statements)?		<input type="text" value="None"/>	Statistics
	NQCOG17	How much DIFFICULTY do you currently have... counting the correct amount of money when making purchases?		<input type="text" value="None"/>	Statistics
	NQCOG22	How much DIFFICULTY do you currently have... reading and following complex instructions (e.g., directions for a new medication)?		<input type="text" value="None"/>	Statistics

View Statistics Pages

How do I use Statistics pages?

Another way you may learn more about an instrument and its items is to review the Instrument and/or Item Statistics pages. These statistics pages are accessed by clicking on the Statistics hyperlinks. For instruments, the Statistics hyperlink is visible on the Study Content and Add an Instrument pages. For items, you must expand an instrument using the plus symbol to see each item along with its Statistics hyperlink. The statistics pages contain data analyzed in previous studies allowing you to review how an instrument and/or item performed in previous analysis. The data entered here has been entered by other Assessment Center users. As a user, you may enter statistical information for instruments and items you create. If you are interested in contributing additional statistics to Public instruments, contact the Assessment Center Administrators at help@assessmentcenter.net or 1-877-283-0596.

Assessment CenterSM

Studies Instruments Set-up Assemble Administration

PDFs Admin My Account Help Logout

Current Study: AC User Manual_Example

[Study Content \(AC User Manual_Example\)](#) >> Add an Instrument

Add an Instrument

First, select instrument or battery (a fixed set of instruments). Use search criteria to find and add instruments / batteries to your study.

- Instrument
 Battery

Study: Type: Domain:

Show Results

Search Results

Select	Name	Administration Study	Type	Domain	Terms of Use
<input type="checkbox"/>	<input checked="" type="checkbox"/> Neuro-QOL Bank v1.0 - Ability to Part. in SRA	Neuro-QOL	Item Bank/CAT (Computerized Adaptive Testing)	Social Function, Ability to Participate in Social Roles/Activities	Statistics  
<input type="checkbox"/>	<input checked="" type="checkbox"/> Neuro-QOL Bank v1.0 - AC - Executive Function	Neuro-QOL	Item Bank/CAT (Computerized Adaptive Testing)	Applied Cognition, Executive Function	Statistics  
	NQCOG16	How much DIFFICULTY do you currently have... checking the accuracy of financial documents, (e.g., bills, checkbook, or bank statements)?		<input type="text" value="None"/>	Statistics
	NQCOG17	How much DIFFICULTY do you currently have... counting the correct amount of money when making purchases?		<input type="text" value="None"/>	Statistics

Publicly Available Instruments

What instruments for adults are available in Assessment Center?

Currently, PROMIS calibrated item banks which are enabled for Computer Adaptive Testing (CAT), PROMIS short forms, and PROMIS Profile instruments are available in Assessment Center. The most recent version (v1.0 or v2.0) may be selected for use in a study. All publicly available instruments will appear by default when you navigate to the Add an Instrument page. The Administration Study field will display the study from which an instrument was created. To learn more about publically available instruments, access the Assessment Center Instrument Library document, <http://assessmentcenter.net/documents/InstrumentLibrary.pdf>

As of January 2013, NeuroQOL (Quality of Life in Neurological Disorders) item banks which are enabled for Computer Adaptive Testing (CAT) and NeuroQOL short forms are publicly available in Assessment Center. As with PROMIS instruments, they will appear by default on the Add an Instrument page. More information about NeuroQOL may be found at www.neuroqol.org.

What are the PROMIS Profile instruments?

PROMIS Profile instruments are short forms containing items from seven of the PROMIS domains (depression, anxiety, physical function, pain impact, fatigue, sleep disturbance, and satisfaction with participation in social roles). The PROMIS-29 includes 4 items from each domain plus one pain intensity item. The PROMIS-43 includes 6 items from each domain plus a pain intensity item. The PROMIS-57 includes 8 items from each domain plus the pain intensity item. When a study participant completes a Profile instrument an individual functional report is created (see Reporting section below).

What is the difference between PROMIS short forms?

You will notice that there are several versions of many of the PROMIS short forms (e.g., the "original" 1.0 short form, as well as the 4a, 6a, and 8a versions). The original short forms were constructed by the domain teams. The goal was to identify 6-8 items that represented the range of the trait and also represented the content of the item bank. Domain experts reviewed short forms to give input on the relevance of each item. Each domain group worked independently and the original short forms are 6-10 items long. Psychometric properties and clinical input were both used and likely varied in importance across domains.

Later, PROMIS Profile instruments were developed. The PROMIS Profile Instruments are a collection "high information" PROMIS short forms for seven domains (Anxiety, Depression, Sleep Disturbance, Fatigue, Pain Interference (Impact), Physical Function, and Satisfaction with Participation in Social Roles). Three PROMIS Profile Instruments were created in which, 4-item, 6-item or 8-items were selected from each domain. The items within each instrument are nested/overlap (e.g., the 8-item form is the 6-item form plus two additional items). The selection of items was in part based on two sets of item rankings within each domain using two psychometric criteria: (1) maximum interval information; and 2) CAT simulations. Item rankings were similar for both criteria. For the maximum interval criterion, each item information function was integrated (without weighting) for the interval from the mean to 2 SDS worse than the mean. For the CAT simulations, responses to all items in each bank were generated using a random sample of 1,000 simulees drawn separately for each bank (centered on 0.5 SD worse than the general population mean). Items were rank ordered based on their average administration rank over the simulees. Content experts reviewed the items and rankings and made cuts of 4, 6, and 8 items.

How should I determine which instrument to use?

In selecting a short form, the difference is really the instrument length. The reliability and precision of the short forms within a domain is highly similar. If you are working in a sample in which you expected huge variability in a domain area and wanted different subdomains covered, you would probably go for the original short form. If you are

working with a sample in which you wanted the most precise measure, you would go for an 8a short form. If you had little room for additional measures but really wanted to capture something as a secondary outcome, you would go for a 4a short form.

What instruments for children are available in Assessment Center?

Currently, PROMIS calibrated item banks, which are enabled for Computer Adaptive Testing (CAT) and short forms for children ages 8 to 17 are available in Assessment Center. These instruments may be selected for use in a study. There are also a set of NeuroQOL items banks, enabled for CAT, and short forms available for pediatric populations. To learn more about publically available instruments, access the Assessment Center Instrument Library document, <http://assessmentcenter.net/documents/InstrumentLibrary.pdf>

Where are the publically available Pediatric Instruments located?

Pediatric instruments may be added to your study from the Add an Instrument page. Steps required to add the pediatric instruments are the same as those required for all instruments (please see Add an Instrument/Battery section above). All public pediatric instruments will appear on the default instrument list. They can be identified by the inclusion of the term “Ped” in the instrument name, e.g. PROMIS Ped Bank v1.0 – Fatigue.

Are the current instruments all that will ever be available in Assessment Center?

Instruments will continue to be added to the public Assessment Center Library. Users can also create their own instruments from existing items as well as create/modify their own items.

Create an Instrument

What is a custom Instrument?

Users can create their own instruments which are called custom instruments within Assessment Center. For example, a user could tailor an existing instrument to for his or her study, or a user may want to enter an instrument that is not currently in the Assessment Center library. A custom instrument can only be viewed by the study team; it is not available to the general public. Instruments can be created in English, Spanish, German or French. Future development will enable data collection in other languages. While PROMIS instruments cannot be translated in Assessment Center, in the future, translated PROMIS instruments will be added to the Assessment Center library.

How do I create an instrument?

To create an instrument in Assessment Center click on the Create button on the Study Content page. A blank Instrument Properties page will be presented; enter instrument properties (e.g., instrument name, type, domain, language, IRT model) here. There are two instrument types, Item Bank/CAT (Computerized Adaptive Testing) or Short Form. The options available in the IRT Model drop list are dependent on the type of instrument you select. If the instrument type is Item Bank/CAT (Computerized Adaptive Testing), you will need to select Graded Response Model Scored from the IRT Model drop list. This is currently the only IRT model available. If you are creating a short form, you will need to select No Total Score (default) or Graded Response Model Scored from the IRT Model field. Once all study properties have been entered and saved, the Study Content page will appear listing the newly created instrument.

Create an Instrument

1. On Study Content page, click Create button
2. Provide an Instrument name
3. Assign one or more Instrument Domains
4. Select default language of administration
5. Provide an Instrument Description
6. Select an Instrument Type
7. Select an IRT Model

Assessment CenterSM

Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Current Study: AC User Manual_Example

[Study Content \(AC User Manual_Example\)](#) >> Instrument Properties

Instrument Properties

Name*
AC User Manual Example Instrument Save Back

Select the domain or domains for this instrument*

- End of Life Concerns
- Fatigue
- Motor
- Pain
 - Pain Behavior
 - Pain Intensity
 - Pain Interference
- Physical Function
 - Mobility
 - Upper Extremity

Language: English
Status: Under Development
Type*: Short Form
IRT Model: Graded Response Model Scored
Upload PDF

Description*
Description of AC User Manual Example Instrument

Comments

(*) fields are required.

To add existing items to your instrument, first, on the Study Content page, click on your custom instrument name hyperlink. This will take you to the Instrument Detail page. From here, access the Assessment Center Item Library by clicking on the Find Items button. Once on the Add Items to a Custom Instrument page, you may select items to include in the custom instrument.

The Add Items to a Custom Instrument page looks very similar to the Add an Instrument page. The search drop lists, the default instruments and the hyperlinks are the same. When adding items to a custom instrument, you can select all or some items from within an instrument. To view items, click on the plus/minus box next to an instrument name. To select all items from an instrument, check the box next to the instrument name. To only add some items from an instrument, expand the instrument and check the boxes next the desired items.

Add Items to Custom Instrument

1. On Study Content page, click on custom instrument name hyperlink
2. System will open Instrument Detail page
3. Click Find Items button
4. Select Study and Domain to search
5. Click Show Results Button
6. Review Item list
7. Select desired items by checking box next to instrument name or expanding the instrument and checking box next to the item ID.
8. Click Add to Instrument button

The library defaults to display All Public instruments. However, you can select any study that is publicly available or any study on which you are a team member. All instruments that have a status of Administered or Public may be viewed. Therefore, if you create an instrument in a pilot study, you can create a revised instrument in a second study and add the unchanged items from your first instrument. This minimizes the need for re-entering custom items.

Add Items to Custom Instrument

Select your search criteria. Then, select the items to add to your custom instrument: AC User Manual Example Instrument

Study: Type: Domain:

Search Results

Select	Name	Administration Study	Type	Domain	Statistics	Unknown
<input type="checkbox"/>	Neuro-QOL Bank v1.0 - Anxiety	Neuro-QOL	Item Bank/CAT (Computerized Adaptive Testing)	Anxiety/Fear	Statistics	Unknown
<input type="checkbox"/>	Neuro-QOL Bank v1.0 - Depression	Neuro-QOL	Item Bank/CAT (Computerized Adaptive Testing)	Depression/Sadness	Statistics	Unknown
<input type="checkbox"/>	EDDEP29	In the past 7 days I felt depressed	<input type="text" value="Never"/>	Statistics		
<input type="checkbox"/>	EDDEP19	In the past 7 days I felt that I wanted to give up on everything	<input type="text" value="Never"/>	Statistics		
<input type="checkbox"/>	EDDEP05	In the past 7 days I felt that I had nothing to look forward to	<input type="text" value="Never"/>	Statistics		
<input type="checkbox"/>	EDDEP07	In the past 7 days I withdrew from other people	<input type="text" value="Never"/>	Statistics		

Create an Item

How do I create my own items to include in a custom instrument?

All items are created within an instrument. To create new items, first click the Create Item button from the Instrument Detail page. You will be navigated to a blank Item Detail page to enter item components. Required components include item ID, item domain and item stem.

Once an item has been created, you can continue to enter new items from the Item Detail page by clicking on the New button or the Copy button. Clicking the Copy will generate an Item Detail page containing all previous item components except for the Item ID field, which will be blank. When copying an item you must enter a new Item ID and may modify any other item components. Once you are done entering new items, it is helpful to navigate back to the Instrument Detail page and review all items in your custom instrument.

Only users with the proper permissions for the current study may add or modify items. The roles with permission to perform this function are the Study Administrator and Instrument/Item Administrator. If you would like to make revisions or create new items but do not have the appropriate permissions, please contact the study administrator. The Item Detail page is editable when an item only appears on a single instrument with a status of Under Development. An item is view-only when it has been added to more than one instrument or it is on an instrument with a status of Public, Administered, or Locked.

Item Detail

ID*: ACUM_4914 Version: Text

Domain*
Communication
Emotion
Emotional Distress/Negative Affect
- Anger
- Anxiety/Fear
- Apathy
- Depression/Sadness
End of Life Concerns
Fatigue
Metast

Context
In the past 7 days,

Stem*
I felt tired

Item Contains Protected Health Information (PHI)

Administration AC User Manual_Example Original Instrument: AC User Manual Example Instrument Creation Date: 4/9/2014

Responses

Type: Multiple Choice Add another row

Score	Response Text	Show Response Score	Delete
1	Not at all	<input type="checkbox"/>	Delete
2	A Little bit	<input type="checkbox"/>	Delete
3	Somewhat	<input type="checkbox"/>	Delete
4	Quite a bit	<input type="checkbox"/>	Delete
5	Very much	<input type="checkbox"/>	Delete

What is the difference between an item context and item stem?

Assessment Center defines an item as the combination of an item context, stem, and responses. The context field is intended for text that will frame the item such as timeframes (“During the past week...”) or conditional statements (“Because of my illness...”). The item context field is optional. The stem field is intended for the text of the actual item or question and is required. During data collection, the item context appears on the first line and the item stem appears on the second line. If an item that is just one sentence or should be displayed as one statement, enter the text into the stem field only.

Item Response Types

What are the available item response types?

There are eight different item response types available within Assessment Center. One response option (informational) should be used when an item has no text or scores applied to the response section. This type should be used for items that give participants additional information, such as additional instructions or text transitioning participants from one concept to another. Four of the response options have a pre-determined format (text, numeric, date and comments). This means that a participant will be presented with a field to type text (a small field for text and a larger field for comments), a number, or be prompted to enter a date using drop lists for month, date and year. The comments response type can be utilized to obtain qualitative data and feedback. Two other response options (multiple choice and drop list) need user defined scoring and response text (e.g., 1=Not at all). A final response option (checkbox) is similar to a multiple choice item although it allows more than one response to be checked (e.g., indicating more than one race). The scoring for this response type is system generated and can be found in the Data Dictionary report within the Administration tab once a study has been launched. These final three response option types initially are assigned two response rows. To add additional response rows, click on the Add Another Row button within the response option box. You may also delete response rows. A checkbox item is limited to 63 response rows.

The screenshot shows the Assessment Center software interface. At the top, there is a navigation menu with tabs for Studies, Instruments, Set-up, Assemble, and Administration. The current study is identified as 'AC User Manual_Example'. The breadcrumb trail indicates the path: Study Content (AC User Manual_Example) >> Instrument Detail (AC User Manual Example Instrument) >> Item Details (ACUM_4914). The main content area is titled 'Item Detail' and includes a 'Responses' section. The 'Responses' section shows a 'Multiple Choice' type with five response options, each with a score and a 'Delete' link. The 'Add another row' button is highlighted with a red box. The 'Item Detail' section includes fields for ID*, Domain*, Version, Context, and Stem*. The 'Administration' section at the bottom provides details about the user, instrument, and creation date.

Score	Response Text	Show Response Score	Delete
1	Not at all	<input type="checkbox"/>	Delete
2	A Little bit	<input type="checkbox"/>	Delete
3	Somewhat	<input type="checkbox"/>	Delete
4	Quite a bit	<input type="checkbox"/>	Delete
5	Very much	<input type="checkbox"/>	Delete

How do I create transition screens (informational item without a response option)?

You may choose not to display a response scale when instructions or transition screens are desired in an instrument. This text is used to inform participants of content changes, give more in-depth, item specific instructions or indicate assessment progress. To create these screens select Informational from the Response Type drop list. This will only display item context (where applicable) and item stem. There will be no response choices. Note that embedding an instruction or transition item within an instrument is useful when a fixed item order is used. If randomizing the order of items within an instrument or utilizing CAT is planned, create a custom instrument that only includes the transition or instruction item.

What is a collapsed response category and how should one be handled?

There are instances when an analyst will collapse two response categories together because of infrequent responses in one of those categories. This means that the two responses are treated identically in an IRT model. When response categories are collapsed, you should change the response scores to reflect which categories are collapsed, i.e. the collapsed categories should have the same response score. Doing this results in the appropriate number of thresholds appearing on the Item Statistics page.

Item Detail

Administration AC User Manual_Example Original Instrument: AC User Manual Example Instrument Creation Date: 4/9/2014

Item Contains Protected Health Information (PHI)

Score	Response Text	Show Response Score	Delete
1	Not at all	<input type="checkbox"/>	Delete
2	A Little bit	<input type="checkbox"/>	Delete
3	Somewhat	<input type="checkbox"/>	Delete
4	Quite a bit	<input type="checkbox"/>	Delete
4	Very much	<input type="checkbox"/>	Delete

Thresholds (Item Statistics page) are another item characteristics that should be considered when there are collapsed categories. Assessment Center uses the number of response scores to determine how many thresholds are available for an item. Normally, when utilizing graded response model (GRM), an item with 5 response options would have 4 thresholds. Since the collapsed response categories are treated as a single response, the result is that you would see one less threshold (i.e. 3 thresholds). The data export will still show you the answer provided by a participant in the Rspnse (Assessment Data Export) field. This field indicates the position within the response options of a participant's selection, i.e. the response option listed first is coded as 1.

How can I display response scores on data collection pages?

There are instances in which it may be useful to display response scores to study participants. For example, an item which asks a participants to place themselves on a 0-10 scale with anchoring text either end of the scale (On a scale from 0-10, how would you rank your fatigue). To make the values entered in the Score field visible to participants, check the Show Response Score box next to each applicable response.

How can I indicate an item contains Protected Health Information (PHI)?

Assessment Center allows you to indicate certain data fields contain PHI. These fields are any custom item, consent endorsement text fields and certain custom registration fields. Several registration fields will always be marked as containing PHI. These are date of birth, doctor, last name, first name, street, city, state, zip, email, phone 1, and phone 2. When a data field/item is marked as containing PHI, all data collected in this field will be flagged in the database and will be reported as containing PHI in applicable data exports. This feature is intended to aid in de-identification efforts and protect participant privacy. To indicate a custom item may contains PHI, check the Item Contains Protected Health Information (PHI) box on the Item Detail page. This field will not be editable after a study is launched.

Item Translation

How do I upload item translations?

Assessment Center enables you to upload translated items in the language you wish to use during data collection. Currently, English, Spanish, German and French are supported by Assessment Center. Additional languages will be

supported in future releases. To add item translations to Assessment Center, you must first export a translation file for your custom instrument, then enter item translations into the exported translation file spreadsheet, and finally import the spreadsheet containing item translations back into Assessment Center. It is best to complete this process once you have added and created all the items in your instrument. However, it can be done at any time prior to launch. To begin the process, click on the “Upload Translation” button on the Instrument Detail page, select the language of the translations you will be adding from the Language drop list and click the Export button.

The screenshot shows the Assessment Center interface. At the top, there are navigation tabs: Studies, Instruments, Set-up, Assemble, and Administration. The current study is 'AC User Manual_Example'. The page title is 'Instrument Detail (AC User Manual Example Instrument)'. Below the title, there are instructions and buttons: 'Save', 'Cancel', 'Create Item', 'Find Items', 'Upload Translation' (highlighted with a red box), 'Analyze', 'Preview', and 'Export'. A 'Translation' modal box is open, prompting the user to 'Select language you would like to add, click Export, and choose Save.' The modal contains a 'Language' dropdown menu with 'Spanish' selected (highlighted with a red box), a 'File Name' field with the text 'No translation file currently exists for this language.', a 'Date of Upload' field with 'N/A', and an 'Action' column with 'Export' and 'Import' buttons (the 'Export' button is highlighted with a red box). Below the modal, there is an 'Instrument Detail' table with columns: Order, ID, Responses, Administration Study, and Include. The table contains one row with the following data: Order 1, ID ACUM_4914, Responses 'In the past 7 days, I felt tired', Administration Study 'AC User Manual_Example', and Include checked.

Upload Item Translations

1. Navigate to the Instrument Detail Page
2. Click Upload Translations button
3. Make selection from Language drop list
4. Click Export button within Translation box
5. Save translation file spreadsheet to your computer
6. Open translation file spreadsheet
7. Enter appropriate translations into Translation column
8. Save translation file changes
9. Click Import button within Translation box
10. Select appropriate translation file
11. Verify File Name and Date of Upload fields have been updated

Once you click on Export, you will be prompted to download an Excel file. This file includes columns containing instrument information (i.e. instrument name, default language, etc.) and item elements (e.g. item ID, item stem, response text, etc.). A column titled Translation is where you will type or copy/paste in the direct translation of the content in the corresponding Description field. The Description column will contain all items (context and stem together) and all response options included in the instrument. You will only need to enter a translation for each response option once, even if it is used for multiple items within the instrument. If you require item-specific variations of the same response option, please contact help@assessmentcenter.net to review alternatives. Within the translation file export, Translation is the only field which may be modified. No changes are allowed in the instrument name, language, item ID, and description fields. If you change any of these fields, you will receive errors when importing the file back into Assessment Center.

	A	B	C	F	G	H	I	J	K
1	Instrument Name	Language	Item ID	Description	Translation				
2	PRO Manual Example	es	* Context	In the past 7 days					
3	PRO Manual Example	es	* Response Option	Always					
4	PRO Manual Example	es	* Response Option	Never					
5	PRO Manual Example	es	* Response Option	Often					
6	PRO Manual Example	es	* Response Option	Rarely					
7	PRO Manual Example	es	* Response Option	Sometimes					
8	PRO Manual Example	es	FATEXP19	How often were you physically drained?					
9	PRO Manual Example	es	FATEXP20	How often did you feel tired?					
10	PRO Manual Example	es	FATEXP22	How often were you bothered by your fatigue?					
11	PRO Manual Example	es	FATEXP26	How often were you too tired to enjoy life?					
12	PRO Manual Example	es	FATEXP6	How often did you feel tired even when you hadn't done anything?					
13	PRO Manual Example	es	FATIMP16	How often did you have trouble finishing things because of your fatigue?					

	A	B	C	F	G	H	I	J	K
1	Instrument Name	Language	Item ID	Description	Translation				
2	PRO Manual Example	es	* Context	In the past 7 days	En los últimos 7 días				
3	PRO Manual Example	es	* Response Option	Always	Siempre				
4	PRO Manual Example	es	* Response Option	Never	Nunca				
5	PRO Manual Example	es	* Response Option	Often	A menudo				
6	PRO Manual Example	es	* Response Option	Rarely	Rara vez				
7	PRO Manual Example	es	* Response Option	Sometimes	Algunas veces				
8	PRO Manual Example	es	FATEXP20	How often did you feel tired?	¿Con qué frecuencia se sintió cansado/a?				
9	PRO Manual Example	es	FATEXP22	How often were you bothered by your fatigue?	¿Con qué frecuencia le molestó el agotamiento?				
10	PRO Manual Example	es	FATEXP6	How often did you feel tired even when you hadn't done anything?	¿Con qué frecuencia se sintió cansado/a a pesar de no haber hecho nada?				
11	PRO Manual Example	es	FATIMP16	How often did you have trouble finishing things because of your fatigue?	¿Con qué frecuencia tuvo dificultad para terminar las cosas debido al agotamiento?				

It is up to you to ensure the proper translation of your items are entered in the translation file spreadsheet. It is recommended that a quality assurance check be completed by a colleague to verify accuracy. Once you have entered all translations and saved the exported file on your computer, initiate the translation file upload process by navigating to the Instrument Detail page in Assessment Center and clicking the Import button. If the file is imported successfully you will receive a confirmation message and the uploaded file will be listed in the File Name column. It is important to note, to initiate the process of uploading translations; items must **first** be created in Assessment Center. You can only import translations for items existing in the specified custom instrument. You cannot create your own translation file spreadsheet first and then upload your items and translations.

The screenshot shows the Assessment Center interface. At the top, there are navigation tabs: Studies, Instruments, Set-up, Assemble, and Administration. The current page is 'Instrument Detail' for 'AC User Manual Example Instrument'. Below this, there are buttons for 'Save' and 'Cancel'. A message states: 'Order items within the instrument by altering the Order column and clicking "Save".' Below that, there is a checkbox for 'Hide Excluded Items' and buttons for 'Create Item', 'Find Items', 'Upload Translation', 'Analyze', 'Preview', and 'Export'. A 'Translation' window is open, showing a message: 'Select language you would like to add, click Export, and choose Save.' The language is set to 'Spanish'. Below this, a message says: 'Your translations were successfully uploaded.' The 'Translation' window also displays the 'File Name' as 'spanishtrans.xlsx', the 'Date of Upload' as 'Apr 9 2014 10:59AM', and buttons for 'Export' and 'Import'. At the bottom, there is a table for 'Instrument Detail' with columns for Order, ID, Responses, Administration Study, and Include. The table shows one item with Order 1, ID ACUM_4914, and a response of 'Not at all'.

Am I able to modify my item translations?

You may modify item translations at any time prior to launching your study into data collection. After the initial import of a translation file to Assessment Center the translation file spreadsheet will be protected. Therefore, to

make modifications to the Translation column you need to first unprotect the spreadsheet. In Excel, this is done by accessing the Review tab and clicking Unprotect Sheet. It is important to note this action will unprotect all fields. You must take caution to only modify the content within the Translation column. Modifications to content in other columns will prevent a successful import of the translation file. Once you have made the desired modifications to your translation file, navigate to the Instrument Detail page and click Import. This will initiate the process of uploading the modified translation file.

Are any public instruments available in other languages?

Yes, several of the public, PROMIS instruments are available for administration in Spanish via Assessment Center. Please refer to Table 1 within the Assessment Center Instrument Library document, located here <http://assessmentcenter.net/documents/InstrumentLibrary.pdf>, for more detailed information.

Am I able to upload translations of items from publicly available instruments?

Item translations are associated with an instrument. You may not make edits to item translations for public instruments, any other custom instruments which have already been launched for data collection or not yet launched instruments for which you do not have appropriate permissions. However, once you have added an item from a publicly available instrument to one of your custom instruments you are able to upload a translation for that item. The translation of your custom instrument and its items will be available to anyone who uses that instrument. Currently, study team members may use your custom instrument in other studies. The translations of the item will not be available if the item is added to another custom instrument, i.e. each custom instrument must upload individual translations within Assessment Center.

Item History

Can I review item development?

In an effort to retain and report steps within item and/or instrument development, Assessment Center includes an item history feature. When an existing item is modified in any way (e.g. addition of response option or grammatical change to stem) an item history entry is required. The Item History page is accessed by the History hyperlink next to the item on the Study Content and Instrument Detail pages or by clicking the Show Item History button from the Item Detail page.

A change category and reason for change is required each time an item is modified. This information is stored in the Item History page so that changes may be reviewed. You may also add comments if you have the appropriate permission on the study in which the instrument was created.

Review Item History

1. Click on the History hyperlink for a specific item or click the Show Item History button
2. Review the current item in upper left corner of screen
3. Review changes in Item History entries

Item History change categories include Expert/Editorial Review, Cognitive/Patient Review, and Translatability Review. Entries are listed in chronological order with the most recent change at the top. In the top left of the screen is the current version of the item. Each row in the table contains the previous version of the item that was subjected to a specific activity such as expert or patient review and comments from the reviews. To add a new row of activity, select a change category, enter comments, and click on the Add a Comment button. To simply add additional text to an existing comment, click on the Append hyperlink below the comment you wish to update.

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Current Study: AC User Manual_Example

Study Content (AC User Manual_Example) >> Instrument Detail (AC User Manual Example Instrument) >> Item Details (ACUM_4914) >> Item History

Item History

Cancel

ID: ACUM_4914
In the past 7 days,
I felt very tired

Responses: Not at all

Context	Responses	Category	Date	Comments
In the past 7 days, I felt very tired	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	Cognitive / Patient Review	04/09/2014	Changes made Append
In the past 7 days, I felt tired	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	New Item	04/09/2014	Append

Item History Category* Please select Date 4/9/2014 Add Comment

Comments*

Instrument Export

How can I export a custom instrument?

At any time during the selection and creation of items within a custom instrument, you have the option to export items into an external file. This functionality is useful when wishing to distribute instrument/item content to study collaborators who may not have access to Assessment Center. To begin the export process, click the Export button on the Instrument Detail page. Once the button is clicked an automatic process will guide the user through how to save and/or open the instrument export.

Export Instrument

1. Navigate to the Instrument Detail Page by clicking on the instrument name hyperlink from the Study Content page
2. Click Export button
3. Click Save button
4. Select name for file
5. Select location for saved document
6. Open Excel file
7. Review for completeness

What are the guidelines for item ID naming for export in SAS?

Exporting is useful when wishing to distribute instrument/item content to study collaborators who may not have access to Assessment Center. When exporting transposed data in statistical analysis software package (SAS), you should keep ID name rules consistent with variable naming rules for that package. If you are going to be exporting items into SAS please be aware that there are some guidelines when it comes to the naming of item ID's. If these guidelines are not followed, you may have errors when you try and upload your data. Below are some guidelines for exporting into SAS.

- With the exception of underscore, SAS does not read non-alpha/numeric characters well. All variables must start with a letter or an underscore (no numbers)
- Although item names can be up to 32 characters, it's best to limit your names to 8 characters.

Exclude an Instrument or Item

Why would I exclude an Instrument or Item?

Assessment Center does not actually delete objects. Rather, to protect the integrity of the instruments and items that are available to all users, features such as Include/Exclude and Hide to help you manage the appearance of your study. You can choose to exclude an instrument from a study or items from an instrument. This functionality is similar to the Archive Study feature previously seen on the Studies page. A checkmark in the Include box indicates that an instrument is included in a study. Unchecking the box will exclude an instrument. When the inclusion status of an instrument is changed, you must provide a reason for inclusion/exclusion in Notes which will automatically pop-up in a second window when inclusion status is changed. It may be helpful to record the date of the status change to help track a study's history. Excluded instruments will automatically be moved to the bottom of the instrument list. Re-include an instrument, check the Include box.

Study Content (AC User Manual Example) >> Instrument Detail (AC User Manual Example Instrument)

Instrument Detail
Instrument: AC User Manual Example Instrument

Order items within the instrument by altering the Order column and clicking "Save".

To exclude an item from this instrument, click on the Include checkbox.

Buttons: Save, Cancel, Create Item, Find Items, Upload Translation, Analyze, Preview, Export, Hide Excluded Items

Order	ID	Item Description	Responses	Administration Study	History Statistics	Include	Notes
1	ACUM_4914	In the past 7 days, I felt very tired	Not at all	AC User Manual_Example	History Statistics	<input checked="" type="checkbox"/>	Notes
2	FATIMP15	In the past 7 days How often did your fatigue interfere with your ability to engage in recreational activities?	Never	PROMIS	History Statistics	<input checked="" type="checkbox"/>	Notes
3	FATIMP16	In the past 7 days How often did you have trouble finishing things because of your fatigue?	Never	PROMIS	History Statistics	<input checked="" type="checkbox"/>	Notes
4	FATIMP17	In the past 7 days How often did your fatigue make it difficult to make decisions?	Never	PROMIS	History Statistics	<input checked="" type="checkbox"/>	Notes
5	FATIMP18	In the past 7 days How often did you have to limit your social activities because of your fatigue?	Never	PROMIS	History Statistics	<input checked="" type="checkbox"/>	Notes
6	FATIMP20	In the past 7 days How often did your fatigue make you feel less alert?	Never	PROMIS	History Statistics	<input checked="" type="checkbox"/>	Notes
	FATIMP19	In the past 7 days How often were you too tired to do your household chores?	Never	PROMIS	History Statistics	<input type="checkbox"/>	Notes
	FATIMP21	In the past 7 days How often were you too tired to take a bath or shower?	Never	PROMIS	History Statistics	<input type="checkbox"/>	Notes

There are some instruments that cannot be excluded from a study as a whole. For example, once you add a Toolbox instrument you are not able to exclude that instrument on the Study Content page using the Include/Exclude feature. However, you are able to exclude a particular instrument from an individual assessment on the Arm/Assessment Details page. For more details on Toolbox instrument ordering please click on the hyperlink below: http://www.nihtoolbox.org/HowDoI/HowToAdministerTheToolbox/Documents/NIH%20Toolbox%20Measure-s-%20order_Adminstration%20Manual%2011-29%20EB.pdf

There are times where you do **not** want to exclude an instrument from the whole study but just a particular assessment. This is accomplished on the Advanced Study Set-up page within the Set-up tab. Click on the Instrument Block drop list and select "Not Included". For more information, please see the "Assign Instruments to Study Arms and Assessments" section of this manual.

Establish Instrument Order

How do I define the order of instrument administration for my study?

Instrument order is defined in multiple places in Assessment Center. Fixed ordering of instruments as well as more complex presentation schemes are allowed. If you want to administer instruments in a fixed order, you can order them on the Study Content page by typing in the correct order number in the Order field. For more complex Instrument ordering, you may group instruments on the Arm/Assessment Details page. More information on how to group instruments is available in the Set-up section of this manual.

The screenshot shows the 'Study Content' page in the Assessment Center. The page title is 'Study Content (AC User Manual_Example)'. Below the title, there are instructions: 'Click the Add button to add instruments to your study. Click the Create button to create custom instruments in your study.' and 'You have selected the following instruments for this study.' There are 'Add', 'Save', and 'Create' buttons. Below this, it says 'Order the instruments by entering the desired position into the text box, then click Save.' and 'To exclude an instrument from your study, click on the Include checkbox.' There is a 'Hide Excluded Instruments' checkbox. The main content is a table with columns: Order, Name, Administration, Study, Include, and Terms of Use. The table lists three instruments: 1. PROMIS Bank v1.0 - Fatigue (Administration: PROMIS), 2. AC User Manual Example Instrument (Administration: AC User Manual_Example), and 3. PROMIS Bank v1.0 - Anxiety (Administration: PROMIS). Each instrument has links for 'Customize', 'Preview', 'Properties', and 'Statistics'. The 'Include' column has checkboxes, and the 'Terms of Use' column has icons for 'Notes', 'Copyright', and 'PDF'.

Order	Name	Administration	Study	Include	Terms of Use
1	PROMIS Bank v1.0 - Fatigue	PROMIS	Customize Preview Properties Statistics	<input checked="" type="checkbox"/>	Notes
2	AC User Manual Example Instrument	AC User Manual_Example	Customize Preview Properties Statistics	<input checked="" type="checkbox"/>	Notes
3	PROMIS Bank v1.0 - Anxiety	PROMIS	Customize Preview Properties Statistics	<input checked="" type="checkbox"/>	Notes

Instrument Customization

Item Order

How do I define the order of item administration for my study?

Item order is defined in multiple places in Assessment Center. It is important to note, that item order is irrelevant for CAT instruments as the CAT administration engine will select order of items. Within a non-CAT instrument, however, you have the flexibility to present items in a fixed, branched, or random order. If you want to administer items within a custom instrument in a fixed (i.e. sequential) order first navigate to the Instrument Detail page by clicking on the instrument name hyperlink from the Study Content page. Then type in the correct order number in the Order field.

If you wish to present items in a random order, navigate to the Instrument Customization page by clicking on the Customize hyperlink next to the instrument name on the Study Content page. Select Random from the Administration Method drop list.

If you select an Administration Method of Random or Sequential, you may group similar items (e.g., shared response options) within an instrument together for administration. All items from an instrument will appear. You may use the Item Block Number field to group similar items together. For example, all items with a “not at all” to “very much” response scale may be in item block 1 whereas all items with “never” to “always” response scale may be in item block 2. If you have selected the administration method of random, you may use the checkboxes at the top of the page to indicate if randomization of blocks and/or items within blocks is desired. If you have selected sequential, the blocks will be administered in sequential order based upon their block number and the items within each block will

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be administered in the order they appear on the Instrument Customization page. To modify the order in which items appear on the Instrument Customization page, access the Instrument Detail page and use the Order field.

The screenshot shows the 'Instrument Customization' page for 'AC User Manual Example Instrument'. The 'Administration Method' is set to 'Random'. Below this, there are two checked checkboxes: 'Randomize Item Blocks' and 'Randomize Items within Item Blocks'. The 'Item Block Number' field is set to '1'. The 'Branching If' field is set to 'Not at all', 'A Little bit', 'Somewhat', 'Quite a bit', and 'Very much'. The 'Then Go To' field is set to 'Please Select'. The 'Template' field is set to 'Vertical 01'. The 'Item Block Number' field is highlighted with a red box.

Branching

Sometimes, you may want a participant to skip specific items dependent upon his or her response to a previous item. This can be accommodated by selecting an Administration Method of Branch. Using the Branching If and Then Go To fields for each item, you can select the response choice that will result in skipping a specific item(s) and direct the participant to the next desired item. To select multiple response choices in the Branching If field, hold down the Ctrl (Control) button and use your mouse to make multiple selections.

The screenshot shows the 'Instrument Customization' page for 'AC User Manual Example Instrument'. The 'Administration Method' is set to 'Branch'. Below this, there are two unchecked checkboxes: 'Randomize Item Blocks' and 'Randomize Items within Item Blocks'. The 'Item Block Number' field is set to '1'. The 'Branching If' field is set to 'Not at all', 'A Little bit', 'Somewhat', 'Quite a bit', and 'Very much'. The 'Then Go To' field is set to 'FATIMP20'. The 'Template' field is set to 'Vertical 01'. The 'Item Block Number' field is highlighted with a red box.

Templates

What templates are available in Assessment Center?

There are five item templates, Vertical 01, Buttons 01, Cartoon Harry 01, Cartoon Harry Buttons 01, and Horizontal 01. All templates have an Auto Advance version as well which uses the same format, but navigates a participant to the next item as soon as a response is selected. Vertical 01 displays responses in a vertical list with radio buttons. A participant can click on the radio button or the response word(s) to select his/her choice. This is the default template in Assessment Center.

In the past 7 days

How often did you feel tired?

- Never
- Rarely
- Sometimes
- Often
- Always

Buttons01 also displays response options vertically, but has the response text printed on a large button. When a participant clicks anywhere on the button to select it, the button becomes yellow. Because this template has a larger selection area, it may be helpful for populations with less fine motor control (e.g., children, physically impaired).

Please rate how you feel you are doing today compared with how you were doing at your last study assessment.

The Cartoon templates mimic either the Vertical 01 or Buttons 01 templates with the inclusion of a cartoon image. This template is intended to be used with children or other similar populations to put them at ease and encourage them during an assessment.



What is your level of pain right now?



What is your level of pain right now?

No pain

Mild

Moderate

Severe

Very severe

Horizontal01 displays response options horizontally with radio buttons. The Horizontal 01 templates are only an option in the Template drop list for multiple choice items. Horizontal 01 templates may only be selected on the item level. Therefore they do not appear as an option on the “Change all item templates to” drop list. Response scores are displayed in data collection when the Show Response Score box is checked on the Item Detail page.

In the past 7 days

How would you rate your pain on average?

0 1 2 3 4 5 6 7 8 9 10

No pain Worst pain imaginable

CAT (IRT) Parameters

Do I need to enter parameters in order for an instrument to be scored?

CAT (IRT) parameters inform the administration engine how to give an assessment accurately according to the algorithm established for that instrument. All CAT (Computerized Adaptive Testing) instruments and all short form instruments with an IRT Model field set to Graded Response Model Scored are scored. An instrument's CAT (IRT) parameters cannot be changed within a study once that study has been launched. Default CAT (IRT) parameters have been set for all public instruments (e.g. PROMIS and NeuroQOL CATs) in Assessment Center. If you utilize a public, scored instrument in a study, you will have the option of modifying the default CAT (IRT) parameters. Assessment Center will then administer the public instrument using the parameters you entered on the CAT Parameters page. You must set parameters for scored instruments you have created. The parameters you set for a custom, scored instrument will become the default parameters for that instrument. Other users utilizing your custom, scored instrument will have the option of using the default parameters or modifying them to their specifications. Any modifications made to default parameters will only be applied for the current study, i.e. the default parameters will not change. Users with Study Administrator or Instrument/Item Administrator roles may add or modify CAT/IRT parameters. You may access a complete list of CAT (IRT) parameter variables and their definitions within Assessment Center Help, <https://www.assessmentcenter.net/ac1/Help/index.html>.

What CAT (IRT) parameters are used for a given instrument?

To view CAT (IRT) parameters, click on the Set IRT Parameters button on the Instrument Customization page. On the CAT Parameters page, users determine the set of item parameters (i.e., threshold and slope values) and, where applicable, modify the default administration parameters (i.e., item selection and stopping conditions) which should be used to administer a scored instrument. An instrument may have one set of administration parameters per language/calibration sample combination.

The screenshot shows the 'Instrument Customization' page for 'PROMIS Bank v1.0 - Fatigue'. The 'Administration Method' is set to 'CAT', and the 'Set IRT Parameters' button is highlighted with a red box. Below this, there are checkboxes for 'Randomize Item Blocks' and 'Randomize Items within Item Blocks'. A table of item parameters is shown, with columns for 'Item Block Number', 'Item ID', 'Item Description', 'Branching If', 'Then Go To', and 'Template'. Two items are listed: FATIMP1 and FATIMP2, both with 'Vertical 01' as the template.

Item Block Number	Item ID	Item Description	Branching If	Then Go To	Template
0	FATIMP1	In the past 7 days To what degree did you have to push yourself to get things done because of your fatigue?	Not at all A little bit Somewhat Quite a bit Very much	Please Select	Vertical 01
0	FATIMP2	In the past 7 days To what degree did your fatigue make you feel slowed down in your thinking?	Not at all A little bit Somewhat Quite a bit Very much	Please Select	Vertical 01

To set parameters for a calibration sample, make a selection from both the Language and Calibration Sample drop lists at the top of each CAT parameters section, modify default parameters as applicable and click Save. The Language drop list is populated with all languages currently supported by Assessment Center. The Calibration Sample drop list is populated with all the calibration samples entered on the Item Statistics page for items within the instrument. If

the drop list selection made on the CAT Parameters page is not applicable for all items within an instrument, the CAT instrument will still run but only administer items which have item parameters for the selected calibration sample.

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Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Current Study: AC User Manual_Example

Study Content (AC User Manual_Example) >> Instrument Customization >> CAT Parameters

CAT Parameters Set Parameters for New Language Save Cancel

Instrument: PROMIS Bank v1.0 - Fatigue
IRT Model: Graded Response Model

- CAT Parameters

Language: All Languages Calibration Sample: Promis Wave 1 Reset to Default Parameters

Item Section

Selection Method* Max Posterior Weighted Info (MPWI)

First Item Select Theta 0.00 Item ID

Prior Distribution: Mean* 0.00 Standard Deviation* 1.00

Stopping Conditions

Number Of Items: Minimum* 4 Maximum* 12 Standard Error* 0.30

Information / Likelihood Function

Theta: Lower Bound* -4.00 Upper Bound* 4.00 Increment* 0.1000

Exposure Control

Group Size* 1

Users may enter a set of administration parameters per language. To establish an additional set of parameters for an additional language, click the Set Parameter for New Language button. This will create another instance of a CAT parameters section. Within the new section, make the appropriate selections from the Language and/or Calibration Sample drop lists, modify default parameters as applicable and click Save. Users only need to set parameters for a language if the parameters are different than those used for the instrument's other languages. For example, if an instrument is to be administered in English, Spanish and French and the English version will use parameters which are different from those to be used for Spanish and French, the user should add an additional parameter section where Language=English, modify applicable parameters and click Save. The user does not need to do the same action for the other two languages as they will be using the same set of parameters (i.e. Language=All Languages).

Users may not modify the Language selection (All Languages) in the default CAT parameters section. The parameters defined in this section will be used for any language not defined in an additional language parameters section. As in the example detailed above, Spanish and French will be administered based upon the parameters defined in the default CAT parameters (All Languages) section while English will be administered based upon the parameters defined in the additional CAT parameters section (Language=English-see below).

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Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Current Study: AC User Manual_Example

Study Content (AC User Manual_Example) >> Instrument Customization >> CAT Parameters

CAT Parameters Set Parameters for New Language Save Cancel

Instrument: AC User Manual Example Instrument
IRT Model: Graded Response Model

+ CAT Parameters

- New CAT Parameters

Language: English Calibration Sample: Promis Wave 1

Item Section

Selection Method* Max Posterior Weighted Info (MPWI)

First Item Select Theta Item ID

Prior Distribution: Mean* 0 Standard Deviation* 1

Stopping Conditions

Number Of Items: Minimum* 4 Maximum* 12 Standard Error* 0.3

Information / Likelihood Function

Theta: Lower Bound* -4 Upper Bound* 4 Increment* 0.1

May I determine the first item to be administered in a CAT or scored Short Form?

Users have the option to select how the first item in a CAT or scored short form will be determined. There are two options within the First Item drop list, theta and item ID. If theta is selected a text box will appear in which the desired theta value of the first item must be entered. If item ID is selected a drop list will appear containing the item IDs of all items within the scored instrument. The item selected from this list will be the first item administered in the instrument. If no selection is made in the First Item drop list, by default the scored instrument will administer the item with the highest information as determined by the algorithm.

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Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Current Study: AC User Manual_Example

Study Content (AC User Manual_Example) >> Instrument Customization >> CAT Parameters

CAT Parameters Set Parameters for New Language Save Cancel

Instrument: AC User Manual Example Instrument
IRT Model: Graded Response Model

- CAT Parameters

Language: All Languages Calibration Sample: Promis Wave 1 Reset to Default Parameters

Item Section

Selection Method* Max Posterior Weighted Info (MPWI)

First Item Select Theta Item ID

Prior Distribution: Mean* 0 Standard Deviation* 1

Stopping Conditions

Number Of Items: Minimum* 4 Maximum* 12 Standard Error* 0.3

Information / Likelihood Function

Theta: Lower Bound* -4 Upper Bound* 4 Increment* 0.1

How do I administer every item from a CAT instrument?

A CAT engine does not administer all items within the instrument. If you want to administer all items that make up the item bank, you will need to access the Set CAT Parameters page and change the standard error to 0. As this is statistically impossible, all items will be administered. You will also need to ensure that the value in the Maximum Number of Items field is larger than the total number of items in the bank.

The screenshot displays the 'CAT Parameters' configuration page in the Assessment Center. The page title is 'Assessment Center' with a sub-header 'CAT Parameters'. The instrument is identified as 'AC User Manual Example Instrument' with an 'IRT Model' of 'Graded Response Model'. The 'CAT Parameters' section includes a 'Language' dropdown set to 'All Languages', a 'Calibration Sample' dropdown set to 'Promis Wave 1', and a 'Selection Method' dropdown set to 'Max Posterior Weighted Info (MPWI)'. Below this, there are fields for 'First Item' (a dropdown set to 'Select'), 'Theta' (a text input), and 'Item ID' (a dropdown). The 'Prior Distribution' section shows 'Mean' set to 0 and 'Standard Deviation' set to 1. The 'Stopping Conditions' section shows 'Minimum' set to 4, 'Maximum' set to 12, and 'Standard Error' set to 0, which is highlighted with a red box. Buttons for 'Set Parameters for New Language', 'Save', and 'Cancel' are located at the top right of the parameter section.

CAT/ Short Form No Duplicates Engine

How do I administer a CAT followed by every item in a short form not selected by the CAT engine?

Some researchers may want to be able to review scores from a CAT instrument as well as from a fixed short form of items from the same item bank. If one were to add the CAT and short form to a single study, it would be possible for the same item to be administered in each instrument. To avoid presentation of duplicate items, navigate to the Advanced sub-menu tab within Set-up. Click on the Specify Instruments hyperlink for the appropriate arm/assessment. The CAT instrument will need to be administered first. Select No Duplicates from the Administer drop list for the appropriate short form. This instructs the administration engine to administer all the CAT items as defined by the parameters, but not administer any items within the short form that have been administered in the CAT. In order for the No Duplicates Engine to be applied, the applicable CAT(s) and short form(s) must have the same Block value. An Administer selection is not available if an instrument is using a non-sequential administration engine, i.e. CAT, branch, random. Note that in the exported data files, the items which appear on both the CAT and short form will appear twice, once with the CAT and once with the short form, even though it was only administered once. In the Mode column of the Assessment Data export, a redundant item will be coded as Participant via Web if a respondent was administered the item or Algorithm/System Generated if the participant was not administered the item.

Arm / Assessment Details

Arm: default Assessment: 1 [Save](#) [Back](#)

Instruments can be blocked. These blocks can be administered randomly or in a fixed order. Instruments in the same block are administered together in a random or pre-defined order.

Instrument Block	Block Administration	Instrument	Order within Block	Completed by Participant	Administer
1	Fixed	PROMIS Bank v1.0 - Fatigue	1	<input checked="" type="checkbox"/>	CAT
1	Fixed	AC User Manual Example Instrument	2	<input checked="" type="checkbox"/>	No Duplicates
1	Fixed	PROMIS Bank v1.0 - Anxiety	3	<input checked="" type="checkbox"/>	CAT

How do I learn more about the instruments in my study?

There are three hyperlinks for each instrument on the Study Content page. These links offer users information about each instrument. One of these links is the Statistics link which was also available on the Add an Instrument page. The other two are Properties and Preview. The Properties link provides detailed information about each instrument. This page is view-only for administered and public instruments. The Preview link opens a pop-up screen that will display an instrument in a selected template, in any applicable language and, if selected, will display information about item administration and selection.

Study Content

Click the Add button to add instruments to your study. Click the Create button to create custom instruments in your study. [Add](#) [Save](#) [Create](#)

You have selected the following instruments for this study.

Order the instruments by entering the desired position into the text box, then click Save.

To exclude an instrument from your study, click on the Include checkbox. Hide Excluded Instruments

Order	Name	Administration Study	Include	Terms of Use
1	<input type="checkbox"/> PROMIS Bank v1.0 - Fatigue	PROMIS Customize Preview Properties Statistics	<input checked="" type="checkbox"/>	Notes © 📄
2	<input type="checkbox"/> AC User Manual Example Instrument	AC User Manual_Example Customize Preview Properties Statistics	<input checked="" type="checkbox"/>	Notes
3	<input type="checkbox"/> PROMIS Bank v1.0 - Anxiety	PROMIS Customize Preview Properties Statistics	<input checked="" type="checkbox"/>	Notes © 📄

Instrument Preview

What is the purpose of previewing instruments?

The Preview link shows what an instrument looks like in various administration templates. It includes all items in an instrument. Selecting the Preview hyperlink will display a View Options popup box from where you can select to view an item list or simulate how the instrument would be viewed by participants in data collection.

View Options

- Preview item list
 Simulate instrument administration with customized settings
 Show Execution Detail (e.g. Item ID and Ability Estimate)

Language:

View Live CAT Scoring

1. Click Preview link next to a CAT instrument name
2. Select Simulate instrument administration with customized settings
3. Check the Show Execution Detail box
4. Click Continue button
5. Answer first item
6. Click the Next button.

View execution details including the theta, standard score, and standard error

Response	Theta	Score	SE
EDDEP29=4	1.50	65.0	4.49
EDDEP41=3	1.48	64.8	3.03

In the past 7 days

I felt worthless

- Never
 Rarely
 Sometimes
 Often
 Always

CAT Settings

Min # of Items to Admin	Max # of Items to Admin	Selection Criterion	Max SE	Pop. Mean	Pop. SD	Calibration Sample
5	20	MPWI	3	50	10	Promis Wave 1

Add Statistics

How do I add statistics to my instrument?

An important feature in Assessment Center is the ability to store, review and update item or instrument statistics. Statistics can only be entered by team members who have the Instrument/Item Administrator role within the originating (Administration) study. Statistics can be entered into the Instrument or Item Statistics pages by clicking the Update buttons. The Item Statistic page also allows users to upload two statistical graphs. These graphs must be created in various statistical programs and then copied into an image format (e.g., .jpeg) prior to being uploaded to

Assessment Center. It is important to note universal image format should be used so that the graphs can be viewed in various browsers.

Enter Instrument Statistics

1. Click a Statistics link for an instrument
2. Click the Update button next to the desired statistical field
3. Enter data into the appropriate statistical fields in the popup screen

Assessment Center

Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Current Study: AC User Manual_Example

Study Content (AC User Manual_Example) >> Instrument Statistics

Instrument Statistics

Instrument: PROMIS Bank v1.0 - Fatigue

Update Back

	10.0	20.0	30.0	40.0	50.0	60.0	70.0	80.0	90.0	Min	Max
Scale Score	10.0	20.0	30.0	40.0	50.0	60.0	70.0	80.0	90.0	0.0	0.0
SE	1.70	.70	.20	.10	.10	.10	.10	.10	.30		
Reliability	.00	.52	.94	.99	.99	.99	.99	.99	.90		

Calibration Sample: Promis Wave 1
 Sample Description: PROMIS Final Wave 1
 Scaling Model Used For Calibration: Graded Response Model
 Total Number of Items: 95

SE	Average CAT Length for Target SE (Type=CAT only)											
0.00												
0.00												

NI	Average SE for Target CAT Length (Type=CAT only)											
0	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00
0	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00

Scale Score Definition

Update

Sample	N	Alpha Reliability
Promis	14931	0.99

Score Distributions									
	Mean	SD	P5	P10	P25	P50	P75	P90	P95
Raw	220.69	91.34	98.00	109.00	142.00	206.00	284.00	356.00	392.00
Scale	51.23	9.41	36.46	39.02	44.31	50.82	57.83	63.97	67.33

Enter Item Statistics

1. Click Statistics link for item
2. Click Update button on Sample Population box
3. Enter data into stats fields
4. Click Update button on Differential Item Functioning (DIF) box
5. Select sample population in drop lists
6. Enter set of data in stats fields
7. Click Save
8. Click Update button on IRT Model box
9. Enter set of data into stats fields
10. Click Save
11. Click Icon next to Item Information Function and/or Category Response Function
12. Click Browse button
13. Select image

[Study Content \(AC User Manual_Example\)](#) >> Item Statistics

Item Statistics

ID: FATEXP20

Domain: Fatigue

[Back](#)

In the past 7 days How often did you feel tired?

Responses

Sample Population

Description

[Update](#)

N-Size	Mean Score	SD Score	Minimum Score	Maximum Score	Alpha Reliability	Adj. Alpha Reliability	Item Total Correlation	Adj. Item Total Correlation	Percent Omit	% Option 1	% Option 2	% Option 3	% Option 4	% Option 5
803	2.84	1.00	1	5	0.99	1.00	0.77	0.80	14.9					

Differential Item Functioning (DIF) Information

[Update](#)

DIF Groups (Reference/Focal)	Uniform	Uniform Prob.	Non-Uniform	Non-Uniform Prob.
<input type="text" value="PROMIS Male - Female"/>	2.84	0.0920	0.00	0.9852

Calibration Sample

Description:

Sample Population: PROMIS Age <65

[Update](#)

IRT Model: Graded Response Model

Category Response Function

Item Information Function

Model Fit & Scalability Indices

	Value	Prob.
S-X ²	0.00	0.0000
S-G ²	0.00	0.0000
X ²	0.00	0.0000
G ²	0.00	0.0000
Loevinger H Scalability	0.00	
Location At Max Information	0.00	

Threshold 1 is between the lowest scored response and the next highest response(s).

IRT Parameters					
Slope (a)	Guessing (c)	Threshold (CB) 1	Threshold (CB) 2	Threshold (CB) 3	Threshold (CB) 4
3.25088	0.0000	-1.6209	-0.4778	0.7291	1.7908

How do I create more than one set of item-level parameters?

Items within Assessment Center may have more than one set of item-level parameters. This enables the system to administer the same item but with different calibrations. Calibrations are identified by the name of the calibration sample. All calibration sample statistics (e.g. IRT parameters) are entered at the item level on the Item Statistics page. It is necessary to complete the Sample Population section of the Item Statistics page prior to attempting to complete the Calibration Sample section. When entering calibration sample data, you will need to select the sample population for which the data applies as there may be more than one calibration sample record per sample population.

Instrument Terms of Use

How do I view an instrument's terms of use?

Instrument may have unique terms of use. Clicking on the symbol © will present the Terms and Conditions for that instrument. You do not have to accept the Terms and Conditions at this point. However, you will need to accept the Terms and Conditions prior to opening an instrument PDF, zip file or launching your study. You may accept the terms and conditions for individual instruments on either the Add an Instrument page or the Study Content page. You may navigate to the Launch Study page or PDF link to accept the Terms and Conditions for a group of instruments, e.g. PROMIS instruments.

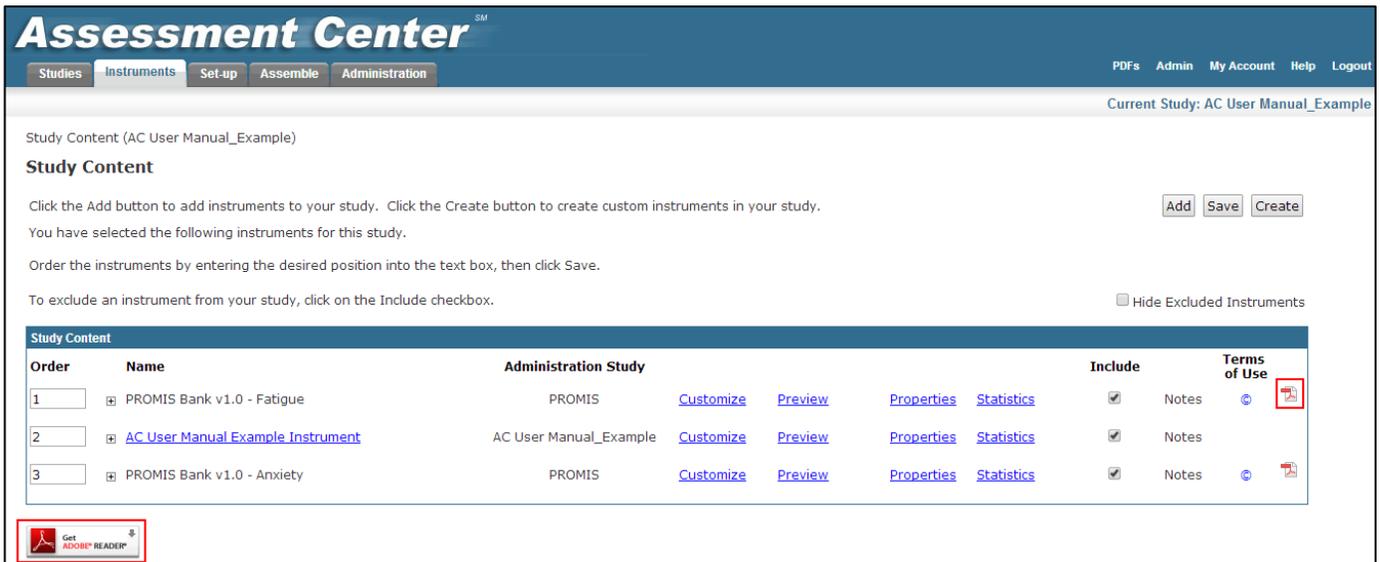
Instrument PDFs

Are paper versions of instruments available?

Assessment Center contains PDFs of existing instruments to be used for paper and pencil administration. These are accessed through the Study Content or the Add Instruments pages by clicking on the PDF icon to the far right of each instrument listing. Additionally, zip files of instrument PDFs are available on the PDF page (hyperlink in the upper right). All of the PROMIS instruments have PDF versions available. You must endorse Terms and Conditions before opening an instrument PDF. In future releases, you may create PDFs of your custom instruments and submit it to Center Administrators (help@assessmentcenter.net) for uploading. If you do not have Adobe Reader, you can download it for free by clicking on the Get Adobe Reader button at the bottom of the page.

Download Instrument PDF

1. Navigate to the Study Content or Add Instrument page
2. Click on the © symbol to read and endorse the Terms & Conditions.
3. Click Accept button
4. Click on the PDF icon.
5. View, print, and/or save the PDF of the instrument. If needed, Adobe Reader can be downloaded through the button at the bottom of the page.



Assessment CenterSM

Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Current Study: AC User Manual_Example

Study Content (AC User Manual_Example)

Study Content

Click the Add button to add instruments to your study. Click the Create button to create custom instruments in your study. Add Save Create

You have selected the following instruments for this study.

Order the instruments by entering the desired position into the text box, then click Save.

To exclude an instrument from your study, click on the Include checkbox. Hide Excluded Instruments

Order	Name	Administration Study	Include	Terms of Use
1	PROMIS Bank v1.0 - Fatigue	PROMIS	<input checked="" type="checkbox"/>	Notes 
2	AC User Manual_Example_Instrument	AC User Manual_Example	<input checked="" type="checkbox"/>	Notes
3	PROMIS Bank v1.0 - Anxiety	PROMIS	<input checked="" type="checkbox"/>	Notes 



Making Instruments Publicly Available

How do I share my instrument with other Assessment Center users?

You are able to create your own instruments by compiling items within the library or entering new items. To make instruments available to all Assessment Center users, the instrument status must be changed to Public. This can only be done by an Assessment Center administrator. To request that an instrument be made public, please contact administrators at help@assessmentcenter.net or 1-877-283-0596. Administrators will request additional information about the instrument development to determine if the instrument should be publicly available.

Set-up

What is the purpose of the Set-up tab?

Assessment Center allows a researcher to set up a study website to collect research participant data. This encompasses detailing in which language your study will be administered, establishing study parameters (e.g., target sample size) how instruments should be administered (e.g., randomization), adding online consent/HIPAA documents, and defining participant self-registration fields.

Language

How do I indicate the language in which my study should be administered?

When you first navigate to the Set-up tab, you are, by default, on the Language page. This page allows you to select the languages which will be available to participants during data collection.

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Studies Instruments **Set-up** Assemble Administration

PDFs Admin My Account Help Logout

Language Basic Advanced Consent Registration | Current Study: AC User Manual_Example

Language (AC User Manual_Example)

Language

In what language(s) would you like to administer your study?

German
 French
 English
 Spanish

Save Cancel

Currently, instruments may be administered in English, Spanish, German or French. Upon instrument creation, one language was set as the default on the Instrument Properties page. If you have uploaded additional language translations or another translation exists, those languages will appear as an additional selection on the Language page. You will have option to select one or more languages for administration. If you select more than one language, a screen will appear at the beginning of data collection prompting participants to select their preferred language. The selection is recorded on a participant's Registration Detail page and is available in the data exports.

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Select your desired language	English
Seleccionar el idioma deseado	Español
Wählen Sie die gewünschte Sprache	Deutsch
Veillez sélectionner une langue	Français

Will all data collection screens be available in my selected language?

Currently, English, Spanish, German and French are supported in Assessment Center. Participants will see all system text (default welcome text, non-custom registration screens, login/password assignment, error messages etc.) in their selected language. If you are collecting data in a non-English language, be sure to review how to upload consent forms and registration fields in the desired language. These instructions are included later in this manual.

What occurs if an item or an instrument does not have applicable language translations uploaded?

All item translations must be uploaded per instrument via the Instrument Detail page. If an item or an instrument does not have applicable language translations uploaded these items or instruments will not be administered to participants who select to complete the assessment in the applicable language. The Preview tab contains a warning which will list the items which are missing an item translation. You may navigate back to the Instrument Detail page at any time prior to Launch to upload additional item translations.

Basic Study Set-up

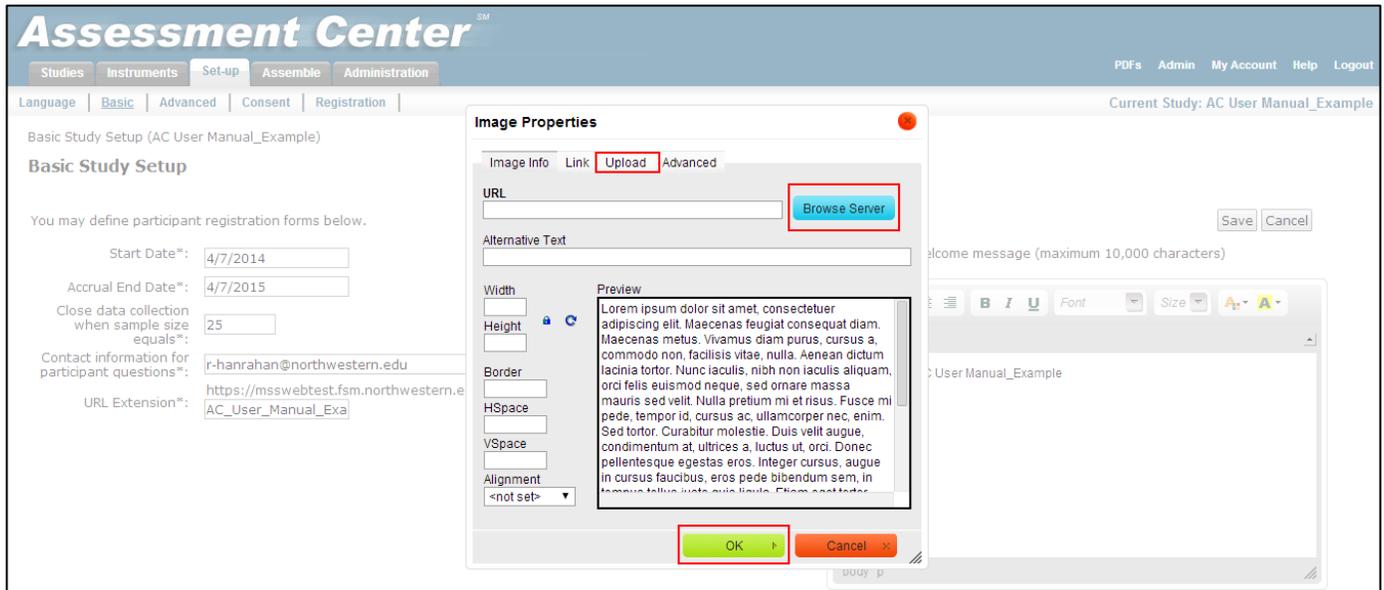
How do I start setting up a website to collect participant data?

The Basic Study Set-up page allows you to create a data collection platform by entering study information about sample size, study web address, start and end dates, and contact information. You may access a detailed description of each field within the Basic Set-up page within Assessment Center Help, <https://www.assessmentcenter.net/ac1/Help/index.html>.

The screenshot displays the 'Basic Study Setup' page in the Assessment Center interface. The page title is 'Basic Study Setup (AC User Manual_Example)'. The main heading is 'Basic Study Setup'. Below this, there is a section titled 'You may define participant registration forms below.' with a 'Save' and 'Cancel' button. The form includes several input fields: 'Start Date*' (4/7/2014), 'Accrual End Date*' (4/7/2015), 'Close data collection when sample size equals*' (25), 'Contact information for participant questions*' (r-hanrahan@northwestern.edu), and 'URL Extension*' (https://msswebtest.fsm.northwestern.edu/assessmentcenter/qa/ac1/Assessments/AC_User_Manual_Example). To the right, there is a 'Login screen welcome message (maximum 10,000 characters)' editor. The editor shows the message 'Welcome to AC User Manual_Example' in English and French. The editor has a toolbar with options for font, size, bold, italic, underline, and text color.

May I include an image on my study's home page?

An image can be uploaded to Assessment Center for inclusion on your study website's home page. To begin the upload process, click on the image icon within the Login Screen box toolbar. An Image Properties window will open. Within this window, navigate to the Upload tab and Browse your computer for the appropriate image. Once the image is found, click the Send it to the Server button to complete the upload. You will receive a confirmation message. To finalize the upload, click Ok on the Image Properties window and you will then see the image within the login screen page.



Advanced Study Set-up

How do I set up a more complex study?

Advanced is the second sub-menu tab under Set-up. The Advanced Study Set-Up page allows you to create studies that have multiple arms (e.g., intervention and control), multiple assessments for longitudinal study designs, and customized instrument presentation per arm/assessment.

Create Multiple Study Arms

How do create a study with more than one arm?

Frequently, research designs have multiple arms. An arm can be defined as a grouping of study participants. Multiple study arms should be used when study participants will not all have the same protocol, e.g. different instruments, different assessment schedule. Assessment Center allows a researcher to tailor the content of the assessment within each arm. If a study utilizes participant self-registration, Assessment Center assigns a participant to a study arm. If a study researcher is registering participants, the study arm can be assigned during registration.

The Advanced Study Set-up page defaults to having a single armed study with a single assessment. If you wish to create multiple arms, click the New Row button. Enter the arm name in the Arm field. *Any variation in the text entered into the Arm field will indicate a new study arm.* Therefore, it is important to ensure the names given to a particular arm, e.g. control, are spelled exactly the same in each new row.

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Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Language Basic Advanced Consent Registration Current Study: AC User Manual_Example

Advanced Study Setup (AC User Manual_Example)

Advanced Study Setup

Create at least one arm/assessment instance and click Save. You will then be able to click on the Specify Instruments link.

- Advanced Study Setup has been saved.

Arm	Assessment	Day Assessment Opens	Window		
<input type="text" value="Control"/>	<input type="text" value="1"/>	Day <input type="text" value="0"/>	<input type="text" value="4"/> Days	Specify Instruments	Delete
<input type="text" value="Control"/>	<input type="text" value="2"/>	Day <input type="text" value="7"/>	<input type="text" value="4"/> Days	Specify Instruments	Delete
<input type="text" value="Intervention"/>	<input type="text" value="1"/>	Day <input type="text" value="0"/>	<input type="text" value="4"/> Days	Specify Instruments	Delete
<input type="text" value="Intervention"/>	<input type="text" value="2"/>	Day <input type="text" value="7"/>	<input type="text" value="4"/> Days	Specify Instruments	Delete

How do I determine how many arms to use in Advanced Set-up?

There are a number of factors to consider when determining how many arms to have in your study. For example, if you have a study design in which different people are getting different measures, you will want to have multiple arms.

How do participants get assigned to a study arm?

If participants self-register (i.e. access the study-specific website, enter registration or consent information and obtain a login), they are assigned to a study arm by Assessment Center. Generally, this works for item calibration testing when you don't need to control who answers what instruments/items. However, this is not appropriate if you want, for example, all patients with breast cancer to get one set of instruments and patients with prostate cancer to get a different set of instruments. If you need to direct participants to a specific arm, researchers should register the participants from the Administration tab assigning each participant to the correct arm. This means that participants will enter their login and password information on the Welcome (home) page of the data collection website. By doing so, they will bypass the registration and consent screens. Therefore, it is important for the researcher registering the participant to collect all applicable registration data and consent the participant (or verify consent has been obtained).

If participant registration by a researcher is not feasible, e.g. participants will complete assessment at home after receiving a newsletter, you can set up a study and subsequently a data collection website per participant population. For example, you could create one study/website for breast cancer patients and one study/website for prostate cancer patients.

How do I create study arms that have an unequal number of participants?

If you are having participants self-register, they will be automatically assigned to a study arm in EQUAL numbers. This is appropriate if you want say, 100 people in Arm A and 100 people in Arm B. If you have uneven group sizes, you can create multiple arms that are identical. For example, in a given study you may want 300 people in Arm A but only 100 people in Arm B. You can create four arms – Arm A1, A2, and A3 are all identical to each other and Arm B is different. Equal numbers of participants are assigned to each arm and as a result you will have 300 people in the A arms and 100 people in the B arm.

Study arm assignment can be summarized from the Registration. Data export. Study Arm appears as column AB when the export is opened in Excel. If your study has specific accrual goals per study arm, it will be important to periodically run the export and assess the number of participants in each arm.

Create Multiple Assessments

How do I set up a longitudinal study?

Assessment Center allows for data collection at multiple points in time. For example, a researcher may want to collect initial baseline data, a 1 month and 6 month follow-up. This can be accomplished through the Assessment, Day Assessment Opens, and Window fields. Enter the assessment number in the Assessment field. The Day Assessment Opens field indicates when an assessment is made available to study participants. This information is not relevant to the first (baseline) assessment and no data will be entered in this field when the Assessment field equals 1. For subsequent assessments, enter the number of days after the first assessment that you want the assessment to be available. In the example below, the 1-week follow-up would be 7 days after baseline and the 2-week follow-up would be 14 days after baseline. The Window field establishes how many calendar days an assessment will remain open to study participants. For example, if participants have one week to complete the assessment, enter 7 in the Window field. A study participant may exit the assessment and return at a later time as long as it is within the assessment window. In the example below Assessment 2 will be open from Day 7 to Day 9. Assessment 3 will be open from Day 14 to Day 16. It is recommended that you **do not** have overlapping assessments. If you do, a person would be immediately transitioned to from one assessment to the following assessment.

Arm	Assessment	Day Assessment Opens	Window	
Control	1	Day 0	2 Days	Specify Instruments Delete
Control	2	Day 7	2 Days	Specify Instruments Delete
Control	3	Day 14	2 Days	Specify Instruments Delete
Intervention	1	Day 0	2 Days	Specify Instruments Delete
Intervention	2	Day 7	2 Days	Specify Instruments Delete
Intervention	3	Day 14	2 Days	Specify Instruments Delete

How do I set up a daily assessment?

To create a study that has a daily assessment, enter 0 in the Window field. A participant will have until midnight central standard time (CST) to complete an assessment for that day. In the example below, a participant is asked to complete an assessment every day for 7 days.

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Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Language Basic Advanced Consent Registration Current Study: AC User Manual_Example

Advanced Study Setup (AC User Manual_Example)

Advanced Study Setup

Create at least one arm/assessment instance and click Save. You will then be able to click on the Specify Instruments link.

Save Cancel

New Row

Arm	Assessment	Day Assessment Opens	Window		
arm1	1	Day 0	0 Days	Specify Instruments	Delete
arm1	2	Day 1	0 Days	Specify Instruments	Delete
arm1	3	Day 2	0 Days	Specify Instruments	Delete
arm1	4	Day 3	0 Days	Specify Instruments	Delete
arm1	5	Day 4	0 Days	Specify Instruments	Delete
arm1	6	Day 5	0 Days	Specify Instruments	Delete

How does Assessment Center calculate the assessment schedule?

The assessment schedule for a study is established on the Advanced Study Setup page with the Day Assessment Opens and Window fields. A day is based on the Central Standard Time (CST) Zone. That means that if a participant in Chicago begins an assessment at 8pm that is only available that day, s/he will have until midnight to complete the assessment. After midnight, the assessment will not be available. If a participant is in New York, his or her schedule will still be based on Central time even though s/he is physically located in the Eastern Time Zone.

Modify Assessment Schedule

How can I change the assessment schedule for one participant?

In Assessment Center, the assessment schedule is set for a study as a whole on the Advanced Set-up page. Sometimes you may need to adjust the schedule for a single participant. This is done in the Administration tab within a participant's individual registration record-see steps below.

Modify a Participant's Schedule

1. On the Study Overview page, access a participant's registration record by entering their login in the Find/create Login field or accessing the Participant List and clicking on the participant's name hyperlink.
2. On the Registration Details page, click the View Schedule hyperlink to the right of the Schedule field
3. Enter the new End Date for the correct assessment in the Participant View row.
4. Click on the pencil icon on the far left to accept changes.
5. Enter the new End Date for the correct assessment in the Clinician View row.
6. Click on the pencil icon on the far left to accept changes.
7. Close the window.

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[PDFs](#) | [Admin](#) | [My Account](#) | [Help](#) | [Logout](#)

[Overview](#) | [Registration Details](#) | [Participant Details](#) | [Contact Information](#) | [Custom Fields](#) | [Reports](#) | [Participant Data](#)
Current Study: AC User Manual_Example

To register a new participant, enter information below and click Register Participant button. Please navigate to Participant Details, Contact Information and Custom Fields tabs prior to clicking Register Participant button to ensure all necessary registration data has been included. **Login:**

** Required Fields * Only required for consented participants

Study Arm:
 Schedule: [View Schedule Details](#)
 Date Approach:
 Site:
 Login: (optional) Create participant login
** Password:
 Study code:
 Baseline:
** Consent: Yes No Test Preview
 Non-Enrollment Reason:
 Off Study:
 Language:

Participant Schedule

Scheduled Event	Mode of Access	Start Date	End Date
✍ Assessment (1)	Participant View	11/15/2011	11/17/2011
✍ Assessment (1)	Clinician View	11/15/2011	11/17/2011
✍ Assessment (2)	Participant View	11/18/2011	11/20/2011
✍ Assessment (2)	Clinician View	11/18/2011	11/20/2011
✍ Assessment (3)	Participant View	12/01/2011	12/03/2011
✍ Assessment (3)	Clinician View	12/01/2011	12/03/2011
✍ Assessment (4)	Participant View	12/08/2011	12/10/2011
✍ Assessment (4)	Clinician View	12/08/2011	12/10/2011
✍ Assessment (5)	Participant View	12/15/2011	12/17/2011
✍ Assessment (5)	Clinician View	12/15/2011	12/17/2011
✍ Assessment (6)	Participant View	12/22/2011	12/24/2011
✍ Assessment (6)	Clinician View	12/22/2011	12/24/2011
✍ Assessment (7)	Participant View	12/29/2011	12/31/2011
✍ Assessment (7)	Clinician View	12/29/2011	12/31/2011
✍ Assessment (8)	Participant View	01/05/2012	01/07/2012

[\[Close Window\]](#)

How would I set up assessments without a predefined assessment schedule?

To create a flexible assessment schedule in Assessment Center, first set up the max number of assessments a participant could possibly take on the Advanced Study Set-up page. Next, set the Day Assessment Opens and window fields so no assessments overlap (e.g. opens every 3-6 months). Finally, each time a participant comes in for a follow-up assessment manually modify the assessment schedule via the participant's registration record (please see "Modify Assessment Schedule" section for details). The final step will open up the assessment being modified so that it will be

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administered to the user when they log into the study website. Please note this step is not necessary for the baseline assessment.

Arm	Assessment	Day Assessment Opens	Window
arm1	1	Day 0	2 Days Specify Instruments Delete
arm1	2	Day 100	2 Days Specify Instruments Delete
arm1	3	Day 200	2 Days Specify Instruments Delete
arm1	4	Day 300	2 Days Specify Instruments Delete

How can I set follow-up assessments to be timed from a particular event (e.g., surgery)?

Assessments may be associated with an event outside of Assessment Center. For example, a researcher may want to have a baseline assessment completed 7-14 days prior to surgery and follow-up assessments completed 6-week and 12-weeks from surgery date, not date of baseline. In this case, Assessment Center needs information on when surgery happened in order to correctly time the follow-up assessments.

There are a couple of ways to complete this requirement. First, a researcher could set up a study with a flexible assessment schedule (see description above). Once a participant's surgery occurs research staff should modify that participant's schedule for Assessment 2 and 3 (please see "Modify Assessment Schedule" section for details).

A second option to accommodate an event-based study design is to create multiple Assessment Center studies. The first study would include only Assessment 1 (i.e. the baseline, pre-event assessment). The second study would include all follow-up assessments which occur after the event. During data collection, once a participant completed the first study research staff would use the participant's login and password to manually register that participant to the second study. In the second study registration, the "Baseline" field on the Registration Details page should be the start date of the first follow-up assessment. It is important to ensure the logins from the two studies are the same (i.e. login from first study used when registering participant to second study) so the databases may be linked together during analyses. An advantage of this solution is that it reduces the amount of manipulation to the study schedule for each individual participant. However, it does require merging data from the two studies.

In both scenarios, it may be useful for data cleaning and analyses purposes to record the event date in a custom instrument/item, e.g. "Please enter date of surgery".

Assign Instruments to Study Arms and Assessments

How do I establish what instruments are administered within an arm and an assessment?

Assessment Center allows you to tailor each assessment within a study arm. For example, you may wish to administer a sociodemographic instrument only at the first assessment and a study evaluation instrument only at the final assessment. On the Advanced Study Set-up page, first establish the arm/assessment schedule for your study by

naming each arm and entering values in the Assessment, Day Assessment Opens and Window fields. Once you have saved your assessment schedule, the Specify Instruments hyperlink will become active. Click on this hyperlink for the arm/ assessment row of interest to access the Arm/Assessment Details page. The arm name and assessment number will be listed at the top of this page. All instruments included in the study are listed. Select Not Included under the Instrument Block field for any instrument within your study that you do not want administered for this arm/assessment.

Establishing instruments included in an Assessment

1. From Set-Up, navigate to the Advanced Study Setup page.
2. Click on the Specify Instruments hyperlink for the arm/assessment
3. In the Instrument Block drop down menu, select Not Included for all of the instruments not administered in this arm/assessment.

Instrument Block	Block Administration	Instrument	Order within Block	Completed by Participant	Administer
1	Fixed	PROMIS Bank v1.0 - Fatigue	1	<input checked="" type="checkbox"/>	CAT
Not Included	Fixed	AC User Manual Example Instrument	2	<input checked="" type="checkbox"/>	All Items
1	Fixed	PROMIS Bank v1.0 - Anxiety	3	<input checked="" type="checkbox"/>	CAT

Instrument Order

How do I define the order of instrument administration for each arm/assessment?

Instruments can be grouped together for administration. For example, you may wish to group sociodemographic instruments or patient-reported outcome instruments together. On the Arm/Assessment Details page, each instrument can be assigned to a group using the Instrument Block field. For example, all sociodemographic instruments could be assigned to Instrument Block 1, and all patient-reported outcome instruments to Instrument Block 2. The order of instruments within a given block can be fixed or random. Under Block Administration, select Fixed if you want blocks presented sequentially. Select Random if blocks should be presented randomly. You can have some blocks presented randomly and some fixed. The Order Within Block field can be used to fix the instrument order or assign random order within an Instrument Block.

In the example below, Block 1, is fixed while Blocks 2 and 3 are set to be administered in a random order. The order of instruments within a given block (see Order within Block column) is sometimes fixed and sometimes random. Here, Instrument Block 1 is always administered first with the demographics instrument followed by clinical instrument. Blocks 2 and 3 are always presented next, but the system will randomly determine if Block 2 or Block 3 will be presented first. The PROMIS instruments within Blocks 2 and 3 are also presented in a randomized order.

If you add an instrument to your study after you have initially set the instrument administration on the Arm/Assessment Details page, the newly included instrument will be placed in the last "Order within Block" position under the first block (block=1). This will be done for all arm/assessments. You will need to access each Arm/Assessment Details instance to make necessary revisions.

Grouping Instruments Together and Establishing Instrument-Level Randomization

1. Click on the Specify Instruments hyperlink for the applicable arm/assessment
2. Assign Instrument Block number on Arm/Assessment Details page
3. Select if Blocks are in a fixed (sequential) or random order
4. Select if instruments within a given block are presented in a fixed (sequential) or random order

Arm: arm1 Assessment: 1 Save Back

Instruments can be blocked. These blocks can be administered randomly or in a fixed order. Instruments in the same block are administered together in a random or pre-defined order.

Instrument Block	Block Administration	Instrument	Order within Block	Completed by Participant	Administer
1	Fixed	PROMIS Sociodemographic Example	1	<input checked="" type="checkbox"/>	All Items
1	Fixed	PROMIS Clinical Form Example	2	<input checked="" type="checkbox"/>	All Items
2	Random	PROMIS Bank v1.0 - Depression	Random	<input checked="" type="checkbox"/>	CAT
2	Random	PROMIS Bank v1.0 - Anxiety	Random	<input checked="" type="checkbox"/>	CAT
3	Random	PROMIS Bank v1.0 - Pain Behavior	Random	<input checked="" type="checkbox"/>	CAT
3	Random	PROMIS Bank v1.0 - Fatigue	Random	<input checked="" type="checkbox"/>	CAT

Identifying Clinician-Rated Instruments

How can I include instruments in my study that are completed by research or clinical staff?

Sometimes researchers want to include instruments that are tied to a given research participant, but are completed by research or clinical staff, e.g. a physician's rating of performance status for a research participant or research assistant completed medical history review. Assessment Center allows for some instruments to only be accessed by research staff through the Participant Data page on the Administration tab. Only team members with proper roles on the study may view (Study Administrator, Study Participant Administrator) or enter/modify (Study Data Entry Administrator) data. By default participants are presented all instruments. On the Arm/Assessment Details page, you can indicate if an instrument should not be presented to the research participant by unchecking the Completed by Participants box.

Establishing Instruments Completed Participants

1. Navigate to the Arm/Assessment Details page by clicking on the Specify Instruments link
2. Ensure Completed by Participants checkbox is checked for all instruments to be completed by participants
3. Uncheck Completed by Participant box for all instruments to be completed by others (e.g. clinical or research staff)

Assessment CenterSM

Studies Instruments **Set-up** Assemble Administration PDFs Admin My Account Help Logout

Language Basic **Advanced** Consent Registration Current Study: AC User Manual_Example

[Advanced Study Setup \(AC User Manual_Example\)](#) >> Specify Instruments

Arm / Assessment Details

Arm: arm1 Assessment: 1 Save Back

Instruments can be blocked. These blocks can be administered randomly or in a fixed order. Instruments in the same block are administered together in a random or pre-defined order.

Instrument Block	Block Administration	Instrument	Order within Block	Completed by Participant	Administer
1	Fixed	PROMIS Sociodemographic Example	1	<input checked="" type="checkbox"/>	All Items
1	Fixed	PROMIS Clinical Form Example	2	<input type="checkbox"/>	All Items
2	Random	PROMIS Bank v1.0 - Depression	Random	<input checked="" type="checkbox"/>	CAT
2	Random	PROMIS Bank v1.0 - Anxiety	Random	<input checked="" type="checkbox"/>	CAT
3	Random	Clinical Performance	1	<input type="checkbox"/>	All Items

Avoiding Redundant Items

Am I able to eliminate an item being administered twice?

The Administer drop lists allow a user to specify whether or not they would like the system to check if an item has already been administered in an assessment and if that is the case, not administer the item on a subsequent instrument within the same arm/assessment. If a user selects No Duplicates under the Administration field any item already administered in the preceding instruments will not be administered a second time. The score recorded when the item was first administered will appear in the export files for both instruments. The Mode field in the Assessment Data export will indicate if the participant's response was captured for that instrument (Participant via Web) or copied from a prior instrument (Algorithm/System Generated). The administration of All Items is the default. An Administer selection is not available if an instrument is using a non-sequential administration engine, i.e. CAT, branch, random.

Assessment CenterSM

Studies Instruments **Set-up** Assemble Administration PDFs Admin My Account Help Logout

Language Basic **Advanced** Consent Registration Current Study: AC User Manual_Example

[Advanced Study Setup \(AC User Manual_Example\)](#) >> Specify Instruments

Arm / Assessment Details

Arm: default Assessment: 1 Save Back

Instruments can be blocked. These blocks can be administered randomly or in a fixed order. Instruments in the same block are administered together in a random or pre-defined order.

Instrument Block	Block Administration	Instrument	Order within Block	Completed by Participant	Administer
1	Fixed	PROMIS Bank v1.0 - Fatigue	1	<input checked="" type="checkbox"/>	CAT
1	Fixed	AC User Manual Example Instrument	2	<input checked="" type="checkbox"/>	No Duplicates
1	Fixed	PROMIS Bank v1.0 - Anxiety	3	<input checked="" type="checkbox"/>	CAT

Add Consent Forms

How do I add study consent forms?

The Consent sub-menu tab allows you to include up to three online consent documents per language for participants (e.g., consent, assent, HIPAA). Consent forms are not required by Assessment Center to administer a study and the inclusion of consent forms is dependent on institution-specific procedures. It is important to verify requirements with your institutional review board (IRB) prior to launching a study in Assessment Center. It is the responsibility of users to ensure compliance with IRB regulations, not Assessment Center or Assessment Center administrators.

What consent forms should I use?

Assessment Center does not regulate the text that is entered into the consent form fields. However, it is essential that users consult with their institution's IRB office to ensure their study has been reviewed and approved. If a study is approved as exempt and not needing a consent form (this can ONLY be determined by the IRB) users should not use the Consent page. If a study has been reviewed and the institution-specific IRB has approved use of the Assessment Center online consent feature, then users should copy and paste their institution-specific, IRB approved consent form(s) into the Consent 1, 2 or 3 fields, as applicable. To do so, expand the applicable section by clicking on the plus/minus sign next to the consent title. You will then be presented additional sections for each language you have determined to use in data collection. Click the plus/minus sign next to the language title to expand the section and view the text box in which you may cut/paste a consent form.

The easiest way to add consent forms in your study is to create them in a word processing program such as Word and use the copy/paste functions to add them into Assessment Center. This will allow you to take full advantage of formatting options (e.g. spell checking, fonts). Within each consent section, there are three checkboxes. The first allows you to denote the consent form may contain Protected Health Information (PHI) by checking the Consent contains Protected Health Information (PHI) box. When a data field is marked as containing PHI, all data collected in this field will be flagged in the database and will be reported as containing PHI in applicable data exports. This feature is intended to aid in de-identification efforts and protect participant privacy.

The next two checkboxes are used to indicate how a participant will provide consent endorsement. The first is a checkbox and the second is an open text field. Users can specify the text they would like accompany these fields, e.g. "Please check this box if you agree to participate" within each consent language section. Users may opt to use one, both or none of these endorsement indicators although IRBs may have institution-specific requirements that may guide a user's decision. The endorsement field will appear at the bottom of the consent form when presented to research participants. If you are collecting data in multiple languages, you should include a consent form in each language. Consent forms within Assessment Center are for online use only. Do not use this feature if you intend to obtain informed consent with paper-based forms. Consent status is recorded within a study participant's registration record, Registration Details page within the Administration tab and Export Consent Data export.

Add Consent Forms

1. From the Consent sub-menu tab, click the plus/minus sign to expand Consent 1 section
2. Check the Consent contains Protected Health Information (PHI), where applicable
3. Indicate the type of endorsement to include
4. Modify endorsement text, where applicable
5. Paste consent form text into consent form content textbox
6. If collecting data in other languages, paste appropriate consent form text in the other language sections.
7. Repeat with Consent 2 and Consent 3 if necessary

Language | Basic | Advanced | **Consent** | Registration | Current Study: ACUM_R8.5

Consent (ACUM_R8.5)

Consent Forms

To add up to three consents forms to your study, expand applicable consent boxes and enter information. Save Cancel

- Consent 1 Include

- Consent contains Protected Health Information (PHI)
- Include an endorsement checkbox
- Include an endorsement text entry

+ English

+ Spanish

+ German

- French

Endorsement checkbox text:

Endorsement text entry text:

Please copy and paste your consent form content into the box below.

+ Consent 2 Include

When are consent forms viewed by participants?

A consent form appears after the Welcome (home) page. A participant is not able to move forward unless the consent is endorsed. However, if a researcher registers a participant from the Administration tab, that participant will NOT view a consent. The system assumes a researcher procured consent before registering a participant in a study. When researchers register participants, consent status is required within a study participant's registration record.

Registration

What is registration?

Registration in Assessment Center is used to collect participant demographic and contact information. Registration screens, as defined on the Registration tab within Setup, are presented after consent forms and before instruments. Assessment Center allows for participants to self-register or for study staff to register participants. Registration information is to be completed by whoever is completing the registration form (i.e., participant or researcher). This means that if a researcher registers a participant, the participant will not view the registration screens. Registration fields are used in tracking participant accrual. Data from these fields is used to populate accrual reports. Age, ethnicity, gender, race must be collected in Registration to take full advantage of the reports, i.e. Enrollment Report and NIH Inclusion Enrollment Report. If you collect these in a study instrument, you will have to MANUALLY construct an accrual report. Additionally, registration information is stored in a database separate from the instrument data. This allows a researcher to keep PHI separate thereby having access to a de-identified dataset (Assessment Data export).

How do I select registration variables to include in my study?

To select registration fields to be administered to participants, navigate to the Registration sub-menu tab within the Set-up tab. On the Registration page there are standard registration fields on the left and customizable registration fields on the right (click the plus/minus symbol to view each field type). Check the Include box for all registration

fields you wish to have administered to participants. If you would like to require that a participant provide information in a field, check the Required box. It is important to note, participants will not be able to move forward without providing required registration information. You may also enter minimum and maximum values for validation. This may be useful when you want to ensure only eligible individuals can access the study (e.g., over age 18). Participants who provide responses outside of the range will receive a message noting they are not eligible for the study. If you are collecting data in a non-English language, the standard registration fields will displayed in the participant’s selected language. Several standard registration fields will always be marked as containing PHI. These are date of birth, doctor, last name, first name, street, city, state, zip, email, phone 1, and phone 2. When a data field is marked as containing PHI, all data collected in this field will be flagged in the database and will be reported as containing PHI in applicable data exports. This feature is intended to aid in de-identification efforts and protect participant privacy.

The Ethnicity and Race fields utilize responses recommended by current NIH guidelines. For Ethnicity, participants indicate if they are Hispanic or Latino, Not Hispanic or Latino, or Not Provided. For Race, participants can select all that apply: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, Not Provided, Other, and White. If this information is collected in registration, it will automatically populate an NIH Inclusion Enrollment report that meets the criteria for NIH progress reports.

There are five custom registration fields. They are organized based on response type. One field allows collection of a date response (e.g. date of diagnosis). There are two fields to collect numeric responses (e.g. number of hospitalizations in the last year). A custom text field allows for open text responses (e.g. name of hospital). Finally, a custom list registration field presents a drop list (e.g. type of cancer–breast, colon, lung, etc.). For this customizable field, responses must be entered in the validation section and be separated by commas. The custom list responses have a character limit of 500. For each custom registration field, you are responsible for entering the field label text. This is the text which will inform the participant what to enter in the field, e.g. “what is the date of you diagnosis” or “please select your disease type from the list”. If your study collects data in multiple languages, there will be a section per language so you may enter text in each applicable language. You will click the plus/minus sign to expand each section. The additional custom fields can be marked as PHI by checking the PHI box within each field row.

Registration (AC User Manual_Example)

Registration

You may define participant registration forms below.

Include	Field Label	Required	Validation	
			Min Value	Max Value
<input checked="" type="checkbox"/>	Age	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	Date of Birth	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Gender	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Ethnicity	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Race	<input type="checkbox"/>		
<input type="checkbox"/>	Doctor	<input type="checkbox"/>		
<input type="checkbox"/>	First Name	<input type="checkbox"/>		
<input type="checkbox"/>	Last Name	<input type="checkbox"/>		
<input type="checkbox"/>	Street	<input type="checkbox"/>		
<input type="checkbox"/>	City	<input type="checkbox"/>		

Additional Custom Fields

+ Date Field

- Number Field

Include	Required	PHI	Validation	
			Min Value	Max Value
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
Field Label				
- English				
			Label for Number Field: <input type="text"/>	
- French				
			Label for Number Field: <input type="text"/>	

+ Number2 Field

Selecting Registration Fields

1. Navigate to the Registration page
2. Check Include for all desired variables
3. Click Required if participants are required to provide a response
4. Click PHI if data may contain protected health information
5. Enter any custom registration field labels and validation values
6. Enter custom registration field text for all additional languages if needed

Assemble

From the Assemble tab, you will be able to review and launch your study for data collection.

How do I create my study's data collection site?

The first step in preparing your study for preview and/or actual data collection is to navigate to the Build Study page. From this page, click the Build button in order for Assessment Center to assemble your study's data collection site.

What do the warning and error messages on the Build Study page mean?

There are warnings which may appear within the Build Study page providing a check on the instruments you have included in your study. Warnings will not prevent a study from being launched. Instead, they are a final check for you to ensure you have no problematic instruments in your study. The first warning is "The following items contain missing/mismatched calibrations. Please set IRT Parameters". This warning identifies if a scored instrument includes uncalibrated items. If this occurs, the uncalibrated items will not be administered to participants. Second, the instruments listed in the "Items from Multiple Domains" check indicate that a CAT has items from more than one domain. CAT construction involves calibrating a unidimensional construct. Consequently, if you have created a CAT from multiple constructs, it may be problematic. Third, the "Instruments with Duplicate Items" warning notes instruments that share items. You may consider using the No Duplicates function on the Arm/Assessment Detail Page to avoid giving a participant the same item multiple times. The final warning, "Translation Warnings", will alert you to items which do not have a translation uploaded. This warning will only be applicable if your study includes more than one administration language.

There are also two errors messages which may appear at the top of the Preview page. If you receive one of these errors the system will require you to resolve it before launching your study. The first error occurs if a study has no instruments added or created. To resolve this issue navigate to the Instruments tab and add or create at least one instrument. The second error, which reads "CAT parameters have not been set", occurs if you have created a scored instrument but have not set CAT (IRT) parameters. To resolve this error, you will need to navigate to the CAT Parameters page to set or modify, as applicable, and save default CAT parameters.

How can I review my study before I preview and/or launch?

The Study Configuration Export details your study set-up as entered on the Advanced set-up tab, e.g. study arms, instrument blocks per arm/assessment, administration engine etc. Click the View Export button to open the Study Configuration Export. When using a Windows platform, the file will open as an Excel file. It is recommended you save the report outside of Assessment Center for future reference. If the export does not match selections within the Advanced sub-menu tab, please review the Arm/Assessment Details page then contact administrators at help@assessmentcenter.net or 1-877-283-0596.

Should I conduct other reviews before previewing my data collection site?

A study summary is displayed on the Build Study page detailing the accrual goal, start date, end date, study URL, and contact information. Also, after you initially launch your study for preview, the Administration tab is available for use. Navigate to the Administration tab to review participant registration and data pages, study reports and data exports.

Assessment CenterSM

The screenshot shows the 'BUILD STUDY' page in the Assessment Center. The page has a blue header with the 'Assessment Center' logo and navigation tabs for 'Studies', 'Instruments', 'Set-up', 'Assemble', and 'Administration'. The current study is 'AC User Manual_Example'. The main content area is titled 'BUILD STUDY' and contains a 'Build' button. Below this is a section for 'Warnings and Error Messages' which states there are no warnings. A 'View Export' button is also present. At the bottom, there are four informational items with 'Go there' links: 'Accrual Goal: 25', 'Start Date: Apr 7 2014 12:00AM', 'End Date: Apr 7 2015 12:00AM', and 'Languages of Administration: English'.

How do I initiate a preview of my study's data collection site?

Once you have reviewed the report you will want to preview your study from the perspective of a participant. The preview will show all study details, e.g. language, items/instruments, administration engines, instrument blocks per arm/assessment, etc. Preview also allows you to review scoring of instruments. If you would like to view response scores during preview, ensure Yes is endorsed on the Preview Study page. It is important to note, you will not need to change your endorsement to ensure response scores are not displayed to participants. The only instance in which response scores will be displayed to participants once a study is launched is if the Show Response Score boxes are checked on the Item Detail page.

The screenshot shows the 'PREVIEW STUDY' page in the Assessment Center. The page has a blue header with the 'Assessment Center' logo and navigation tabs for 'Studies', 'Instruments', 'Set-up', 'Assemble', and 'Administration'. The current study is 'AC User Manual_Example'. The main content area is titled 'PREVIEW STUDY' and contains a radio button selection for 'Yes' (selected) and 'No'. Below this is a 'Preview' button. The page also displays the text 'Ready to preview your study?' and 'This study was last built on Apr 7 2014 2:22PM.' followed by instructions on how to preview the study.

Click the Preview sub-menu tab to access the Preview Study page. To initiate the preview, click on the Preview button. The system will launch your study for preview. The preview launch pop-up will indicate the launch is

Assessment CenterSM

complete and after you have clicked the Continue button, you will be navigated to your preview data collection website. The data collection pages will have a Preview watermark only while in preview mode.

Assessment CenterSM

Welcome to PRO Manual Example

If you already have a Login and Password, please enter them in the boxes.

Login

Password

If you are a first time user, click Start below.

If you have any questions or problems, please contact r-hanrahan@northwestern.edu.

PREVIEW

Complete all assessments to ensure everything is working as intended. If study configuration is not as expected or if an instrument, item or study parameter is identified as needing modification, you will need to make the appropriate modifications within the Instruments or Set-up tabs. Most study parameters (e.g. add/create instrument/item, create study arm, instrument order etc.) **may not be modified once the study has been launched**. Therefore it is essential to make any applicable revisions prior to launching your study. If you have problems making corrections, please contact administrators at help@assessmentcenter.net or 1-877-283-0596.

Preview Study

1. Click Build button on the Build Study page
2. Navigate to the Preview Study page by clicking the Preview sub-menu tab
3. Click the Preview button
4. Click Continue button after launch process is complete
5. Review data collection website for accuracy and complete assessment
6. Close browser
7. Open browser and navigate to Assessment Center (www.assessmentcenter.net)
8. Adjust preview participant schedule as necessary to review all assessments
9. Make any applicable modifications to instruments/item and study configuration, as applicable
10. Click Build button, if any changes were made to the study
11. Click Preview button to launch preview of study
12. Re-review Preview data collection pages, as applicable

How do I create preview test logins?

When previewing a study, you will first have to self-register a participant by clicking the “Start” button on the Welcome page. After the initial preview, you can create additional pins to test different arms and time points. Go to the Administration tab and click the Find/Create Login button. This will navigate you to a blank registration page. Complete all applicable fields, be sure to select Preview from the Consent Obtained field, and then click the Register Participant button. This will register a test participant. You may then navigate to the study’s data collection (preview) site and complete the assessment as a participant.

Please note there are some instances in which it may be necessary to review/test a data collection website *after* a study has officially been launched into data collection. A specific example is when administering Toolbox

instruments/batteries. In order to learn how to administer NIH Toolbox instruments, it is strongly recommended that you practice prior to working with a patient/participant. It is easiest to do this in the study you plan on using for actual data collection. To ensure preview (test) data is not included in the dataset you will later use for analyses, you must flag these logins as “Test” participants. To do so, after you have completed your tests, navigate to the Administration tab and find the logins/test participants by clicking the Participant List button. Find the hyperlink next to the test participant’s login and password. If you collected name in Registration, the hyperlink will be the participant’s name. If not, it will be “zzzMissingMissing”. You will then be navigated to the Registration Details page. Change the Consent Obtained field from “Yes” to “Test.” Click Register Participant to save the change. In all data exports, you will want to only analyze participants with a value of 1 in the Consent field. Other values (2= No consent, 3 = test participant, 4 = preview participant) are not suitable for analyses.

How can I ensure I conduct a comprehensive review using the Preview feature?

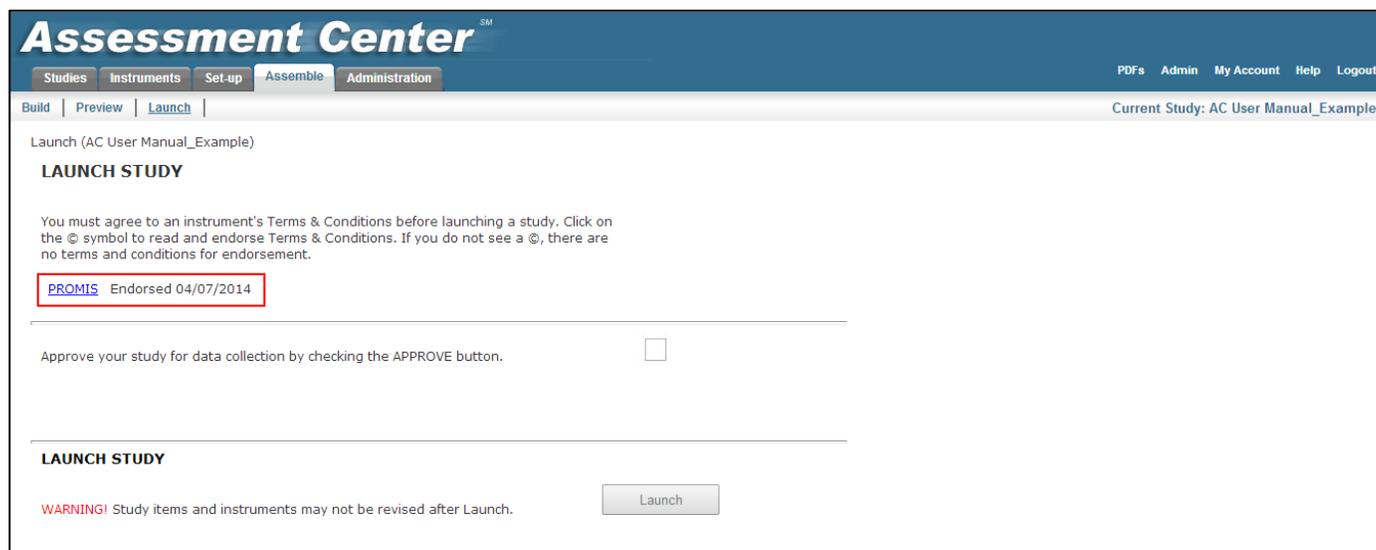
During the preview of your data collection site, the study should be reviewed by all applicable study team members (e.g. RAs, Study Coordinators, PIs) to ensure all study elements and requirements are acceptable and accurate. It is important to review all study arms and assessments. Also, it is important to enter test data and export data to confirm data is being recorded as intended. All preview participants will appear in study exports with a consent value of 4. If you have created a custom CAT for your study it is important to ensure the CAT is scoring correctly. All public CATs and scored short forms have been tested and confirmed by Assessment Center administrators.

How can I preview all study assessments?

Once you have launched your study for preview, the Administration tab is active and may be utilized during your study preview. To review more than one assessment, you should manually adjust a preview participant’s schedule (see Modify Assessment Schedule section above). To access follow-up assessments, re-launch the preview by accessing the Preview Study page and clicking the Preview button. Enter the preview participant’s login and password on the Welcome (home) page.

How can I endorse Terms & Conditions?

Prior to launching study, you must agree to applicable Terms & Conditions. Studies which require Terms & Conditions endorsement will be listed on the Launch Study page. To read and accept the Terms & Conditions, click on the © symbol for each study listed. A pop-up will then appear from which you can review and endorse the Terms & Conditions by clicking the Accept button.



Assessment CenterSM

Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Build | Preview | **Launch** | Current Study: AC User Manual_Example

Launch (AC User Manual_Example)

LAUNCH STUDY

You must agree to an instrument's Terms & Conditions before launching a study. Click on the © symbol to read and endorse Terms & Conditions. If you do not see a ©, there are no terms and conditions for endorsement.

PROMIS Endorsed 04/07/2014

Approve your study for data collection by checking the APPROVE button.

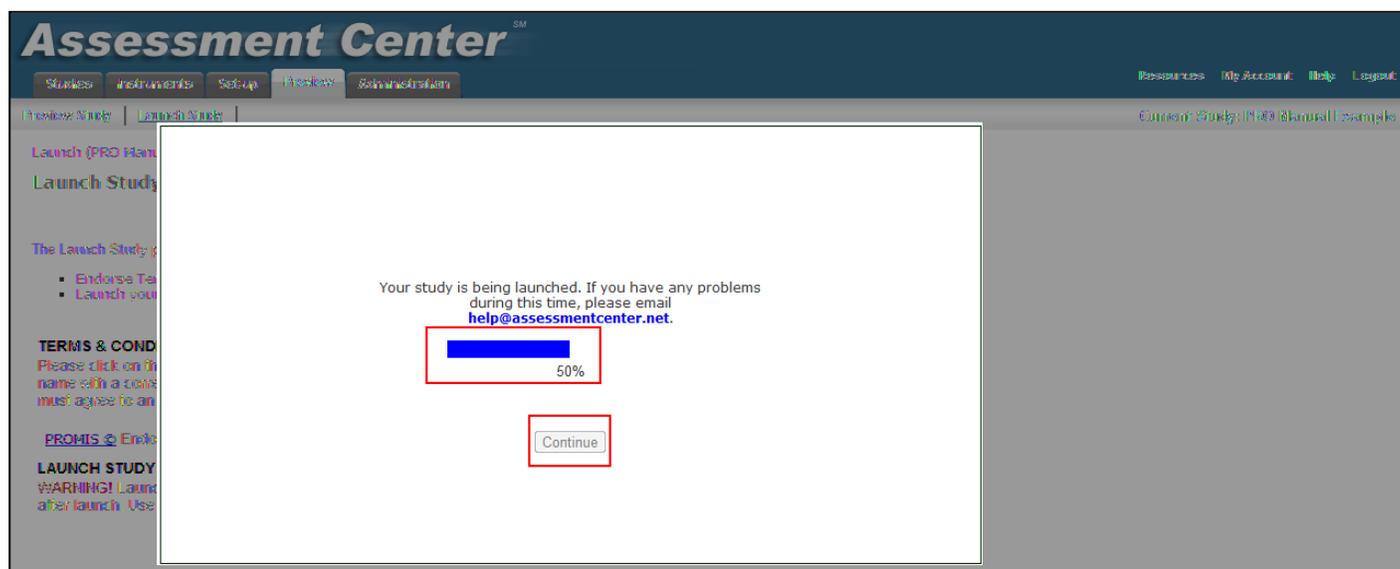
LAUNCH STUDY

WARNING! Study items and instruments may not be revised after Launch.

Launch

How do I create a website to collect participant data?

The Launch function allows you to create a data collection website. After you have reviewed your study configuration export, previewed your data collection site and endorsed applicable Terms & Conditions, you may click the Launch button to create the data collection website. The amount of time it takes for Assessment Center to complete the launch process is dependent upon the size of your study, i.e. number of instruments or assessments, and how many other studies are concurrently being launched. Once the launch is initiated, a progress screen will appear detailing the percentage of study content to have completed the launch process. Once the launch process is complete, a hyperlink to the data collection website will appear at the top of the Launch Study page.



What information can be modified after a study has been launched?

Assessment Center allows users to update some Set-up fields after a study has been launched for data collection. These fields include the study end date, accrual goal, contact information, login screen welcome text, date assessments open, assessment window, text of consent documents, endorsement type, endorsement text, addition/deletion of registration fields, addition/deletion of required status for registration fields, and changes to registration field validation. After saving any of these modifications, it may be necessary to re-launch the study from the Launch Study page so that the modifications are applied to the data collection website. Note that changes cannot be made to instruments after a study has been launched for data collection. Therefore, it is highly recommended an extensive review of instruments and items is completed using the Preview feature.

Why can't I modify a launched study?

Based on end-user feedback, Assessment Center does not allow revisions to study content. Researchers requested that the system preserve the integrity of a study so that at the time of analyses, it would be obvious exactly what instruments a participant completed rather than having to identify the time of completion and the study version that was available at that time. For this reason, it is critical to review the Study Configuration Report and preview your study prior to launch.

Study-Specific Data Collection Website

How can I access my data collection website?

Once a data collection website has been generated, you may navigate to it by either clicking on the link at the top of the Launch page or typing in/copying the web address directly into your internet browser.

What devices may I use for data collection?

The data collection module may be run on any windows PC, laptop, or tablet PC. We currently support Internet Explorer in all the Windows environments. The Apple iPad is supported for data collection only. Apple iPhone and touch devices, Android tablets and handhelds, and other mobile devices are not yet supported.

What does the data collection website look like?

The Welcome (home) page of the data collection website contains the welcome message created on the Basic Set-up page and default login text. When a participant navigates to the website for the first time he or she will click the Start button to begin the assessment. The home page contains login and password fields for participants to enter their information so they may complete follow-up assessments or complete an incomplete assessment. Participants will also enter a login and password if the research team has previously registered them within the Administration tab. Once a researcher registers a participant, they should provide the participant their login/password information so that the participant may enter them on the home page and be immediately navigated to the study instruments.

If the participant has opted to complete the assessment in a non-English language (see Language section above), the Welcome page and all introductory pages will be presented in the specified language. The navigation button and messages on item pages will also be in the appropriate language.

Assessment CenterSM

Assessment CenterSM

Welcome to PRO Manual
Example

Si ya tiene información de acceso y contraseña, ingréselos en los espacios correspondientes.

Información de acceso	<input type="text"/>
Contraseña	<input type="password"/>

Haga clic en Empezar a continuación si usa el sistema por primera vez.

Si tiene preguntas o algún problema, comuníquese con r-hanrahan@northwestern.edu.
If you would like to bookmark this page, click this [Add to Favorites](#) link.

After the Home page, participants will be navigated to applicable online consent forms and the registration pages. After these pages have been completed, users will receive a system generated login number and password so they may log back into the website to complete future assessments or if they do not complete the current in one sitting. The same login and password will be used for all study assessments.

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Click the button below to begin the survey. Your participation in the study is appreciated.
Below is your password for the study. Please write down this login and password for your records.

Your Login (51275) and Password (mus)

Administration

What is the purpose of the Administration tab?

The Administration section of Assessment Center is used to track accrual, review participant information, run reports and export study data. The default page under the Administration tab is the Study Overview page. There are several features on this page that will be frequently accessed once a study is in data collection. The Study Overview page will provide users with essential accrual information and reports. The other sub-menu tabs (Registration Details, Participant Details, Contact Information, Custom Fields, Reports, and Participant Data) are only accessed from within an individual participant's record.

Accrual

How do I track study participant accrual?

The Study Overview page displays the current study name in the top left hand corner. Below this is the Accrual "Dashboard". The dashboard provides a quick summary of current accrual status and can be used to calculate

response rates. Users may also access the Enrollment Report to review study accrual in more detail. The accrual dashboard is updated on 20 minute intervals.

Accrual Dashboard fields

- **Goal Participants:** The desired sample size entered during Study Set-up.
- **Registered:** The number of participants who have been assigned a study login number.
- **Accessed Study:** The number of participants who accessed the study, i.e. moved beyond the Welcome page.
- **Started:** The number of participants who have successfully endorsed the Consent form and/or completed registration.
- **Completed:** The number of participants who have seen all the study instruments and items.
- **Off Study:** The number of participants marked as Off Study by study staff.
- **Refusal:** The number of participants marked as Refused to Participate by study staff.

Assessment CenterSM

Studies Instruments Set-up Assemble Administration PDFs Admin My Account Help Logout

Overview Registration Details Participant Details Contact Information Custom Fields Reports Participant Data Current Study: AC User Manual_Example2

Study Overview

Study: AC User Manual_Example2

Goal Participants	Accessed Study	Registered	Started	Completed	Off Study	Refusal
25	2	2	1	0	0	0

To create a new participant registration record, click the Find/Create Login button.

Enter participant login then click Find/Create Login button to view an existing participant registration.

Find/create Login

To view a list of participants in this study, click the Participant List button below.

[Participant List](#)

[NIH Inclusion Enrollment Report](#)
[Data Dictionary Report](#)
[Enrollment Report](#)

Request and Download Data

When your data is available, an email notification will be sent to the email below. Click buttons to request or download data. Please make sure that you are able to accept emails from this site.

Participant Registration

How can I access a participant's registration information?

There are two ways in which a user can access a specific participant's registration records. The first is an open search field in which a user must input a participant's study login number and click the Find/Create Login button. This is particularly useful when a study participant has contacted the study team because of a lost or forgotten password. The second way to access registration information is the Participant List button. When a user clicks on this button, a dialog box will appear which contains the last name, first name, login and password of each participant within a given study. The user may click on a participant's name and be directed to his/her registration information. If name was not collected during at registration, the list will display the text "zzz-{Missing}, {Missing}". This text is also a hyperlink which may be used to access the participant's registration.

The screenshot displays the 'Assessment Center' web application interface. At the top, there is a navigation bar with tabs for 'Studies', 'Instruments', 'Set-up', 'Assemble', and 'Administration'. Below this is a secondary navigation bar with links for 'Overview', 'Registration Details', 'Participant Details', 'Contact Information', 'Custom Fields', 'Reports', and 'Participant Data'. The current study is identified as 'AC User Manual_Example2'. The main content area is titled 'Study Overview' and shows the following data:

Goal	Participants	Accessed	Study	Registered	Started	Completed	Off Study	Refusal
25	2	2	1	0	0	0	0	0

Below the table, there are two red-bordered boxes highlighting specific instructions and buttons:

- The first box contains the text: "To create a new participant registration record, click the Find/Create Login button. Enter participant login then click Find/Create Login button to view an existing participant registration." Below this text is an input field and a button labeled "Find/create Login".
- The second box contains the text: "To view a list of participants in this study, click the Participant List button below." Below this text is a button labeled "Participant List".

At the bottom of the page, there are links for "NIH Inclusion Enrollment Report", "Data Dictionary Report", and "Enrollment Report". A section titled "Request and Download Data" includes a text box for an email address, with "r-hanrahan@northwestern.edu" entered.

What participant registration information can be accessed by study staff?

To be able to access registration pages for a particular study, staff must have the Study Administrator, Study Participant Administrator or Study Data Entry Administrator roles. After conducting a participant search, the first registration page to be accessed is the Registration Details page. Once this page has been accessed, users may also navigate to the subsequent registration pages, i.e. Participant Details, Contact Information, Custom Fields, Reports and Participant Data, by using the sub-menu tabs.

The Registration Details page contains study-specific information such as consent status, password, date of first assessment and administration language. Some of the information on the Registration Details pages is default information that is automatically populated when a participant registers to the study. If you are completing an assessment yourself for quality assurance purposes, you would select Test from the Consent Obtained field. This will segregate test data from true participant data in the database and data exports. If a participant must withdraw from a study for any reason, the reason for withdrawal can be recorded on this page using the Off-study drop list. If a participant refused to participate in the study and you would like to record the reason, use the Non-Enrollment Reason drop list.

Assessment CenterSM

The screenshot shows the 'Registration Details' page in the Assessment Center system. The page title is 'Assessment CenterSM'. The navigation menu includes 'Studies', 'Instruments', 'Set-up', 'Assemble', and 'Administration'. The 'Registration Details' tab is highlighted. The page content includes a header with 'Overview', 'Registration Details', 'Participant Details', 'Contact Information', 'Custom Fields', 'Reports', and 'Participant Data'. The current study is identified as 'AC User Manual_Example2'. The main content area contains instructions for registering a new participant and a form with the following fields: Study Arm (default), Schedule (Default), Date Approach (4/30/2014), Site (Internet), Login (optional) (82623), Password (** Password) (usg), Study code (6002), Baseline, Consent (Yes selected), Non-Enrollment Reason, Off Study, and Language (English). A 'Create participant login' checkbox is also present.

The Participant Details page contains sociodemographic information such as race, age, and gender. This page also includes a comments field that may be used to input additional details about a participant.

The screenshot shows the 'Participant Details' page in the Assessment Center system. The page title is 'Assessment CenterSM'. The navigation menu includes 'Studies', 'Instruments', 'Set-up', 'Assemble', and 'Administration'. The 'Participant Details' tab is highlighted. The page content includes a header with 'Overview', 'Registration Details', 'Participant Details', 'Contact Information', 'Custom Fields', 'Reports', and 'Participant Data'. The current study is identified as 'AC User Manual_Example2'. The main content area contains instructions for registering a new participant and a form with the following fields: Age (33), DOB (01/14/1965), Gender (Male selected), Ethnicity (Not Hispanic or Latino selected), Race (Asian selected), and Doctor. A large 'Comments' text area is also present.

The Contact Information page contains details of how a participant may be contacted. If this information was provided by participants on the registration screens, only those variables marked as "Include" in the Registration sub-menu tab will be populated with data. It is important to record the first and last name of participants if conducting a longitudinal study as this is the best means of locating registration records when a participant has a question, issue or has lost their login/password.

Assessment CenterSM

The screenshot shows the 'Assessment Center' logo at the top left. Below it is a navigation bar with tabs: Studies, Instruments, Set-up, Assemble, and Administration. The 'Administration' tab is active, and within it, the 'Contact Information' sub-tab is selected and highlighted with a red box. To the right of the navigation bar are links for PDFs, Admin, My Account, Help, and Logout. Below the navigation bar is a breadcrumb trail: Overview | Registration Details | Participant Details | Contact Information | Custom Fields | Reports | Participant Data. The current study is identified as 'AC User Manual_Example2'. The main content area contains instructions for registering a new participant and a 'Login: 82623' button. A legend indicates that fields with two asterisks are required, and fields with one asterisk are only required for consented participants. The registration form includes the following fields: First Name (Rachel), Last Name (Hanrahan), Street (625 N. Michigan), City (Chicago), State (IL), Zip (60611), EMail, Day Ph. #, Cell Ph. # (555-555-6767), Call Time (Evenings), and Comments.

The Custom Fields page contains the custom registration fields as defined on the Registration page of the Set-up tab. The custom label field(s) and participant's response(s) will be displayed. If no custom fields were included, this page will be blank.

The screenshot shows the 'Assessment Center' logo at the top left. Below it is a navigation bar with tabs: Studies, Instruments, Set-up, Assemble, and Administration. The 'Administration' tab is active, and within it, the 'Custom Fields' sub-tab is selected and highlighted with a red box. To the right of the navigation bar are links for PDFs, Admin, My Account, Help, and Logout. Below the navigation bar is a breadcrumb trail: Overview | Registration Details | Participant Details | Contact Information | Custom Fields | Reports | Participant Data. The current study is identified as 'AC User Manual_Example2'. The main content area contains instructions for registering a new participant and a 'Login: 82623' button. A legend indicates that fields with two asterisks are required, and fields with one asterisk are only required for consented participants. The registration form includes the following custom fields: 'Enter your date of diagnosis::' (09/13/2013), 'Enter the number of nights you have spent in the hospital in the past year::' (4), and 'Enter the name of the hospital at which you had surgery::' (Northwestern Memorial).

How can study staff register participants?

Assessment Center allows researchers to complete the registration process for participants within the Administration tab. Note that the study must be launched in order for registration to occur. To register a participant, click on the Find/Create Login button. Complete applicable fields on the Registration Details page. Click on the additional registration submenu tabs (Participant Details, Contact Information, Custom Fields) and fill in any required information. When finished, click on the Register Participant button at the bottom of the page. The Login will appear in the top right. Note that researcher-based registration requires that consent is obtained outside of Assessment Center. A login is not able to be created if the Consent Field is not completed. Additionally, researcher-based registration assumes that a researcher is entering all required registration information (e.g., demographic variables). A participant will not see any consent or registration screens if his or her login was created by a researcher.

Register Study Participant

1. Navigate to the Administration tab
2. Click Find/Create Login button on the Study Overview page
3. Complete all applicable fields on the Registration Details page
4. Click on additional sub-menu tabs to complete all required/applicable fields
5. Click Register Participant button
6. Note assigned Login number in bold blue text at the top of each registration page

How should a participant registered by study staff access the data collection website?

After registration is complete, a study participant should be provided the data collection website URL which can be found on the Launch page within Set-up. Once they access the study Welcome (home) page, they will be asked to enter their assigned login and password and click Start. They will then be navigated to the first assessment item. Alternatively, you may provide them a participant-specific URL created once you finalize their registration, i.e. click Register Participant button. This URL will allow the participant to bypass the study Welcome page, i.e. they will not be required to enter their login/password before accessing the study assessment. The participant-specific URL is longer than the URL created on the Launch Study page. Therefore, the URL should be given to a participant electronically, e.g. email, so they may simply click on the hyperlink.

The screenshot shows the 'Administration' tab in the Assessment Center interface. The 'Registration Details' sub-tab is active. The form contains the following fields and options:

- Study Arm: default
- Schedule: Default
- Date Approach: 4/30/2014
- Site: Internet
- Login (optional): 82623
- Password: usg
- Study code: 6002
- Baseline: (empty)
- Consent: Yes (selected), No, Test, Preview
- Non-Enrollment Reason: (empty)
- Off Study: (empty)
- Language: English

A red box highlights the URL for the registered participant to access their study at:

The registered participant can access their study at:
https://msswebtest.fsm.northwestern.edu/assessmentcenter/qa/ac1/Action.aspx?Module=48&txtUID2=82623&txtPWD2=usg&Action=autologin&Study=AC_User_Manual_Example2&locale=en-US

May study staff create a participant login?

A login may be created by study staff on the Registration Details page. To enable the login field, check the "Create Participant Login" box. The login must be between 5 and 10 characters long, may contain both letters and numbers and may not contain spaces or special characters. When you create a login, you must also enter a password. The system will not automatically assign a password. Passwords must be at least one character and can be up to 25 characters. Passwords may contain any combination of letters, numbers, or special characters.

Create Participant Login

1. Navigate to the Administration tab
2. Click Find/Create Login button on the Study Overview page
3. Check "Create Participant Login" box
4. Enter a login containing letters and/or numbers without spaces or special characters
5. Complete all subsequent, applicable registration fields
6. Click Register Participant button

The screenshot shows the Assessment Center Administration interface. The 'Administration' tab is selected, and the 'Registration Details' sub-tab is active. The form contains the following fields and options:

- Study Arm: default (dropdown)
- Schedule: Default (dropdown) with a [View Schedule Details](#) link
- Date Approach: 4/30/2014 (text)
- Site: Internet (dropdown)
- Login (optional): 82623 (text) with a **Create participant login** checkbox
- ** Password: usg (text)
- Study code: 6002 (text)
- Baseline: (text)
- ** Consent: Yes No Test Preview
- Non-Enrollment Reason: (dropdown)
- Off Study: (dropdown)
- Language: English (dropdown)

Instructions at the top of the form: "To register a new participant, enter information below and click Register Participant button. Please navigate to Participant Details, Contact Information and Custom Fields tabs prior to clicking Register Participant button to ensure all necessary registration data has been included." A "Login: 82623" label is visible next to the login field.

What triggers Assessment Center to know when to open the first assessment for a given participant?

A schedule is determined by the date in the Baseline field on Registration Details. If a researcher completes the Baseline field when registering a participant, the study schedule will be established and the baseline assessment window will open. If the baseline field is left blank, the study schedule will not be established until the participant logs into the data collection website. This is useful if a researcher is not requiring a participant complete the baseline assessment on a specific date, but at the participant's convenience in the future. If a participant self-registers, the baseline date is stored as the date the login and password are assigned.

How can a researcher assign a participant to a specific study arm?

If a study has more than one arm, how a participant registers is important. If participant self-registration is utilized, Assessment Center will assign each participant to a study arm. A researcher can look up what study arm was assigned through the Administration tab. If the researcher registers participants, a specific study arm may be selected at that time.

How can study staff record information about those who didn't enroll in the study?

Assessment Center allows for a researcher to track participants that were approached but not enrolled in a study. First, a researcher would click on the Find/Create Login button on the Administration tab's Study Overview page and be navigated to a blank Registration Details page. A researcher would select No in the Consent field and optionally select a response from the Non-enrollment Reason drop list. If a researcher has information on other registration variables such as age, race, or name, this information can be entered on the other registration submenu tabs. Non-enrollment information is aggregated in the Enrollment Report.

How can study staff take a participant off of a study?

From the Administration tab, access the participant's record either through the Find/Create Login or Participant List buttons. On the Registration Details page, select the appropriate Off-Study reason from the drop list provided. Do not modify the Consent field. Click on the Register Participant button to save changes. This information automatically updates the Accrual Dashboard and the accrual reports.

The screenshot shows the 'Administration' tab in the Assessment Center. The 'Registration Details' page is active, displaying a form for registering a new participant. The form includes the following fields and options:

- Study Arm: default (dropdown)
- Schedule: Default (dropdown) with a 'View Schedule Details' link
- Date Approach: 4/30/2014 (text input)
- Site: Internet (dropdown)
- Login (optional): 82623 (text input) with a 'Create participant login' checkbox
- Password: usg (text input)
- Study code: 6002 (text input)
- Baseline: (text input)
- Consent: Radio buttons for Yes (selected), No, Test, and Preview
- Non-Enrollment Reason: (dropdown menu)
- Off Study: (dropdown menu)

A red box highlights the Consent and Off Study fields. The page also includes navigation tabs (Studies, Instruments, Set-up, Assemble, Administration) and a top navigation bar with links for PDFs, Admin, My Account, Help, and Logout. The current study is identified as 'AC User Manual_Example2'.

Link Participant Data

How can I link multiple participants?

In some studies, multiple participants need to be “linked” to one another so that their data can be analyzed together, e.g. proxy studies. This can be achieved in Assessment Center through a variety of strategies.

1. When a participant is registered by a researcher, the Study code field can be used to link participants by entering a researcher defined ID code. For example, you would create registration records for a parent and child and give them both the same Study code (e.g. 1001) so that statisticians can use this field to associate the two sets of data.
 - ◆ Another way to link participant records when participants are registered by a researcher would be to use the Create Participant Login feature and assign the “linked” participants similar logins. For example, in a parent proxy study you could assign a parent and child the same login number followed by differing letters (e.g. 1001p and 1001c). In this example, it would be important for the research staff to record the meaning of each letter and communicate this with the analysis team. Please note multiple participants may not have the exact same login within the same study.
2. If a participant is registering themselves via the data collection website, a custom registration field or an item could be used to link participants. In this case, the custom registration or item would need to ask a question in which the participant could easily answer but would also be unique enough so that multiple participants would not respond with the same response. For example, in a parent proxy study you could ask the parent to provide their child's name and/or date of birth while asking the child to provide this same information.
 - ◆ Another way to link participant records when utilizing participant self-registration is to have the participant and proxy complete the same assessment. For example, the proxy instruments could be the first set of instruments, a transition screen (i.e. item with Informational response type) could be

included immediately prior to the participant items which informs the proxy they have completed their part of the assessment and the participant should complete the remaining items.

Assessment Schedule

How can I view a participant's assessment schedule?

To view a participant's schedule, you must access his/her registration record within the Administration tab, and then click the View Schedule Details hyperlink on the Registration Details sub-menu tab.

The screenshot shows the 'Assessment Center' Administration interface. The 'Registration Details' sub-menu is active. A form for registering a new participant is visible, with fields for Study Arm, Schedule, Date Approach, Site, Login, Password, Study code, Baseline, Consent, Non-Enrollment Reason, Off Study, and Language. A 'View Schedule Details' button is highlighted with a red box.

How can I change a participant's assessment schedule?

Sometimes a researcher may wish to change a participant's assessment schedule. For example, when pilot testing a longitudinal study to ensure that it is functioning correctly, a researcher may want to be able to access follow-up assessments on the same day as the baseline assessment. Or, a participant may be granted an extension of the assessment. After clicking on the View Schedule Details hyperlink, a pop-up window with the participant's assessment schedule will appear. Assessments that are currently open are green. Assessments that are past due are red. Assessments that are in the future are gray. Start and end dates are displayed. The span between start and end date corresponds with the Window variable entered on the Advanced Study Set-up page. To implement a date change, first enter the new date, and then click the pencil icon to the left of the row. It is necessary to modify one row at a time. Note that each assessment has a row labeled Participant View and a row labeled Clinician View. You will want to change both rows.

Participant Schedule				
Scheduled Event	Mode of Access	Start Date	End Date	
Assessment	Participant View	08/20/2009	08/24/2009	
Assessment	Clinician View	08/20/2009	08/24/2009	

Participant Reports

What participant-level reports are available?

Studies that include a PROMIS Profile instrument or a subset of adult PROMIS CATs will automatically generate single time point reports for each participant. These reports are located under the Reports sub-menu tab. The date an instrument was completed is listed as a hyperlink, click to open the report. If no PROMIS v1.0 CATs or Profile instruments were included in your study, this page will be blank.

The screenshot shows the Assessment Center web application interface. The navigation menu at the top includes 'Studies', 'Instruments', 'Set-up', 'Assemble', and 'Administration'. The 'Reports' tab is highlighted with a red box. Below the navigation menu, there are links for 'Overview', 'Registration Details', 'Participant Details', 'Contact Information', 'Custom Fields', 'Reports', and 'Participant Data'. The 'Current Study' is identified as 'AC User Manual_Example2'. The main content area contains a registration form with the following fields and options:

- Study Arm:** default (dropdown)
- Schedule:** Default (dropdown) with a [View Schedule Details](#) link
- Date Approach:** 4/16/2014
- Site:** Internet (dropdown)
- Login: (optional):** 86918 (text input) with a [Create participant login](#) checkbox
- ** Password:** nsw (text input)
- Study code:** 6001 (text input)
- Baseline:** 4/16/2014 (text input)
- ** Consent:** Yes (selected), No, Test, Preview (radio buttons)
- Non-Enrollment Reason:** (dropdown menu)
- Off Study:** (dropdown menu)
- Language:** English (dropdown)

What information do the CAT and Profile reports provide?

The PROMIS CAT and PROMIS Profile reports open as PDF documents that can be printed or saved outside of Assessment Center. For each domain, the participant's standard score is provided along with information on how that score compares with other people in the general population. If age and gender was collected during registration, the participant's score is compared to other individuals in his/her age group and of his/her gender. The second portion of the report includes a graph showing scores with standard error bars.

August 20, 2009

38653

PROMIS-29 Profile 1.0 Report

Your age: 50 Your gender: Female

For every questionnaire, the average score is 50 in the US general population.

Your estimated score on the Anxiety questionnaire is 54. Your estimated score indicates that your level of Anxiety is higher (worse) than:

- 66 percent of people in the general population
- 60 percent of people age 45-54
- 81 percent of females

Your estimated score on the Depression questionnaire is 62. Your estimated score indicates that your level of Depressive Symptoms is higher (worse) than:

- 88 percent of people in the general population
- 83 percent of people age 45-54
- 86 percent of females

Your estimated score on the Fatigue questionnaire is 61. Your estimated score indicates that your level of Fatigue is higher (worse) than:

- 85 percent of people in the general population
- 78 percent of people age 45-54
- 81 percent of females

Your estimated score on the Pain Impact questionnaire is 56. Your estimated score indicates that your level of Pain Impact is higher (worse) than:

- 66 percent of people in the general population
- 56 percent of people age 45-54
- 62 percent of females

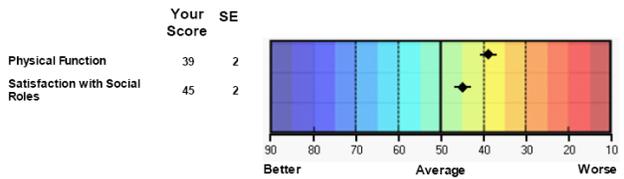
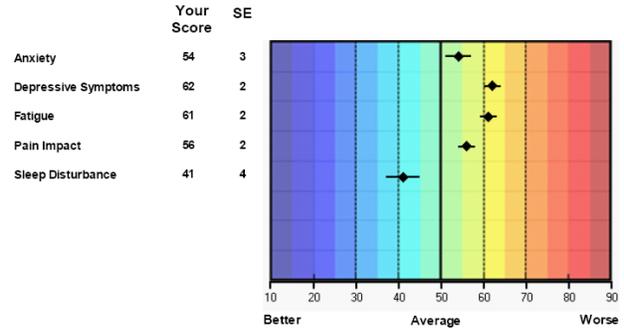
Your estimated score on the Physical Function questionnaire is 39. Your estimated score indicates that your level of Physical Function is higher (better) than:

- 19 percent of people in the general population
- 23 percent of people age 45-54
- 22 percent of females

Your estimated score on the Satisfaction with Social Roles questionnaire is 45. Your estimated score indicates that your level of Satisfaction with Social Roles is higher (better) than:

- 34 percent of people in the general population
- 32 percent of people age 45-54
- 38 percent of females

Your scores for the instruments you completed are shown below.



The diamond is your estimated score. For each of the areas above, a score of 50 is average for the United States general population. Most people will score between 40 and 60 and almost all people will score between 30 and 70. The Standard Error (SE) is a statistical measure of variance and represents a "margin of error" around your estimated score. The lines on either side of each diamond reflect the likely range of your actual score.

Researcher Reports

Are there study reports available?

There are three standard reports for researchers on the Study Overview page: the Data Dictionary report, the NIH Inclusion Enrollment Report, and the Enrollment Report. These reports open in PDF format. They can be printed or saved outside of Assessment Center.

Assessment Center SM

[PDFs](#) [Admin](#) [My Account](#) [Help](#) [Logout](#)

Studies Instruments Set-up Assemble Administration

Overview Registration Details Participant Details Contact Information Custom Fields Reports Participant Data
Current Study: AC User Manual_Example2

Study Overview

Study: AC User Manual_Example2

Goal	Participants	Accessed	Study	Registered	Started	Completed	Off Study	Refusal
25	3	2	1	0	0	0	0	0

To create a new participant registration record, click the Find/Create Login button.

Enter participant login then click Find/Create Login button to view an existing participant registration.

[NIH Inclusion Enrollment Report](#)
[Data Dictionary Report](#)
[Enrollment Report](#)

Request and Download Data

When your data is available, an email notification will be sent to the email below. Click buttons to request or download data. Please make sure that you are able to accept emails from this site.

The data dictionary report is a tool for study analysts. The report details all instruments, items and provides a list of item IDs and scoring information.

Data Dictionary: UAT215
PROMIS SF-Depression 1.0
EDDEP04
In the past 7 days
I felt worthless
1 = Never
2 = Rarely
3 = Sometimes
4 = Often
5 = Always
EDDEP05
In the past 7 days
I felt that I had nothing to look forward to
1 = Never
2 = Rarely
3 = Sometimes
4 = Often
5 = Always
EDDEP06
In the past 7 days
I felt helpless
1 = Never
2 = Rarely
3 = Sometimes
4 = Often
5 = Always

The NIH inclusion enrollment report is a tool for monitoring study accrual. The format adheres to the requirements from the National Institutes of Health (NIH) for periodic progress reports. Information about gender is cross tabulated with race and ethnicity information. This report is populated by data from the registration fields and is automatically updated as new participants are registered.

The Enrollment Report is a tool for monitoring study accrual. The report details current counts of study participants by enrolled, those off-study and those refused by gender and race. This report is automatically updated as participants are registered for the study. Demographic information in this report is pulled from registration information.

Inclusion Enrollment Report				
PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	1	1	2
Not Hispanic or Latino	1	1	0	2
Unknown (individuals not reporting ethnicity)	1	0	0	1
Ethnic Category: Total of All Subjects	2	2	1	5
Racial Category	Females	Males	Unknown or Not Reported	Total
American Indian/Alaska Native	0	1	0	1
Asian	1	0	1	2
Native Hawaiian or Other Pacific Islanders	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	1	0	0	1
Unknown, Not Reported or Skipped	0	1	0	1
Racial Category: Total of All Subjects	2	2	1	5
PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Category	Females	Males	Unknown or Not Reported	Total
American Indian/Alaska Native	0	1	0	1
Asian	0	0	1	1
Native Hawaiian or Other Pacific Islanders	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown, Not Reported or Skipped	0	0	0	0
Racial Category: Total of All Subjects	0	1	1	2

PROMIS ENROLLED (Consented and on-study)																			
Site	Count	Mean (SD)	Range	Age		Gender		Race					Ethnicity						
				Female	Male	Native American	Asian	Black	Hawaiian Pacific Is.	White	Other	Hispanic	Non Hispanic	Not Provided					
Intivnet	0	0 (0)	0 - 0	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Total	0	0 (0)	0 - 0	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%

Study Data

Data Entry

How can study staff review and enter participant-level data?

The Administration tab allows for a researcher with appropriate permission to review and/or enter participant-level data from the Participant Data page. For example, a research assistant in the clinic may want to review a participant's responses to check for missing data or enter data on a clinician rated form. The Participant Data page is **NOT** intended for participant self-report or researcher interview. The CAT administration engine and customization (templates, branching, randomization) are **NOT** integrated into the Participant Data page.

The Participant Data page displays a list of all applicable assessments on the left panel of the page. Clicking on the name of the assessment will expand the list to show all instruments. Text color indicates a participant's progress within the study schedule, red indicates an assessments has occurred in the past, i.e. the participant is no longer in the defined assessment window, green indicates an assessment is currently open and black indicates an assessment is in the future and not currently available. If an instrument has line through it, the participant *viewed* all items within that instrument. This could mean that a participant responded to all items within the instrument, or accessed each item screen but chose to skip it without answering.

To review or enter participant data, click on the applicable assessment, then the instrument name. This action will open the questionnaire in the main panel of the page. The system defaults to presenting all items in a sequential list. For CAT instruments, all items are listed but only those that were presented to the participant will have a response option selected. Item response score and response text will be displayed. While response scores are always shown on the Participant Data page, scores are only displayed on the data collection website if the "Show Response Scores" box is checked on the Item Detail page. You can use the scroll bar on the right to navigate to see every item in the instrument. If you are entering data using these screens, be sure to click on the Save button before moving on to the next instrument. To be able to view the Participant Data page, staff must have the Study Administrator or Study Participant Administrator roles. To be able to modify participant data, staff must have the Study Data Entry Administrator role.

The screenshot shows the Assessment Center interface. At the top, the 'Assessment Center' logo is visible. Below it, a navigation bar includes tabs for 'Studies', 'Instruments', 'Set-up', 'Assemble', and 'Administration'. The 'Administration' tab is active, and within it, the 'Participant Data' sub-tab is highlighted. The main content area is divided into two columns. The left column, titled 'Scheduled Events', lists three assessments: 'Assessment (1)' (red text), 'Assessment (2)' (green text), and 'Assessment (3)' (black text). Each assessment lists its associated forms. The right column displays a questionnaire item: 'In the past 7 days I tried to sleep whenever I could.' Below this item are five radio button options: '1 - Never', '2 - Rarely', '3 - Sometimes', '4 - Often', and '5 - Always'. A 'Save' button is located at the bottom of the questionnaire. A large 'PREVIEW' watermark is overlaid on the right side of the page. The top right corner shows 'Current Study: AC User Manual Example 3' and 'Login: 16610'.

Response Tracking

How can research staff track participant responses to identify at-risk responses?

A researcher may want to track responses to specific items in a timely manner over the course of a study (please see previous topic to understand how to access participant data). For example, a researcher may want to identify responses that may indicate a participant is experiencing thoughts that may result in self-harm or harm to other people. The first step in tracking participant's at-risk responses is to identify which instruments within your study contain items which have concepts, e.g. suicidal ideation, that should be monitored. Research staff should be instructed to review a participant's response to such items after each assessment. Intervention thresholds should be established by the research team prior to the start of the study, e.g. response of quite a bit or very much to the item "I have thought about suicide" will result in the research staff contacting available mental health staff. Research teams are advised to create standard operating procedures so that staff can consistently follow-up when participants meet or exceed the established thresholds. Assessment Center does not have the capability of automatically communicating at-risk responses to research staff. Therefore, it is of utmost importance that staff monitors participant data to ensure individuals who are at-risk will be followed-up with properly.

How do I access the study database?

Study data can be exported from Assessment Center by running five different exports. The data exports open CSV files and can be opened and saved outside of Assessment Center in Excel, SAS or SPSS. Note that only 255 columns of data will fit in an Excel worksheet. If a study has many instruments and assessments, the CSV file should be opened in a statistical software package to avoid truncating data. The data exports must be requested by clicking the Request Data buttons on the Study Overview page. The system will generate the export and send an email to the address entered in the Email Notification field once the export is ready for download. Once the email is received, you may click on the Download Data button which will open the CSV file. The file is organized by participant, then assessment.

What is included in each data export?

The first export, Assessment Data, contains a de-identified dataset of all study instrument and item data; no registration data is included. Note that this export is organized so that each item in each assessment for each participant is its own unique row. This allows for capturing additional information (e.g. time and date stamp of response), but is not organized as typically requested by statistical analysis programs. Instructions for pivoting the data set are provided in a later section of this manual. The second export, Assessment Scores contains participant's t-scores for CAT and short form instruments. The t-scores are based on general population norms. These scores can be used to evaluate an individual's status.

The third export, Registration Data, contains the data entered into the registration fields. The fourth export, Consent Data, includes information from consent forms. It includes whether or not a participant endorsed a consent checkbox, the text entered in a consent textbox, and the date and time when consent was provided. Finally, the fifth export, Pivoted Assessment Data, presents assessment data in a format that is typically used by statistical analysts. Each participant is represented in a single row with each column represented scores from an item. Item columns are organized in alphabetically order based upon the item ID. In a longitudinal study, each assessment is stored in a different row. Currently, the Pivoted Assessment Data Export is only functional for smaller studies.

Who can view my Study data?

Only members of the study team with appropriate permission assigned on the Study Team page, i.e. role of Data and Statistics Administrator, will be able to access the data export files.

The screenshot shows the 'Administration' tab of the Assessment Center interface. The 'Study Overview' section displays a table with the following data:

Goal	Participants	Accessed	Study	Registered	Started	Completed	Off Study	Refusal
25	0	0	0	0	0	0	0	0

Below the table, there are instructions for finding or creating login records and a 'Participant List' button. The 'Request and Download Data' section is highlighted with a red box. It contains an email input field with the address 'r-hanrahan@northwestern.edu' and a 'Request Assessment Data' button. A confirmation message is displayed: 'Assessment Data as of 5/8/2014 2:34:07 PM CST'.

Export Field Descriptions

What variables are included in the data exports?

For a detailed list and description of all the fields in each data export, please refer to Assessment Center Help files at <https://www.assessmentcenter.net/ac1/Help/index.html>

Can I look at my data in the middle of a study?

Users can run exports at any time during a study. To retain a version of the export, without adding additional cases, users must save the export files outside of Assessment Center. The data exports will always contain all study data and will not be able to truncate data based upon previous exports.

Pivot Data Export

How can I pivot the Assessment Data export or other export files?

As previously noted, the Assessment Data export is organized with each item in each assessment for each participant in its own unique row. The Pivoted Assessment export is functional only for smaller studies. However, one can pivot or transpose larger datasets using Excel's PivotTable function. Using this method, the numeric data from any Assessment Center export can be transposed into a "flat file" as long as there are no more than 1,048,576 rows in the data export file. If using a version prior to 2007, the row limit is 65,536.

To pivot a data export, first, open the Assessment Center data export .csv file in Excel and saved on your computer. Next, delete the first two header rows at the top of the worksheet. Then I, select the insert tab and click on the PivotTable button.

Once you have clicked on the PivotTable button, the “Create PivotTable” dialog box will appear (see Figure 1). Select the options “Select a table or range” and “New Worksheet.” It is important to verify that the entire data set is selected (selected cells will have a flashing dotted line around the perimeter). Next, drag “PIN” to the white field

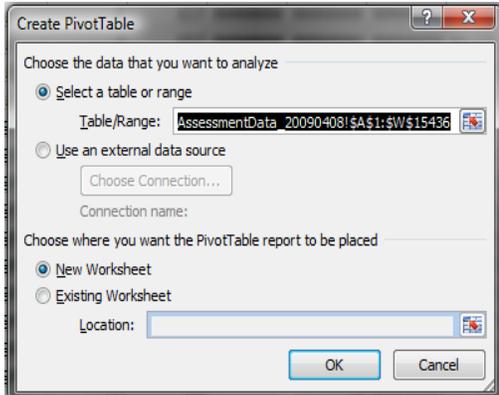


Figure 2

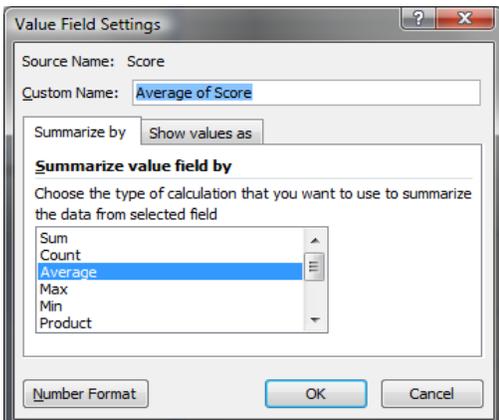


Figure 3

under the heading “Row Labels.” (see Figure 2) Drag ItemID to the field under Column Labels. Drag Score to the Values Field, and DataType to Report Filter. Click on the triangle in the yellow field under values. Click on “Value Field Settings” in the drop-down menu that appears. In the Value Field Settings dialog box, select “Average” on the “Summarize by” tab, and click “OK.” (see Figure 3). Click on the upper right-hand x to close the PivotTable Field List dialog box. On the pivot table, click on the triangle button next to DataType (all). In the box that appears, check the box next to “Select Multiple Items”. Click the OK button. To complete the process, click on the “Insert Worksheet” icon on the tabs at the bottom of the Excel window. Select and copy all fields from the PivotTable you wish to keep in your final data set, and then paste them into the new worksheet.

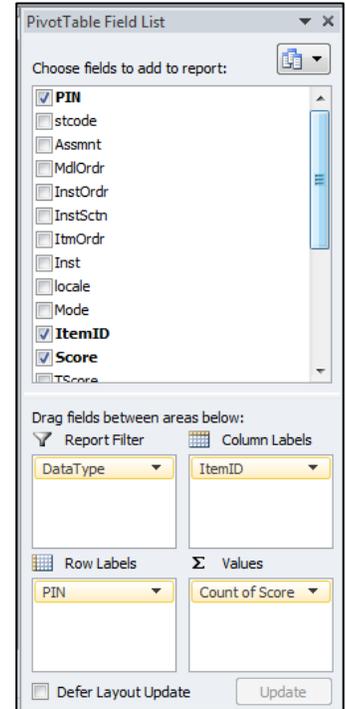


Figure 1

You can now save the final data set in the format you wish to work with (xls, csv, txt, etc.) by selecting “Save As” from the menu in the upper left corner of the Excel window.

When I include checkbox item, how do I unbundle the bitwise value in the data export?

Bitwise values are used for checkbox items. Each response is assigned a numeric value (i.e., 1, 2, 4, 8, 16, 32, 64, etc.). These values are summed and the total is stored as the score for the item ID. Therefore, if a participant has a score of 9, you know that he or she endorsed the first and fourth responses (scores 1 and 8 summed). For statistical analyses, you will need to unbundle this summed score and create additional variables to indicate if a participant endorsed the first response (yes/no), second response (yes/no) and so on. In SAS, you can use the BAND (bitwise logical AND operator) function below. In this example below, we have a checkbox item named Treatment_Regimen. The response choices are Treatment_A, Treatment_B, Treatment_C, and Treatment_D.

```

if Treatment_Regimen ne. then do;
    treatmenta= (band (Treatment_Regimen, 1)>0);
    treatmentb=(band(Treatment_Regimen, 2)>0);
    treatmentc=(band(Treatment_Regimen, 4)>0);
    treatmentd=(band(Treatment_Regimen, 8)>0);
end;

```

Protected Health Information (PHI)

Is there Protected Health Information (PHI) in data exports?

Any data export could contain PHI based upon the data fields included in your study. If include in a study, the system will flag the following registration fields as containing PHI in data exports, date of birth, doctor, last name, first name, street, city, state, zip, email, phone 1, phone 2 will always be marked as containing PHI. Users may choose to flag other fields as PHI, i.e. any custom item, consent endorsement text fields and certain custom registration fields.

When a data field is marked as containing PHI, all data collected in this field will be flagged in the database and will be reported as containing PHI in applicable data exports. In applicable data export PHI fields, “True” indicates a PHI checkbox was endorsed by study staff during set-up. This feature is intended to aid in de-identification efforts and protect participant privacy.

Data exports can only be accessed by study team members with appropriate permissions. However, once the data is exported outside of Assessment Center, the user is responsible for adopting security measures and regulations.

Help

What should I do if I am having problems with Assessment Center?

Assessment Center includes a Help feature which can be accessed at any time via the link in the top right corner of the application. The organization of Help parallels that of Assessment Center. Help includes field definitions, explanations of how to complete particular tasks, tips, and additional useful information. Help opens into a second window to allow the user’s work to not be disturbed while seeking additional information.

Users may also contact center administrators at help@assessmentcenter.net or 1-877-283-0596 for assistance or access further Assessment Center technical documentation, e.g FAQs, Scoring Manuals, from the Assessment Center homepage, <http://assessmentcenter.net/>.

Requirement Questions

What information should I know about my study before setting it up in Assessment Center?

It is helpful to know your study protocol before attempting to set up a study-specific website in Assessment Center.

Information you should know includes:

1. What instruments are in my study? (Study Content page)
2. Are any instruments included that are completed by someone other than the participant (e.g., clinician rating)? (Arm/Assessment Details page)
3. How are responses for each item scored? (Item detail page)
4. How should items appear on a computer screen to participants? (template) (Instrument Customization page)
5. How are items ordered? Sequential? Branched? Randomized? Grouped together at all? (Instrument customization page)
6. How are instruments ordered? Sequential? Randomized? Grouped together? (Arm/Assessment Details page)
7. Do you need any transition screens? How should they be phrased? (Study Content & Item Detail page)
8. How many assessments are included in this study? (Advanced Set-up page)

9. What is the timing of each assessment? Specifically, how many days does a participant have to complete an assessment? How many days are between each assessment? (Advanced Set-up page)
10. Are there multiple arms in the study? (Advanced Set-up page)
11. Are participants assigned to a study arm by the system or placed in a study arm by a researcher?
12. What instruments are administered in each assessment for each arm? (Arm/Assessment Details page)
13. What protected health (e.g., name, address, date of birth) and other registration information (e.g., gender, race, ethnicity) need to be captured? (Registration page)
14. Who else on the study team should have access to the study site? What is his/her role? (e.g., need to export data, enter data, register participants). (Team Member page)
15. Will an online consent form be needed? (Consent page)
16. Do some participants receive different consents? (e.g., 3 sites with 3 different institutional consent forms would require 3 studies with separate URLs)
17. Will participants register themselves or will a study team member register participants?
18. Who should participants contact with questions? (Basic Set-up page)
19. What information should be on the study welcome screen? (Basic Set-up page)
20. When should the study close? (e.g., date or accrual goal) (Basic Set-up page)
21. Does the study include scored instruments, e.g. CATs; do they have parameters? (CAT Parameters page)

How can I reduce errors in creating a study?

Utilization of the study Preview feature and going through all assessments as a test participant are highly recommended before beginning participant accrual. The Preview feature described earlier will allow you to check the format of items including how they appear in the selected template, test administration engines and verify all instruments are included as planned and instructions or transition screens are appropriate. Completing all assessments as a participant and exporting the data will minimize the likelihood of conducting data collection with errors or bugs. The Assessment Center Administrator (help@assessmentcenter.net or 1-877-283-0596) is available to address any problems you may encounter that are not covered within this manual.

Copyright and Terms of Use

What are my responsibilities when using a PROMIS Instrument?

Additional information about PROMIS instruments including bank development history, available banks and short forms, domain definitions, administration, scoring, validity, and interpretation is available on the PROMIS website (www.nihpromis.org). Additional information including limitations of use, copyright, and expectations for sharing summary data are outlined in the Terms and Conditions (<https://www.assessmentcenter.net/TandC.aspx>). All users indicate agreement in adhering to the Terms and Conditions at the time that they register in Assessment Center. The Terms and Conditions include a lot of information. Here are a few highlights. First, users of PROMIS version 1.0 tools are required to submit a brief report to help@assessmentcenter.net including sample demographic information, clinical data sufficient to define the sample without indicating treatment response data, and PROMIS score distributions (e.g., baseline mean and standard deviations or change scores blinded to treatment information) for internal review. No data will be published without the participation of the submitter. Second, clinical researchers are strongly encouraged to collaborate with a PROMIS investigator when applying these instruments to their research. Third, any publication or presentation of results should include a statement that PROMIS v1.0 instruments were used and reference www.nihpromis.org for further information. Finally, permission to use PROMIS v1.0 instruments does not grant permission to modify the wording or layout of items, to distribute to others for a fee, or to translate items into any other language.

What are my responsibilities when using Assessment Center?

Assessment Center is provided for use by the clinical research community without charge. Additional information about use is available in the Terms and Conditions document (<https://www.assessmentcenter.net/TandC.aspx>). As an Assessment Center user, adherence to the Terms and Conditions guidelines is required.

Security

What security exists for Assessment Center?

Assessment Center utilizes multiple layers of protection for its users. First, it uses role-based permissions. The study creator decides who to add to the study team and assign each member the appropriate level of permission. Team members will be able to view information in your study, based on their roles. Assessment Center users that are not part of the study team will not have access to any study information or participant data. New team members are automatically assigned the role of Associate; this role has read-only access to study elements. To reassign roles, select a team member's name, and then check the Role box(s) that best identifies their responsibilities within the study.

The only roles that will be able to view participants' data and personal health information are Study Administrator (study creator's default role), Study Participant Administrator, Study Data Entry Administrator, and Data & Statistics Administrator. It is important to be very cautious and thoughtful when assigning these roles. Only the Study Data Entry Administrator may edit participant data while only the Data & Statistics Administrator may export raw data files.

You can check more than one Role box for your team members, in any combination that is useful to you. Each role has very specific rights. For example, some roles allow a team member to modify items whereas some roles allow a team member to manage participant data. It is likely that you will assign team members to multiple roles unless you have a very large team with individuals holding narrow responsibilities.

Second, Assessment Center data is segregated into different files. Participants' registration, consent, and assessment responses are stored separately. This means that PHI that is needed for study management (e.g., participant name, contact information for sending study incentive, or endorsement text for an online consent form) are stored in files separated from participants' responses to study items.

Finally, all data collected in Assessment Center including confidential, personal health information is maintained and secured at Northwestern University Research Data Center in Chicago, IL. The following text will provide information about security measures at Northwestern University Research Data Center which ensure all data collected, stored, and maintained in Assessment Center is protected.

We observe high standards of data security practices. Our approach to security consists of a collection of policies, procedures, and practices that are designed to balance the following three characteristics for critical resources: confidentiality, integrity, and availability. Secure communication lines are set in place to prevent the interception of data transmission by utilizing various data encryption technologies, such as Secured Socket Layer (SSL) and digital certificates; signatures may be used to encrypt data, validate data integrity, and authenticate the parties in a transaction. An infrastructure for confidential data management that includes the sophisticated use of firewall technologies, dedicated database and application servers, automatic failover design, real-time monitoring and related technological capabilities has been established.

Assessment CenterSM

Comprehensive Information Systems (IS) operating procedures and guidelines which include descriptions of system architecture, delivery platform, data sharing plan, privacy, security and issues of ADA/Accessibility has been developed. Each is presented below in greater detail.

System Architecture

Our web-based research application, Assessment Center, has been developed using ASP.NET technology in the C# programming language. C# offers rapid development and true object-oriented programming. While C# is a Microsoft proprietary language, Microsoft, HP, and Intel co-sponsored submission of the language specifications to the ECMA for standardization, and is currently ratified under the ECMA-334 standard. It is also ratified under the ISO/IEC 23270 standard.

Centralized databases commonly used in data collection have been constructed using Microsoft SQL Server 2008 R2. Direct data access will be allowed only through views and stored procedures, and all data changes will be logged. In compliance with FDA 21 CFR Part 11, all data will be time-stamped and no data will be overwritten, thus preserving an audit trail. All data transfers will occur through XML files, defined by published XML schemas.

Delivery Platform

The internet will provide the primary delivery platform. Expertise lies with the Microsoft line of software, which will be used to develop the website GUI and backend. Study websites will be accessible only through a SSL encryption layer, ensuring the confidentiality of the data transferred. Study websites will comply with the accessibility guidelines outlined by the World Wide Web Consortium (“Web Content Accessibility Guidelines 1.0” – <http://www.w3.org/TR/1999/WAI-WEBCONTENT-19990505/>). These guidelines help promote accessibility by people with disabilities. See also “ADA Issues” below.

Data Sharing

XML is an industry standard method of data sharing. The application will implement a standard set of XML schemas for data transfer. These XML schemas will be publicly published, outlining the format of the data. The XML files containing the data itself will be encrypted prior to transport.

Privacy

HIPAA requirements will drive the privacy of data. The PHI will be stored separately from the individual’s other data (e.g., survey responses). Other data associated with an individual will be indexed only by a generic ID. Encryption will also be used wherever data is transferred (SSL for webpages, etc.).

Security

The importance for confidentiality of the participant’s PHI is recognized. PHI will be collected and transferred only where necessary. Where possible, participants will be identified only by generic ID’s. SSL encryption will be used with all internet web pages to ensure confidential form submission. For data files that need to be transferred electronically, the information will be encrypted prior to transport.

The web servers and associated database servers will be housed on dedicated hardware housed at Northwestern University Research Data Center. These will be physically protected from intrusion as well as natural disasters. The secure facilities are protected electronically by hardware and software firewalls, intrusion detection software, anti-virus scans, and 24x7 monitoring by onsite professionals.

Northwestern University Research Data Center is completely fitted with redundancy for HVAC, power and fire detection/suppression systems.

Redundant HVAC

To provide optimum conditions for equipment operation and minimize downtime due to components overheating, the HVAC system provides appropriate airflow, temperature and humidity. Redundancy features provide additional protection for system operations.

Fire Detection and Suppressions

The data centers are equipped with either a Halon or FM-200 fire extinguishing systems. This system provides a highly effective, gas-based method of fire suppression that diminishes the risk of damage to computer equipment and storage media that can result from a water-based system. The data center Halon and FM-200 are maintained under contract with an outside fire systems vendor and are inspected and tested semi-annually.

Flood Control

The data center is located above ground- with tightly sealed conduits, moisture barriers on exterior walls, and dedicated pump rooms; drainage/evacuation systems; moisture detection sensors.

Earthquake

The data center adheres to location-specific seismic compliance. Structural systems meet or exceed seismic design requirements of local building codes for lateral seismic design forces. In addition, equipment and nonstructural components, including cabinets, are anchored and braced in accordance with the requirements of the 1997 Uniform Building Code.

Data Management Systems Security

All data collected via Assessment Center will be securely stored at the Northwestern University Research Data Center. The following information details how Northwestern University Research Data Center protects its network and all data stored at the Research Data Center. The Assessment Center repository is built using the SQL Server 2008 R2 platform. The data management environment will meet the security requirements identified in the AISSP Handbook. The following text describes the minimum information security systems safeguards at Northwestern University Data Center as required by federal standards to be used for Assessment Center:

- Ensure that a complete and current set of documentation exists for all operating systems: Operating System documentation can be obtained by visiting the Microsoft website: <http://www.microsoft.com/windowsserver2008/en/us/product-documentation.aspx>. Specific information for supported systems included in a systems profile document is maintained by the System Support team.
- Require use of current passwords and log-on codes to protect sensitive AIS (Automated Information System) data from unauthorized access: All system access requires a user name and password. All users who require anything more than "internet user" security to the Northwestern University campus network must have a unique ID assigned. The Northwestern University ID is used to control access to data files and applications that reside on the network. Every Northwestern University ID is required to have a complex password assigned. Access to Assessment Center is restricted to participants by means of a username and password incorporated within the participant registration process. Because SQL Server 2008 R2 is integrated with Windows, SQL Server and Windows authentication is used to prevent unauthorized access.
- Establish procedures to register and protect secrecy of passwords and log-on codes, including the use of a non-print, non-display feature: Procedures have been established and maintained by Northwestern University to maintain passwords and log in codes. All application and network passwords are non-printing and non-display. User-level access to Assessment Center is maintained by the Assessment Center team.

- Limit the number of unsuccessful attempts to access an AIS or database: Intrusion detection is enabled and will lock out user after 5 unsuccessful logins.
- Develop means whereby the user's authorization can be determined: (This may include answer back capability.) Restriction to Assessment Center involves maintaining an encrypted list of current users and authorizations based on permissions and roles assigned to each user. Northwestern University provides Assessment Center administrators with secure Virtual Private Network (VPN) access. Operating system and database based permissions are set by the Assessment Center administrators.
- Ensure that the operating system contains controls to prevent unauthorized access to the executive or control software system: Root and administrator passwords are limited to authorized Information Systems administrators. User accounts have limited system resource access.
- Ensure that the operating system contains controls that separate user and master modes of operations: Operating Systems in use allow for the separation of different classes of users and administrators.
- Install software feature(s) that will automatically lock out the terminal if it is not used for a predetermined period of lapsed inactive time, and/or if a password is not entered correctly after a specified number of attempts: Standard timeouts for PC access to systems lock after 10 minutes of inactivity for terminals or 30 minutes for an office PC.
- Establish controls over the handling of sensitive data, including labeling materials and controlling the availability and flow of data: The availability and flow of data is limited to the security access identified and signed off by management. The availability and flow of participant data in Assessment Center is controlled by the database administrator who will pre-define security access levels. This will ensure that only data necessary for that individual's work function are viewable. All requests are validated before attempting to submit data to the database. Any internal or stored reference to a participant is accomplished through a unique identifier key. Data is stored and accessed in full compliance with institutional and governmental regulations regarding privacy and security.
- Require that all sensitive material be stored in a secure location when not in use: Sensitive data is stored in the data center. Northwestern University has a secure data center that houses all servers. This center is limited to authorized employees via the use of a card swiping system and biometric reader on the entrance doors. The data center is manned 10 hours a day, 5 days a week, 260 days a year, but access is 24x7 throughout the year.
- Dispose of unneeded sensitive hard copy documents and erase sensitive data from storage media in a manner which will prevent unauthorized use: Unneeded sensitive data on storage media is degaussed from disk drives after the equipment has been taken out of service. This procedure is defined in a best practice document. Sensitive printed information is disposed of through a bonded document destruction service that performs this service on site at a regularly defined basis. Northwestern University's Department of Medical Social Sciences has established standard operating procedures relevant to data retention and removal based on NIH data retention requirements. Sensitive participant identifiers of on-going studies are encrypted and kept confidential. This procedure was initially designed to comply with HIPAA requirements. Terminated studies will have all participant identifiers removed from electronic media storage after the retention period. Hard copy documents with participant identifiers will be shredded in a timely manner.

Assessment CenterSM

- Prepare and maintain lists of persons authorized to access facilities and AISs processing sensitive data: All authorized employee access ID's are maintained in a secure database for the badge system that secures the Building and Data Center doors. Access to this database is limited to system administrators and is audited on a regular basis. New access requests must be signed off by an IS Director Level or above. Only Northwestern University's Department of Medical Social Sciences employees actively participating in the NIH project(s) will have access to the NIH participant data. This is accomplished by system and application level security based on application roles cross referenced with Windows authentication.
- Establish procedures for controlling access to facilities and AISs processing sensitive data: Authorized personnel's visit to the data center is automatically logged by the biometric/key control system. Visitors are required to sign a visitor's log and are required to be escorted whenever they are in the Data Center. Assessment Center is housed in Northwestern University's Data Center.
- Furnish locks and other protective measures on doors and windows to prevent unauthorized access to computer and support areas: The Operations Center has limited access to unauthorized employees via the use of a card swiping system and biometric reader on the entrance doors. The data center is also manned 10 hours a day, 5 days a week, 260 days a year, but access is 24x7 throughout the year. After hour entrance to the building is also on a card swipe system.
- Install emergency (panic) hardware on Emergency Exit doors; ensure that emergency exits are appropriately marked: Panic Hardware is installed on all Emergency Exit doors. All Emergency exits are properly marked.
- Install fire suppression equipment in the computer facility, which may include area sprinkler systems with protected control valves and/or fire extinguishers: Emergency fire suppression equipment is installed in the computer facility and is tested on a periodic basis. Fire extinguishers are located throughout the building and are appropriately marked for easy access.
- Provide emergency power shutdown controls to shut down AIS equipment and air conditioning systems in the event of fire or other emergencies: Emergency Power shutdown controls are located at each entrance to the operations center.
- Establish a fire emergency preparedness plan to include training of fire emergency response teams, development and testing of an evacuation plan, and on-site orientation visits for the local fire department: An Emergency preparedness plan is in affect which include training, evacuation plan, and on site orientation with the local fire department.
- Northwestern University provides comprehensive data backup. All data is stored in a dedicated storage server on top of redundant disk array. A snapshot of the virtual machines is taken every night and stored on backup storage that is alternated every two weeks. A full backup of the database is taken every night with incremental backups taken every two hours.
- Secure communication lines: Communications lines terminate in locked PBX rooms and in the data center. Physical access is limited to secure and authorized personnel.
- Establish Computer Systems Security Plans for sensitive systems: Security plans are in place for secure systems that house sensitive participant and financial data.

- Conduct formal risk analyses: Risk analyses are performed periodically as part of a more comprehensive audit process of the Information Systems department.
- Establish employee security awareness and training programs: Security awareness and training programs are in place. They are included in employee orientation and are included in the Northwestern University's Emergency Response Procedures. In addition, Northwestern University's Department of Medical Social Sciences provides its own employees with security training with regards to data collection and storage.
- Maintain accurate inventory of all hardware and software: Computer inventory and software are maintained in both hard copy (paper), spreadsheet and database programs. Northwestern University's Department of Medical Social Sciences maintains an inventory management database detailing all hardware, software, and software licenses.
- Establish contingency plan: Contingency plan for disaster recovery is in place.
- Establish emergency power program: The Northwestern University Research Data Center has (2) Uninterruptible Power Supplies and a Diesel generator in the event of a power shutdown. These units are tested on a routine basis.
- Ensure that all personnel positions have been assigned security level designations: Each Northwestern University's Department of Medical Social Sciences employee receives a pre-defined data access security designation based on their employment position. The internal security feature of Assessment Center limits these individual's ability to view or access data based on pre-defined roles. For example, only users with the data entry administrator role will have the ability to insert data directly into the repository. No Northwestern University's Department of Medical Social Sciences employee, with the exception of the database owner(s), will have the ability to manipulate data directly from the base tables. All data manipulations are conducted through SQL views which are also restricted by means of established data access guidelines. Any transaction made against Assessment Center is captured by means of an audit trail.
- Conduct periodic security level designation reviews: An audit on the database that controls the card swipe system is performed on a routine basis to review appropriate employee access. The results are reviewed by the IS Director. The database administrator conducts similar reviews for Assessment Center and will be responsible for keeping an updated employee list.
- Ensure that all personnel, including contractors, have received appropriate background investigations: All IS employees and contractors have received background investigations. All Northwestern University's Department of Medical Social Sciences employees have had proper background investigations conducted by the human resource department.

Acknowledgement of Security Requirements

A detailed outline of our present and proposed Information Technology systems security program are outlined above, and demonstrate compliance with the AISSP security requirements of the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS AISSP Handbook at or above the minimum requirements of a Security Level Designation 2 identified in the DHHS AISSP Handbook, Exhibit III-A, Matrix of Minimum Security Safeguards.