Internet System for Assessing Autistic Children (ISAAC)

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Introduction

The ISAAC Health Research Information system is a web-based application for administering and managing health research projects/studies and the associated data. ISAAC’s easy to use layout allows users to quickly and easily enter and validate (double data enter) study information collected on paper forms, manage users (such as data entry staff), add and update participant ID’s and information, and share study data with other researchers by means of data and codebook downloads.

ISAAC’s proprietary form management system, called DEFE (Database of Electronic Form Elements), automates the process of developing data entry, data validation, and data edit forms. It also tightly links the online forms to the data tables that store the entered values and the code book that describes the downloaded data. In this way, researchers can be confident that the data they download for use in statistical analysis packages is accurately described in all the related documentation.

Since all data entry, validation and editing is performed via web-based electronic forms, users can be located anywhere in the world and can be processing forms at any time, twenty four hours a day, seven days a week. All data that has been entered is available at any time for download. Data can be initially entered by a user at one site, and immediately validated by another user at another site. The data entry and validation forms also give the user the choice of the number of questions they want to see on a single page, allowing flexibility when entering data from sites with different levels of Internet connectivity.

The revolutionary feature of the ISAAC system is its ability to share entered data between researchers. Principal Investigators can easily designate research data to be made available to other ISAAC users on a multiple levels. They can share all of their data with a particular researcher, or a particular data set with all other researchers. The sharing level is in the complete control of the PI. ISAAC will never share data that has not been specifically registered to do so. It is the hope of the ISAAC team and its funders that eventually all of the data stored within the ISAAC system will be made available to every researcher. It is through this aggregation and collaboration of health research information that new cures and better understandings of health issues will be more quickly advanced.

How to Use the ISAAC User’s Guide

The ISAAC User's Guide is designed to help you quickly begin to use the ISAAC system for entering, storing and sharing research data. The Guide begins by a providing an overview of the system, its users, and the main set of menu functions.

Next, the Guide provides detailed instructions on how to use the Start Page, to begin entering, validating, editing data, or performing a number of other functions. Each function is accompanied with detailed step by step instructions and screen shots of the actual application.

Through the guide, there a hints and suggestions on how to use ISAAC most efficiently, and to ensure accuracy of data entry.

Let’s begin.
Users

The ISAAC system users fall into one of four categories. Each user type has specific entitlements and levels of access and is assigned to particular project or projects and Principal Investigators (PI). The Principal Investigator for each project typically designates access, but the Data Manager also has these rights.

<table>
<thead>
<tr>
<th>Security Level</th>
<th>Role</th>
<th>Access level and entitlements</th>
<th>How Added</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Worker (RW)*</td>
<td>Listed in the Research Worker drop down on</td>
<td>None</td>
<td>PI or DM</td>
</tr>
<tr>
<td></td>
<td>the Data Initialization page.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guest Researcher</td>
<td>Download data, view code book</td>
<td>Download page only. Cannot view, entry, change any other information.</td>
<td>PI or DM</td>
</tr>
<tr>
<td>Data Entry Clerk (DEC)</td>
<td>Enters, validates and edits data on specified forms.</td>
<td>Data Entry, Data Validation, Data Edit, Download Data, View CodeBook. View patient information. Only sees active patients</td>
<td>PI or DM</td>
</tr>
<tr>
<td>Data Entry Clerk Plus</td>
<td>Performs all of the actions of a DEC, but</td>
<td>Same as DEC, and has access to the add/update patient information fields.</td>
<td>PI or DM</td>
</tr>
<tr>
<td>(DECP)</td>
<td>can also add/edit patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Manager (DM)</td>
<td>Performs all of the functions of the PI.</td>
<td>Has Data Entry Clerk access, as well as Adding Users/updating users. DM’s can also set up and modify Summary download files as well as view information for inactive patients</td>
<td>PI</td>
</tr>
<tr>
<td>Principal Investigator</td>
<td>Controls all aspects of a project</td>
<td>Has access to all features and functions on the site.</td>
<td>ISAAC Administrator</td>
</tr>
<tr>
<td>(PI)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Research Workers, though not strictly users of ISAAC, are included in the Users list for three reasons: 1) Much of the information the system requires for RW’s is the same as for regular Users, 2) Many RW’s also perform a data entry role, and would therefore already be set up as a User, 3) A study may, in the future, require that RW’s enter the data the collect. Since their information is already set up in the User’s table, it is a simple matter to provide them with access.
General Information

A. Technical Requirements
Because ISAAC uses some of the latest in web technology, your software and settings must be at a certain minimum for the system to work properly. Please ensure that you meet these minimums before attempting to log onto the site. Unless you or the organization you work for has changed the security or privacy settings of your browser, the default settings for IE should be sufficient to use the site.

- Browser: Internet Explorer 5.0 or later
- PC with at least 128 MB RAM
- Cookies: Enabled, Allow Session Cookies.
- Active Scripting: Enabled.
- Security: 128b SSL encryption

B. Logging On
All of the ISAAC functions are available to authorized users only. You must have been assigned a User Name and a Password in order to access the site. If you do not have a User Name, or do not know your password, please contact your projects PI or DM.

To logon on to ISAAC, point your browser to http://www.autismtools.org. You will be redirected to secure site (https://www.autismtools.org/isaactools/index.cfm ). The login page will display.

For security purposes, no identification as to the use of the site is given on the login page.

Enter your assigned User Name and Password and click Submit.

If you enter an invalid User Name or User Name/Password combination, you will not be logged in and a message will display stating “The User Name and Password you supplied does not match any in our system.”

If you have entered a valid User Name and Password and clicked Submit, the ISAAC Tools Menu and Start Page will display.

If you allow any page you are viewing to remain inactive for twenty minutes, your current session will be closed and you will be forced to re-enter your User Name and Password when you next perform an action on the page. You will be returned to the start page and your session will be reset.
C. The ISAAC Tools Menu and Start Page

The Start Page provides access to all of the features and forms on the site. From here you can elect to enter new data into a form, validate existing data, complete entry of partially completed forms, or navigate to the the User management, Patient Management pages, among others.

Predominantly, you will use this page to choose the form/tool to use, the patient for which you want to enter data, and the particular task you wish to complete.

It is extremely important that you take care when choosing the Patient ID for whom you are entering data. Entering the incorrect Patient ID will assign data to the wrong person and will be difficult to correct. Check and recheck the number before continuing.

Later on, we will explain how to add new patients if the patient for whom you are entering data does not appear on the patient ID lookup list.

D. The Relationship between your User Name and Entered Data

For security and ease of use, ISAAC maintains a tight relationship between your User Name, the active project, and the data you have entered. This ensures that your data cannot be viewed by others (unless you specifically allow them to) and allows ISAAC to keep track of and provide lists of data that you have entered.

This is particularly useful when you want to validate, resume, or edit records. Because ISAAC knows which records belong to your project(s), it can display a list appropriate for the task you have chosen. For example, if you are going to validate data, you are provided a list of all of the records that have been entered but have not yet been validated assigned to your study. You will not see incomplete records, or records that have already been validated. You will also not see records entered by others not associated with your study.

E. Session Timeouts

After logging in, ISAAC maintains your session while you continue to work within the system. If you allow the system to remain idle for a period of 20 minutes, your session will time out and you will be asked to reenter your User Name and password and will be returned to the start page.

It is extremely important that you do not allow your session to timeout while entering, validating, or editing data. Though the system always tracks what field you last saved, you will lose the data entered on a page that has not been submitted. If you cannot complete the entire form in one session, it is always best to Exit and Save the form, then Logout. You will be allowed to resume entry of the data at the point you last completed.

F. Navigation

In almost all cases, use only the navigation provided on the screen. Though the system is built to allow you to use the browser’s Back button, this should be done as infrequently as possible. It is always better to complete an action by clicking on the buttons placed on the page then to use the browsers other functions. It is possible to lose the data you entered on a page or may cause other data errors if you regularly use the Back and Forward buttons.
When entering data on a data entry/validation page, you are typically given two choices. You may continue entering data for the next set of questions (by clicking Save and Continue), or you can save your work and your current spot on the form and exit (by clicking Save and Exit). If the system is returning unusual messages (such as giving you validation errors when both the first value entered and the value most recently entered match), you have probably used the Back button in a way the system is unprepared for. In this case, Save and Exit your work, return to the start page, and resume entry on the record. This will reset the system and allow you to proceed normally.

G. Version Control

Every paper form containing the responses you are to enter into ISAAC is of a particular version (the version ID will typically appear on the bottom left of the paper form, but may appear in other areas (i.e. only on title page, top left, etc., or perhaps, not at all)). Before beginning entry of the data, verify the version id (this can be an alphanumeric code, for example, VIN32A, or a date, such as 2001).

When you begin data entry (or resume, validate, edit, etc.) you will be asked to select the version of the form you are working from. In order to ensure the data entry fields match the form questions, the versions must match. Entry of data from one version of a paper form to another version of the electronic form will likely result in data integrity problems.

H. Scoring and copyrights

The forms/tools that ISAAC already contains in its catalogue, and those that will be added in the future, may include the ability to enter manual scores and/or have ISAAC automatically score the forms based on the raw/interview data. If a form includes fields from a score sheet in addition to the raw scores, those fields can be grouped in one or more manual scoring sections and then set as optional. As optional sections, on completion of entry of the interview data, the user is asked if they would like to proceed to entry of the manual scores.

If the manual scores must be entered, then they can be included in a separate section with the raw values.

If a form has automated scoring, the scoring is performed by ISAAC at three different points. First, when the raw scores on which the scoring is based are initially entered, ISAAC runs the associated scoring algorithms. Then, when a form is validated, because values could change, the scoring is rerun. Finally, if a user edits a value in the form, the scoring is run again. In this way, the scoring always accurately reflects the raw scores.

Scoring is a special feature that ISAAC offers for some forms. Many of these forms are copyrighted, along with their scoring algorithms. ISAAC has been able to secure agreements with the publishers of these copyrighted materials to allow the display of specific section and question text, and perform the scoring. Anyone who has programmatically copied the scoring algorithm for a copyrighted form, or is using specific language in the form, but has not secured permission from the publishers, is in violation of copyright laws.

Because it is through the kindness of these publishers that ISAAC is able to offer the detailed information about some of these standard assessment tools and questionnaires, we insist that users properly purchase whatever copyrighted materials they plan to use in their study. Licensing ISAAC is
not a replacement for purchasing original interview forms and score sheets.
ISAAC Menu Functions

Below is a list of the main functions of the ISAAC system not directly related to the entry/validation/editing of form data. All functions are accessed through the menu list located at the left side of the page. Since not all functions are available to all users some of the functions listed below may not appear on your menu. The list below also provides only cursory explanations of the functions. Where necessary, the functions are described in more detail later in the User’s Guide.

Form activity also will be described in more detail later in the User’s Guide.

A. Log Off

The Log Off button performs two actions when selected. It first closes the current user session and then returns the user to the login page. Logging out ensures that if you leave your computer workstation unattended, someone else cannot gain access to the data within ISAAC.

It does not, however, save unsaved data. Therefore, if you have partially completed data entry on a form, always click Save and Exit before logging out. Always logout before leaving the site, even if you plan on returning in a few minutes.

1. Users Access
   All Users

2. Features
   The Log off button is available from all pages.

B. Enter Data Menu Item

The Enter Data menu item provides the user with an easy method of returning to the start page from whatever page is currently being displayed. It is available on every page on the site. Clicking on the item resets all activity and allows the user to start on a new activity.

You can find more detailed information on this topic in the Data Management section of the User’s Guide.

C. Get Data – Data Download

One of the most important features of the site is to allow you access to your own and shared data, which you can download in a standard format (xls – tab delimited) and import into statistical packages, local databases, or keep in Excel spreadsheet form. The Get Data page also serves as a quick way to get record counts on the data that has been entered for the active study (and any other studies the user has access to).

1. Users Access
   All Users
2. Features

From the Get Data page, select the data and high level filters you want to apply, then click the View Download List button. All forms with data matching your selections will be displayed with record counts. There are some forms which are only available through download.

You may select to download all or only a portion of the fields for a particular form if that form has more than one entry type. Entry types are defined as Interview Data (regular Form data), Manual Scoring Data, or Automated Scoring Data. Interview Data is most often the data that is collected from a patient by a research worker. Manual Scoring data can be a summary of the Interview data that leads to a potential diagnosis. The summary is performed by a research worker. Automated Scoring data is usually a duplicate of the Manual Scoring data, only the values are not calculated by a research worker and entered through the ISAAC Data Entry Screens. Instead, ISAAC programatically calculates the scores and saves them in the appropriate fields. For example, the domain scores for an assessment tool like the ADIR can be calculated and entered manually. At the same time, they are calculated by ISAAC based on the interview values. Not all forms have scores (i.e. a medical history form). If you choose to only download scoring data, no data will be available for these forms.

You also can download the Patient Summary File from the Get Data page.

Some users may also choose to include data from other projects/studies for which they have been giving access.

- [Active Project] Data – Download only the data that has been entered for the project that is currently active.
- [Active Project] and Shared Data – Download all of the data for the active project, plus data entered by other researchers that has been made available by them to the user for the same form.
- Only Shared Date Only – Download only the data entered by other researchers that has been made available by them. Do not download the users own data.

Additionally, if you have rights, you may be able to include records that have not be validated (double data entered), or have been entered for patients that are currently inactive.

Since the downloaded data could be used in a number of different applications, each with there own limits on the number of columns that can be included in a single file, ISAAC allows you to dictate the number of columns to include in any given file, and automatically breaks up data
accordingly. Each file contains a record key that can be used to rejoin split tables. For example, if you plan to import into or link to the data from Access, you should leave the number of columns at 250, as Access has a 255 limit on the number of columns. If instead, you want to pull the data into SAS or something similar, you can set the number at 999 and be confident that each form’s data will be included in a single file.

When you click on the “Download This Data” link associated with a particular form, the system generates the file matching the filters and data groups you selected, zips the file(s) and displays a link to the zipped file in a new window. Click this link to begin download.

If you wish to download another data set, click the link below that form and the process described above runs again.

You can find more detailed information on this topic in the Download Data section of the User’s Guide

**D. Get Data – Display Codebook**

From the same page from which you can download data, you can also view the Codebook for the form, which maps the column headings in the download file back to the originating question/field. The Codebook is ISAAC’s Data Dictionary for the forms it allows you to enter and store. The Display Codebook feature allows you to quickly and easily research how downloaded data compares to the associated questions. It provides all of the information associated with a form in the order in which it is entered, along with explanatory text on fields that are included in the downloaded data set but are not entered (i.e. automated scoring values).

1. **Users Access**
   All Users

2. **Features**
   From the Get Data page, follow the instructions above to display a list of the forms available for download. Select the appropriate View this Form’s Codebook link.

   A new window opens, displaying all of the fields for the form with their associated questions. The page is formatted in HTML, and can be saved as such to your local drive to be referred to later. Of course, you can always re-view the page at any time.

   The page is broken down by version, data type (Interview Data, Manual Scoring Data, Automated Scoring Data), then section, and question. This matches the column order of the download file1. For each question, the system provides the on screen

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1 If a tool has multiple versions, the older version is displayed first on the codebook. In the download file, fields that appear in both versions are only listed once.
E. Add/Update User and Update User Profile

1. Users Access
   All users

2. Features
   a) Modify your profile
      From this page, every user can change the user information stored about them, including the first name, last name, username, and password, among others
   
   b) Add new users
      PIs and DMs can add users whom are new to ISAAC, and set their security settings
   
   c) Add existing ISAAC users to your project
      PIs and DMs can add users from other ISAAC projects to their project. This is especially helpful if you are running several projects on ISAAC. Each project maintains its own list of users and their security settings. But to add users that are already registered in ISAAC, you simply enter their username, “get” their user information, and set their security settings. You do not have to reenter all of their user information.

      This allows users to work on different projects at different capacities. In one case, a user may be data entry clerk, in another, they may be a research worker.

      More detailed information about setting up users can be found in the User Management section of the User’s Guide.
d) Add Research Workers

When initiating entry of any form, you are asked to choose the research worker that collected the information from a drop down list. This list is made of users for whom the “Is Research Worker” as been set to “Yes”. Any user can be a research worker.

You can find more detailed information on this topic in the Users Administration section of the User’s Guide.
F. Patient Management

The Patient Management page allows users to Add, Edit and View patient information. Patient information must be entered prior to data entry on any form for that patient.

ISAAC is not designed to store complete patient demographic information in its patient records. The fields that are provided are for non-identifying information (ID’s for ISAAC and other systems). Your patient contact information should be stored in an offline system that you maintain.

1. Users Access
PI, DM, DECP, DEC

2. Features
All patient management is handled from this single page. From here, you can add new patients, modify existing patients, and view patient information, including a list of all related data that has been entered for a particular patient.

All of the labels for the patient information fields can be set on a project by project basis. Therefore, if you are running two different projects, in one you may want a patient field labeled Blood ID, in another, you may want the label Consensus Diagnosis Code.

a) Add New Patient.
   If you have rights (PI, DM, and DECP), you can add new patients. The only required fields are the Patient ID, Date of Birth, and Status. All of the other fields are optional. Enter information in all required fields and any optional fields. Click Add this Patient.

b) Modify Existing Patients
   If you have rights (PI, DM, and DECP), you can modify existing patients. Enter the patient ID in the designated field (or select it from the Lookup screen). Click Edit to view the patients information. Then make appropriate modifications and click Update this Patient.

c) View Patient Information
   If you have rights (PI, DM, DECP, DEC), you can view patient information. For PI, DM, DECP, this is the same as editing patient information. For DEC, the Edit button is replaced

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2 View patient only. DECs are not allowed to add new patients, or modify existing patient information.
with a View button. After entering the Patient ID and clicking Edit/View, the patient’s information is loaded into the fields on the left side of the page. At the same time, all data records entered for this patient are listed on the right side of the page. Each data record is accompanied with a link to the most likely action for that record.

You can find more detailed information on this topic in the Patient Administration section of the User’s Guide

G. Patient Summary File Set Up

The Patient Summary File set up page allows you to add or remove fields from the summary file. The Summary File is a single downloadable file that can hold up to 250 fields from any of the existing data entry forms. At the time of download, the system pulls data for all of the fields in the summary file and merges them into a single download file. The Summary File is available for download on the Get Data page.

The downloaded file contains at least one record for each patient. If a form was collected and entered more than once for a single patient, then that patient could have more than one record in the Summary file.

1. User Access

PI, DM

2. Features

From the Summary Set Up page, you can choose to list the questions from any form in your project. You then can elect to add one or more of the question to the Summary file, or, remove any fields you no longer want to include.

You first select the Form/Tool for which you want to add or remove fields. Once the fields are displayed, you can select the appropriate check box.

All of the fields currently contained in the summary file are listed on the right side of the screen.

You can find more detailed information on this topic in the Patient Summary Files section of the User’s Guide.
Patient Administration

A. Adding Patients

Users that have the rights to do so, may enter new patients at any time from Patients Administration page. This can be accessed by clicking on the Patients menu item on the left hand menu bar, or clicking the Add patient link in the Patients section of the Start Page. We will now describe in more detail the fields on the page and which information must be entered for you to add the patient to the patient list.

The Patient Administration page, as with most of the pages in ISAAC, is divided into two sections. When the page first displays, the fields on the left side of the screen are blank with the button to Add this Patient. You can fill in these fields and click the Add This Patient button to quickly add a new patient.

The right hand side of the page is reserved for selecting a patient to Edit or View, and displaying that patients related data records.

As you can see from the screen, the Patient information contained in ISAAC is not meant to include identifying information (such as SSNs, Names, Addresses, etc.). This information should be maintained in an offline system separate from ISAAC.

All of the patient fields are included with each record downloaded from ISAAC.

1. Required Fields

   Patient ID/Individual ID Number – The unique identifier for the patient. This can be any series of letters and numbers. This value is used throughout the site to select the Patient. This system will not allow you to add two patients with the same ID.

   Date of Birth – In order to calculate the patients age at the time an interview was conducted (when a form was filled out), the system must maintain the patient’s date of birth.

   Gender – Though this value is not used anywhere within ISAAC, it is universally included in research. Instead have requiring that forms include this field as part of their data entry values, we have included it here for convenience.

Patient information can be automatically maintained in ISAAC from another system using WDDX. If you wish to find out more about how your patient contact/enrollment system can interact with ISAAC, please contact the ISAAC team at support@autismtools.org.
Status – Active, Inactive, Remove. Active is the status for most patients. It implies that the patient information is accurate and up-to-date and that the patient’s data can be included on downloads. Inactive is for patients who are still participating in the study but whose patient information and/or data records may not be accurate and should not be included in downloads. The Remove status is for patients that were incorrectly added to the list, have left the study with incomplete data records, and will ultimately be removed, along with any associated data records, from the system. Patients with the Remove status are deleted from the system by the ISAAC team whenever requested by the DM or PI. Currently, there is no method for a user to delete a patient record.

2. Non-required Fields

Family ID – The Identifier for the family
RefID1 – The first open, user defined ID field. This along with RefID2 and RefID3 fields can be used by studies for additional patient-related information.
RefID2 – same as RefID1
RefID3 – same as RefID1

All of the labels for the Non-Required fields can be set to any value you wish for your study. If you are running multiple studies/projects on ISAAC, you can set each one with different ID labels. For example, you may use Reference Field 1 in one study for a blood sample ID. In another study, you may want to use the field for a consensus diagnosis code. Since these fields are included with every download, it can be helpful to include information which you may want to broadly use for analysis, or to link the downloaded information to information contained in another system (patient records, genotypic data, etc.).

3. Add this Patient

By clicking this button, you submit the information you have entered for the patient to the system for inclusion in the patient list. If any errors are encountered on submit (blank required fields, duplicate Individual ID, invalid DOB), the page is returned with an appropriate error message. If no errors are encountered, the page is returned with a message stating the user has been successfully added.

Whole groups of related patients (i.e., same family id) can be easily added by changing only the appropriate fields (Individual ID, DOB, Sex, etc.) while keeping the Family Number unchanged. This not only speeds the entry process of patients, it ensures that family members will be accurately grouped together (that all will have the same family ID).

Return to Start Menu – Allows you to jump directly back to the Start Page without performing any other action (such as saving entered information). Use this after you have successfully added a patient or patients, or if you brought up the Add Patient page inadvertently and do not want to perform that action.

B. Edit Patient Information

Editing Patient information is performed through the same page that patient information is added to the patient list. To bring up a patient for editing, enter the patient id in the provided field on the top right side of the page. You may also lookup the patient id from the lookup link.
Once you have entered the patient id, click the Edit button to load the patient information into the patient fields on the left side of the screen. At the same time, the Add this Patient will be replaced with an Update this Patient button.

Make any changes you desire and click the Update this Patient button. As with adding patients, the system will verify that the information is complete and correct. You will not be able to change the patient id to one that already exists in the system. All required fields must have values.

C. View Patients

For Users that do not have rights to Add/Edit patients, they may have rights to View Patient information. This works the same way as Editing patients, only the information loaded into the patient fields on the left side of the screen will be uneditable (the fields will be disabled) and no Update This Patient button will be displayed.

To view a patient, enter the patient ID in the provided field (or select the patient ID from the lookup window) and click the View button.

If the Patient exists, the page will be redisplayed with the patient information loaded in the left side of the page, and the patient’s record list displayed on the right.

If the patient does not exist, the page will redisplay with an error message stating as such.

D. Patient Records List.

At the time you click the Edit or View buttons, the system collects information on all of the records associated with the entered patient ID. These records are listed on the right hand side of the screen, grouped by the form/tool from which they came. With each record, you can view the current status, and are provided a link to the next logical action for this record. For example, if the record has been completed but not double data entered, the link displayed with that record is “Validate”. Records that have been completely validated are displayed with a link to “Edit”.

This list provides users with a quick way to assess whether a patient has data entered on all required forms for the study. It also allows a quick reference for ensuring that all records have been removed for a patient that is no longer valid in the study.
User Administration

Research staff play many varied roles in the successful completion of a research study. From a PI that provides oversight or a Database Manager that directs day-to-day operations, to a Data Entry Clerk that focuses solely on getting data into the system or Guest Researchers who have been called in to help analyze the data, the number of people that need some form of access to the data can be difficult and complicated to maintain. ISAAC makes this much easier with its integrated User Management features and built in multiple security levels.

All user administration tasks are accomplished on the User Management page. From here, users with appropriate rights can add new users to ISAAC and their project, add existing ISAAC users to their project, modify user’s security levels and status, and modifying their own profile.

To access the User Management page, click on the “users” menu item at the left side of the screen. Depending on your security level, you may see one of the action groups (listed below) on the right side of the screen, and fields for entering a new user on the left side.

Action Groups

- Add Existing Users to Project
- Select/Edit User Information
  - Edit Your Profile
  - Regular User Edit
  - Research Worker Edit
  - Guest Researcher Edit

Each of the four “Select/Edit User Information” action groups provide a list of users that fit the particular category. This gives users with sufficient rights a quick overview of the project’s users.

Users with a higher or equal security level as the current user will be listed in their appropriate group, but the radio button that allows you to select the user for editing will not be displayed. Only users of higher security level can edit another user’s information.

The User’s Information is broken into two parts, the profile, and the project information. The user’s profile is the same across all projects and contains first name, last name, organization, email address, etc. The project information is how each user is set up within a project. This includes the security level,
status, and active until date. In this way, a user can have different security levels for each project and can access each of the projects with a single user name and password.

The features available to any user are dependent on that user's security rights. Though all users can view the page, as all users can update their profile, only those with sufficient security levels can perform certain functions. This list of functions and their associated security levels are listed below.

<table>
<thead>
<tr>
<th>Action Group</th>
<th>Security Level of Users with Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Editing own profile</td>
<td>All users</td>
</tr>
<tr>
<td>Adding new users</td>
<td>DM, PI</td>
</tr>
<tr>
<td>Editing a user's project information</td>
<td>DM, PI</td>
</tr>
<tr>
<td>Adding existing users to active project</td>
<td>DM, PI</td>
</tr>
<tr>
<td>Editing Research Workers</td>
<td>DM, PI</td>
</tr>
<tr>
<td>Editing Guest Researchers</td>
<td>DM, PI</td>
</tr>
</tbody>
</table>

Each of the action groups is explained in more detail below.

**A. Adding New Users**

Adding new users is the only time you will be affecting information in the user profile and project information sections at the same time. When you add a new user, you enter that user's profile information and set that user's security level, then click the Add this User button.

All of the fields on the User profile are required. This is true even if the user being added is to be a Research Worker and will not be access the site.

The fields are as follows:

- **First Name** – The first name of the user
- **Last Name** – The last name of the user. ISAAC will check if a user with the name first and last name already exists in the system. This will help eliminate assigning a single user with duplicate access. If ISAAC finds a match, the page will redisplay with an error message. Modify the user's first or last name (for example, by including a middle initial in the first name, i.e. “Tom D.”)
- **Organization** – The organization that the user represents (educational institution, private firm, non-profit organization, etc.)
- **Email address** – The email address that the user will want ISAAC to use when notifying of outages, new features, new tools, etc. The email address must be in the correct email format of ABC@123.XYZ.
- **User Name** – The unique user name the user will use to access ISAAC. On submittal of the page, ISAAC will check if the name already exists in the system and will return an error message if it finds a match. Please modify the user name and resubmit.
- **Password** – The password the user will use, in combination with their username, to access the site. The password must be at least 5 characters long and contain both alphabetic and numeric characters (i.e. hg19Bz32). To maintain the site's security, it is imperative that users never share their password with others, and that they periodically change their password.
- **Reenter Password** – The duplicate of the password above to ensure that the user did not mistype the original password. Both passwords must be identical. If on submittal of the page ISAAC finds the passwords do not match, it will return an error message requesting to reenter the passwords.
• **Is Research Worker** – Any user of ISAAC could also be a research worker. That being the case, a user with any security level, e.g., Guest Researcher, can be added to the research worker list. By checking “Yes” here, the user will be added to the list of research workers to select from during the initiation of new form data entry. This flag is independent of the user’s security level. This flag must be selected if the user is also going to have a security level of Research Worker.

• **Security Level** – The value selected here determines which features of ISAAC, if any, a user may access. The chart below describes those features for each security level.

<table>
<thead>
<tr>
<th>Security Level</th>
<th>Role</th>
<th>Access level and entitlements</th>
<th>How Added</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Worker (RW)*</td>
<td>Listed in the Research Worker drop down on the Data Initialization page.</td>
<td>None</td>
<td>PI or DM</td>
</tr>
<tr>
<td>Guest Researcher</td>
<td>Download data, view code book</td>
<td>Download page and users page only. Cannot view, entry, change any other information. Can modify their own user profile</td>
<td>PI or DM</td>
</tr>
<tr>
<td>Data Entry Clerk (DEC)</td>
<td>Enters, validates and edits data on specified forms.</td>
<td>Data Entry, Data Validation, Data Edit, Download Data, View CodeBook. View patient information. Only sees active patients</td>
<td>PI or DM</td>
</tr>
<tr>
<td>Data Entry Clerk Plus (DECP)</td>
<td>Performs all of the actions of a DEC, but can also add/edit patients.</td>
<td>Same as DEC, and has access to the add/update patient information fields.</td>
<td>PI or DM</td>
</tr>
<tr>
<td>Data Manager (DM)</td>
<td>Performs all of the functions of the PI.</td>
<td>Has Data Entry Clerk access, as well as Adding Users/updating users. DM’s can also set up and modify Summary download files as well as view information for inactive patients</td>
<td>PI</td>
</tr>
<tr>
<td>Principal Investigator (PI)</td>
<td>Controls all aspects of a project</td>
<td>Has access to all features and functions on the site.</td>
<td>ISAAC Administrator</td>
</tr>
</tbody>
</table>

• **Status** – This dictates whether existing users can continue to access a particular project or ISAAC at all. Only users set to “Active” have access to a project. A user that no longer is active in any projects cannot access ISAAC. Setting a user to inactive is typically done to immediately disable access. This can be for many reasons, including termination of employment of a study staff member, a student worker that leaves the project, a guest research that uses the data improperly, etc. In general, all new users will be set as active.

• **Active Until Date** – This is especially helpful when setting up temporary data entry staff, or for allowing guest researchers limited access to the data. If a user attempts to log in after the Active Until Date as passed, they will be given a message that they no longer have access and are returned to the login screen. When adding a user to your project, the system will automatically add one year for the current date as the default for the Active Until Date. You may change this to whatever date is appropriate.

After completing all of the user’s fields, click the Add this User button to submit the user to ISAAC. If any errors are found with the information submitted, the page will be redisplayed with an error message indicating the problem. Please make necessary changes and resubmit.

**B. Adding Research Workers**

Adding Research Workers is no different from adding any other user, other than the additional step of selecting the “Yes” value for the **Is Research Worker** question. If this flag is not set either at the time
the user is added, or later if the user’s project information is modified, the user will not be listed in the Research Worker list, even if the user’s security level is set to Research Worker.

The reason for having to indicate that a user is a research worker in two places is to allow any user to be included in the list of Research Workers for a project. This is especially helpful if you are collecting information from multiple sites or are sending workers to patients homes or nearby clinics and want to allow the research worker to enter their data themselves from their offices or from the road. In that case, you can set the Security Level to Data Entry Clerk for that user and set the Is Research Worker flag to “Yes”. The research worker can then enter the data they collect, choosing their name on the data entry initiation page, then send the paper forms to the study center for filing and double data entry. This disperses the need for a larger centralized data entry staff, ensures the data is entered in a timely fashion, and helps confirm its accuracy. If the research worker encounters a value entered on the form that cannot be entered into ISAAC, they can correct it on the spot, instead a data entry clerk having to contact a research worker some time in the future when the patient and data are not longer clear in his/her mind.

For research workers that will not be expected to or allowed to enter the data they collect, set the Security Level to Research Worker. Though you still have to provide a valid user name and password, the user will not be allowed to access the site. Or, if they have access to ISAAC through another project, they will not be allowed to access the data for your project.

If later on you decide to allow the research access to the site and to enter data, you can change the security level to data entry clerk and the user will have access.

**C. Modifying your Profile**

To modify your profile, you must first load your profile information. Do this by clicking on the **Edit Me** button in the **Edit your User Profile** action group.

This loads your user profile information into the fields on the left side of the screen. All of the profile fields are enabled and allow modification. The project information fields at the bottom left of the screen remain disabled, as a user cannot adjust their own security levels, status, and Active Until Date.

To make changes to the profile, edit any or all of the profile fields and click the **Update My Profile** button. All of the fields must conform to the New Users rules and will be checked for correctness when you submit the page. Therefore, you cannot change your user name to another that is already in the system, nor can you erase and leave blank your email address. If any of the modifications you made to your profile are invalid, the page will be redisplayed with an error message indicating the error. Make the necessary changes and resubmit the page.

**D. Modifying a User’s Project Information**

During the course of a study there will likely be several occasions where a users security level, status or Active Until Date values will need to change. This can be because the user is leaving the project, is changing her role, or one of several other reasons. In all cases, modifying the user’s project information is accomplished in the same way.

First select the user from the appropriate group of users -- regular form users, research workers, or guest researchers, by clicking on the radio button to the right of the person’s name. You will not be able
to select a user that has a higher security level than yourself. Once selected, click the appropriate Edit User button.

The user’s information will load into the fields on the left side of the page. The profile information fields are disabled. Though you can view the profile information, you will not be able to modify it. You can, however, modify the project information. Change any or all of the values and click the **Update this User** button to submit. Any changes you submit must still conform to the project information rules that apply to new users. Therefore, you will not be able to leave any of the fields blank, nor set the Active Until Date to prior to the current date, among others. If the system does encounter an error on submittal, the page will redisplay with an error message and the user’s project information will not be updated.

**E. Adding Existing Users to your Project**

To add existing users to your current project, you will need to get that user’s user name. Once obtained, enter the user name in the field provided in the **Add Existing Users to Project** action group. Then click the Get User button.

If the user name is found in the ISAAC user list, the user’s profile information is displayed in the profile fields on the left side of the screen. If it is not found, the page is redisplayed with an error message stating as such.

As with modifying existing project users, the profile fields are disabled. Though you can view the information to confirm you have selected the correct user, you will not be able to modify any of the information.

To complete addition of the existing user to your project, select and enter the appropriate values in the project information fields and click the **Add User to Project** button. The project information submitted must conform to the rules for adding new users. As such, all of the fields must contain valid values. On submittal, the system will verify the information. If any errors are encountered, the page will redisplay with an appropriate error message and the user will not be added to your project. Make the necessary changes and resubmit.

**F. Guest Researchers**

Guest Researchers are special users because their access is severely limited and they are likely not a member of your study staff.

ISAAC allows guest researchers for several reasons. Primarily, it provides a controlled and safe way for researchers to share the data they have collected with other researchers. It is especially an especially powerful feature when researchers from one project share their data with other ISAAC researchers. Then the data collected in disparate studies using the same form (i.e. the ADIR) can easily be combined. All of the combined is made available in a single download.

Allowing a user access to your project is as easy as adding a new user. It is also as controlled as any other user management process. Therefore, you have full control on who has access to your data. You can limit the time they have access using the Active Until Date. At any point you can disable their access by setting their Status to Inactive.
You can also limit which form’s data is available to guest researchers. Therefore, if you want to share pieces of your data, but want to keep private others, you can do so through the ISAAC team. They can set any form to be shareable or not. All non-shareable forms will not be available to Guest Researchers but is available to other project users.

Adding a Guest Researcher is the same as adding any other user. You simply select the Guest Researcher Security Level. Guest Researchers, as with other users, can be added as new users or added to your project from an existing project. For example, if you would like to share your data with the PI from another ISAAC study, simply enter their username in provided field in the Add Existing Users to Project action group field and click the Get User button. Complete the project information section and choose the Guest Researcher security level. Click the Add User to Project button.

The information entered in the project information fields must be valid. If the system encounters invalid information (i.e. an Active Until Date prior to current date), the page will redisplay with an error message and the user will not be added. Make the necessary changes and resubmit.

The next time the PI logs onto ISAAC, your project’s data will be available to the researcher through the download page.

Guest Researcher only have access to the download page and to their profile. If a user is a guest researcher in your project, but a PI or DM in another project, they have access to that project’s other pages, but no access to your projects pages. This includes your patient and users lists, as well as your summary file.
Data Management

A. Using the Start Page.

The Start Page is the jumping off point for all form data entry. Though the user can access some of the form data entry functions from other pages (such as the Patient Edit page), all functions can be originated from this page, and it is the only page for where a user can enter new data on a form. The Start page is designed to easily allow the user to select the appropriate form, version, and patient to work on, along with controls on how the data entry page should be displayed.

To demonstrate how to begin the data entry process, we will walk through selecting the appropriate information for the ADOS-G 2000 Module 1: Pre-Verbal/Single Words form. The steps to select and begin entering information for all forms will largely be the same.

1. Steps to selecting a Form/Tool and Patient ID

From the ISAAC Start page, complete the following steps.

1) Step 1: Selecting a form/tool
   a) From the drop down box titled 1. Select Tool, choose the ADOS-G 2000 Module 1: Pre-Verbal/Single Words form (or whichever form you are entering data for).
   b) Once you have selected the Tool/Form, select the appropriate version from the Version field. The values in this box pertain only to the form just selected. In the case of the ADOS-G 2000 Module 1: Pre-Verbal/Single Words, select 1999.
      
      If the Version window appears grayed out, select another form in forms window, then reselect your form.

2) 2: Select a task
   From the Select a Task drop down box, select the activity you wish to complete for the chosen patient/Tool. For example, if you are entering the ADOS Mod 1 information for the first time for a particular patient, select Enter New Form Data.
   a) Enter New Form Data– Whenever you are entering data for the first time for a particular patient and Tool/Form, you must select this task. You will first be asked to complete the Initiation Screen (which is the same for all forms), before beginning entry on the actual form. The Initiation Screen is described in more detail below.
   b) Resume Form Data Entry – Used when you were not able to complete the entry of the Tool/Form in one session. ISAAC places you at the point just after the last field for which
you successfully entered data. You can learn more about Resuming data entry in the Resume Data Entry section later in the User’s Guide.

c) **Validate Existing Form Data** – After completing the initial entry of a form/tool, all data must be validated (double data entered) to ensure that it is correct. Choose this task when beginning validation for a particular Tool/Form-Patient-Interview Date. After selecting Validate Existing Form Data you will be asked to identify the record you wish to validate by the Interview Date/Form ID. You can learn more about Resuming data entry in the Validate Existing Form Data section later in the User’s Guide.

d) **Resume Validation of Form Data** – If you have begun validating a Tool/Form and were not able to complete it during a single session, you would resume the validation by selecting this task. Resuming validation of a record is very much like resuming form data entry, in that it allows you to select the Form/Tool by Interview Date from a list of all of your incompletely validated records for the Form/Tool-Patient combination associated with your PI/Project. You can learn more about resuming validation in the Resume Validation of Form Data section later in the User’s Guide.

e) **Enter Manual Scores for Existing Form Data** – This task is only valid for Tools/Forms that have scoring. If you try to select this task for a form that does not require scoring, ISAAC will return that there are no records appropriate for this action. Entering manual scores works exactly the same as entering regular form data. The only difference is you will be asked to select a record from a list appropriate for the patient/form you wish to work instead of creating a new record. All other functions are identical. Refer to the Enter New Form Data section later in the User’s Guide for more information.

f) **Validate Manual Scores for Existing Form Data** – This task is only valid for Tools/Forms that have scoring. If you try to select this task for a form that does not require scoring, ISAAC will return no records appropriate for this action. Like validation of form data, this allows the user to select the appropriate record by Interview Date/Form ID and enter the values. It functions identically to the Validate Form Data process.

g) **Edit Form Data and Scoring Responses** – If the data that has been entered for a particular patient turns out to have values that are incorrect (i.e., the paper form was incorrectly completed), you may have to edit that information to correct the entered value. This is separate from the validation step, and would typically be done after validation has already been completed. You can learn more about Editing Form Data in the Edit Form Data and Scoring Responses section later in the User’s Guide.

h) **Delete a Record from a Form** – At times, you may need to delete a record that has been entered for a form. This can be for any number of reasons (i.e., the record was entered against the incorrect patient). Only the DM or PI have rights to delete a record. You can learn more about deleting records in the Delete a Record from a Form section later in the User’s Guide.

3) **Choose Patient**
   
a) Under the **Choose Patient** section, enter the ID of the patient for whom you are entering data.

b) If you are unsure of the exact patient id, you can click on the lookup link to select the patient from the list of patients active in your study. When you click on the lookup link, the Lookup Patient page opens in a new window. The list of patients is presented in alphabetic order. Select the appropriate patient id, click on the select button. The window will close and the patient ID will be placed in the Enter Patient ID field on the start page.
c) If the desired ID does not appear on the list, you can go to the Add Patient screen by clicking on the link to the right of the lookup link.

4) Enter the Question per page
When you have selected to Enter or Validate data, you can use the Question Per Page field to dictate how many questions you want displayed on each data Entry/Validation page ISAAC displays. Though the system will display only the questions for a single section on each page, for sections that contained many questions, this is a good way to limit data loss due to dropped connections. All of the values entered on a page are saved whenever the user moves to the next page of questions. Therefore, if you limit the number of questions displayed on page, you more frequently request a new page of questions and save the values just entered.

However, this increases the time required to complete the data entry. If your connection to the Internet is robust, as through a school or company (as opposed to a dial up connection through an ISP), you can select many questions to be displayed on a single page.

The Question per Page field is ignored if the number of questions in a particular section is fewer than the value in the Questions per Page field. It is also ignored when Editing records. Typically, you should not request more questions than you can comfortably complete in a few minutes. The suggested number to start with is ten. As you grow more experienced in entering data, you can increase that value to twenty, thirty or more.

If you do not enter a value in the Question Per Page field, 10 is used as the default.

5) Display Comment Questions
Comment Questions are handled slightly differently than any other type of question in ISAAC. Comment questions are not typically analyzed the same way as numeric or selection questions, and are therefore not mandatory. Therefore, you can choose to not display these fields during data entry. Whether to or not display the comment fields will likely be up to the Data Manager or PI for your study.

If you choose to not display the comment fields, you can always use the Edit Form Data task to enter comment information after completing regular form data entry.

6) Click the Go button to begin entry.
   a) Clicking on the Go! button begins whatever task you have selected.

2. Selecting a record from the Tasks in Progress Section.
On the right hand side of the Start Page, ISAAC lists all of the data records for the project that are considered “in progress”. These fall into one of three different categories. All records for the active project that fall into any of these categories will be listed. In this way, a PI or DM can quickly see what records need to be worked on, making the management of the data entry workload more simple.

Whenever you use the Task In Progress list to initiate a data entry task, you must confirm that the Form ID for the record you select matches the Form ID of the paper form you are working on. The Tasks In Progress are offered as a convenient way to review the current status of the project and to quickly jump to the appropriate task and question for a given

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4 You must have Data Entry Clerk Plus rights or above to access the Patient Add page.
record. However, if the data entry staff is careless about the record selected from the list, it can lead to data errors.

a) **Resume Data Entry** – Any record for which a user in the active project has begun entry but not yet completed the record will be listed in this section. By clicking on the **Resume** link, you will be taken to the question following the last correctly entered question for the record. At the same time, the record is rechecked for errors. Any errors that are encountered are displayed for correction before allowing you to continue with data entry.

b) **Requires Validation** – Any record that has been entered in its entirety, and for which the project requires Validation (double data entry), but Validation has not yet begun, will be displayed in this Tasks in Progress group. By clicking on the Validate link, you will be taken to the first question of the form. For each page of data you complete, ISAAC will verify that the data entered is correct (Verification cycle), then will compare it against the data that was previously entered for this record (Validation cycle). Any questions for which the newly entered value does not match to previously entered value will be displayed with a request to correct the value.

c) **Resume Validation** – Any record for which a user has begun validation but that has not been completely validated will be listed in this section. By selecting the Resume Val. link, you will be taken to the question after the last successfully validated question.
B. Enter New Form Data

Entering New Form Data is how all data entry on the ISAAC site begins. Entering form data can also be referred to as entering the interview data, entering the raw values, and entering the data record, among others. In all cases, the overarching theme is that you are taking data written on a paper form and are transferring the entries to the electronic form on ISAAC. Each paper form you enter is considered a new record and is uniquely identified by its Form ID.

When you enter new form data, you will be creating a new record. A new data record is one for which the values have not been entered before. A data record is different than a patient record. A single patient may have data records in many different forms, and may even have multiple records in a single form (if the project has the patient fill out or respond to the same form multiple times).

After entering new form data, your project may have you validate the data record, enter manual scores and validate the manual scores. None of those steps can be completed prior to entering the form data.

1. Select client and tool, etc.

As was discussed in the Start Page section, the first step to entering data in a form (after the Patient(s) and Research Worker(s) have been added) is to follow the steps on the Start page:

Step 1. From the Select a Tool field choose the tool and version for which you want to add data.

Step 2. From the Select a Task field, choose Enter New Form Data

Step 3. Enter the Patient ID of the patient for which you are entering data. You may also look the ID up in the list of available patient id’s by clicking the lookup link (see below).

Step 4. Enter the number of questions to display per Page.

Step 5. Indicate whether comment questions should be displayed along with all other questions types.

Step 6. Click the Go! button.

For purposes of an example, we are going to use the ADOS-G Module 1 form, a test patient, showing 15 questions per page with no comment questions. Given these choices, the Start Page will look like the image at right before clicking the Go! button.

2. Selecting a Patient from the lookup window.

For DEC’s and DECP’s, the patient list includes only active patients. For DM and PI, the patient list includes all patients.

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5 For DEC’s and DECP’s, the patient list includes only active patients. For DM and PI, the patient list includes all patients.
Depending on how the data entry for your study is to be completed, deciding whether to use the patient lookup to fill in the patient ID in the patient fields or to enter the id directly will largely come down to personal preference. If the ID’s your study is using are particularly long, it may be easier to select than enter. On the other hand, if you have a long list of ID’s and they are not particular long or complicated, it may be easier to simply type them in.

If you wish to use the patient lookup function, do so by clicking on the lookup tab to the right of whichever patient field for which you are being asked to provide a value. The patient window, as illustrated to the right, will appear.

To have the patient id you want filled into the appropriate patient id field, select it from the list and click the Select button.

The patient lookup window will close, and the patient id will be deposited into the patient field.

3. Enter Initiation Page Information

The first page to appear after clicking the Go! button is the Initiation page. This typically asks a couple of questions that help determine whether the form being entered meets certain minimum requirements and is not a duplicate of an existing form. If the information entered does not meet these requirements or the system finds that this is a duplicate of existing data, the page will be returned with an error message describing the issue. You will have the opportunity to change the information entered and proceed, or return to the Start Page.

For all of the existing forms, you will be asked two questions, the date of the Interview and the person who conducted the interview (it is understood that the information collected on the form may not have been through an interview, but for simplicity sake we use that term to describe both a Research Worker and the process with which the Research Worker (Interviewer) collects the form information).

You will also be asked to reenter the patient id. This is to ensure that the record about to be entered applies to the correct patient and that an incorrect patient was not inadvertently selected from the Start page.

To complete the Initiation page, select the appropriate values and click Continue. If all criteria are met, the system will display the first page of questions for the actual form.
4. Initiation values passed, Data Entry page displayed

As the first page displays, a new browser window will also display called “Reminder”. The window contains the system generated Form ID and a message instructing you on its use. Primarily, the Form ID is used to identify a particular record. Though there are other items which you are asked to enter that would likely serve to uniquely define a form data record, the Form ID ensures uniqueness.

Write the number on the paper form, preferably the top-right hand corner of the first page of the form. The ID will be used in other areas of the site to identify the form. Once you have written the ID on the paper form, you can close the Reminder window and proceed with data entry.

5. Question Types

Entering data is simply responding to the displayed questions, transferring the responses written by the Interviewer to the ISAAC systems related form. There are four styles of questions that could appear within a data entry form.

Selection (also called Drop Down) – This provides the user with a limited number of possible choices. The first item listed is blank, indicating no selection has been made. Depending on the requirements of your study, you may be allowed to leave the question as blank, if the form did not have a corresponding value. In most cases, however, you will be required to select one of the non-blank values. The non-blank values are only those allowed by the question.

To the right of every selection field is a link that can provide more detail on the list of possible responses, including a full text explanation of each item on the list. The amount of information contained in the link is dependent on the form being displayed and the nature of the question. Though all selection type questions will have a “description” link, some may contain little more information than what is in the drop down box.

In the example at right, the dropdown box is showing four values. The “Yes” and “No” are the two allowed by the question. The Research Worker could also have indicated that they didn’t ask the respondent this question. Finally, the data entry clerk could choose “- Blank on Form” if no value was indicated. These, like all exception values are dependent on the requirements of your particular study, the form for which you are entering data, and the question.

All selection values require double data entry (validation phase).

*Hint: Any item in the selection window can be selected by typing the item’s first letter. If more than one item begins with the same letter, repeatedly typing that letter will cycle through the matching responses.*
**Numeric Range** – This field requires that the user enter a numeric value. Though it is possible for you to enter any character string into the field, when submitted (by clicking the Save and Continue button), the system ensures that every numerical range field is non-blank (meaning something was entered in the field), is numeric (contains no non-numeric characters), and is within the specified range or within a value list.

You can view the range by clicking on the Range link to the right of the field. This will cause the system to display a new window with the High and Low range values highlighted. If the question also has a value list associated with it, this will also be displayed. The value list allows users to enter values outside of the range. For example, there may be a question that requires values to be entered between 1 and 20, but also allows a 99 to indicate that the value was out of the range. Close the window when you are finished viewing the range.

To the right of the range link, a list of Exception values may be provided (depending on the requirements of your study). These values, like value list values, are outside of the range. Typically, they will indicate that the question was not responded to on the form. In the example provided above, this particular question has two exception values, Didn’t Ask and Blank on form.

All numeric range values require double data entry.

**Text Field** – The user is given a field to enter alphanumeric values of up to 255 characters. The only constraint the system places on the text field is that it must not be blank.

This field is subject to double data entry, so when entering values into the field, understand that you will have to reenter them during the validation phase.

As with the other fields in ISAAC, the field may allow you to enter a specific value to indicate whether or not the field is blank. This is dependent on how the specifications of your project, the form, and the particular question.

**Comment Field** – The comment field allows users to enter extended text descriptions. Typically, this information would not be part of analysis, but is entered to provide researchers with additional information regarding the patient or a particular aspect of the record being entered. It can also be used to augment the information contained in the response to another question.

There are distinct differences between this type of question and a regular text question. Primarily, this field allows for unlimited text, as opposed to the 255 character limit on the text field. In addition, the information contained in the comment field is not subject to double data entry. Since the amount of information a comment field can hold can be extensive, asking a data entry clerk to reenter the information a second time, and in the exact manner of the first, would be too time consuming and of little value.
As you can see from the example provided, the comment field is also not required to have any value entered. Therefore, no error checking is performed on the field.

6. Exception Values (Blank on Form, Didn’t Ask, Don’t Know)

Whenever information is collected on a paper form, there is always the possibility that some questions will not be filled in. The reasons for this can be many, including the research worker accidentally skipping the question, the respondent refusing to answer, the respondent not knowing the answer, among others.

In any one of these cases, the data entry clerk may be given the option of entering a value which is not part of the form or question, but which, none the less, provides the researcher with an understanding that the question was not answered on the form.

This is distinctly different from leaving the field blank. Though a blank value in the data record could indicate that the paper form was also blank, it may be that the data entry clerk accidentally skipped the value during entry.

By forcing the entry of a value indicating that the form was blank, the researcher can be assured that no values are missing from the data record.

In most cases, the data entry staff will enter a value for “Blank on form”. There may also be times when “Didn’t Ask”, and “Don’t Know” are more meaningful.

ISAAC provides your study with the option of including any of these values on any type of question (excluding comment fields). You may also stipulate what value you want to store for each of these exception values depending on the field. For example, you may want to enter a -1 to indicate blank on form for a numeric question, and a “-” for a text field. You may also want to enter a 99 for Don’t Know on a numeric field, and a “DK” for a text field. Each of the values can be set at the project and form level. Within a form, each of the exception value/field type pairs must be the same. In other words, within a form, you cannot have one text question that asks for a “DK” for don’t know and another that asks for “DontK”. You can, however, have different value pairs from one form to another, though this is discouraged by the ISAAC staff.

You may turn off any of the exception values for any question, form, or for the entire project.

7. Navigation

There are two areas of navigation that need to be discussed: Intra-page, and from page-to-page. Intra-page is moving from one data entry field to another. Page-to-page is using the buttons at the bottom of the screen to verify and advance the data entry pages.

**Intra-Page**

ISAAC was designed specifically to make data entry as fast and easy as possible, using the fewest number of key strokes and to be fully navigable via your keyboard. *With that in mind, to move*
from one field to another, you use the Tab Right key on your keyboard (→|). The fields are placed on the screen in such a way to allow you to move progressively through the page, from the first to the last.

Depending on your browser and how you have it configured, your cursor will automatically be placed in the first field on the page, whenever a new page of questions is displayed.

Obviously, numeric range, text and comment questions can be entered via the keyboard (there is no other way to enter them). But the values in a selection type question can also be chosen using the keyboard. Simply type the first letter of the value you want to enter. The field will display the first value whose first character matches what you typed. If no values in the list start with the character typed, the value in the selection box does not change. By repeatedly typing a character, you can cycle through all of the values in the list that begin with that character.

If you need to skip over a field (such as a comment field), you can click the tab key twice.

To move backwards from one field to the previous, hold down your shift key and click the tab key (|←).

**Page-to-Page**
Moving from one page to another is accomplished via the **Save and Continue**, **Save and Exit**, and **Finish** buttons. Each button serves a specific and different function, though all are relatively self-explanatory.

The **Save and Continue** button appears on all data entry pages except the page containing the last question of the form. Clicking on the button submits the information entered on the data entry page for verification, saves the information, and moves you to the next page. The next page can be the next set of questions, or if there was a verification error (numerical range value not within the given range, blank text value, etc.), the question or questions with errors on the page just submitted.

The **Save and Exit** button appears on all data entry pages except the page containing the last questions of the form. Clicking on the button saves the answers entered on the page and returns you to the start page. The system, in this case, does not attempt to verify the information entered, so no error messages will be displayed at this time. Verification of the entered information occurs when you resume entry of the saved record.

The **Finish** button appears only when the displayed questions are the final questions of the form. The Finish button replaces the Save and Continue button, but serves a similar purpose. The Save and Exit button is not displayed on pages with the Finish button. On clicking the Finish button, the entered information is submitted for verification. If errors are found, the questions with errors are redisplayed. If no errors are found, the record is marked as complete, and the Completed Form page is displayed.

**Hint:** When you reach the last field on a page, typing the Tab Right key (→|) one final time will highlight the Save and Continue button (or the Finish button if you are on the last question in a form). Pressing the Enter key will save your data and move you to the next
page. But be careful, if you have tabbed beyond the Save and Continue button, the cursor could be on the Save and Exit button, or somewhere else on the page. Pressing Enter in that case could have unexpected results.

8. Handling Verification Errors

All questions (except comment type questions) have some minimum constraints that must be met for the information entered to be stored with other responses on the form. For example, a Text field must not be blank. During data entry, if any of the constraints are not met, ISAAC returns an error for that question. All errors occurring on a data entry page must be corrected before moving on to the next page.

Each question for which an error is found is redisplayed with a message explaining the error, providing you with the opportunity to reenter the information. This is the first line of defense against data entry errors, helping to capture them prior to when the data would be available for download.

For the example at right, notice that question 4 of this first section of the AGRE Medical History: Mother form was entered with a value of 200. This exceeds the range allowed for the field. The other two questions are entered correctly.

On clicking Save and Continue button, the page at right appears. As you can see, the question is redisplayed with both a general error message at the top of the page, and a specific error message for the question. To correct the error, enter an appropriate response for the question (in this case you would need to enter a value between 1 and 70) and click Save and Continue.

The question will be re-verified (the question will continue to redisplay as long as the system finds an error with the response) and if no errors are found, ISAAC will take you to the next set of questions.

9. Completing the Form

As discussed above, when the last questions of a form are displayed, the Next button is replaced with a Finish button and the Save and Exit button is not displayed. On clicking the Finish button, if no errors are found on the values entered on the data entry page, the Completed Form page is
displayed. Depending on the form you are entering, the Completed Form page will display two or three different options.

**Enter values for a different patient using the same form** – This allows you to select another patient from the patient list and begin entering data on the same form for this patient. It skips the step of having to return to the start page and reselect the form. The number of questions to display and whether to include comment fields remains at what you had set it when you began data entry.

To use this option, enter a patient id into the provided field, or chose a value from the patient lookup window, and click the Begin Entry for New Patient button. If you attempt to click the button without first selecting a patient, you will receive an error message and will not be able to proceed. After entering a patient and clicking the button, the Initiation page for the chosen form will display and you can begin entry for that patient.

If the patient ID you entered does not exist in the patient list, you will be returned to the start page and a message stating as such will be displayed.

**Return to the Start Menu to select a different form** – This returns you to the start page and resets all of the form settings. If you plan to begin entering information on a new form, or want to validate the information on this form, use this option. When you click the Return to Start Menu button, you will be taken to the Start Menu.

**Enter Manual Scores for this Patient/Form**. – Some forms, including the ADIR and ADOS, have scoring sections associated with them. These sections, though part of the form, are optional, so a form may be considered complete without entry of the manual scoring values. It is up to the PI on your project to determine whether or not the manual scoring values should be entered.

This section allows you to go directly from entering the form values to entering the Manual Score values without having to return to the Start Page. You do so by clicking the Begin Scoring for this Patient button. On clicking the button, you will be immediately taken to the first page of the Manual Scoring questions. **Manual Scoring, in all regards, is handled the same way as regular form (interview) data entry.** You will proceed through the Manual Scoring pages in the same manner as you did through the regular form data entry pages. All of the same field level constraints apply.
C. Resume Form Data Entry

Because some forms can have hundreds of responses to enter, the system allows you to stop entry of a particular form, and pick up later where you left off. Stopping entry is done by clicking the Save and Exit button on a data entry page. You would also need to resume entry on a form if your connection to the Internet dropped while you were in the middle of entry of form. When you log back in, the record will be listed with any other incomplete records. This would also occur if you timed-out while entry. For example, you were in the process of entering a record, and you were called to a meeting and did not click Save and Exit. If you were gone for more than 20 minutes, for security purposes, your session would timed out and on return, you would be forced to log in with your username and password. The record your were working on would be listed with other incomplete records.

Resuming entry can be initiated in one of three ways: By selecting the form, patient, and Resume Form Data Entry task from the Start page, selecting the record from the list of incomplete records at the bottom of the Start Page, or selecting the record from the Patient Edit page.

Once the data entry pages are displayed, proceeding through the form is exactly the same as New Form Data entry.

Selecting a record to resume entry

Start Page
Using the Start page to resume data is similar to using the Start Page to perform any other data related function. Follow the steps on the Start page:
Step 1. Select a form and a version to use
Step 2. Select a task: Resume Form Data Entry
Step 3. Enter a Patient ID or select one from the lookup window
Step 4. Enter the number of questions to display per Page
Step 5. Choose whether or not to display comment questions.
Step 5. Click the Go! button.

At right, we have chosen to Resume entry on a Medical History: Mother form for patient TEST1201. We have stipulated that ISAAC is to show as many as 30 questions per page, and to include comment fields.

Clicking Go! with Resume Form Data Entry selected in the Task field will take you to a page displaying all of the records for the selected patient and task. From there you will be asked to select the record for which you want to proceed.

Incomplete Records Section
The Incomplete Records section lists all of records for your project that have been started but not finished. The example at right shows an incomplete record for the AGRE Medical History: Mother form. The Patient ID is TEST1201 and the Form ID 29, with an Interview Date of January 2, 2000. The...
information provided for each item is sufficient to identify the specific record that requires completion. Make sure both the patient ID and the Form ID match the data you are entering before selecting the Resume link.

To resume entry for a record, simply click on its link in the Incomplete Records section. Clicking on a link will take you directly to the question after the last question correctly answered for that record.

Using the Edit Patient page
As described in the Patient Administration section, when you view or edit a patient, all data records associated with a patient are listed to the right of the patient information. Each record that is listed includes a link to the most appropriate action for that record. In the case of incomplete records, the link is for resuming entry of the data for that form.

As illustrated in the example at right, the same record we can see on the Incomplete Records section of the Start Page is again listed on the Edit Patient page. In this case, the listed records are grouped by the associated form. The current status of the record is listed after the interview date. The last text on the record line is the link to the most appropriate action. As you can see, the link in this case is to Resume.

Clicking on this link takes you directly to the appropriate data entry page and question for the selected record.

1. Select record from the choose record page
Because using the Start Page steps to resume entry, as apposed to selecting a record from the Tasks In Progress List, does not allow you to select a specific record, on clicking Go!, the Choose Patient Record page is displayed.

At the top of the page, the selected form and Patient are displayed. Below that, the page will display a list of all of the records for the patient and form that match the task you selected from the previous page, in this case, incomplete records. Each record will include its ID, Interview date, and a link. Clicking on the link will take you directly to the appropriate data entry page and question for the selected record.

2. Correcting initial verification errors.
Because the values that are stored in the data record are not verified when you select Save and Exit, they are verified when you resume. This ensures that any invalid responses will be corrected before you proceed with regular form data entry.

If the system encounters errors when resuming, the same verification error pages are displayed that are displayed when verification errors are encountered during regular form data entry. It doesn’t matter which method was used to initiate resumption of data entry, the system will still verify the data before allowing you to proceed.
After all errors are corrected, or if no errors were encountered, the first question that had not previously been responded to is displayed. Proceeding through the remainder of the questions in the form is exactly the same as Form Data entry.
D. Validate Existing Form Data

Validation of existing form data is an important part of ensuring data accuracy. Like the verification checks performed by the system during Form Data Entry, validation is another line of defense against “bad data”.

The method that the ISAAC system uses for validating data entry is flexible enough to meet the needs of almost all projects. In brief, the data that was entered during the Form Data Entry phase is re-entered on the same data entry screens during the Validation Entry phase. In addition to having the individual values verified (as was done during form data entry), the entered value is compared to the stored value for each question.

Whenever the system encounters a difference between the previously entered (form data entry) and newly entered (validation entry), the question is redisplayed and you are given an option to correct it.

Since the Form Data Entry is separate from the Validation Entry, these can be performed by different users, in different physical locations (as long as they both have Internet access). Obviously, the Form Data Entry must precede the Validation Entry for a specific record.

Validation Entry can be initiated in one of three ways: By selecting the form, patient, and Validate Existing Form Data task from the Start Page, selecting the record from the list of records requiring validation on the right side of the Start Page, or selecting the record from the Patient page when you view or edit the patient.

Proceeding through the form questions is identical to Form Data Entry, unless the system encounters a validation error.

1. Select a Record for Validation

Start Page

Using the Start page to resume data is similar to using the Start Page to perform any other data related function. Follow the steps on the Start page:

Step 1. Select a form and a version to use
Step 2. Select a task: Validate Existing Form Data
Step 3. Enter a Patient ID
Step 4. Enter the number of questions to display per Page
Step 5. Choose whether or not to include comment fields.
Step 6. Click the Go! button.

On the example at right, we are going to validate an ADOS Mod1 record using test patient ID TEST1201 and showing 25 questions per page. Given these choices, the Start Page will look like...
the image at right before clicking the Go! button.

Clicking Go! with Validate Existing Form Data selected in the Task field will take you to a page displaying all of the records for the selected patient and task.

**Records Requiring Validation Section**

The Requires Validation section lists all of records for your project that have been completed but not validated. In the example shown at right, there are three records requiring validation, for Patient ID Test1201 and forms ADOS Mod 1, ADOS Mod 2, and the AGRE Physical Examination. The information provided for each item is sufficient to identify the specific record that requires validation.

Before selecting a link, always verify that the Form ID, Interview Date and Patient ID match the paper form you are working from.

To begin validation for a record, simply click on its Validate link in the Requires Validation section. Clicking on a link will take you directly to the appropriate validation data entry page for that record.

**Using the Edit Patient page**

As described in the Patient Administration section, all data records associated with a patient are listed to the right of the patient information, after you have selected the patient by clicking Edit or View from the Patient Administration page. With each a link is provided to the most appropriate action for that record. In the case of records that have been completed but not validated, the link is for validating the data for that form.

As illustrated in the example at right, the same records we can find on the Requires Validation section of the Start Page are again listed on the Edit Patient page. In this case, the listed records are ordered by the associated form. The current status of the record is listed along with the Form ID, Interview Date, and Version. The last text item on the record line is the link to the most appropriate action.

For patient ID TEST1201, there are two records shown at right that require validation, an ADOS Mod1 and ADOS Mod 2. Both have links to Validate.

Before selecting a link, always verify that the Form ID and Interview Date match the paper form you are working from.

Clicking on the link takes you directly to the first data validation page for the selected record.

2. **Select record by Interview date**

Because using the Start Page, selecting Validate Existing Form Data from the Task list, does not allow you to select a specific record, on clicking Go!, the Choose Patient Record page is displayed.
At the top of the page, the selected form and Patient are displayed. Below that, the page will display a list of all of the records for the patient and form that require validation. Each record will be accompanied by a link. Clicking on the link will take you directly to the first data validation page for the selected record.

3. Enter data

Entering the validation data is exactly the same as entering the data during form data entry. All of the questions, fields, and navigation controls look and act the same way. The only differences are that on the top right of the data entry screen, the word Validate appears instead of Data Entry and no Comment style questions will be displayed, as they do not require validation.

Refer to the Enter New Form Data section for more information on entering form data.

4. Handling Errors

Verification Errors

Because entering data for Validation is identical to entering it during regular form data entry, the entered responses need to be checked for verification errors prior to being validated against the data originally entered. An example of a verification error is entering alphabetic character in a question calling for a number. Any verification errors encountered during the validation phase are handled exactly the same way as during regular form data. Please refer to the Handling Verification Errors section for more information.

Validation Errors

Once values have passed the verification checks, they are passed to the validation module to be compared to their corresponding originally entered values. If the two values are not exactly the same (excluding capitalization in a text field), the question is flagged with a validation error and is redisplayed.

On redisplay, the system gives you several options on how to address the error.

a) Use the previously entered value

By selecting this option, the value stored for this question on the data record will remain what had been entered during the regular form data entry phase.

b) Use the just entered value

By selecting this option, the value stored for this question on the data record will be changed to the value entered during the validation phase.
c) Enter a new value and validation value

By choosing this option, you are able to enter a new value, one not entered during either the regular form data entry phase, or the validation phase. In order to ensure accuracy of the data, the system requires you to enter or select the values twice, once in the New Value field, and again in the Validate New Value field. If you fail to select the Enter new value option, any values entered in the New Value fields are ignored.

As you would expect, the system tests the New Values for both verification and validation errors. In other words, if you chose the Enter a new value option, then fail to enter values in the New Value and Validation New Value fields, the question will be flagged with a verification error and will be redisplayed with a message stating you must enter/select a value. Likewise, if you chose the Enter a new value option and enter two different values in the New Value fields, the question will be flagged for a validation error and redisplayed that the values are different. It will ask you to reenter them.

Not until all verification and validation errors have been resolved will ISAAC take you to the next page of questions for validation entry.

5. Exit and Save

As with regular form data entry, at any time during the validation process, you can elect to stop entry, save your data and return to the start page. Similarly, you can resume entry at the exact spot where you left off.

To end your validation session before completing all of the questions for a form, click the Save and Exit button at the bottom of every validation entry page (except the page containing the last questions of the form).

The ISAAC system will scan all of the questions on the displayed form, searching for the first question that fails the validation tests (or the last question on the displayed form if none prior fail). The system will mark that question as the entry point for resuming validation.

This means that any values you entered after the question with the errors are lost. Therefore, it is always best to submit a page by clicking the Save and Continue button, then click the Save and Exit button after the new page has been displayed (and any errors from the previous page have been rectified).

6. Complete

On successful completion of validation of a data record, the system will display the Completed Form Data Entry page, providing appropriate next actions.

As discussed earlier in the User’s Guide, when the last questions of a form are displayed, the Save and Continue button is replaced with a Finish button and the Save and Exit button is not displayed. On clicking the Finish button, if
no verification or validation errors are found on the values entered on the data entry page, the Complete Form page is displayed with two options.

**Validate values for a different patient using the same form** – This allows you to select another patient from the patient list and begin validating data on the same form for this patient. It skips the step of having to return to the start page and reselect the form. The number of questions to display remains what you had set it when you began data entry.

To use this option, enter a patient id in the provided field (or select a value from the lookup patient window), and click the Validate Form for New Patient button. If you attempt to click the button without first entering a patient, you will receive an error message and will not be able to proceed. After entering a patient and clicking the button, the Choose Record page for the chosen form and patient will display. Selecting a record will return you to the validation entry pages.

**Return to the Start Menu to select a different form** – This returns you to the start page and resets all of the form settings. If you plan to begin entering information on a new form, or want to validate the information of a different form, use this option. When you click the Return to Start Menu button, you will be taken to the Start Menu.
E. Edit Form Data and Scoring Response

Verification and validation error detection are effective assurances against incorrectly entering form data into the ISAAC system. After data has been entered and validated, you can be confident that it accurately reflects the values written on the original form.

That being said, there may still be times when you will want to modify some of the values you have previously entered. You can do this through the Edit Form Data and Scoring Responses task. **You will only be able to edit records that are complete; however, they do not need to be validated.** Keep in mind that even though a record is complete, entry of scoring values may not be complete. In this case, you will only be able to edit the form (interview) data, the scoring questions will not be in the list of questions to choose to edit. Obviously, forms that do not have scoring sections will not have any scores to edit also.

In general, to edit form data, you will perform the following steps: Select a record to edit, select which questions to edit, modify the answers to those questions, save the values and exit. Below we will walk through each of these steps.

Initiating form data and scoring responses editing can be done in two ways: By selecting the form, patient and task of *Edit Form Data and Scoring Responses* from the Start page, or selecting the record from the appropriate patient edit screen. Only records that have been completely validated are listed in on the patients Related Form sections with a link to the Edit screens. All other records are listed with links to other, more appropriate, actions.

1. Select a record to edit

   **Start Page**
   Using the Start page to edit form data is similar to using the Start Page to perform any other data related function. Follow the steps on the Start page:
   
   Step 1. Select a form and a version to use
   Step 2. Select a task: Edit Form Data and Scoring Responses
   Step 3. Enter a Patient ID
   Step 4. Enter the number of questions to display per Page
   Step 5. Click the Go! button.

   You do not need to select the number of questions to display per page, as this value is ignored when editing questions.

   You do not need to select whether or not to display comment questions, as only questions that are selected to be edited are displayed, including comment questions.

   As an example, at right we have selected to edit an ADOS-G Module 1 form record for test patient TEST1201. Given these choices, the Start Page will look like the image at right before clicking the Go! button.
Clicking Go! with Edit Form Data and Scoring Responses selected in the Task field will take you to a page displaying all of the completed records for the selected patient and task. From this page, you will select a record to edit.

Using the Edit Patient page
As described in the Edit Patient section, all data records associated with a patient are listed to the right of the patient’s information after clicking the View or Edit button. Each Related record is accompanied with a link to the most appropriate action for that record. In the case of completed records (records that have both been successfully entered and validated), the link is for editing the data for that form/record.

As illustrated in the example at right, the record listed in the Related Forms section of the Patient Administration page was not listed on the Start Page. This is because only incomplete records are listed on the Start page, indicating that further action must be taken. With completed and validated records, no further action is required.

In the Patient Edit page, however, all records for the patient are listed, including completed records. They too are linked to their appropriate or logical next action, in this case, editing. The current status of the record is listed, along with the Form ID, version and interview date. The last text on the record line is the link to the action. As you can see, the link for Form ID 243 for the ADOS Mod 1 is Edit. If you need to edit a record that is complete but not fully validated, you must use the start page, as that record will be listed on the patient edit page with a link to validation.

Clicking on Go To Edit link takes you directly to the Select Questions to Edit page for that record.

2. Select record from the choose record page
Because using the Start Page, selecting Edit Form Data and Scoring Responses from the Task list, does not allow you to select a specific record, on clicking Go!, the Choose Patient Record page is displayed.

At the top of the page, the selected form and Patient are displayed. Below that, the page will display a list of all of the records for the patient and form that are complete. They may or may not be validated. Each record will be shown as a link. Clicking on the link will take you directly to the select questions to edit page for the selected record.

3. Select Questions to Edit
The Select Questions to Edit page lists all of the form’s questions that are available for editing in the order in which they appear on the form (and in the data entry pages). They are grouped by the section from which they came.

The Select Questions to Edit Page will always display all of the regular form questions (interview questions) and may also include the manual scoring questions if that section (or sections) has
been completed (it does not have to be validated. If the form has many questions, this page may take a while to display.

To the left of every question is a blank check box. You will use the check box, by clicking on it (switching it from unchecked to checked), to indicate which questions you wish to edit. You may select as few as one or as many as all (though this is not recommended). Once you have selected the questions you wish to edit, click on the Edit Selected Question Responses button at the bottom of the page to proceed to the Edit Questions page. You can deselect questions to edit by clicking a second time on the check box to uncheck the question.

Notice also that for every question listed, the current value of the response is provided (in bold to the right of the question). This allows you to get a quick view of all of the entered values for a record. **You can print this out to compare to the paper form for another data assurance check.**

For selection style questions, the values stored in the database are replaced by the matching selection value for display. For example, if the question was on the gender of the patient, and a 0 was stored to indicate Male, and a 1 to indicate Female, the zero or one would be replaced by the text Male or Female. For non-selection questions (numeric, text, and comment), the actual values entered are displayed. Numeric values are displayed with up to two decimal places of precision.

At the bottom of the page, is the Edit Selected Question Responses button. After you have selected all of the questions you want to edit, click this to proceed to the Edit Questions page.

### 4. Edit Question Responses

On clicking the Edit Selected Question Responses, the Edit page will display. In keeping with the other portions of ISAAC, this page is very similar to the data entry, validation, and validation correction screens you have seen.

At the top of the page, along with the form name, form ID, and version ID, the number of questions selected is displayed on the right.

The questions are listed in the order in which they occur in the form. If you have selected questions from multiple sections, it may appear that the questions are out of sequence. For example, if you

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7 In the case where you have a large amount of questions to edit, it is better to delete the record and reenter it.
selected question four of section one and question two of section three to be edited, the Edit page would show a question number four, followed by a question number two. This is because the section information is not provided on this edit screen (it was provided on the Select Question page); only the question number is displayed.

For each question displayed, you are given two editing options.

**Use the previously entered value** – By selecting this option, the value stored for this question on the data record will remain what had been entered during the regular form data entry phase.

**Enter a new value and validation value** – By choosing this option, you are able to enter a new value, one not entered during either the regular form data entry phase, or the validation phase. In order to ensure accuracy of the data, the system requires you to enter or select the values twice, once in the New Value field, and again in the Validate New Value field. **If you fail to select the Enter new value option, any values entered in the New Value fields are ignored.**

As you would expect, the system tests the New Values for both verification and validation errors. In other words, if you chose the Enter a new value option, then fail to enter values in the New Value and Validation New value field, or enter values unacceptable for the question, the question will be flagged with a verification error and will be redisplayed. Likewise, if you chose the Enter a new value option and enter two different values in the New Value fields, the question will be flagged for a validation error and redisplayed.

Click the Finish button to submit your edits or enter your corrections to your edits. The data entered will be saved and you will be returned to the Start Page.
F. Delete a Record from a Form

Even with the utmost of care applied, there is always the possibility that a record could be entered that later needs to be removed from the system. This could be for several reasons: the record was applied to the wrong patient, the patient has left the study and there is no reason to retain his record, or a duplicate record was entered with a different interview date, among others.

Editing a record can be initiated in only one way: By selecting the form, patient, and Delete a Record from a Form task from the Start page.

Unlike other functions that are initiated from the Start Page, deleting a record is not available to all project users. Instead, the task is removed from the task list for all users except DMs and PIs. This is to help ensure that records are not inadvertently deleted. If a DEC incorrectly enters a record, they can request from the DM or PI to have it deleted.

Also unlike the other data tasks, deleting a record does not lead you to the data entry pages. Instead, you are asked to confirm your desire to have a particular record removed from the system. Deletions are only allowed on a single record basis, eliminating the disastrous possibility of an unintentional mass delete.

1. Selecting a record to delete

Start Page

Using the Start page to delete a record is similar to using the Start Page to perform any other data related function. Follow the steps on the Start page:

Step 1. Select a form and a version to use

Step 2. Select a task: Delete a Record from a Form

Step 3. Enter a Patient ID

Step 4. Click the Go! button.

You do not need to change the number of question to display per page, as this is ignored for this task.

You do not need to select whether or not to display comment questions, as this is ignored for this task.

As an example, at right we have selected to delete an ADOS-G Module 1 form record for test patient TEST1201. Given these choices, the Start Page will look like the image at right before clicking the Go! button.
2. **Select record from the choose record page**

Clicking Go! with *Delete a record from a form* selected in the Task field will take you to a page displaying all of the records for the selected patient/form. Unlike other tasks, when you ask to delete a record from a form, all records that have been entered for that patient/form are displayed. This includes fully complete and only partially entered forms.

All of the records are accompanied with their form ID, and their current status to better help you identify which record it is that you want to delete. The record selection page will look like the one displayed at right.

As you can see, this particular patient has three ADOS Mod 1 records. Two are fully completed, and one is only partially entered.

From this page you will choose the appropriate record to delete by clicking on the Delete this record link beside the target record.

```
Delete a Record for ADOS-G 2000 Module 1: Pre-Verbal/Single Words
Version: 1999
For Patient: TEST1201

  FormID: 243 Date: 10/22/2002, Completed and Validated. Delete this record
  FormID: 245 Date: 10/20/2002, Completed and Validated. Delete this record
Version: 1999
FormID: 254 Date: 1/1/2002, Incomplete. Delete this record
```

3. **Confirm the record to delete.**

Once a record has been selected from the record selection page, the Delete Record confirmation page is displayed.

An example of the page is displayed at right.

All of the information about the record is included for the user to review before clicking the Delete this Record button.

If the incorrect record has been selected, the user can click the Return to Start Page link, or click the Back button of their browser to return to the record selection page to select a different record.

Once the user clicks the Delete this Record button, the system removes the selected record from the system. **At this point, the record cannot be recovered, so it is imperative this function is used with care.**

After clicking the Delete this Record button, you are returned to the start page and a confirmation message is displayed.

**Hint:** If you intend to delete more than one record from a particular form for a patient, after deleting the first, you can use your browser’s Back button to return to the Record Selection page and select another record (you will need to click the button twice). As with the first record, you will be asked to confirm you want to delete the record.
Data Download

Though ISAAC has been designed specifically to handle research data, it is understood that collecting and assuring the accuracy of data is only the first part to a research project’s data needs. It is the analysis of the data that yields the fruit for which ISAAC was built. Analysis, for the most part, will take place outside of ISAAC. ISAAC supplies the raw material -- applications such as SPSS or SAS turns them into a finished product.

How do you, therefore, move data from ISAAC into those applications (or others you may want to use). This is done through the Data Download page.

But the Data Download page serves as more than a simple window into your data. From this page you can:
- get a quick overview of the record counts,
- view detailed data descriptions (codebook) of the downloads,
- access your project’s summary file,
- see other project’s data that has been made available to you, and
- use the high level filters to control what you download.

When you download data, it always arrives in a standard format, a tab delimited file with an .xls extension. The first row consists of field names, all subsequent rows are data records. Because this file uses a common format, almost all other data applications can easily import or link to the downloaded files.

The uses and features of the data download page are described in more detail below.

A. Using the High Level Filters

In order to allow flexibility in viewing record counts and downloading data, ISAAC has several high level filters that can be applied from the data download page. The filters can act alone, or in conjunction with other filters on the page. Not all of the filters are available for all users. For example, Guest Researchers cannot download non-validated data, nor can they access data for inactive patients.

Note: Whenever you change a filter selection, you must re-click the View Download List for it to affect the download records.

There are four groups of filters that are offered:
- Select the question/section type,
- Include/exclude data from other projects,
- Additional attributes, and
- Number of columns

1. Select the questions you want to include:

This filter section enables you to include or exclude certain types of data. Some forms on ISAAC (like the ADIR) allow users to enter the raw interview data, manual scores calculated by research workers, and those same scores calculated automatically by ISAAC. From a research point of view, it may be that the calculated scores are more important to one researcher, when the raw scores are important to another. So that researchers can more easily get to only the information
they need, ISAAC allows them to turn on or off whether to include the raw interview data, the manually scored data, or the automatically scored data.

At least one data type must be selected. The system will tell you as such if you attempt to submit to view the download list with not data types selected.

It is assumed that researchers will most often choose to download the interview data and any automatically scored data. Because entering manually scored data is optional, by default it is not included in the download files.

If you select only manual or automated scores to download, then select a file that does not have scoring, a new window will open with a message that the form selected does not have scoring values and the interview data must be selected in order to download anything from this form.

2. Select whether to include or not include shared data.

Collaboration is a key feature of ISAAC. It is through standardizing the collection and storage of commonly used instruments and questions, and then the sharing of that data, that the founders of ISAAC believe will more quickly lead us to understanding and cures of debilitating diseases like Autism.

Through the simple process of granting access to your data to other researchers, allowing them to download that data and easily combine it with their own that begets sharing.

When viewing data through the download page, you have the option of including or excluding your own data or other project’s data (if you have been granted such access). If you select the first option, your project’s data, then only the active project’s data will be included. If you choose the second option, then the active data is combined with all of the data from other projects for which you have been granted access. If you choose the last option, then you will only see the data from other projects.

If you have selected to combine your data with other project’s data, on clicking the View Download List button, the page will redisplay with the list of forms available for download. Each form will include record counts from each of the sharing projects.

For example, at right, the user has rights to both the Demo project and the AGRE project and selected to view the download list with both projects’ data combined. As you can see, for the ADOS Mod 2 form, there are 94 AGRE records and 3 Demo records. When the file is downloaded, the records from each project are grouped together and columns called ProjNum and ProjName identify from which project the data is derived.

This is especially useful if a study is running several major sites, where each site has its own set of users, patients, and even forms. For the majority of these users, operating within their own project is sufficient. But the PIs and DMs of the disparate sites could grant each other access, thereby immediately combining the data sets. No longer do you have to email spreadsheets and data files and spend hours to convert and merge them to get data combined in a single file. It also alleviates the worrisome habit of database developers using their own codes to describe the data, which may be different site to site. Or having to spend months ensuring that each site used the same data rules before collecting any data.
3. Select additional download attributes.
Within this section, you have the ability to limit records for all downloadable files to just those whose records have been validated -- or you can open it up to any completed record, regardless of whether it had been validated. Incomplete records are never available for download.

At the same time, you can choose to limit records to only those associated with active patients, or choose to include records for inactive patients as well.

4. Enter the max. number of columns to include in each file.
It will be no surprise to researchers that some forms can contain upwards of 300 or more individual data points. Especially if the form includes associated manual and automated scoring values. Since each data element represents a column of data, this means more than 300 columns could be included on download files. Though ISAAC easily handles these types of forms, many applications, including MS Access and Excel cannot. They are limited to 255 columns of data.

Knowing this, and not wanting to restrict how the data that comes from ISAAC is used, the system allows the user to select the maximum number of columns to include in each download file. If the form to be downloaded includes more columns of data than the maximum submitted when the View Download List button was clicked, ISAAC will break up the data set into multiple files and include them together in the downloaded WinZip file. The first column of each file contains a unique record identifier that can be used to merge the files together.

ISAAC will break the form into as many files as necessary. If the total number of columns in a form is four times the maximum number of columns to include in a file, then four files will be created.

The default is to break up files that exceed 250 columns, but if you are going to pull the file into an application that does not have a column number limit, then you can set the maximum number to a very high number, assuring that each record is contained in a single row within a single file.

B. Viewing Record Counts
One of the first and most often used features of the download page is to provide quick and comprehensive counts of the records that have been entered for a project. For a PI or DM, assessing the status of the project through the data records that have been collected is imperative. Depending on how a study is run outside of ISAAC, this could sometimes be difficult to ascertain, and was rarely available real-time. Within ISAAC, record counts are fundamental to the operation of the site, and best of all, are available 24 hours a day, seven days a week, from wherever the user is located, as long as they have web access.

Record counts are provided by default whenever you select the View Download List button and the list of available forms to download is displayed. However, these counts can change depending on what filters have been selected when you submit the page.

For example, if none of the records in your project for a particular form have been validated (double data entered) and you have chosen to exclude non-validated records, the form will not be listed (and can be assumed to have zero validated records). On the other hand, by selecting to include non-validated records and clicking the View Download List button, you can get a quick count of the number of records that have been entered, regardless of
whether or not they have been validated. Alternating between these two filter options tells you the number of records entered that need to be validated.

Above is a sample data download page that indicates that the project has records for three forms, and gives the number of records for each. It also indicates that there are 7 patients in the project (Patient Records in the Patient Summary Fields listing).

C. Downloading Data

Now that you understand how the ISAAC filters work, and what the record counts indicate, it is time to download the data. As has been described above and in other areas of the User’s Guide, the download file is a single zip file, containing one or more tab delimited .xls files.

To begin the download process, after displaying the download list by selecting the desired filter options and clicking the View Download List button, click on one of the Download this Data links.

A new window will open as the system begins the process of collecting the data and formatting the file. The window documents each step of the file formation process (though it can happen so quickly that it all looks like it happens at once).

At right is a sample of what the download file window looks like after it has completed the formation of the file. As you can see, the window provides a link. Clicking on the link initiates the download of the prepared file to your computer. Depending on your browser version (though only Internet Explorer 5.0 or greater, running on a PC, is recommended), you will be asked whether you want to open or save the file. If you want to immediately view the files, click to view them.

You will need a copy of Winzip to access the data. On selecting view, Winzip will open and the file(s) contained in the zip file will be listed.

To open a file in Excel, double click on it.

D. Understanding the Download file

As mentioned previously, the files downloaded from ISAAC are formatted so they can be used in almost any other data management/analysis application. Though the files come with an .xls extension (for Excel), they are not true Excel files. Instead, they are simple tab delimited text files. Tab delimitation is a base format for spreadsheets. ISAAC uses the .xls extension so they will automatically open in Excel when double clicked.

If you intend on using the files in applications other than Excel, instead of opening them in Excel from Winzip, save them to your disk. You then will be able to pull them into other applications (either import or link). When you do so, you must tell the application that the file is tab delimited and that the first row contains field names.
All of the files downloaded from ISAAC follow the same pattern. The first fields/columns are reserved for patient information and record status. After that, the fields contained in the selected form are listed. If the download has been split into multiple files, the first file contains the patient information and any subsequent files are headed with a record id column and patient and project identifiers.

The column labels for the patient information are based on your projects settings, so can vary from project to project. The labels that appear on the patient management screen are the same that are used in the download.

The following is the list of patient and system fields that precede the form data in every data file. Those field names with an asterisks are dependent on the project settings and could vary from project to project.

- RecordID – The unique identifier for the record
- Version – The version of the form from which the data was captured
- PatientNum – The system’s numeric representation of the patient
- ProjectNum – The system’s numeric representation of the project
- ProjectName – A short name for the project
- Gender – The gender of the patient: 1 – Male, 2 – Female.
- General ID* – Typically used for a family id
- Patient ID* – The unique text ID for the patient.
- Ref1* – First additional patient identifier
- Ref2* – Second additional patient identifier
- RefID3* – Third additional patient identifier
- Status – Current status of the patient: 1 – Active, 2 – Inactive, 3 - Remove
- InterviewMonth – The month of the interview for the data record
- InterviewDay – The day of the interview for the data record
- InterviewYear – The year of the interview for the data record
- Age – The age of the patient at the time of the interview (calculated by ISAAC, based on the DOB in the patient record and the date of interview entered in the initiation page of the data record)
- ResearchWorkernum – The system user number assigned to the Research Worker attributed to this record
- Validated – A flag indicating whether or not the record has been validated: 0 – Not validated, 1 – Validated.

Below is a sample data record in Excel. The fields from column A to column R are the patient and system fields. Starting with column S are the form fields, in this case, for the ADOS Mod 1.

![Sample Data Record in Excel]

**E. Display Codebook**

During the process of data analysis, there is nothing more frustrating than trying to understand a data set that is poorly described. It is not unheard of for research databases to undergo several changes
during the course of a study, perhaps performed by different individuals with a wide range of technical skills and experience. When this happens, a once detailed and accurate data dictionary can become “disconnected” from the data it is supposed to describe. Columns added to form tables late in the process may not also be added to the dictionary. The values used to store responses for particular questions can change, or new responses can be added. If these modifications to the database are not accurately documented, then when it comes time to analyze the data, a time-wasting research process must be undertaken to “reconnect” a dictionary with the data.

Another typical issue that researchers face is trying to use data from studies that were concluded in years past. Often the person or persons who were responsible for the data are no longer with the institution and fields that seemed understandable at the time of the study are no longer so clear. Also, the same question asked in a form from a previous study may be stored differently from one study to the next. Take the question of gender. This can be stored in many different ways. To indicate that the patient is male can be done with a “M”, 0, 1 or almost anything else, making difficult to reuse or compare data from one study to another.

ISAAC is perfectly designed to remove the barriers to reuse and to reduce confusion at the time of analysis. One way the system does this is by providing a detail description of the data, the codebook.

The codebook shows every question from the form/tool in the order it appears on the paper form and in the data entry screens. With each question, you see all of the related question’s text, the type of question (selection, numeric, text, comment), its selection values, range limitations, and associated field name that’s used in the download file as the field’s column header.

You access the Codebook from the download page. The list of files available for download, obtained by selecting the desired filtering options, then clicking the View Download List button, include both a link to download the data, and to view the associated codebook. At right is a sample entry from the download list for the ADOS Mod 1. The second link, View this Form’s Codebook, when selected will open a new browser window and load the Codebook. If the form contains many questions (200 or more), it can take several seconds to display the page.

The page is broken down by the form version, section data type (Interview Data, Manual Scoring Data, Automated Scoring Data), section, then question. This matches the column order of the download file.

At right is a sample question listing from the Codebook. In this case, it is a selection field. The selection list provides three columns. The Select Value is the value that is displayed in the selection window on the data entry page. The Stored Value is the representative value that is stored in the database and included in the download file. The Answer Text is the explanatory text that was provided on the paper form to guide the interviewer and patient to the proper selection.

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3 If a tool has multiple versions, the older version is displayed first on the codebook. In the download file, fields that appear in both versions are only listed once.
If this had been a numeric style question, the selection list would have been replaced with the range values (high and low) and the value list (values that are outside of the range but still legitimate responses). Text and Comment type questions do not include additional information like the selection list or range values.

To save the codebook for later review, right click on the page, then select Print or Export to Excel (not available with all browsers/operating systems).

**Summary File Administration**

The Summary File is at the core of the powerful benefits of using ISAAC, where your paper forms are "profiled" in our Database of Electronic Form Elements (DEFE). Since all of the information that is contained on your paper forms, from sectional explanatory text, to possible responses on individual questions, data can be accessed not only by the standard method of field names, but also by the specific questions from which the responses are derived.

In using the summary file, you can begin to understand the flexibility of such a system, and how the potential for additional uses is limited only by the needs and imagination of its users.

In brief, the summary file allows you to merge values (fields, columns, etc) from one form with those of any other form within your study. ISAAC handles the sometimes complex relationships between the disparate data elements, and combines them in a single file, driven from the patient list.

The downloaded file will contain at least one record for every patient in your study. There will be a column for every field/question you choose to include. If a patient has more than one record for a particular form, then that patient will appear in the file with a matching number of records.

If a patient does not have a record for a form that is included in the summary file, than fields/columns from that form will be blank for that patient.

**A. Adding a Form’s Fields to the Summary File.**

Users that have the rights to do so, will use the Summary File Administration page to set up and modify the project’s summary file. Only DMs and PIs have access to the page, though most other users will be able to download the summary file.

To get to the page, click on the “summary” menu item at the left side of the screen.

When you first visit the summary page, before the summary file has been set up, the system will notify you that no summary fields have been selected. This is displayed in the bottom right corner of the page (as shown at right).

Once summary fields have been added, the “no summary fields” message is replaced with the list of fields included in the summary file.
To begin adding fields to the summary file, first select a form/tool and version from which you want to include fields, and click the Get Questions button. The page will redisplay with all of the questions from the form listed in the following order:
1. Section type (normal, manual scoring, automated scoring)
2. Section Order
3. Question Order.

Accompanying each question are two checkboxes, one of which will always be disabled. The left checkbox is used for adding questions to the summary list, and the right checkbox is used to remove them. This is indicated with column headings below each section heading. Any question that has not yet been added to the summary file will have an enabled “add” checkbox and a disabled “remove” checkbox. If the field has already been added to the summary file, the opposite is true. In this way, you cannot attempt to remove a field that is not already in the file, and you cannot attempt to add a field that is already included in the summary file.

To add a field, check its “add” checkbox by clicking on it. You can add as many fields from a single form/tool at one time as you want. Once you have selected all of the fields from the displayed tool/form, click on the Update Summary List button at the bottom of the page.

The page will redisplay with the same tool’s list of questions. However, now those questions which you had selected will be listed with a disabled “add” checkbox and an enabled “remove” checkbox. Also, the newly added fields will be listed below the instructions on the right side of the screen in the Current Summary File Fields section. At right, is an example of what the field list looks like after adding two fields from the ADOS Mod 1 form. In this case, question 4 from Section A and the CSASComSoc question from the Diagnosis section.

To add questions from another tool, return to the top of the page and select the tool and version from the provided list. Click on the Get Questions button to display the list of questions for the selected tool.

Again, click on the “add” checkbox for the fields you want to include, then click the Update Summary List button at the bottom of the page. If you accidentally select a question that you do not wish to include, you can deselect questions before adding by clicking on the “add” checkbox a second time.

At right is an example of the Summary list with fields from both the ADIR and ADOS Mod 1 forms.

Currently, the only limitation on the summary file is a limit of 255 fields.

If a form/tool contains many fields (upwards of 200) it may take a while to display.
B. Removing fields from the Summary File

As with adding fields to the summary file, removing fields, or modifying an existing summary file is performed through the Summary Administration page. You access the Summary Admin. page by clicking on the “summary” menu item at the right of the screen.

Also similar to adding fields, the only users that can modify an existing summary file are DMs and PIs.

When you visit the Summary Admin page after a summary file has already been set up, the list of current fields will be displayed on the right side of the screen beneath the instructions.

To remove a field that was previously added, select the tool and version from which the field(s) comes, then click the “Get Questions button”. The page redisplays with all of the questions associated with the selected form/tool listed on the left hand side. Those questions that were previously added to the summary file have an enabled “remove” checkbox and a disabled “add” checkbox. All other fields have the reverse. Select the fields you want to remove by clicking on the associated “remove” checkbox. At the same time, you may select fields from the same form/tool to add that are not already included by clicking on their associated “add” checkbox. Click the Update Summary List button at the bottom of the screen to submit your changes. At right above is a previously included field that is selected for removal.

On clicking the Update Summary List button, the page is redisplayed and the selected changes are indicated in the field list. Also, those fields that have been removed are now associated with enabled “add” checkboxes and disabled “remove” checkboxes.

C. Downloading the Summary File

After you have set up a summary file, you can access it from the Get Data page (also known as the Download Data page). The summary file is available to all project users except Guest Researchers.

As with the files associated with single forms, the data contained in the summary file is controlled by the selections made on the left side of the data download page prior to clicking the View Download List button. The options that affect the summary file as well as the individual form files are limited to the “Include non-validated records” and the “Include non-active patients”.

If you choose to include non-validated records, fields from forms for patient records that are not validated will be included in the summary file. If you do not select this value then those same values would be blank until the record is validated.

By default, only active patients are included in the summary file. You can, however, chose to include inactive patients by selecting the “Include non-active patients” checkbox and then clicking the View Download List button.
The summary file will be included in the list of files to download regardless of whether summary fields have been added to the summary file list. If no summary fields have been added, then the download file will consist of a single record for each patient with patient information making up the only columns.

When you click on the View Download List button and the list of files available for download is displayed, the Summary file, always the last file displayed in the list, will provide two counts, the number of patients and the number of summary fields. In the example at right, the project has 6 patients and 4 summary fields.

Please note that the number of patient records listed on the download page may not match the total number of records included in the downloaded file. The patient record value provided here is the total number of patients that match the selection criteria, independent of the forms that have been entered for them. The number of records in the download file can be more because some patients may have more than one record for a particular form. The downloaded summary file will never have less records than the number of patient records displayed in the download list.

As with other forms, accompanying the Patient Summary Fields listing on the download page are two links. One link runs the download routine and prepares the download file. The other link opens a new browser window and displays the codebook for the summary file. The codebook lists all of the form fields included in the summary file and information on their associated form, section and question. The codebook is displayed in the same order as the fields are placed in the downloaded file (exclusive of the patient information fields), sorted first by form/tool, then section type (normal, manual scoring, automated scoring), section order, question order.

When you click the download link, the system merges the forms, creates an excel file, zips the file, and finally supplies a link to the zipped file. Clicking on the link initiates the download to your computer.

In the example shown at right, fields from both the ADIR and ADOS are shown in a downloaded patient summary file. When building the Excel file (a simple tab delimited file with an .xls extension), ISAAC affixes to the front of each fieldname, the short form name of the associated form. This is so that fields from two different forms that have the same or similar fields name can be easily identified.

From the example, you can also see that some cells are blank, while others contain values. When a field has no values, it usually indicates that the associate patient has no records entered for that form. It can also mean that the record for that patient has not been validated and the user chose to only view validated records. Finally, some fields, such as comment style fields, do not have to have a value associated with them, they can be left blank.

The patient information that is included with the Patient Summary file download consists of all of the patient fields on the Patient Administration page. The column headings of those fields match the labels from the Patient Administration page and so can be different from one project to another.
For additional information on the downloading data, please refer to the Data Download section of the User's Guide.
Getting Started With Your Project

ISAAC is designed to make managing your research data as simple and as secure as possible. From the outset, the researchers that have been involved with its development have repeatedly stressed that for ISAAC to reach its full potential as a collaborative tool, it must provide immediate benefit to researchers in their efforts to streamline the data management process. Therefore, it must demonstrate its usefulness in reducing many of the typical hurdles researchers and data managers face throughout the course of a study.

The flexibility that is built into ISAAC translates into an environment that conforms to the demands of almost any study that is collecting information off of paper forms, storing that data, then analyzing it.

Below, we outline how a typical study would be run in ISAAC. This in no way implies that this is the only way to manage a study, but instead will provide you with ideas about how your study would fit into the ISAAC Framework.

A. Project Setup/Initiation

In order to ISAAC to function in a way that matches your study's protocol, time must be spent reviewing and deciding on how to best apply the features of ISAAC to your data collection process. Foremost of these are the forms to be used to collect data.

Though ISAAC comes with a catalogue of data entry templates, it is likely that any particular study will have several forms which are unique, or will want to have existing forms modified to meet the specific challenges of their study. This process is typically a feedback loop of the ISAAC team offering suggestions on how a particular paper form would best be “profiled” in ISAAC, and researchers returning insights into likely responses and the likelihood of requiring exception values.

Along with adding forms, decision makers within the study will need to decide such items as:
- Which forms will require validation
- Whether all or some of the forms will allow exception values and what they should be.
- How the patient administration additional identifier fields should be labeled.
- Whether fields should be allowed to be left blank.

One of the greatest benefits to researchers that use ISAAC is that each subsequent study becomes that much less to set up, as standard forms are already “profiled” and stored in the catalogue, along with rules on how the particular researcher prefers to manage the data entry process.

B. Form Testing

Since ISAAC uses the DEFE (Database of Electronic Form Elements) to store form information, display the data entry screens, drive the Codebooks and all other data related functions, building new data entry templates is a matter of data entry instead of programming. This does not mean that the form will function exactly as you wish it to the first time it is enabled. Even after several cycles of review prior to entry of the form information, there will likely be fields, explanatory text, response lists, etc, that will need to be modified in some fashion in order for the templates to best match and capture the information that has been recorded on the paper forms.
This is accomplished through a series of test entries, where study staff attempt to enter data from completed forms into the newly created templates. Any differences they encounter between expected form function and actual appearance is documented and sent to the ISAAC staff for modification of the form. As mentioned before, since no programming is involved in the generation of these forms, modifying them can often be turned around quickly.

Once the forms are performing to the satisfaction of the study staff, they are moved from the test phase to active. At the same time, all test records are deleted.

Note: Studies will often begin entry on some forms before finalizing others. For example, if there is a pilot study that uses a subset of forms for the full study, before all of the full study’s forms are added, the pilot study forms may already be collecting data.

C. Add Users

Now you are ready to begin entering data. Before you can you need to add the users that will likely be using ISAAC. You do not have to add everybody, but certainly those users that will be most active in the site, and responsible for entering data should be given access.

For security, after setting up new users, please have them log in and change their password.

D. Add Research Workers

As part of adding users to your project, you need also to add research workers. Some of your users will also be research workers, but it is likely that there will also be others that will not need to access the site. In order to have them included in the list of research workers that is presented when initiating data entry of a new data record, you will need to add them in the User Management area.

E. Add Patients

Obviously, you can’t enter data for a patient unless that patient has been added to your patient list. You can do this in any manner you choose, from adding all of the patients at once, before entering any other data for them, to adding them in one at a time with each set of data forms.

F. Enter Data

So now you have your patient and users setup, it is time to begin entering data. Again, you can do this in any fashion that works best for your study. Some will chose to centralize the paper records and the data entry, others will allow the entry to occur from multiple sites simultaneously. You may want to enter a stack of a particular form, then validate it, before moving onto another form. Or enter all of the forms for a particular patient, them proceed to another patient.

How you decide to manage your data entry process is separate from how ISAAC stores the data. It is totally up to you and does not have to stay the same through the course of the study, or even for all forms.

For example, you may find that a particular form lends it self well to distributed entry, while another makes more sense to centralize. In either case, all of the data resides in one location and is immediately available upon entry.
G. Download Data
At any point in the entry process, you not only can get a quick overview of the total number of data records that have been entered, you can also download them and begin looking at the data in whatever application best suits your needs.

Since the data comes to you in a standard format (tab delimited), you can easily bring it into any other application, be it Access, Excel, SPSS, SAS, etc.

What has been found most useful is to create links from the downloaded files to the analysis application. Whenever you want to update the files, simply redownload and overwrite the existing files. In this way, you won’t have to import them each time you want an update, and multiple applications can use the same data records simultaneously.

H. Build Summary File
As soon as you begin to accumulate data in your project, you may also want to look at specific fields from one form, coupled with other fields from other forms, on a patient but patient basis.

To do this, set up your summary file in the summary file maintenance page, then go to the Get Data page to download the file.

As with the other downloaded files, you can link to this file in most data analysis software applications.

The summary file is perfect for supplying quick counts of records entered, patients with particular characteristics, or an overview of which forms have been completed for which patients.

I. Share Data
Ultimately, the power of ISAAC is as a collaborative tool. Though not required, any of the data you collect can be easily shared with colleagues and other researchers. You do this by adding the person to your user list as a guest researcher and if they are not already an ISAAC user, provide them their user name and password.