

**DATA ENTRY SYSTEM
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I. INTRODUCTION

The data management system used for data collection in the Type 1 Diabetes Genetics Consortium (T1DGC) utilizes a web browser-based interface, with electronic data stored and managed centrally at the Coordinating Center. This model was chosen both for its rapid, efficient collection of clinical information using the existing technology of the Internet, as well as the ease of use and familiarity with web browsers. User-friendly screens, identical to the data collection forms, have been developed using hypertext mark-up language (HTML). Participant data entered by Regional Network Center staff resides on a Microsoft Windows NT server at the Coordinating Center with *Cold Fusion* software enabling connectivity to the back-end SQL server database.

The web-based data management system can be used with any PC with a compatible browser (e.g., Internet Explorer 5.5.2). There are two reasons for using Internet Explorer 5.5.2 (or higher versions) for the data entry system: (1) in some cases, the web-based forms are dynamically generated; and (2) using a non-compliant browser may hinder certain system functions.

The web-based system allows the user to interact with all phases of the research data. Family initialization, validating eligibility, and entry of each of the study forms are available in this application. Depending on security access, users may be allowed to enter and edit data as well as view reports. (Appendix A provides an overview of the data entry web site.)

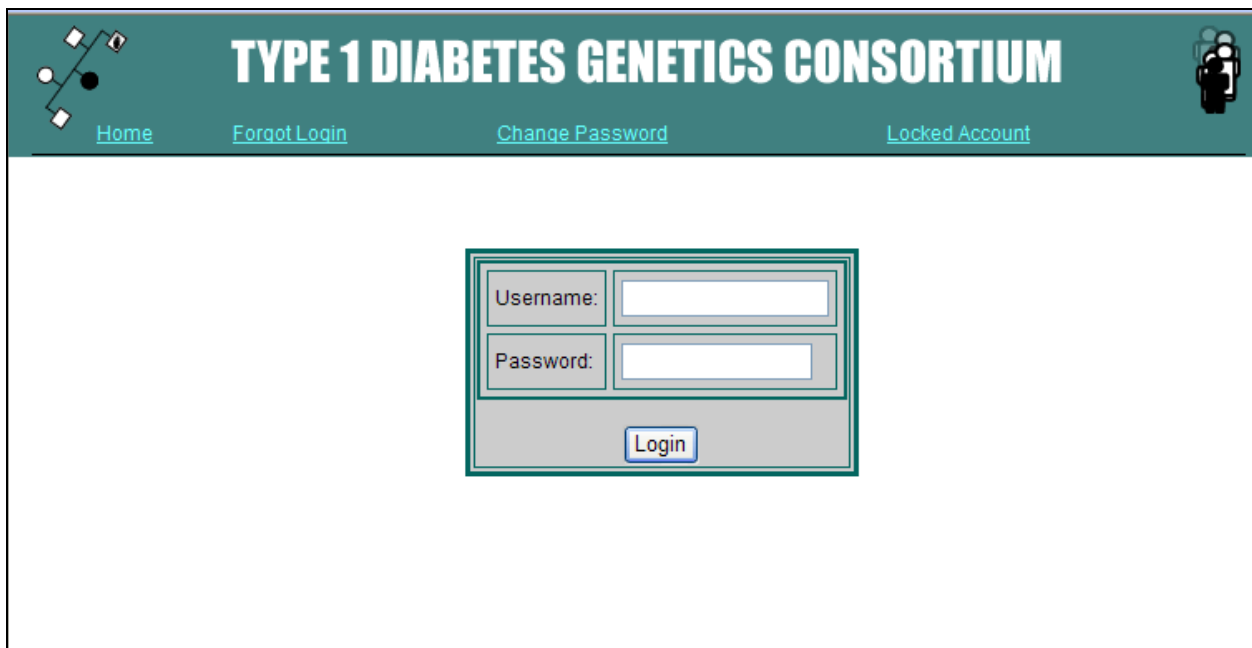
II. DATABASE MANAGEMENT SYSTEM (DBMS)

A. Login

The Coordinating Center provides a username and password for each person authorized to have access to the data entry system prior to the start of data collection. Username will always be the first initial of the user's first name and entire last name. If the last name is more than 7 letters, only the first 7 letters will be used for the username. Passwords must be a minimum of 6 characters, mixed case (upper and

lower), and alphanumeric. Account passwords must be kept confidential. Username and password will always be the same as used for the main T1DGC web site.

Once Internet Explorer 5.5.2 browser (or a compatible version) is invoked on the client computer, the following URL is entered: <https://www.T1DGCDataEntry.org/>. The page loads and the system prompts the user to enter his/her username and password into the appropriate fields (Figure 1). The system is password-protected in order to prevent unauthorized access. Once a valid username and password combination are entered and verified, the user clicks on the **login** button below these fields and the system proceeds to the main screen.



The image shows a web browser window for the T1DGC data entry system. The header is a teal bar with the text "TYPE 1 DIABETES GENETICS CONSORTIUM" in white. On the left of the header is a small icon of a family tree, and on the right is an icon of two people. Below the header are four navigation links: "Home", "Forgot Login", "Change Password", and "Locked Account". The main content area is white and contains a login form. The form has two input fields: "Username:" and "Password:". Below the "Password:" field is a "Login" button. The form is enclosed in a double-line border.

Figure 1. Login window for T1DGC data entry system.

If the user forgets his/her username or password, he/she selects the “Forgot Login” option (Figure 2). After entering his/her e-mail address, the system e-mails the password to the documented e-mail address. To further enhance security, data encryption techniques during transmission are employed throughout the web application. If the user is unsure of the e-mail registered on the web site, the user can

select the appropriate Coordinating Center Project Manager and e-mail the request. The Project Manager will e-mail the address registered to the user.

TYPE 1 DIABETES GENETICS CONSORTIUM

[Home](#) [Forgot Login](#) [Change Password](#) [Locked Account](#)

Enter the email address registered with your Type1 Account Information and your Login Information will be sent to you via this email address. If you don't know what email address is registered call or email your project manager.

For North American or United Kingdom email Elizabeth Sides
For Asia-Pacific or European email Letitia Howard

Figure 2. Forgot login for T1DGC data entry system.

If the user unsuccessfully enters his/her username and password three consecutive times, the system will lock the user out of the web site. The user selects the “Locked Account” option (Figure 3). After confirming that he/she locked out his/her own account, the user selects his/her username from the drop down menu and enters the e-mail address associated with the T1DGC and clicks the **submit** button. The system will automatically unlock the account. If the user is unsure of the e-mail registered on the web site, the user can select the appropriate Project Manager and e-mail the request to unlock the account.

TYPE 1 DIABETES GENETICS CONSORTIUM

[Home](#) [Forgot Login](#) [Change Password](#) [Locked Account](#)

To unlock your account please answer the questions listed below.

Please confirm that you locked out your account by unsuccessfully attempting to login:

Select your username:

Enter your e-mail address associated with T1DGC:

If you need additional support:
 For North America or United Kingdom e-mail Elizabeth Sides
 For Asia-Pacific or Europe e-mail Letitia Howard

Figure 3. Locked account for T1DGC data entry system.

B. Administrative Functions

Depending on the security level set when the account was created, a user can change his/her password, scan family or case-control ID bar-codes into the system, enter a request from a Contributing Investigator for data and/or samples, enter a Contributing Investigator request for genotyping data sets, enter a *Conversion to Case Form*, enter a *Clinic Close-Out Form*, and/or upload a document for another user(s). Additional options are available for Coordinating Center staff. The “Administration” home page is accessed via the upper navigational menu (Figure 4).

TYPE 1 DIABETES GENETICS CONSORTIUM

[Home](#) [Forms](#) [Double Data Entry](#) [HLA Lab](#) [DNA Lab](#) [AA Lab](#) [Administration](#) [Query System](#) [Reports](#) [Logout](#)

You are logged in as Username: lperdue --

Administration Page

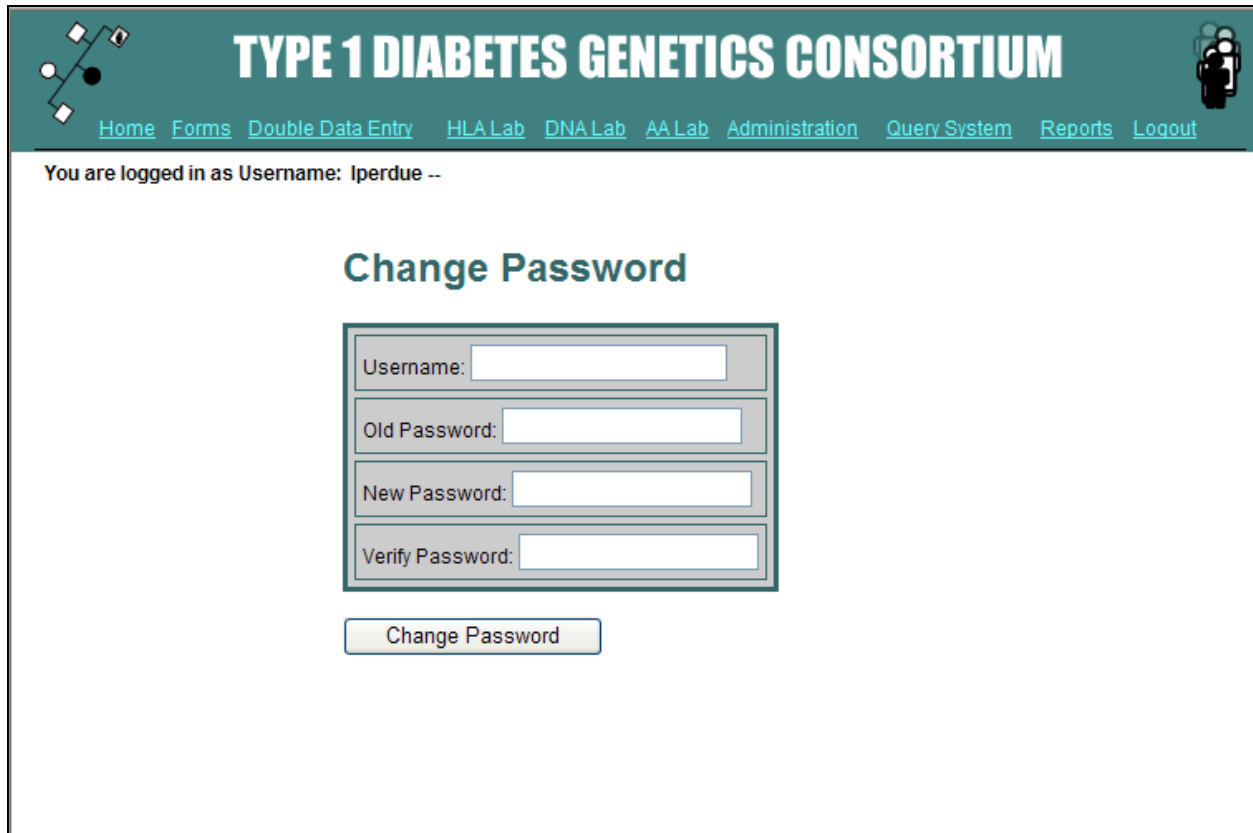
- [Barcode Maintenance](#)
- [Request for Quarterly Data and/or Samples](#)
- [Request for Genotyping Data Sets](#)
- [Convert to Case Form](#)
- [Clinic Close Out Form](#)
- [SCORE/StripScan Upload/Download](#)
- [File Upload Page](#)
- [Change Password](#)
- [Shipments to Rutgers](#)
- [PedCheck Upload](#)
- [Update Existing Files](#)
- [Security Model](#)
- [Update Notification to Destroy Samples](#)
- [Label Printing](#)
- [Data Request Activation](#)
- [DNA Yield File Upload](#)
- [DNA Failures File Upload](#)
- [Clinic Maintenance Form](#)
- [T1DGC Notification to Destroy Samples](#)
- [ID's Marked as To Delete](#)
- [Update Participant Status](#)
- [Application to Eligibility Committee: ASP and Trio Families](#)
- [Application to Eligibility Committee for Cases](#)
- [T1DGC ID Status](#)

Figure 4. Administration home page for T1DGC data entry system (Coordinating Center user view).

1. Change Password

To change a password, the user chooses “Change Password” before login; or at first login, selects “Administration” from the upper navigational menu and selects “Change Password” on the list of administrative options. After selecting “Change Password,” the user is instructed to enter the username, the old password, and a new password, and to verify the new password (Figure 5). The user clicks on the **Change**

Password button. Changing your password on the data entry web site will automatically change your password on the main T1DGC web site, and vice versa.



The screenshot shows the website header for the 'TYPE 1 DIABETES GENETICS CONSORTIUM'. The navigation menu includes links for Home, Forms, Double Data Entry, HLA Lab, DNALab, AA Lab, Administration, Query System, Reports, and Logout. Below the header, a message states 'You are logged in as Username: lperdue --'. The main content area features a 'Change Password' section with a form containing four input fields: Username, Old Password, New Password, and Verify Password. A 'Change Password' button is located below the form.

Figure 5. Changing password for login.

If username and previous password match a record in the database, the system will automatically change the password of the account to the new password entered. Passwords must be a minimum of 6 characters, mixed case (upper and lower), and alphanumeric. Account passwords must be kept confidential; passwords should not be based on the user's first or last name.

2. Bar-code Maintenance

Family and case-control IDs must be scanned at the Coordinating Center and the Regional Network Center to initiate a valid range of IDs in the data entry system. The term "scanned out" refers to family or case-control IDs scanned from the label sets generated at the Coordinating Center prior to shipping to the Regional Network Center.

The term “scanned in” refers to family or case-control IDs scanned from the same label sets when they arrive at the Regional Network Center. All family and case-control ID label sets must be “scanned out” and “scanned in.” QC label sets do not have to be either “scanned out” or “scanned in.”

To scan family or case-control ID bar-codes into the system, the user selects “Bar-code Maintenance” from the list of administrative options. The user is directed to a selection page and selects the type of ID to be entered (Figure 6).

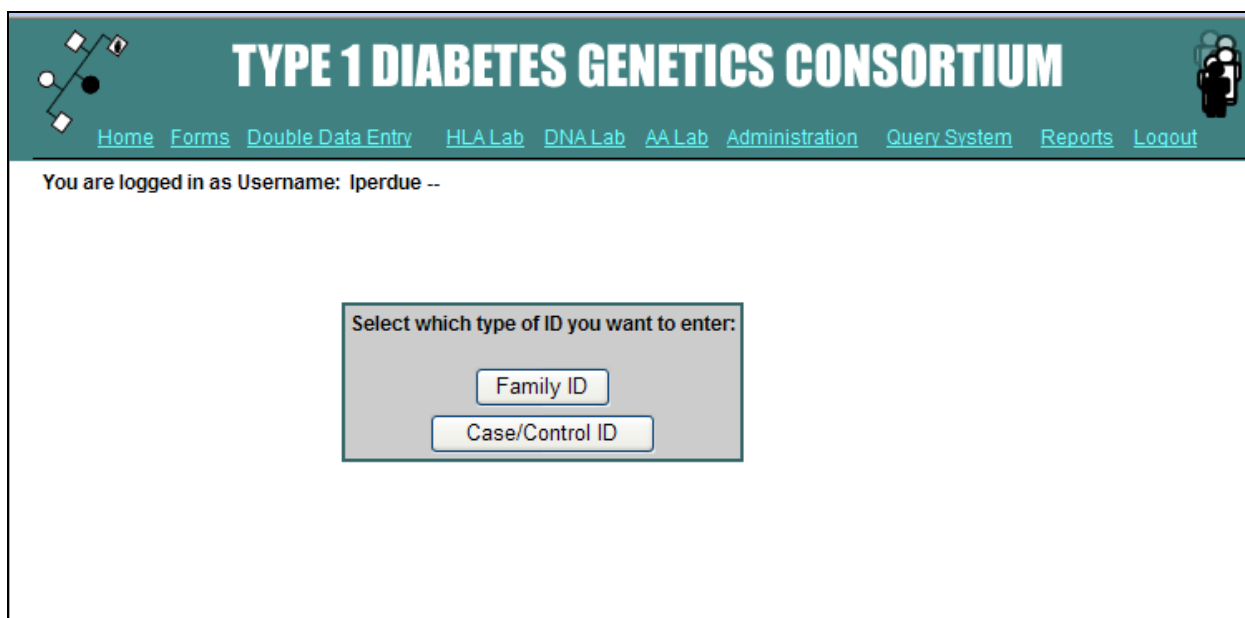


Figure 6. Bar-code maintenance selection page.

The user enters the number of IDs to be scanned and clicks **Add**. The user then scans each ID and clicks **Save** (Figure 7). The newly entered IDs will appear to the right of the screen under the search options (Figure 8). The user will be able to view and delete records, but not edit.

TYPE 1 DIABETES GENETICS CONSORTIUM

Home Forms Double Data Entry HLA Lab DNA Lab AALab Administration Query System Reports Logout

You are logged in as Username: lperdue --

Family ID Bar-code Maintenance Form

Scan New ID(s):
 new records.

Search for an existing family ID:

Family ID equals

Scanned Out By equals

Scanned Out Date after YYYY-MM-DD

Scanned In By equals

Scanned In Date after YYYY-MM-DD

5868 matches found.

| Family ID ^ | Scanned Out By | Scanned Out Date/Time | Scanned In By | Scanned In Date/Time | Delete |
|-------------|-----------------|-----------------------|---------------|-----------------------|--------------------------|
| 10001 | Elisabeth Sides | 2003-09-15 00:00:00.0 | Amanda Loth | 2003-10-14 06:55:00.0 | <input type="checkbox"/> |
| 10002 | Elisabeth Sides | 2003-09-15 00:00:00.0 | Amanda Loth | 2003-10-14 06:55:00.0 | <input type="checkbox"/> |
| 10004 | Elisabeth Sides | 2003-09-15 00:00:00.0 | Amanda Loth | 2003-10-14 06:55:00.0 | <input type="checkbox"/> |
| 10005 | Elisabeth Sides | 2003-09-15 00:00:00.0 | Amanda Loth | 2003-10-14 06:55:00.0 | <input type="checkbox"/> |
| 10007 | Elisabeth Sides | 2003-09-15 00:00:00.0 | Amanda Loth | 2003-10-14 06:55:00.0 | <input type="checkbox"/> |
| 10008 | Elisabeth Sides | 2003-09-15 00:00:00.0 | Amanda Loth | 2003-10-14 06:55:00.0 | <input type="checkbox"/> |
| 10010 | Elisabeth Sides | 2003-09-15 00:00:00.0 | Amanda Loth | 2003-10-14 06:55:00.0 | <input type="checkbox"/> |
| 10011 | Elisabeth Sides | 2003-09-15 00:00:00.0 | Amanda Loth | 2003-10-14 06:55:00.0 | <input type="checkbox"/> |
| 10013 | Elisabeth Sides | 2003-09-15 00:00:00.0 | Amanda Loth | 2003-10-14 06:55:00.0 | <input type="checkbox"/> |
| 10014 | Elisabeth Sides | 2003-09-15 00:00:00.0 | Amanda Loth | 2003-10-14 06:55:00.0 | <input type="checkbox"/> |
| 10016 | Elisabeth Sides | 2003-09-15 00:00:00.0 | Amanda Loth | 2003-10-14 06:55:00.0 | <input type="checkbox"/> |

Figure 8. Bar-code maintenance system.

To search for an existing ID in the system, the user enters specific search criteria and clicks **Find!**. The user can search by: family (or case-control) ID; who scanned out one or more IDs (at the Coordinating Center); the date the IDs were scanned out (at the Coordinating Center); who scanned in one or more IDs (at the Regional Network Center); or the date the IDs were scanned in (at the Regional Network Center).

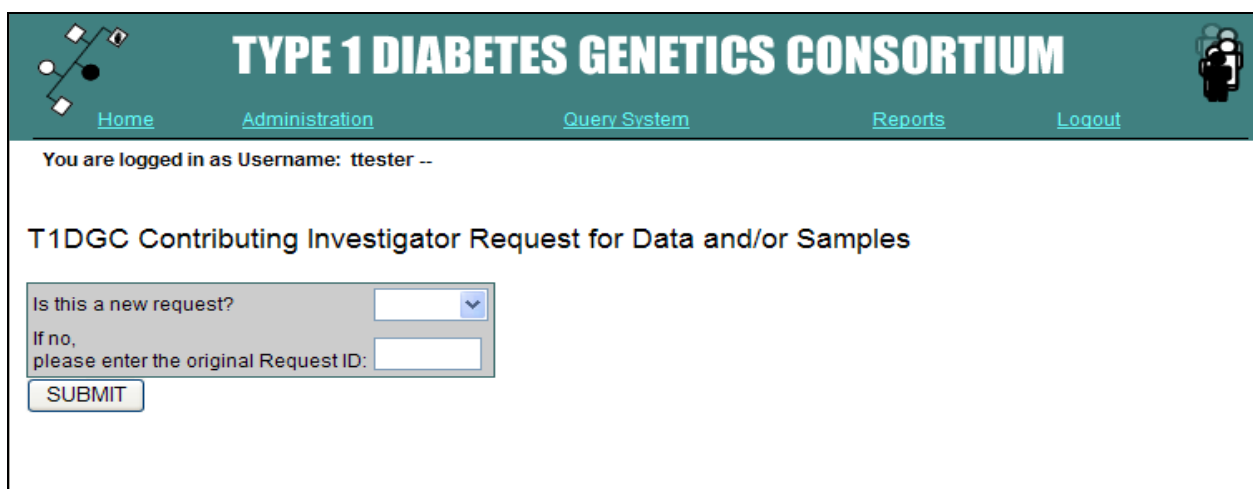
If searching by family (or case-control) ID, the user enters the family (or case-control) ID and selects one of the following options: “equals”, “less than” or “greater than”. If searching by the person who scanned out the IDs, the user selects a name from the drop down menu. If searching by date that the IDs were scanned out, the user enters the date and selects from the following options: “equals”, “less than” or “greater than”. The same search options exist for IDs scanned in by the Regional Network

Center. The user can view all IDs that have been scanned with the specific search criteria by clicking **Show All**.

3. Request for Quarterly Data and/or Samples

The T1DGC study database is frozen on a quarterly basis (*i.e.*, on January 1, April 1, July 1 and October 1). A Contributing Investigator may request the most recent data set for participants he/she contributed at any time. Samples must be requested in either January-February or July-August. All requests for samples and/or data from a Contributing Investigator must be submitted to the investigator's respective Regional Network Center. Investigators requesting information should complete the *T1DGC Contributing Investigator Request for Quarterly Data and Samples Form* and submit the form to the Regional Network Center (via FAX or as an e-mail attachment).

The Regional Network Center submits this request to the Coordinating Center by selecting "Administration" from the upper navigational menu on the T1DGC data entry web site and selecting "Request for Quarterly Data and/or Samples." The user is directed to the Contributing Investigator Request for Data and/or Samples page (Figure 9). The user selects whether this is a new request. If the request is not new, the original Request ID (assigned by the system) is entered.



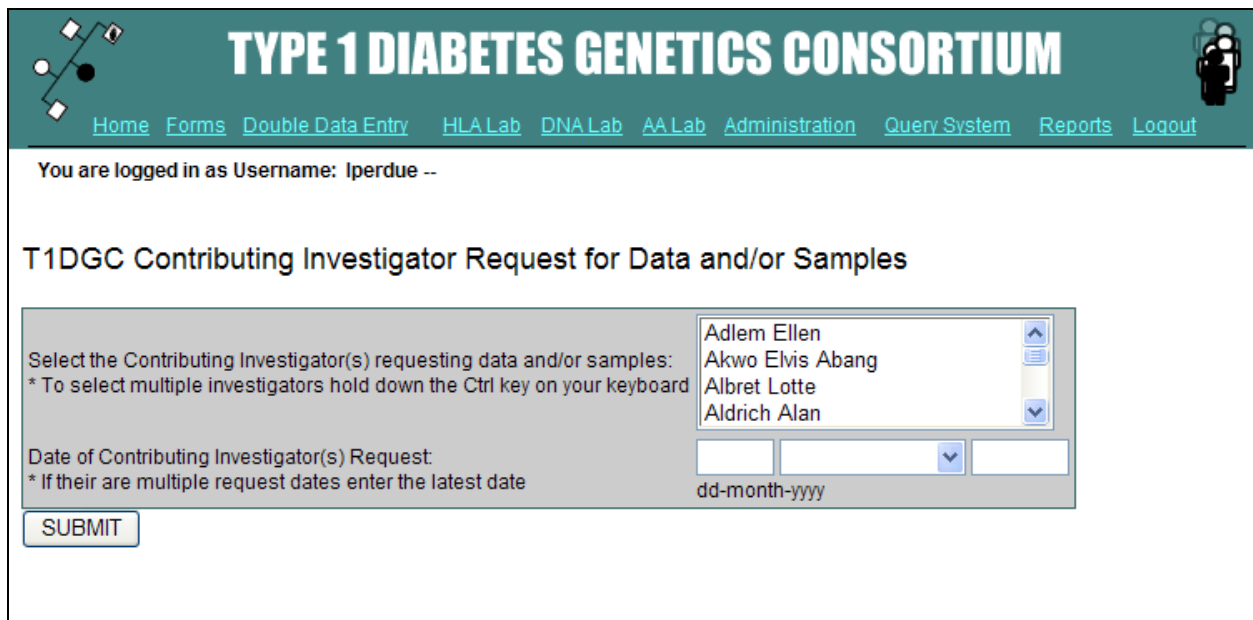
The screenshot shows the web interface for the T1DGC Contributing Investigator Request for Data and/or Samples. At the top, there is a teal header with the text "TYPE 1 DIABETES GENETICS CONSORTIUM" and a navigation menu with links for Home, Administration, Query System, Reports, and Logout. Below the header, it indicates the user is logged in as "ttester --". The main content area is titled "T1DGC Contributing Investigator Request for Data and/or Samples" and contains a form with the following elements:

- A dropdown menu labeled "Is this a new request?" with a downward arrow.
- A text input field labeled "If no, please enter the original Request ID:".
- A "SUBMIT" button.

Figure 9. Contributing Investigator request for quarterly freeze data and/or samples.

The Request ID is a 4-digit number assigned automatically by the system. All communication regarding the request should include the Request ID. Regardless of whether this is a new or previously submitted request, the user is directed to the Contributing Investigator Selection page and asked to identify the Contributing Investigator(s) affiliated with the request and the date of the request (Figure 10).

Multiple investigators can be selected by holding down the 'Ctrl' key and selecting the investigator with the mouse. If multiple dates are identified on the form(s) received at the Regional Network Center, the latest date should be entered.



The screenshot shows the 'TYPE 1 DIABETES GENETICS CONSORTIUM' website interface. At the top, there is a navigation menu with links: Home, Forms, Double Data Entry, HLA Lab, DNALab, AALab, Administration, Query System, Reports, and Logout. Below the menu, it indicates the user is logged in as 'Username: lperdue --'. The main heading is 'T1DGC Contributing Investigator Request for Data and/or Samples'. The form contains a dropdown menu for selecting the Contributing Investigator(s) with the following options: Adlem Ellen, Akwo Elvis Abang, Albret Lotte, and Aldrich Alan. Below this is a date selection field with a dropdown arrow and a placeholder 'dd-month-yyyy'. A 'SUBMIT' button is located at the bottom left of the form area.

Figure 10. Contributing Investigator request selection page for quarterly data and/or samples.

The user is then directed to the Clinic and Resources Selection page (Figure 11). The system lists the clinic IDs affiliated with the investigator(s) selected on the previous page. The user selects the clinics where data and/or samples are requested by checking the box underneath the clinic or by selection "Check All." The user can uncheck all clinic IDs by selecting "Uncheck All."

The user identifies whether data, samples or both are being requested. If only data or only samples are being requested, the user completes only one of the questions (*i.e.*, “data set requested” or “samples requested”). If data are requested, the user indicates whether any additional individuals (besides the Contributing Investigator) should have access to these data. The additional individuals must be listed in the T1DGC directory. Multiple investigators can be selected by holding down the ‘Ctrl’ key and selecting the investigator with the mouse. If samples are requested, all information on the form must be completed or the form will not be saved. If only data are requested, the user is not required to put a shipping address in the form. All other fields are required.

TYPE 1 DIABETES GENETICS CONSORTIUM

Home Forms Double Data Entry HLA Lab DNA Lab AA Lab Administration Query System Reports Logout

You are logged in as Username: lperdue --

T1DGC Contributing Investigator Request for Data and/or Samples

Select clinic(s) affiliated with Contributing Investigator(s):

| | | |
|--|--|---|
| Olga Kordonouri 2095 Kordonouri@hka.de <input type="checkbox"/> | Dora Krikovszky 2111 hecsito1@axelero.hu <input type="checkbox"/> | Janelle Noble 4068 jnoble@chori.org <input type="checkbox"/> |
|--|--|---|

Request for:

Data Set Requested:

Are there additional individuals who should have access to these data?

If yes, please provide the names of these individuals
NOTE: INDIVIDUALS MUST BE LISTED IN THE T1DGC DIRECTORY.

Fatima Abbas
Annie Abraham
Marie-Therese Achermann
Ellen Adlem

Samples Requested:

Name of Shipping Contact:

Shipping Address:

E-mail of Shipping Contact:

Phone Number of Shipping Contact:

Figure 11. Clinic and resources selection page for quarterly data and/or samples.

If the clinic ID associated with the Contributing Investigator is not listed, the Network Center should contact the Coordinating Center Project Manager for his/her network.

If the data is saved, the Contributing Investigator Request for Quarterly Freeze data and/or samples page is re-displayed with “Your request ID is XXXX and it has been sent to the CoC” at the top of the page (Figure 12).

The screenshot shows the top navigation bar of the T1DGC website with the title "TYPE 1 DIABETES GENETICS CONSORTIUM". The navigation menu includes links for Home, Forms, Double Data Entry, HLA Lab, DNA Lab, AA Lab, Administration, Query System, Reports, and Logout. Below the navigation bar, the user is logged in as "Username: lhoward --". A red message states: "Your request ID number is 0034 and it has been sent to the CoC." The main heading is "T1DGC Contributing Investigator Request for Data and/or Samples". The form contains a dropdown menu for "Is this a new request?", a text input field for "If no, please enter the original Request ID:", and a "SUBMIT" button.

Figure 12. Contributing Investigator request for quarterly data and/or samples saved.

An e-mail is automatically generated to the Regional Network Center, the Coordinating Center and the Contributing Investigator. The Coordinating Center will process the request and prepare a data set and/or shipping manifest to be forwarded to the Network DNA Repository. The Coordinating Center will notify the Contributing Investigator via e-mail when the data set is available on the T1DGC web site. The DNA Repository will contact the Contributing Investigator to arrange a shipping date. The DNA Repository will complete the *T1DGC Shipping Form: Shipments to Contributing Investigators* when the samples are shipped. The entry of this form into the Specimen Tracking system will generate an automatic e-mail that is sent to the Regional Network Center, the Coordinating Center and the Contributing Investigator.


If the request needs to be cancelled, the user should contact the appropriate Project Manager at the Coordinating Center.

4. Request for Genotyping Data Sets

Genotyping data sets from sample submissions to CIDR, the MHC Fine Mapping Laboratory, the Rapid Response Laboratory and the TaqMan Laboratory are made

available to Contributing Investigators. Contributing Investigators will be notified when these data sets are available.

The Regional Network Center submits this request to the Coordinating Center by selecting “Administration” from the upper navigational menu on the T1DGC data entry web site and selecting “Request for Genotyping Data Sets.” The user is directed to the Contributing Investigator Request for Genotyping Data Sets page (Figure 13). The user selects whether this is a new request. If the request is not new, the original Request ID (assigned by the system) is entered.



The screenshot shows a web application interface for the Type 1 Diabetes Genetics Consortium. At the top, there is a teal header with the title "TYPE 1 DIABETES GENETICS CONSORTIUM" in white. To the left of the title is a logo consisting of a network of nodes and lines, and to the right is a small icon of two people. Below the title, there are five navigation links: "Home", "Administration", "Query System", "Reports", and "Logout", all in teal text. Below the navigation is a white area with the text "You are logged in as Username: ttester --". The main content area has a heading "T1DGC Contributing Investigator Request for Genotyping Data Sets". Below this heading is a form with a dropdown menu labeled "Is this a new request?" and a "SUBMIT" button. Below the dropdown is a text input field with the label "If no, please enter the original Request ID:".

Figure 13. Contributing Investigator request for genotyping data sets.

The Request ID is a 5-digit number (in contrast to the 4-digit number that is assigned to Contributing Investigator requests for quarterly freeze data and/or samples) assigned automatically assigned by the system. All communication regarding the request should include the Request ID. Regardless of whether this is a new or previously submitted request, the user is directed to the Contributing Investigator Selection page and asked to identify the Contributing Investigator(s) affiliated with the request and the date of the request (Figure 14).

TYPE 1 DIABETES GENETICS CONSORTIUM

Home Forms Double Data Entry HLA Lab DNA Lab AA Lab Administration Query System Reports Logout

You are logged in as Username: lperdue --

T1DGC Contributing Investigator Request for Genotyping Data Sets

Select the Contributing Investigator(s) requesting data and/or samples:
 * To select multiple investigators hold down the Ctrl key on your keyboard

Adlem Ellen
 Akwo Elvis Abang
 Albret Lotte
 Aldrich Alan

Date form completed:
 dd-month-yyyy

Figure 14. Contributing Investigator request selection page for genotyping data sets.

Multiple investigators can be selected by holding down the ‘Ctrl’ key and selecting the investigator with the mouse. If multiple dates are identified on the form(s) received at the Regional Network Center, the latest date should be entered.

The user is then directed to the Clinic and Data Set Selection page (Figure 15). The system lists the clinic IDs affiliated with the investigator(s) selected on the previous page. The user selects the clinics where data and/or samples are requested by checking the box underneath the clinic or by selection “Check All.” The user can uncheck all clinic IDs by selecting “UnCheck All.”

T1DGC Contributing Investigator Request for Genotyping Data Sets

Select clinic(s) affiliated with Contributing Investigator(s):

| | | |
|---|--|---|
| Janelle Noble 4068 jnoble@chori.org (510) 450-7657 <input type="checkbox"/> | Moshe Phillip 2280 mosheph@post.tau.ac.il 972 3 9253731 <input type="checkbox"/> | Valdis Pirags 2130 pirags@latnet.lv 371 9137 731 <input type="checkbox"/> |
|---|--|---|

Data Set Requested:
MARK ALL THAT APPLY

- 2006.03.CIDR
- 2006.09.MHC
- 2006.12.MHC
- 2007.02.MHC
- 2007.03.RR
- 2007.07.CIDR
- 2007.11.CIDR.6K_1_2
- 2007.11.MHC
- 2007.12.RR
- 2008.01.CIDR.6K_1_2
- 2008.08.RR2
- 2008.07.RR
- 2009.04.CIDR.6K
- 2009.06.CIDR.6K_1_2_3
- 2009.07.TAQMAN
- 2010.03.TAQMAN

Type of data set requested:
MARK ALL THAT APPLY.

- Raw data
- Filtered data
- Final data

Are there additional individuals who should have access to these data?

If yes, please provide the names of these individuals
NOTE: INDIVIDUALS MUST BE LISTED IN THE T1DGC DIRECTORY.

Fatima Abbas
Annie Abraham
Marie-Therese Achermann
Ellen Adlem

Figure 15. Clinic and data set selection page for genotyping data sets.

The user identifies which data set(s) is (are) requested and the type of data set(s) that is (are) requested. The user should mark all data sets or types of data sets that apply. User must select at least one data set and one type of data set. The user indicates whether any additional individuals (besides the Contributing Investigator) should have access to these data. The additional individuals must be listed in the T1DGC directory. Multiple investigators can be selected by holding down the 'Ctrl' key and selecting the investigator with the mouse.

If the clinic ID associated with the Contributing Investigator is not listed, the Network Center should contact the Coordinating Center Project Manager for their network.

If the data are saved, the Contributing Investigator request for quarterly freeze data and/or samples page is re-displayed with "Your request ID is XXXX and it has been sent to the CoC" at the top of the page (Figure 16).

TYPE 1 DIABETES GENETICS CONSORTIUM

[Home](#) [Forms](#) [Double Data Entry](#) [HLA Lab](#) [DNA Lab](#) [AA Lab](#) [Administration](#) [Query System](#) [Reports](#) [Logout](#)

You are logged in as Username: lhoward --

Your request ID number is 10003 and it has been sent to the CoC.

T1DGC Contributing Investigator Request for Genotyping Data Sets

Is this a new request?

If no,
please enter the original Request ID:

Figure 16. Contributing Investigator request for genotyping data sets saved.

An e-mail is automatically generated to the Regional Network Center, the Coordinating Center and the Contributing Investigator. The Coordinating Center will process the request, preparing the requested data set(s). The Coordinating Center will notify the Contributing Investigator via e-mail when the data set is available on the T1DGC web site.

If the request needs to be cancelled, the user should contact the appropriate Project Manager at the Coordinating Center.

5. Conversion to Case Form

In some situations, it may become necessary for the proband in a trio or ASP family to be converted to a case participant. The form largely can be completed by the clinic or Regional Network Center based upon the participant's response to the questions from the *Eligibility Form* and the *Exam Form*. This form is the only participant form that is accessed from the Administration menu rather than the home page of the data entry web site.

The Regional Network Center enters this form by selecting "Administration" from the upper navigational menu on the T1DGC data entry web site and selecting "Convert to Case Form." The user is directed to the Conversion to Case ID Entry page (Figure 17). The user scans or enters the 7-digit participant ID. The user will then be directed to the data entry screen for the *Conversion to Case Form* (Figure 18). If the form has been entered, it will be displayed with any previously entered information.

TYPE 1 DIABETES GENETICS CONSORTIUM

Home Forms Double Data Entry HLA Lab DNA Lab AA Lab Administration Query System Reports Logout

You are logged in as Username: lperdue --

Scan or Enter a Participant ID:

Figure 17. Conversion to case ID entry page.

TYPE 1 DIABETES GENETICS CONSORTIUM

Home Forms Double Data Entry HLA Lab DNA Lab AA Lab Administration Query System Reports Logout

You are logged in as Username: lperdue --

T1DGC Conversion to Case Form
(Administered to Participant or Guardian)

Participant ID

Clinic ID

Secondary ID

COMPLETE THIS FORM FOR ANY MINORITY PROBAND OR MINORITY AFFECTED SIBLING WHOSE FAMILY IS INELIGIBLE DUE TO MISSING CORE MEMBERS

1. Case was previously a:

2. Interview Date - -
Day Month Year

3. How was this form completed?
MARK ALL THAT APPLY.

Phone interview

Face-to-face interview

From existing records

4. Who is completing this form?

5. Is your (your child's) origin of birth, or primary ethnic origin one of the following?

FAMILY HISTORY

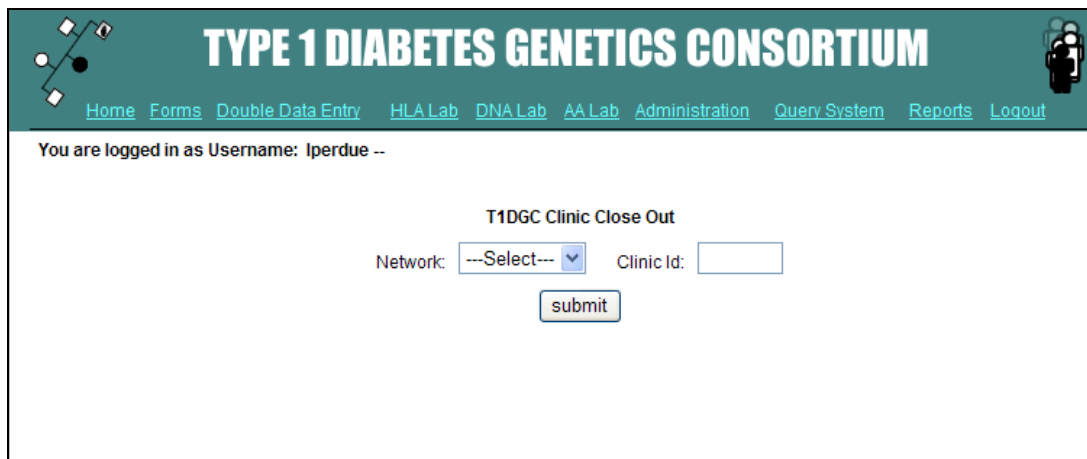
In this section, we wish to obtain information about living and deceased members of your (child's) family. We are only interested in your (child's) biological relatives.

Figure 18. Entry screen for T1DGC Conversion to Case Form.

6. Clinic Close-out Form

The Regional Network Center Coordinator is responsible for initial entry of the *T1DGC Clinic Close-out Form*. The Coordinating Center will review the form for completeness and update the Coordinating Center section of the form.

The Regional Network Center enters this form by selecting “Administration” from the upper navigational menu on the T1DGC data entry web site and selecting “Clinic Close-Out Form.” The user is directed to the Clinic Close-out Form selection page (Figure 19). The user selects the network from the drop-down box and types in the 4-digit clinic ID. The user will then be directed to the data entry screen for the *Clinic Close-Out Form* (Figure 20). If the form has been entered, it will be displayed with any previously entered information.



The screenshot shows the 'TYPE 1 DIABETES GENETICS CONSORTIUM' website interface. At the top, there is a navigation menu with links for Home, Forms, Double Data Entry, HLA Lab, DNA Lab, AA Lab, Administration, Query System, Reports, and Logout. Below the menu, a message states 'You are logged in as Username: lperdue --'. The main content area is titled 'T1DGC Clinic Close Out' and contains a form with a 'Network:' label, a dropdown menu showing '---Select---', a 'Clinic Id:' label, and an empty text input field. A 'submit' button is located below the input fields.

Figure 19. Clinic close-out form selection page.

TYPE 1 DIABETES GENETICS CONSORTIUM

Home Forms Double Data Entry HLA Lab DNA Lab AALab Administration Query System Reports Logout

You are logged in as Username: lperdue --

T1DGC Clinic Close Out Network 5 Clinic ID: 1209

1. Date Final Participant Seen -- - - - - Not applicable

2. Date Final Form received at Regional Network Center -- - - - - Not applicable

3. Date Final Form entered at Regional Network Center -- - - - - Not applicable

4. Date last shipment received at Network DNA Repository -- - - - - Not applicable

5. Date last shipment received at Network Autoantibody & Storage Laboratory -- - - - - Not applicable

6. Please mark all that have been completed.

Each family status assessed with Regional Network Center and Clinic

All irregularities resolved or confirmed

All queries resolved or confirmed

All re-collections resolved or confirmed

Not applicable

7. Date original Data Collection Forms received at Regional Network Center -- - - - - Not applicable

8. Date copies of all Data Collection Forms shipped to clinic -- - - - - Not applicable

9. Date lab supplies received at Regional Network Center -- - - - - Not applicable

10a. Extra label sets destroyed or redistributed? Destroyed Redistributed

10b. Date extra label sets destroyed or received at Regional Network Center for -- - - - -

Figure 20. Entry screen for *Clinic Close-out Form*.

7. File Upload Page

The File Upload page was created as a means to transfer files containing identifying information or especially large files to the Coordinating Center. All users are able to upload files; only designated Coordinating Center personnel are able to download files.

The user accesses this option by selecting “Administration” from the upper navigational menu on the T1DGC data entry web site and selecting “File Upload Page.” The user is directed to the File Upload page (Figure 21). To upload a file, click “Browse” to locate the file on the computer. Click “Open” or double click on the file to

submit the file address. The user should indicate the intended recipient of the file and enter any additional comments in the appropriate field. Upon successful upload, the file will appear on the uploaded file list (on the right hand side of the screen) as the last uploaded file (Figure 22).

Figure 21. File upload page.

| File Name | Upload Date | Who Uploaded | Intended For |
|---|-----------------------|--------------|----------------|
| Access_Policy_Ver7_10-09-08.pdf | 2011-08-31 16:43:00.0 | Tisha Tester | Letitia Perdue |

Figure 22. File upload page (following successful upload).

III. DATA ENTRY OF FORM SETS

A. General Instructions for Data Entry

Individuals entering data must be familiar with the following operations of the database management system:

1. Each screen displays a certain number of fields or slots where data from T1DGC forms are entered. These fields may appear on the screen as boxes of a different color from the screen background. Other fields are called "radio buttons", "list boxes", and "check boxes." These fields allow the user to select from several choices. If information has been omitted on the forms, do not enter the data. For more on missing data, see item 7.
2. Move from field to field by using the "Tab" key, or by clicking on another field with the mouse.
3. All data entry must be done with the "Caps Lock" key on. Data entered in lower case will not be saved.
4. Correct keying errors in a specific field by backspacing over the error and re-typing the data. If a mistake is made after moving to a new field, use the mouse, Shift-Tab or Tab keys to move to the field that needs correction.
5. At the end of a screen, check entries to be sure they are correct. Save each form after it is entered. To save the entered form data, click on the **Save Data** button at the top or bottom of the screen.
6. Each time a family or case-control ID is entered, the system checks that the ID is valid. If the ID is invalid, access to the forms will be denied.

7. The database system sets all data items to “missing” by default. Numeric and date fields, for which no data have been entered, are assigned a NULL value. If an answer is missing on the paper form, do not change the value on the screen.
8. If data are invalid on the paper form, **do not** enter any information in the field and consult the Clinic Coordinator. Record these discrepancies on the *T1DGC Data Editing Log*, documenting the current date, participant or family ID, clinic ID, form name, question number, interview date, and the nature of the discrepancy. Once the discrepancies are resolved, entry of the data can occur.
9. The system will note data that are out of "expected" ranges and "valid" ranges. For example, the expected range for interview dates are between the years of 2004-2010. You may encounter valid values outside the expected range. In such cases, the system will note this with an orange mark next to the field in question, but entry **is** permitted. This alerts the user who can either confirm the value or correct the value. Data values that are missing and must be answered are noted with a red mark next to the field in question, and the user must correct the value before data are saved. All data requiring correction **must** be corrected at the clinic level. The Regional Network Center staff **cannot** correct data without consulting the clinic where the forms originated. Informational messages, indicated by a blue mark, should be reviewed to ensure that a data entry error has not been made; however, these messages do not have to be confirmed at the clinic level.

B. Family and Form Selection

Once the user is logged in, he/she is asked to scan or enter a family or case-control ID from the bar-coded label (Figure 23). It is important that the cursor is in the appropriate box prior to scanning of the ID. Scanning the IDs is the preferred method; manual entry of IDs is possible, but discouraged. If the bar-code scanner is inoperable and manual entry is necessary, do not enter the hyphens that appear on the bar-coded ID label.

The screenshot shows the top navigation bar of the Type 1 Diabetes Genetics Consortium website. The header includes a logo on the left, the title "TYPE 1 DIABETES GENETICS CONSORTIUM" in the center, and a user icon on the right. Below the header is a navigation menu with links: Home, Forms, Double Data Entry, HLA Lab, DNA Lab, AA Lab, Administration, Query System, Reports, and Logout. A status message indicates the user is logged in as "Username: lperdue --".

On the left side, there is a "News and Notes" section with the following text: "1. The Data Entry website is back online. If you experience any issues please email Dustin Williams at dtwillia@wfubmc.edu".

The main content area contains three identical input forms, each with a text label, an input field, and a "SUBMIT" button:

- Form 1: "Scan or Enter a Family ID:"
- Form 2: "Scan or Enter a Case/Control ID:"
- Form 3: "Scan or Enter a Shipping ID:"

Figure 23. Scanning family or case-control IDs from bar-coded labels.

After scanning the bar-code, the system processes the ID, testing for validity. (Appendix B provides an overview of the data entry web site form flow.) If a family ID is invalid, the user will not be able to enter the forms (Figure 24). The user should confirm the bar-code was read correctly and matches the written ID. If the label was read correctly, the user should contact the Coordinating Center to resolve the problem.

The screenshot shows the top navigation bar of the Type 1 Diabetes Genetics Consortium website. The header is dark teal with the title 'TYPE 1 DIABETES GENETICS CONSORTIUM' in white. Navigation links for 'Home', 'Administration', 'Reports', and 'Logout' are visible. Below the header, a message states: 'You are logged in as Username: lperdue -- Family ID: 12356 --'. A red error message follows: 'That Family ID does not exist. If you feel you have gotten this by mistake contact the Regional Center.' On the left, a 'News and Notes' box contains a message about the Data Entry website being back online. On the right, there are three input forms: 'Scan or Enter a Family ID:', 'Scan or Enter a Case/Control ID:', and 'Scan or Enter a Shipping ID:'. Each form has a 'SUBMIT' button.

Figure 24. Entry of an invalid ID.

Once the family or case-control ID is entered, the system automatically determines if this is a previously initialized ID. For family IDs, if the ID has not been entered previously, the user may have to select whether an ASP or trio family is being initialized in the system (Figure 25). This screen will only appear in networks where trio families are being collected in conjunction with ASP families. The user is then able to access and complete the required data entry forms. If the family was initialized during a prior data entry operation (*i.e.*, family type has already been selected), the user is not prompted again for type of family.

The screenshot shows the top navigation bar of the Type 1 Diabetes Genetics Consortium website. The header is teal with the title "TYPE 1 DIABETES GENETICS CONSORTIUM" in white. Navigation links for "Home", "Administration", "Reports", and "Logout" are visible. A user status bar indicates the user is logged in as "lhoward" with Family ID "99989". The main content area prompts the user to "Please select which type of family this is:" and provides two options: "ASP Family" with an "ASP" button and "Trio Family" with a "TRIO" button.

Figure 25. Selection of family type.

C. Informational Messages, Warnings and Errors

Once entry of a data form is complete, the system will evaluate the entered information against a series of rules for missing data, range checks, and valid responses. There are three types of messages, represented by different color boxes and dots. Informational messages, warnings and error messages will appear if data entered are out of “expected” ranges or fields are left blank for all forms.

1. Informational Messages (Blue Dots):

- a. Informational messages will appear for non-essential questions.
- b. If data entered are out of an “expected” range or a field is left blank, the form is redisplayed with a blue box at the top describing the potential mistake and a blue dot beside the specific question on the form (Figure 26).
- c. Confirm that the data on the form matches that entered on the web page.
- d. If the data match, click the “Save with Warnings” button. If the data do not match, correct the discrepant data and click the “Save” button.

2. Warnings (Orange Dots):

- a. Warnings will appear for essential questions.
- b. If data entered are out of an “expected” range or a field is left blank, the form is redisplayed with an orange box at the top describing the potential mistake and an orange dot beside the specific question on the form (Figure 26).
- c. Confirm that the data on the form matches that entered on the web page.
- d. If the data match, click the “Save with Warnings” button. If the data do not match, correct the discrepant data and click the “Save” button.

3. Errors (Red Dots):

- a. Errors will appear on required questions. Forms that contain an error **have not** been saved in the database. This error **must be** corrected prior to the form saving.
- b. If data entered are out of an “expected” range or a **required** field is left blank, the form is redisplayed with a red box at the top describing the potential error and a red dot beside the specific question on the field (Figure 26).
- c. Confirm that the data on the form matches that entered on the web page.
- d. If the data match and are valid, the Coordinating Center should be contacted.

TYPE 1 DIABETES GENETICS CONSORTIUM

Home Forms Administration Query System Reports Logout

You are logged in as Username: lperdue -- Family ID: 9997 --

Form Submission Errors
 IDs-2) Clinic ID can not be missing, and must consist of a 4-digit number

Form Submission Warnings
 Q01) Interview date appears out of range (before 2004), please confirm
 Q06) Is missing

Form Submission Info
 Q02) At least one response should be checked (Q2), please confirm
 Q12) Is missing
 Q13) Is missing

SAVE

T1DGC ASP Exam Form
 (Affected Sibling Data from Participant or Guardian)

Participant ID 999704
 Clinic ID ●
 Secondary ID AS2

1. Interview Date - -
Day Month Year

2. How was this form completed?
 MARK ALL THAT APPLY.

Phone interview
 Face-to-face interview
 From existing records

3. Who is completing this form?
 AFFECTED SIBLING IS THE SECOND CHILD DIAGNOSED

Figure 26. Entry screen for ASP Consent Summary Form with warnings and errors.

D. North American Trio Pre-Eligibility Form

Note: This section applies only to trio families collected in the North American Network.

If a trio family is selected in the North American Network, the *T1DGC North American Trio Pre-Eligibility Form* will appear and must be entered prior to entering the *T1DGC Consent Summary Form* (Figure 27).

Figure 27. Entry screen for North American T1DGC Trio Pre-Eligibility Form.

E. Consent Summary Forms

Note: This section applies only to ASP and trio families.

With the exception of trio families within the North American Network, for new families, the *T1DGC Consent Summary Form* is entered first (Figure 28).

Data entry of forms for a family cannot be initiated without an appropriately completed *T1DGC Consent Summary Form*. For ASP families, the form must contain both the bar-coded ID label for the proband and the affected sibling, the date the *Informed Consent* was signed **and** the consent status. For trios, the bar-coded ID label, the date the *Informed Consent* was signed **and** the consent status must be complete for the proband, father and mother.

For clinics within the United States, *Written Authorization* must be obtained in addition to the *Informed Consent*. Consult the Clinic Coordinator if any of these data are missing on the *T1DGC Consent Summary Form*. Information must be obtained from the clinic to correct the forms prior to entry of the data.

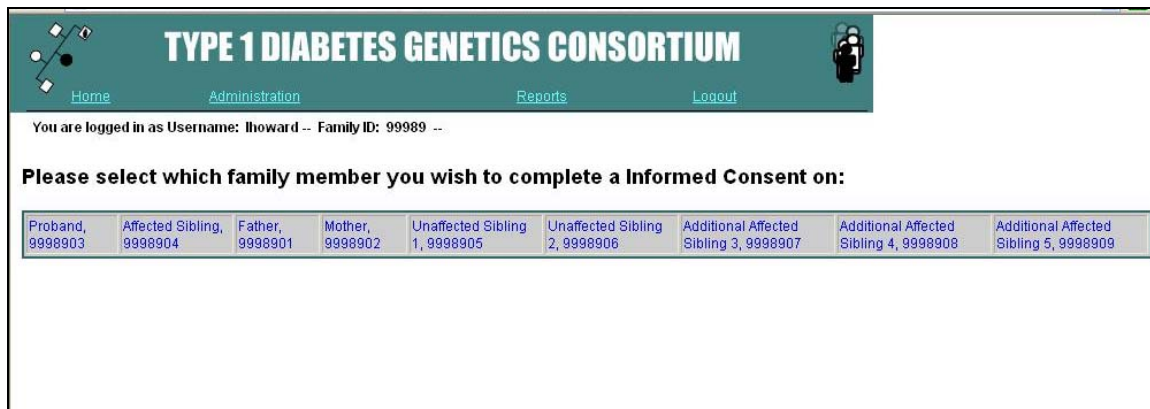
Figure 28. Entry screen for *T1DGC ASP Consent Summary Form*.

F. Informed Consent Database

1. ASP and Trio Families

Once you have entered the required data on the *T1DGC Consent Summary Form*, the user is taken to the Consent Selection page (Figure 29). The user sees the name and participant ID of every family member for whom information was entered on the *Consent Summary Form*. Once a user clicks on a family member, he/she is taken to the layered portion of the consent for this person (Figure 30). The user enters the information from the layered portion and clicks “Save.” If errors are made on the entry

of information on this page, it cannot be modified. Regional Network Center staff can view previously entered layered portions of the participant's consent form; however any changes to the layered portion of the participant's consent form must be e-mailed to the Network Project Manager at the Coordinating Center for correction.



TYPE 1 DIABETES GENETICS CONSORTIUM

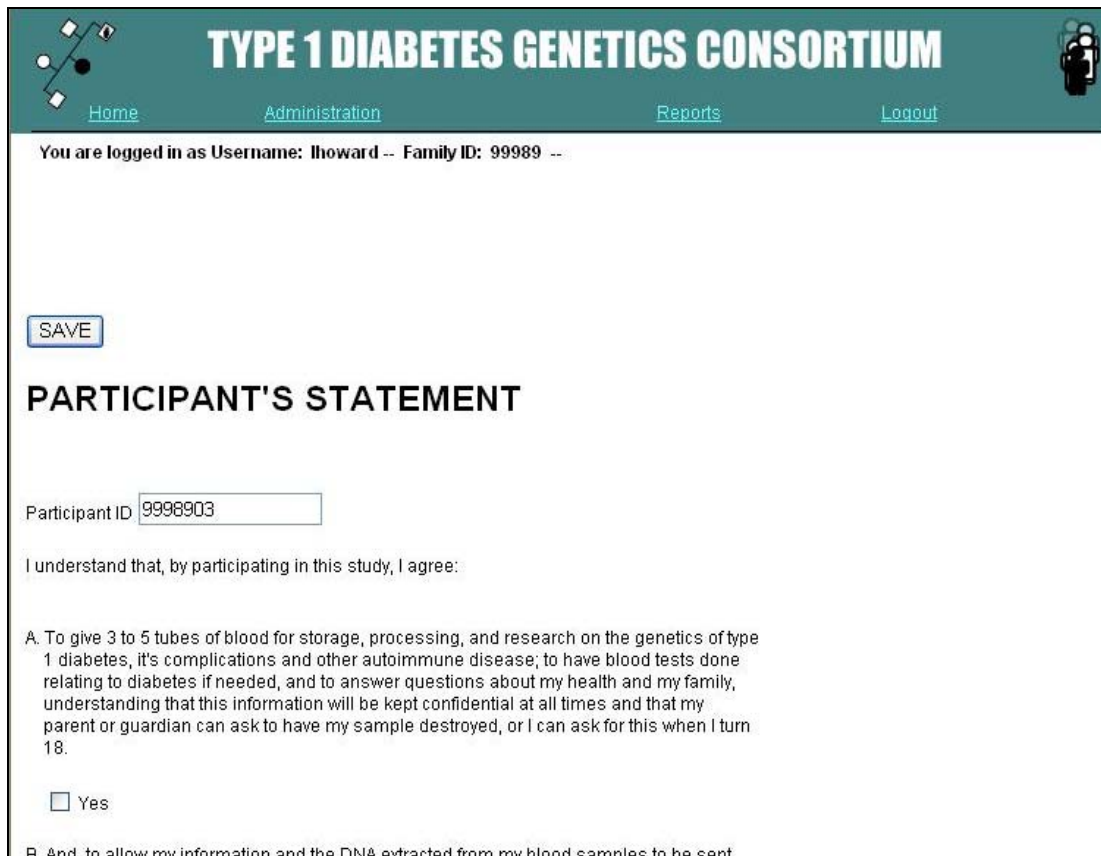
Home Administration Reports Logout

You are logged in as Username: lhoward -- Family ID: 99989 --

Please select which family member you wish to complete a Informed Consent on:

| | | | | | | | | |
|------------------|---------------------------|-----------------|-----------------|-------------------------------|-------------------------------|--|--|--|
| Proband, 9998903 | Affected Sibling, 9998904 | Father, 9998901 | Mother, 9998902 | Unaffected Sibling 1, 9998905 | Unaffected Sibling 2, 9998906 | Additional Affected Sibling 3, 9998907 | Additional Affected Sibling 4, 9998908 | Additional Affected Sibling 5, 9998909 |
|------------------|---------------------------|-----------------|-----------------|-------------------------------|-------------------------------|--|--|--|

Figure 29. Informed consent selection page.



TYPE 1 DIABETES GENETICS CONSORTIUM

Home Administration Reports Logout

You are logged in as Username: lhoward -- Family ID: 99989 --

SAVE

PARTICIPANT'S STATEMENT

Participant ID: 9998903

I understand that, by participating in this study, I agree:

A. To give 3 to 5 tubes of blood for storage, processing, and research on the genetics of type 1 diabetes, it's complications and other autoimmune disease; to have blood tests done relating to diabetes if needed, and to answer questions about my health and my family, understanding that this information will be kept confidential at all times and that my parent or guardian can ask to have my sample destroyed, or I can ask for this when I turn 18.

Yes

B. And to allow my information and the DNA extracted from my blood samples to be sent

Figure 30. Layered portion of *Informed Consent Form* for family participant.

2. Case and Control Participants

For case and control participants, the layered portion of the informed consent is entered first (Figure 31). This form is similar to that for participants from ASP and trio families, with the addition of key questions collected on the *Consent Summary Form* for the T1DGC families, including: type of consent and date informed consent signed. Data entry of forms for this participant cannot be initiated without an appropriately completed Layered Consent Form.

G. Eligibility Forms

After completing and submitting the required data on the *T1DGC Consent Summary Form* and the *Layered Consent Form*, **one** of the two *T1DGC Eligibility Forms* is entered. The system directs the user to the *T1DGC Eligibility Form* page and the user must select one of the two *T1DGC Eligibility Forms* (Figure 32). Either the *T1DGC Eligibility Form (Administered to Proband)* is entered (Figure 33) or the *T1DGC Eligibility Form (Administered to Guardian)* is entered (Figure 34). One of the two *T1DGC Eligibility Forms* must be completed prior to continuing to the remaining data collection forms.

PARTICIPANT'S STATEMENT

Participant ID

Clinic ID Secondary ID

I understand that, by participating in this study, I agree:

A. To give 3 to 5 tubes of blood for storage, processing, and research on the genetics of type 1 diabetes, its complications and other autoimmune disease; to have blood tests done relating to diabetes if needed, and to answer questions about my health and my family, understanding that this information will be kept confidential at all times and that my parent or guardian can ask to have my sample destroyed, or I can ask for this when I turn 18.

Yes

B. And, to allow my information and the DNA extracted from my blood samples to be sent to the United States and given to other qualified scientists worldwide, even after this study ends, to be analyzed for genetic information relating to Type 1 diabetes, its complications, and other autoimmune diseases.

Yes

I also agree:

C. To allow my genetic material to be made into a living cell line that will create an unlimited supply of DNA that can be used in the future to study type 1 diabetes, its complications, and other autoimmune diseases.

D. To be contacted in the future about possibly participating in additional studies related to diabetes, its complications, and other autoimmune diseases.

E. Type of consent

Date informed consent signed

Figure 31. Entry screen for *Layered Consent Form* for case-control participants.

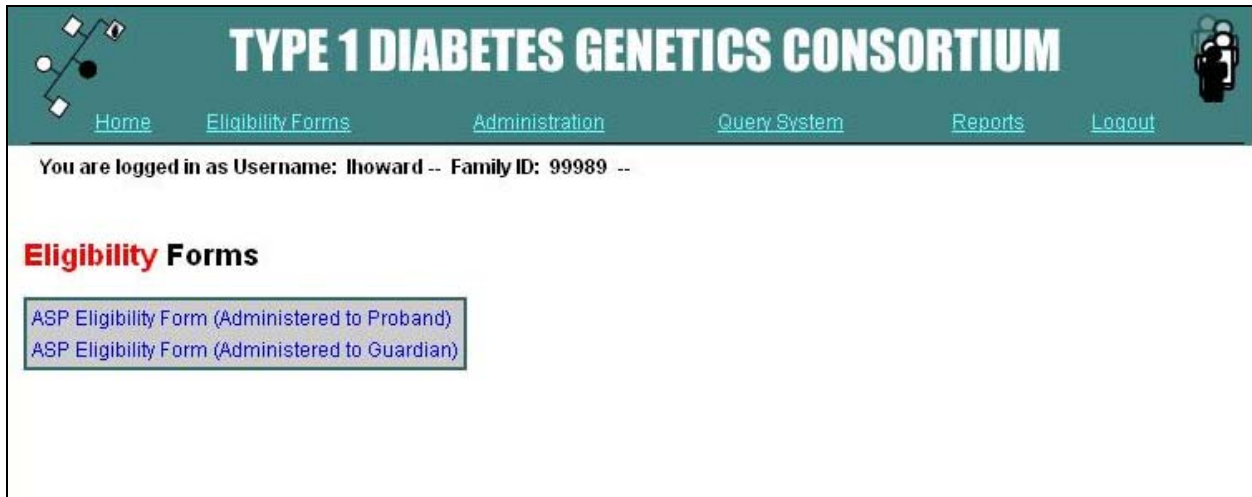


Figure 32. Selection of *T1DGC ASP Eligibility Form*.

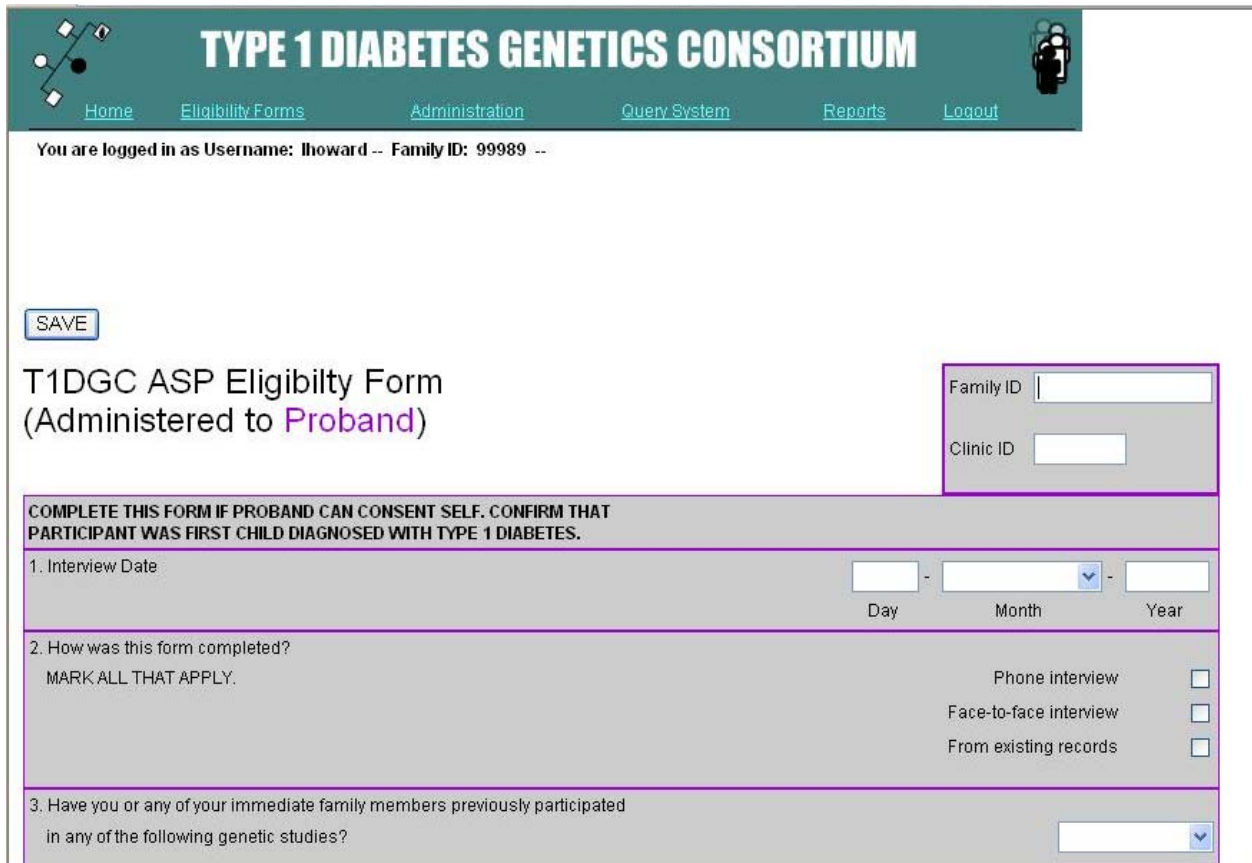


Figure 33. Entry screen for *T1DGC ASP Eligibility Form (Proband)*.

Figure 34. Entry screen for *T1DGC ASP Eligibility Form (Guardian)*.

H. Core Data Entry Forms

Upon completion of the eligibility form, the remainder of the “Core Data Entry Forms” can be accessed and entered. The system directs the user to the “Core Data Entry Forms” page that lists all the forms that must be data entered for the proband and the affected sibling in affected sibling pair (ASP) families (Figure 35); or in trio families, the proband and both biological parents; or for cases or controls, the participant. Note that forms for these essential participants must be entered before entering forms for any other family members. That is, entry of the *T1DGC Exam Form* and the *T1DGC Blood Collection Form* for the proband and the affected sibling must be entered for ASP families before proceeding to data entry for mother, father or unaffected siblings. For trio families, cases and controls, all members of the family are considered to be essential, and thus, all forms are required to be entered.

The screenshot shows the website interface for the Type 1 Diabetes Genetics Consortium. At the top, there is a teal header with the title "TYPE 1 DIABETES GENETICS CONSORTIUM" in white. To the left of the title is a logo consisting of a network of nodes and lines. To the right is a small icon of a person. Below the header is a navigation bar with links for "Home", "Core Forms", "Administration", "Query System", "Reports", and "Logout". Below the navigation bar, a status message reads "You are logged in as Username: lhoward -- Family ID: 99989 --". The main content area is titled "Core Data Entry Forms" in red. Below this title is a grey-bordered box containing a list of seven forms: "ASP Eligibility Form (Administered to Proband)", "ASP Eligibility Form (Administered to Guardian)", "ASP Consent Summary Form", "Layered Portion of Informed Consent Form", "ASP Exam Form (Proband Data from Participant or Guardian)", "ASP Exam Form (Affected Sibling Data from Participant or Guardian)", and "Blood Collection Form: Original Draw".

Figure 35. List of core data entry forms for ASP families.

To data enter a form, locate the desired form in the list, place the mouse over the form title and click the mouse button. The form to complete is presented. If the form has been entered, it is displayed with any previously entered information per family or participant ID.

I. Data Entry Forms

After completion of the core data entry forms, a list of all data entry forms for all members of the family is shown (Figure 36). Entry of all remaining forms should be completed.

The screenshot shows the website interface for the Type 1 Diabetes Genetics Consortium. At the top, there is a navigation bar with the title "TYPE 1 DIABETES GENETICS CONSORTIUM" and a logo on the right. Below the title, there are links for "Home", "Forms", "Administration", "Query System", "Reports", and "Logout". A status bar indicates the user is logged in as "Username: lhoward -- Family ID: 99989 --". The main content area is titled "Data Entry Forms" and contains a list of ten forms:

- ASP Eligibility Form (Administered to Proband)
- ASP Eligibility Form (Administered to Guardian)
- ASP Consent Summary Form
- Layered Portion of Informed Consent Form
- ASP Exam Form (Proband Data from Participant or Guardian)
- ASP Exam Form (Affected Sibling Data from Participant or Guardian)
- ASP Exam Form (Parent Data from Participant)
- ASP Exam Form (Unaffected Sibling Data from Participant or Guardian)
- Blood Collection Form: Original Draw
- Blood Collection Form: Re-collection
- ASP Application for Additional Affected Sibling

Figure 36. List of all ASP data entry forms.

If the same form is completed on multiple family members as in the case of the *T1DGC Blood Collection Form*, *T1DGC Blood Re-Collection Form*, *T1DGC ASP Exam Form (Affected Sibling Data)*, *T1DGC Exam Form (Parent Data)*, *T1DGC ASP Exam Form (Unaffected Sibling Data)*, and *T1DGC ASP Application for Additional Affected Sibling*, the system will prompt the user to select the family member for which the form is completed (Figure 37).

The screenshot shows the 'TYPE 1 DIABETES GENETICS CONSORTIUM' web application interface. At the top, there is a navigation bar with links for Home, Forms, Administration, Query System, Reports, and Logout. Below the navigation bar, a message indicates the user is logged in as 'Username: lhoward -- Family ID: 99989 --'. The main content area displays the instruction: 'Please select which family member you want to data enter or view:'. Below this instruction, there are ten selection buttons arranged in two columns. The buttons are: 'Father' (blue border), 'Mother' (pink border), 'Proband' (purple border), 'Affected Sibling 2' (green border), 'UnAffected Sibling 1' (yellow border), 'UnAffected Sibling 2' (yellow border), 'Affected Sibling 3' (green border), 'Affected Sibling 4' (green border), and 'Affected Sibling 5' (green border). Each button contains the name of the family member and is enclosed in a grey box with a colored border.

Figure 37. Family member selection for *T1DGC Blood Collection Form*.

J. *T1DGC ASP Application for Additional Affected Sibling*

If information has been entered on the *T1DGC ASP Consent Summary* regarding additional affected siblings, the *T1DGC ASP Application for Additional Affected Sibling* will be a form listed on the Data Entry Forms page. Dependent on the number of additional affected siblings identified on the *T1DGC ASP Consent Summary*, the user will be prompted to select “Affected Sibling 3”, “Affected Sibling 4” or “Affected Sibling 5.” The *T1DGC ASP Exam Form (Affected Sibling Data)* and *T1DGC Blood Collection Form* must also be completed for each additional affected sibling.

IV. DATA VALIDATION PROCEDURES

The database management system performs several validation checks during the entry process, both before and after data are submitted. Data must: (1) match the correct type (e.g., numeric data in numeric fields); (2) be in the correct range of valid responses; and (3) be left blank when the paper form field is missing. Data that fail the established validation checks generate messages, or prompts, that describe the problem and required actions on the part of the user.

Once data entry of all the fields on the form is completed, clicking **Save** begins the data validation process (see Section III.C). If a data item is categorized as a critical field, it cannot be saved until the data can be validated. Any errors in critical fields that are detected during the validation process are displayed at the top of the screen in red. The user must correct the values in order to continue. Warnings or messages displayed in orange or blue do not have to be corrected in order to continue. However, the user should confirm that the correct value from the paper form has been entered and follow-up with the Clinic Coordinator at the data collection site to confirm the response. Warnings (displayed in orange) must be verified through the query system.

All questions have pre-assigned missing values for the purpose of data entry. The data entry screens require a set degree of completeness before a form is accepted. Should the forms be incomplete, the missing value is entered into the database.

V. CLINIC SHIPPING FORMS

A. Data Entry by Laboratories

The *T1DGC Clinic Shipping Forms* for specimen shipments from clinics are data entered by the laboratory receiving the samples. The Regional Network Center staff is responsible for ensuring the shipping forms have been entered correctly. Any errors found by Regional Network Center staff should be corrected on the data entry screen and the laboratory should be notified. **Chapter XII, *Specimen Tracking and Inventory System***, provides detailed instructions for completion and entry of the shipping forms.

B. Review of Shipping Forms by Regional Network Centers

The Regional Network Centers will receive two copies of the *T1DGC Clinic Shipping Form*, one partially completed (received from the clinic) and one fully completed (received from the receiving laboratory). The Regional Network Center should confirm they have received two copies of each shipping form. After the completed *T1DGC Clinic Shipping Forms* have been sent by the laboratory, the Regional Network Center should review the form to ensure entry was completed accurately.

Once the user is logged in, he/she scans the Shipping ID from the *T1DGC Clinic Shipping Form – Face Sheet* (Figure 24) in the box labeled “Scan or Enter a Shipping ID.” If the laboratory has previously entered the shipment, the user will be directed to the Shipping Form Selection page (Figure 38). If the shipping form has not previously been entered, the user will be directed to a blank Face Sheet. If directed to a blank Face sheet, the Regional Network Center staff should contact the T1DGC laboratory and ask them to enter the shipping form.



The screenshot shows the web interface for the Type 1 Diabetes Genetics Consortium. At the top, there is a teal header with the text "TYPE 1 DIABETES GENETICS CONSORTIUM" in white. To the left of the header is a logo consisting of a network of nodes and lines, and to the right is a small icon of a person. Below the header is a navigation bar with links for "Home", "Forms", "Administration", "Query System", "Reports", and "Logout". Below the navigation bar, the user is logged in as "Username: lhoward -- Family ID: 99989 -- Shipping ID: 9999999999 --". The main content area is titled "Please select what you would like to do:" and contains three options: "Add a Shipping Contents Sheet" with an "ADD" button, "Start over with a new Shipment" with a "New Shipment" button, and "Select which you page you would like to view:" with links for "Face Sheet," "Contents Sheet Page: 1," and "2,".

Figure 38. Shipping form selection page.

Once directed to the Shipping Form Selection page, the user has three options:

1. add a shipping contents sheet;
2. start over with a new shipment; or
3. select a page they would like to view.

Regional Network Center staff should use the third option to view the Face Sheet (Figure 39) and each Contents Sheet (Figure 40) in order to ensure entry is complete and the paper version of the form matches exactly to the information in the system. If the information on the hard copy of the shipping forms does not correspond with the information in the system, the Regional Network Center staff must contact the laboratory to correct the entry. The Regional Network Center should **never** update the information entered into the *T1DGC Clinic Shipping Form* without consulting the shipping clinic and the receiving laboratory.

TYPE 1 DIABETES GENETICS CONSORTIUM

Home Administration Reports Logout

You are logged in as Username: lperdue -- Family ID: 99997 -- Shipping ID: 10000000001 --

SAVE Save With Warnings

**TYPE 1 DIABETES GENETICS CONSORTIUM
CLINIC SHIPPING FORM - FACE SHEET**

TO: FROM:

SHIPPING ID LABEL: 10000000001 TYPE OF SAMPLES ENCLOSED: 1 - Cell Line (green or yellow tops) and/or Cell Pack (purple tops) (shipped daily, room temperature)

COURIER/SHIPPING COMPANY: TRACKING NUMBER:

NAME OF CLINIC CONTACT: PHONE:

| | COMPLETED BY CLINIC | COMPLETED BY LABORATORY |
|----------|--|---|
| ID: | 1. CLINIC 1010 | 7. LABORATORY 102 |
| DATE: | 2. SAMPLES PACKED 18 - 3 - March - 2004 Day Month Year | 8. SAMPLES ARRIVED 18 - 3 - March - 2004 Day Month Year |
| TIME: | 3. SAMPLES PACKED 11 : 22 24-hour clock | 9. SAMPLES ARRIVED 14 : 11 24-hour clock |
| SAMPLES: | 4. NUMBER PACKED 2 | 10. NUMBER RECEIVED 2 |
| CONTENT: | 5. NUMBER INCLUDED (excludes this sheet) | 11. NUMBER RECEIVED |

Figure 39. T1DGC Clinic Shipping Form – Face Sheet.

TYPE 1 DIABETES GENETICS CONSORTIUM

[Home](#) [Administration](#) [Reports](#) [Logout](#)

You are logged in as Username: lperdue -- Family ID: 99997 -- Shipping ID: 20000000010 --

SAVE
Save With Warnings

Page:

TYPE 1 DIABETES GENETICS CONSORTIUM CLINIC SHIPPING FORM - CONTENTS OF SHIPMENT

| T1DGC PARTICIPANT ID | Vial Cap | Number of Vials | | Comments on Samples (MARK ALL THAT APPLY.) |
|--|--|---|---|---|
| | Color(s) | Sent | Arrived | |
| 1. <input style="width: 80px;" type="text" value="2016401"/> | Red <input checked="" type="checkbox"/> | <input style="width: 30px;" type="text" value="5"/> | <input style="width: 30px;" type="text" value="5"/> | Red samples hemolyzed <input type="checkbox"/> |
| | Purple <input checked="" type="checkbox"/> | <input style="width: 30px;" type="text" value="4"/> | <input style="width: 30px;" type="text" value="4"/> | Purple samples hemolyzed <input type="checkbox"/> |
| | Green/Yellow <input type="checkbox"/> | <input style="width: 30px;" type="text"/> | <input style="width: 30px;" type="text"/> | Tube(s) broken <input type="checkbox"/> |
| 2. <input style="width: 80px;" type="text" value="2016402"/> | Red <input checked="" type="checkbox"/> | <input style="width: 30px;" type="text" value="5"/> | <input style="width: 30px;" type="text" value="5"/> | Samples thawed <input type="checkbox"/> |
| | Purple <input checked="" type="checkbox"/> | <input style="width: 30px;" type="text" value="3"/> | <input style="width: 30px;" type="text" value="3"/> | Samples missing <input type="checkbox"/> |
| | Green/Yellow <input type="checkbox"/> | <input style="width: 30px;" type="text"/> | <input style="width: 30px;" type="text"/> | Other <input type="checkbox"/> |
| 3. <input style="width: 80px;" type="text" value="2017602"/> | Red <input checked="" type="checkbox"/> | <input style="width: 30px;" type="text" value="5"/> | <input style="width: 30px;" type="text" value="5"/> | Red samples hemolyzed <input type="checkbox"/> |
| | Purple <input checked="" type="checkbox"/> | <input style="width: 30px;" type="text" value="4"/> | <input style="width: 30px;" type="text" value="4"/> | Purple samples hemolyzed <input type="checkbox"/> |
| | | | | Tube(s) broken <input type="checkbox"/> |
| | | | | Samples thawed <input type="checkbox"/> |

Figure 40. T1DGC Clinic Shipping Form – Contents Sheet.

VI. QUERY SYSTEM

The T1DGC Query System has been created in order to resolve data editing questions. This is to be used as a tool for the Regional Network Centers to record and identify sources of action required to correct mistakes or clarify unexpected database values. The responses that the Regional Network Centers enter into this system will be used to create reports for the Steering Committee, Forms Data Committee, and External Advisory Committee.

The Query System is a dynamic system that updates within 30 minutes after data forms have been entered or a query has been corrected. The process that updates the query data tables is run every 30 minutes and starts at 15 and 45 minutes after the hour. Any changes in the underlying data will be reflected in the query system after the next run. The Regional Network Centers can use the query system as a tool shortly

after data forms have been entered into the database (*i.e.*, within the same timetable as described above) to review data entry.

A. Query System Responses

Queries can be answered in seven ways (Figure 41):

1. RNC - Data Edited: This is selected if a data entry error occurred at the Regional Network Center; the Regional Network Center must go to the form and correct the data entry error. This query does not need to be sent to the clinic.

Note: It is not required to enter this response into the query system. If the form is corrected in the data entry system and the query has been resolved appropriately, the query will no longer appear in the query system after the next automated run (as described above).

2. RNC - Verified: This is selected when the Regional Network Center has reviewed the form and verified that the form was entered correctly into the system.

3. Clinic - Edited: This is selected when the clinic has reviewed the form and found the form was recorded incorrectly, edited the form, and returned the edited forms to the Regional Network Center. The Regional Network Center should enter the correct forms and then indicate the query has been "Clinic – Edited."

Note: It is not required to enter this response into the query system. If the form is corrected in the data entry system and the query has been resolved appropriately, the query will no longer appear in the query system after the next automated run (as described above).

4. Clinic - Verified: This is selected when the clinic has reviewed the form and verified that the form was recorded correctly. It is the Regional Network Center's responsibility to document the verification of the query.
5. Past Verified: This option is no longer active. Previously, Regional Network Centers were instructed to select this option when they had already received information from the clinic that the information was correct. The value is an automated, display-only response and cannot be selected. Queries marked this way do not have to be changed to "Clinic – Verified," but should be marked accordingly in the future.
6. CoC - Must Correct: The Coordinating Center marks this response if a query has been selected as "RNC – Verified" or "Clinic – Verified", but needs to be edited or corrected. The Regional Network Center cannot select this option. If this selection is marked, the Regional Network Center should review the form to confirm data entry and then must go back to the clinic to resolve the query. This response is used for queries regarding a crucial field that must be correct.
7. CoC - Clinic Verify: The Coordinating Center marks this response if a query has been selected as "RNC – Verified", but needs to be verified at the clinic level. The Regional Network Center cannot select this option. If this selection is marked, the Regional Network Center must go back to the clinic to verify the query. This response is used for queries where verification of data entry "RNC-Verified" is not sufficient.

The screenshot shows the 'TYPE 1 DIABETES GENETICS CONSORTIUM' header with navigation links: Home, Forms, Double Data Entry, HLA Lab, DNA Lab, AA Lab, Administration, Query System, Reports, Logout. Below the header, it indicates the user is logged in as 'lperdue --' and is viewing messages for 'Region 2 Clinic 2280 and Family 20553'. A 'View Filter' dropdown is set to 'ALL' with an 'Update View' button and a 'Back to Filter Page' link. The main content is a table with 5 rows of query data. Each row includes columns for Form, ID, Value, Rule Name/Message, Regional Disposition, and OK. The 'Regional Disposition' column contains dropdown menus with various status options like 'RNC - Verified', 'RNC - Data edited', 'Clinic - Edited', 'Clinic - Verified', 'Past Verified', 'CoC: Must Correct', and 'CoC: Clinic Verify'. The 'OK' column contains 'Yes' dropdown menus. A 'Submit' button is located at the bottom of the table.

| | Form | ID | Value | Rule Name/Message | Regional Disposition | OK |
|---|--------------|---------|-------|---|---|-----|
| 1 | Blood | 2055301 | 2 | Q06_Aliquots. Q06c) Confirm: No (2) | RNC - Verified | Yes |
| 2 | Blood | 2055303 | 2 | Q06_Aliquots. Q06c) Confirm: No (2) | RNC - Data edited RNC - Verified | Yes |
| 3 | Blood | 2055304 | 2 | Q06_Aliquots. Q06c) Confirm: No (2) | Clinic - Edited Clinic - Verified Past Verified | Yes |
| 4 | Blood | 2055307 | 2 | Q06_Aliquots. Q06c) Confirm: No (2) | CoC: Must Correct CoC: Clinic Verify | Yes |
| 5 | Blood Redraw | 2055301 | 2 | Q07_Blood_Collection. Q07c) Please confirm: No (2) | RNC - Verified | Yes |

Figure 41. Query system regional dispositions.

B. Filtering the Query List

The query list can be filtered to only display queries with one type of status; queries only from a specific region (location); and/or clinic (region). When a user first opens the query system, the default filter displays all queries. However, the user can modify the list of queries using one or more of the three filters if so desired. There are 13 status options for filtering the queries (Figure 42):

1. All: This will show all queries in the query system.
2. All but Past Verified: This will show all queries except those that have been verified in the past by a clinic or the Regional Network Center and are marked as “Past Verified”
3. RNC - Data Edited: This will show all queries that have been marked as “RNC-data edited” (*i.e.*, a data entry error has occurred). If all forms have been appropriately updated in the query system, no queries should be marked this way after the system has been updated (*i.e.*, every half hour).

4. RNC - Verified: This will show all queries that have been marked as “RNC - Verified” (*i.e.*, the Regional Network Center has confirmed that the data entry system entry reflects what is on the data form).
5. Clinic - Edited: This will show all queries that have been marked as “Clinic - Edited” (*i.e.*, clinic has sent a revised copy of the form and the Regional Network Center will or has modified the data entry system accordingly). If all forms have been appropriately updated in the query system, no queries should be marked this way, after the system has been updated (*i.e.*, every half hour).
6. Clinic - Verified: This will show all queries that have been marked “Clinic - Verified” (*i.e.*, the clinic has verified the information is correct through written documentation).
7. Unanswered: This will show all queries that do not have a response entered or for which “Unanswered” has been selected.
8. Past Verified: This will show all queries that the clinic or Regional Network Center has verified in the past. This will not include queries that have been marked as “RNC – Verified” or “Clinic – Verified.”
9. CoC: Must Correct: This will show all queries the Coordinating Center has reviewed that must be corrected by either the Regional Network Center or the clinic.
10. CoC: Clinic Verify: This will show all queries the Coordinating Center has reviewed and must be verified by the clinic rather than the Regional Network Center.

11. OK: This will show all queries that the Coordinating Center has reviewed and are acceptable as verified by the Regional Network Center. When all queries have been reviewed, all queries should be marked as "OK."
12. CoC: To Review: This filter will be used primarily by the Coordinating Center to show only the queries that the Regional Network Center has verified, but have not been approved by the Coordinating Center. All queries will be signed off by the Coordinating Center, after the Regional Network has marked the queries as verified.

TYPE 1 DIABETES GENETICS CONSORTIUM

Home Forms Double Data Entry HLA Lab DNA Lab AA Lab Administration Query System Reports Logout

You are logged in as Username: lperdue --

| Status | Region (Location) | Clinic (Region) | Enter Id |
|--------|-------------------|-----------------|----------------------|
| ALL | ---Select--- | ---Select--- | <input type="text"/> |

Filter Records

Submit

Note: This displays (except data entry screens) are based upon a "point in time" view of the data. The process, which updates the data, will not be reflected in the query system until the next run. Any updates through the query system will update the actual live data.

Last PIT update: 2011-01-31 12:45:01.887

Figure 42. Filtering the T1DGC query system, using query status.

The user can filter the queries by status at any level of the query system: region, clinic, family or within the family data form queries. Once the user selects the filter the system, the user must click **Update View**. The system does not filter automatically once the user selects one of the above choices. Once a user has filtered the query system, to change the filter again, the user must select the new way to filter the system and click **Update View**. As the user moves between the levels (region, clinic, family,

family data forms), the system remembers the last filtering selection the user made and will carry the filter selection throughout each level.

C. Query System Basics

To use the query system:

1. Login to the T1DGC data entry web site.
2. Click on the link at the top of the page entitled “Query System.”
3. Based upon the status selected, the total count of queries is listed beside the region (location) and clinic (region).
4. If the user is working on a specific family or case-control participant, the user can enter the family or case-control ID under “Enter ID” and click the **Submit** button. If no queries are associated with the ID entered, the system will display a message at the top of the screen “No queries associated with Family ID XXXXX.”
5. The user should filter the system based upon their needs, as described above.
6. The user will be directed to a listing of all family IDs and case-control IDs associated with the filtered view. A separate listing is present for any queries on the Shipping Forms since these may contain multiple family IDs. Family IDs are associated with the clinic where the *T1DGC Consent Summary Form* is completed (Figure 43).

TYPE 1 DIABETES GENETICS CONSORTIUM

Home Forms Double Data Entry HLA Lab DNA Lab AA Lab Administration Query System Reports Logout

You are logged in as Username: lperdue --

Status: ALL Region (Location): Asia-Pacific (Philippines) - 22 Clinic (Region): ---Select---

Filter Records

Enter Id: Submit

| Family | Clinic | Message Count |
|----------|--------|---------------|
| Shipping | 1120 | 5 |
| 10016 | 1120 | 1 |
| 10028 | 1120 | 1 |
| 10308 | 1120 | 1 |
| 10311 | 1120 | 1 |
| 10455 | 1120 | 3 |
| 10566 | 1120 | 1 |
| 10568 | 1120 | 1 |
| 10655 | 1120 | 1 |
| 10839 | 1120 | 2 |
| 10886 | 1120 | 2 |
| 10931 | 1120 | 1 |
| 11354 | 1120 | 2 |

Figure 43. View of the query system after filtering by region (location).

- The user can view the queries associated with the family ID, case-control ID or shipping forms by click on the message count (Figure 44).

TYPE 1 DIABETES GENETICS CONSORTIUM

Home Forms Double Data Entry HLA Lab DNA Lab AA Lab Administration Query System Reports Logout

You are logged in as Username: lperdue --

Viewing Messages for Region 1 Clinic 1120 and Family 10455.

View Filter: ALL Update View

[Back to Filter Page](#)

| Form | ID | Value | Rule Name/Message | Regional Disposition | OK |
|---------------------|---------|-------|--|----------------------|----|
| 1 Trio Blood Redraw | 1045502 | 2006 | Q01_Redraw_Date. Q01) Blood re-collection date appears out of range (before 2008), please confirm | - | - |
| 2 Trio Blood Redraw | 1045502 | 2 | Q07_Blood_Collection. Q07a) Please confirm: No (2) | - | - |
| 3 Trio Blood Redraw | 1045502 | 1 | Q07_Blood_Collection. Q7c) Conflicts with green or yellow tubes collected (Q7a), please confirm | - | - |

Submit

Figure 44. List of queries associated with a family ID.

8. Queries are listed with certain information in order to better help the user determine the query:
 - a. *Form*: The form on which the query appears. The query system also contains cross-form checks. Cross-form queries will appear twice in the query list, once for each form (*i.e.*, if date of birth is not recorded the same on the Eligibility Form and the Exam Form, this query will appear under both forms). The query response on the forms in cross-form checks should be the same for both forms.
 - b. *ID*: This lists the family or participant ID relevant to the form. For the Consent Summary Form and Eligibility Forms, this will be the family ID; for all other forms, the participant ID will appear in this column.
 - c. *Value*: This is the value that has been entered in the T1DGC data entry system. This value should be checked against the forms by the Regional Network Center.
 - d. *Rule Name/Message*: This will list the warning or error that was displayed during data entry. If this is a cross-form check, the rule name is displayed as “Irregularities” and follows with information specific to the problem encountered on the form.
 - e. *Regional Disposition*: This is the column the Regional Network Center and/or Coordinating Center will update according to how the query was resolved.
 - f. *OK*: This lists whether the Coordinating Center has reviewed the query once a response has been marked. If “Yes” is entered, the response is approved. If the Coordinating Center determines

further action is needed, the Coordinating Center will update the “Regional Disposition” field. The Regional Network Center staff cannot answer in this column.

D. Resolving Queries at the Regional Network Center

The Regional Network Center should have the copy of the form set on hand when entering information into the query system in order to accurately portray how the query is resolved.

When a query is reported, the Regional Network Center first ensures the information was correctly entered into the database. The user should refer to the specified form and check what is on the form against what is reported in the “Value” column. (Helpful hint: To enable the user to make the corrections more easily, having two data entry system pages open at the same time will allow the user to move between the query system and the home page where the family/participant data forms can be accessed.)

In some cases, the Regional Network Center may already know that the information in the database is correct. The Regional Network Center does not need to re-confirm a query with the clinic in cases such as these. The Regional Network marks queries as “RNC-Verified” only for cases where the Regional Network Center is sure the information is correct. Queries marked this way are reviewed by the Coordinating Center. If the Coordinating Center determines the query must be resolved at the clinic level, the Coordinating Center will update the “Regional Disposition” appropriately. See Appendix C for a list of queries that can be verified by the Regional Network Center and those queries that must be verified or corrected by the clinic.

If the user determines a particular query is not a data entry error or is unaware of the circumstances surrounding the query, this query must be sent to the clinic for correction or verification. Queries cannot be corrected or confirmed with clinic staff over

the phone; some type of written documentation must exist (*i.e.*, for corrections, this must be the corrected form).

All queries marked with a “Regional Disposition” will be reviewed by the Coordinating Center. The Coordinating Center will update the “Regional Disposition” field appropriately for queries that must be corrected and cannot be verified.

E. Confirming Verification at the Coordinating Center

The Coordinating Center reviews each query that is verified at either the Regional Network Center or clinic level. There are certain essential fields that must be corrected and cannot be verified. (See Appendix C for a list of queries that must be corrected.) Other fields should only be verified at the clinic level, and cannot be verified at the Regional Network Center.

The Coordinating Center has three options when reviewing queries that have been verified: (1) instruct the Regional Network Center to send the query back to the clinic and/or lab for correction; (2) instruct the Regional Network Center to send the query to the clinic for verification; or (3) approve the verification. For guidelines as to the type of queries in each of these categories, see Appendix C.

1. Critical Fields (“CoC: Must Correct”)

The Coordinating Center has designated certain fields that cannot be left blank or incorrect. If the Regional Network Center or clinic verifies any queries in these critical fields, the Coordinating Center will instruct the Regional Network Center to send the query back to the clinic and/or laboratory (for some Shipping Form problems) for correction. A corrected version of the form must be received and re-entered at the Regional Network Center.

2. Queries Requiring Verification by the Clinic (“CoC: Clinic Verify”)

The Coordinating Center has designated certain fields that cannot be verified by the Regional Network Center, but must be verified at the clinic level. If the Coordinating

Center marks a query as “CoC: Clinic Verify” the query must be sent to the clinic, the Regional Network Center cannot verify this query. Documentation of verification by the clinic must be retained at the Regional Network Center. Once the verification has been received, the Regional Network Center should update the “Regional Disposition” to “Clinic – Verified.”

3. Approved Verification Queries

The Coordinating Center will mark “Yes” in the “Ok” column for queries that have been resolved correctly and no further action is required. Once these queries have been approved by the Coordinating Center, they will be removed from reports.

Occasionally, there may be queries in the first two categories that are special circumstances. The Regional Network Center should communicate the circumstances with their Network Project Manager in order for the verification to be approved.

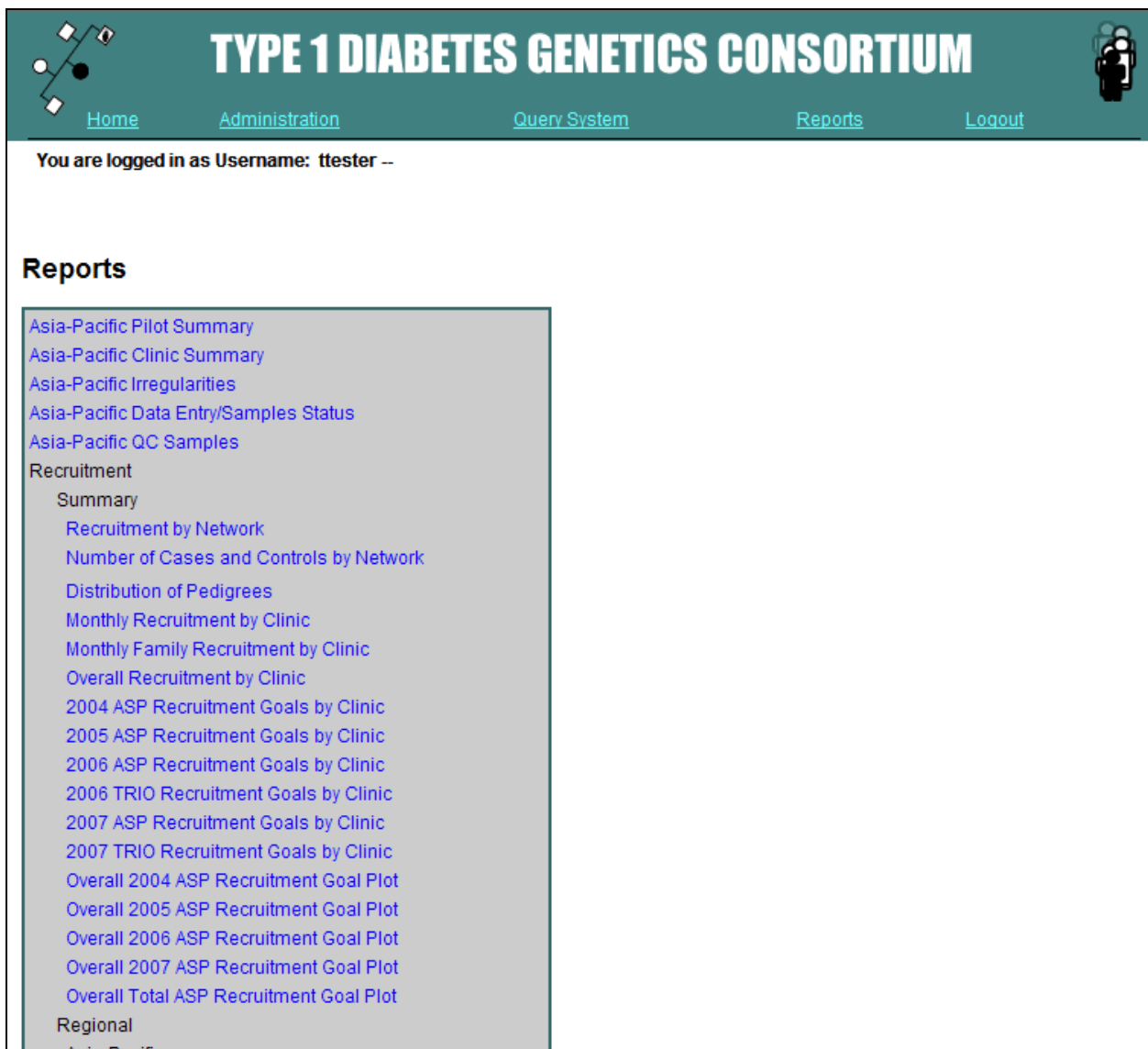
F. Useful Tips

1. When filtering the query system, the user must select the type of filter to apply and click “Update View.”
2. When a user first opens the query system, filtering by “unanswered” will allow the user to view only queries that have not been answered. As each query is answered, it will disappear from the screen.
3. To view all queries that the Coordinating Center has reviewed, but not approved, filter by “CoC: To Review.” This allows the Regional Network Center to view all queries that have been answered but require further attention by the Coordinating Center.
4. Using the “Back to Filter Page” selection centered above the top of the tables throughout the query system marks the clinic or family that the user was most

recently working on with a star. Clicking the “back” button on the web browser will not star the clinic or family last viewed.

VII. REPORTS

To view online reports, the user selects “Reports” from the upper navigational menu. Reports are divided into three sections: Recruitment, QC, and Statistical (Figure 45). To view a report, the user clicks on the name of the desired report to view and is taken directly to the report.



The screenshot shows the website interface for the Type 1 Diabetes Genetics Consortium. At the top, there is a teal header with the title "TYPE 1 DIABETES GENETICS CONSORTIUM" in white. To the left of the title is a logo consisting of a network diagram with white and black nodes. To the right is a small icon of two people. Below the title, there is a navigation menu with links for "Home", "Administration", "Query System", "Reports", and "Logout". Below the navigation menu, a message states "You are logged in as Username: ttester --". The main content area is titled "Reports" and contains a list of report links. The links are organized into sections: "Asia-Pacific Pilot Summary", "Asia-Pacific Clinic Summary", "Asia-Pacific Irregularities", "Asia-Pacific Data Entry/Samples Status", "Asia-Pacific QC Samples", "Recruitment", "Summary", "Recruitment by Network", "Number of Cases and Controls by Network", "Distribution of Pedigrees", "Monthly Recruitment by Clinic", "Monthly Family Recruitment by Clinic", "Overall Recruitment by Clinic", "2004 ASP Recruitment Goals by Clinic", "2005 ASP Recruitment Goals by Clinic", "2006 ASP Recruitment Goals by Clinic", "2006 TRIO Recruitment Goals by Clinic", "2007 ASP Recruitment Goals by Clinic", "2007 TRIO Recruitment Goals by Clinic", "Overall 2004 ASP Recruitment Goal Plot", "Overall 2005 ASP Recruitment Goal Plot", "Overall 2006 ASP Recruitment Goal Plot", "Overall 2007 ASP Recruitment Goal Plot", "Overall Total ASP Recruitment Goal Plot", "Regional", and "Asia Pacific".


Figure 45. List of online reports.

A. Monitoring of Reports

Monitoring of study data occurs at both the Coordinating Center and the Regional Network Center in order to achieve and maintain a high level of quality and comparability of data collection worldwide. Some of the monitoring and quality control reports are transmitted to the Regional Network Centers for immediate action and attention. Other quality control and monitoring reports are generated for the Quality Control Committee, Project Office, Steering Committee, and External Advisory Committee on an as-needed basis.

B. Participant Shipments Report

The Participant Shipments Report was created to allow the user to determine all shipping IDs associated with a participant. The user selects “Participant Shipments” from the list of reports and is directed to enter the participant ID and the shipments and/or HLA plates to search for the participant ID (Figure 46). Participant IDs should be scanned or entered without any dashes (e.g., 1000101). The user can check the shipments and/or HLA plates they want to have displayed or if no forms are checked, the report will default and display all the associated shipping IDs and HLA plates. The Participant Shipments Report lists all associated shipping IDs and/or HLA plates where the participant ID is listed. The number and type of samples included in each shipment is also displayed (Figure 47).



TYPE 1 DIABETES GENETICS CONSORTIUM

[Home](#)
[Administration](#)
[Query System](#)
[Reports](#)
[Logout](#)

You are logged in as Username: **ttester** --

Enter the participant ID for which you would like to view shipments and/or plates:

Check the different shipping forms and/or HLA Plates you want to search in.
If left blank all shipping forms and plates will be searched.

| | |
|---|--|
| <input type="checkbox"/> CLINIC SHIPPING FORM | <input type="checkbox"/> AA to McKesson |
| <input type="checkbox"/> DNA to HLA | <input type="checkbox"/> DNA to Rutgers - DNA Samples |
| <input type="checkbox"/> DNA to CIDR | <input type="checkbox"/> DNA to Rutgers - Cell Lines |
| <input type="checkbox"/> DNA to Contributing Investigator | <input type="checkbox"/> DNA to MHC Fine Mapping Lab |
| <input type="checkbox"/> DNA to Rapid Response Lab | <input type="checkbox"/> DNA for HLA QC Exercise |
| <input type="checkbox"/> DNA to Fisher - DNA Samples | <input type="checkbox"/> DNA to DIL |
| <input type="checkbox"/> DNA to Fisher - PBMC | <input type="checkbox"/> AA to Denver |
| <input type="checkbox"/> DNA to Consortium Members | <input type="checkbox"/> HLA to Chori |
| <input type="checkbox"/> DNA to UVA - PBMC | <input type="checkbox"/> DNA to UVA - Cell Packs |
| <input type="checkbox"/> DNA to UVA - Cell Lines | <input type="checkbox"/> DNA to NIDDK - Whole Genome Amplified |
| <input type="checkbox"/> HLA Master PCR Plate | <input type="checkbox"/> HLA Subtyping PCR Plate |
| <input type="checkbox"/> HLA Redo PCR Plate | |

Figure 46. Entering a participant ID into the Participant Shipments Report.

TYPE 1 DIABETES GENETICS CONSORTIUM

[Home](#)
[Administration](#)
[Query System](#)
[Reports](#)
[Logout](#)

You are logged in as Username: **ttester --**

Enter the participant ID for which you would like to view shipments and/or plates:

Check the different shipping forms and/or HLA Plates you want to search in.
If left blank all shipping forms and plates will be searched.

| | |
|--|---|
| <input type="checkbox"/> CLINIC SHIPPING FORM <input type="checkbox"/> DNA to HLA <input type="checkbox"/> DNA to CIDR <input type="checkbox"/> DNA to Contributing Investigator <input type="checkbox"/> DNA to Rapid Response Lab <input type="checkbox"/> DNA to Fisher - DNA Samples <input type="checkbox"/> DNA to Fisher - PBMC <input type="checkbox"/> DNA to Consortium Members <input type="checkbox"/> DNA to UVA - PBMC <input type="checkbox"/> DNA to UVA - Cell Lines <input type="checkbox"/> HLA Master PCR Plate <input type="checkbox"/> HLA Redo PCR Plate | <input type="checkbox"/> AA to McKesson <input type="checkbox"/> DNA to Rutgers - DNA Samples <input type="checkbox"/> DNA to Rutgers - Cell Lines <input type="checkbox"/> DNA to MHC Fine Mapping Lab <input type="checkbox"/> DNA for HLA QC Exercise <input type="checkbox"/> DNA to DIL <input type="checkbox"/> AA to Denver <input type="checkbox"/> HLA to Chori <input type="checkbox"/> DNA to UVA - Cell Packs <input type="checkbox"/> DNA to NIDDK - Whole Genome Amplified <input type="checkbox"/> HLA Subtyping PCR Plate |
|--|---|

Participant ID 1007304 appears in the Clinic shipping form 2 times.

| Shipping ID | Date Shipped | Date Received | Clinic ID | Type of Shipment | Red Sent | Red Arrived | Purple Sent | Purple Arrived | Green Sent |
|-------------|--------------|---------------|-----------|---|----------|-------------|-------------|----------------|------------|
| 10000000285 | 11/4/2004 | 11/5/2004 | 1030 | Autoantibody/Storage (red/purple caps; shipped monthly; frozen) | 5 | 5 | 4 | 4 | |
| 10000000272 | 10/26/2004 | 10/27/2004 | 1030 | Cell Line (green or yellow tops) and/or Cell Pack (purple tops) (shipped daily; room temperature) | | | 1 | 1 | 2 |

Participant ID 1007304 appears in the AA to McKesson shipping form 2 times.

| AA Shipping ID | Date Shipped | NIDDK CENTRAL REPOSITORY | Number Packed | Number of unique IDs in shipment | Serum Sent | Plasm |
|----------------|--------------|--------------------------|---------------|----------------------------------|------------|-------|
| 10000001167 | 1/22/2007 | 701 | 81 | 21 | 2 | |
| 10000001148 | 2/20/2006 | 701 | 81 | 20 | 2 | |

Figure 47. Participant Shipments Report, listing all shipments associated with a participant.

VIII. SECURITY

Normally, data are transmitted across the Internet as plain text. It is possible, though highly unlikely, for someone to monitor this traffic, and using the proper equipment, reconstruct the individual pieces into the original data. Due to this threat, we employ a digital server certificate from Verisign, Inc. This certificate allows communications between the web server and the client system to be encrypted. This encryption is as advanced as is now allowable by the United States government. This is the same mechanism used by the banking industry and for electronic commerce. This system provides more than adequate security against unauthorized use.

Restricted areas of the web site are protected by user login. Prior to gaining access to the restricted area, the user is required to enter a username and password that is checked against a database. If the combination is correct, a "flag" is set to allow

the user to enter certain areas of the web site. If a user's username or password is entered incorrectly 3 times or more, he/she is locked out of the system and must contact the Coordinating Center. For security purposes, once a user has successfully logged into the system, inactivity for a period of 30 minutes automatically forces the user to re-authenticate prior to using the system again. It is strongly recommended that users log out of the system before leaving their work area for any extended period.

The Coordinating Center is protected by a Cisco firewall that limits the source and type of traffic coming into the institution. This product remains under constant monitoring and control.

IX. DATABASE MANAGEMENT SYSTEM (DBMS) SOFTWARE UPDATES

Throughout the T1DGC study, the Coordinating Center will periodically update the database management system. If significant changes are made to the system, all Regional Network Center staff are notified via the main page of the web site (Figure 48).

TYPE 1 DIABETES GENETICS CONSORTIUM

[Home](#) [Forms](#) [Double Data Entry](#) [HLA Lab](#) [DNA Lab](#) [AA Lab](#) [Administration](#) [Query System](#) [Reports](#) [Logout](#)

You are logged in as Username: lhoward --

News and Notes

1. Updates to many aspects of the website will be pushed out live tonight. Thus, certain pieces of the website might be unavailable from 6 till 8 EST in the US.
2. FOR LABS ONLY: The shipments entered report has been updated to reflect the new shipping forms. The report can be used to verify whether shipments have been entered into the system. The report is located on the reports page under Summary Reports.
3. The system will automatically logout any user who has been inactive for more than 30 minutes.

Scan or Enter a Family ID:

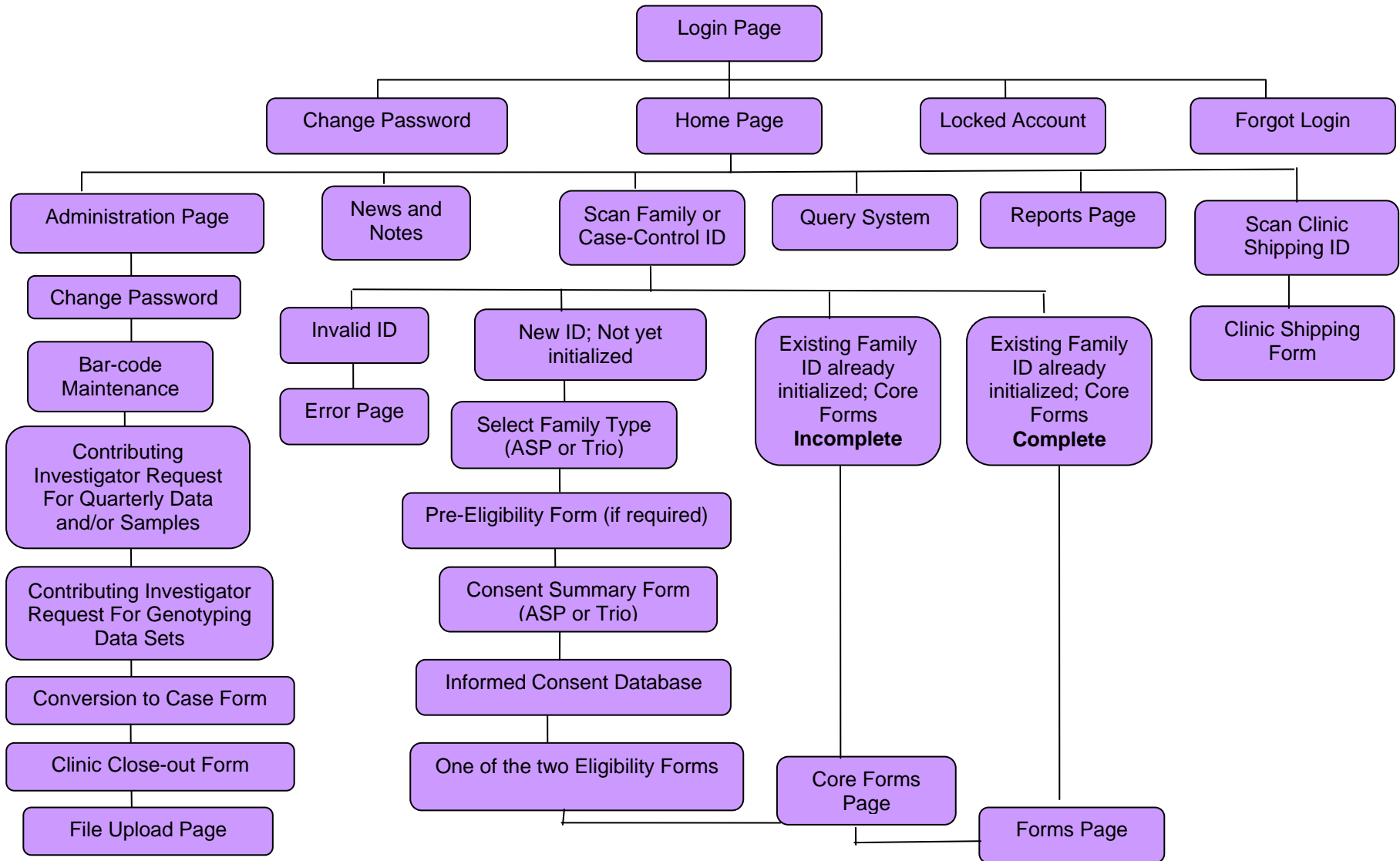
Scan or Enter a Shipping ID:

Figure 48. Data entry system home page with sample news.

X. DISASTER RECOVERY

All data, programs, code, and documents associated with the T1DGC project are backed up to a DLT tape library every night. These tapes are kept indefinitely and are located in a fireproof cabinet that remains locked at all times. Periodically, copies of tapes are moved to an off-site location for storage. In the event that there is loss of any data, the information can be restored from tape in a matter of hours. The entire computer facility is provided with conditioned power, UPS capability and environmental sensors with notification protocols.

APPENDIX A DATA ENTRY WEB SITE FLOW CHART



APPENDIX C
EXAMPLES OF QUERY SYSTEM RESPONSES

| Form | Question | Rule Message | Who Can Verify Query |
|-------------|-----------------|--|-----------------------------|
| Blood | 2 | Should be missing, see blood collected | RNC, Clinic |
| Blood | 3 | Appears out of range | RNC, Clinic |
| Blood | 4 | Appears out of range | RNC, Clinic |
| Blood | 4 | Appears out of range (before time collected) | RNC, Clinic |
| Blood | 4 | Missing | RNC, Clinic |
| Blood | 5 | Appears out of range | RNC, Clinic |
| Blood | 5 | Appears out of range (before time collected) | RNC, Clinic |
| Blood | 5 | Missing | RNC, Clinic |
| Blood | 6a | Should be missing, see blood collected | RNC, Clinic |
| Blood | 6a | Confirm no | Clinic |
| Blood | 6b | Appears out of range | RNC, Clinic |
| Blood | 6c | Missing | Must be corrected |
| Blood | 6c | Conflicts with green tubes collected (6a) | RNC, Clinic |
| Blood | 6c | Should be missing, see blood collected | RNC, Clinic |
| Blood | 6d | Should be missing, see blood collected | RNC, Clinic |
| Blood | 6d | Confirm no | RNC, Clinic |
| Blood | 6e | Appears out of range | RNC, Clinic |
| Blood | 6f | 6f is no, 6h is yes | Must be corrected |
| Blood | 6f | Should be missing, see blood collected | RNC, Clinic |
| Blood | 6f | Confirm no | RNC, Clinic |
| Blood | 6g | Appears out of range | Clinic |
| Blood | 6h | Should be missing, see blood collected | RNC, Clinic |
| Blood | 6h | Confirm no | RNC, Clinic |
| Blood | 6h | Confirm yes, conflicts with Q6f | Must be corrected |
| Blood | 6h | Should be missing, see blood collected | RNC, Clinic |
| Blood | 7 | Missing | Must be corrected |
| Blood | 7 | Should be missing, see blood collected | RNC, Clinic |
| Blood | 10b | Appears out of range | Clinic |

| | | | |
|-----------------|-----|---|-------------------|
| Blood | 10c | 10c is no, 10e is yes | Must be corrected |
| Blood | 10d | Appears out of range | Clinic |
| Blood | 10e | Confirm no | RNC, Clinic |
| Blood | 10e | Missing | RNC, Clinic |
| Blood | | Cell line samples inconsistent | Must be corrected |
| Blood | | Cell pack collection missing | Must be corrected |
| Blood | | Cell pack samples inconsistent | Must be corrected |
| Blood | | Serum samples inconsistent | Must be corrected |
| Blood | | Plasma samples inconsistent | Must be corrected |
| Blood | | Clinic ID inconsistent | RNC, Clinic |
| Blood | | QC serum samples inconsistent | Must be corrected |
| Blood | | QC plasma samples inconsistent | Must be corrected |
| Blood | | QC cell pack samples inconsistent | Must be corrected |
| Blood | | Samples inconsistent | Must be corrected |
| Blood Redraw | 7a | Should be missing, see blood collected | RNC, Clinic |
| Blood Redraw | 7a | Confirm no | Clinic |
| Blood Redraw | 7b | Appears out of range | RNC, Clinic |
| Blood Redraw | 7c | Missing | Must be corrected |
| Blood Redraw | 7c | Conflicts with green tubes collected (7a) | RNC, Clinic |
| Blood Redraw | 7c | Should be missing, see blood collected | RNC, Clinic |
| Blood Redraw | 7d | Should be missing, see blood collected | RNC, Clinic |
| Blood Redraw | 7d | Confirm no | RNC, Clinic |
| Blood Redraw | 7e | Appears out of range | RNC, Clinic |
| Blood Redraw | 7f | 7f is no, 7h is yes | Must be corrected |
| Blood Redraw | 7f | Should be missing, see blood collected | RNC, Clinic |
| Blood Redraw | 7f | Confirm no | RNC, Clinic |
| Blood Redraw | 7g | Appears out of range | Clinic |
| Blood Redraw | 7h | Should be missing, see blood collected | RNC, Clinic |
| Blood Redraw | 7h | Confirm no | RNC, Clinic |
| Blood Redraw | 7h | Confirm Yes, conflicts with Q7f | Must be corrected |
| Blood Redraw | | Cell line samples inconsistent | Must be corrected |
| Blood Redraw | | Cell pack collection missing | Must be corrected |
| Blood Redraw | | Cell pack samples inconsistent | Must be corrected |
| Blood Redraw | | Serum samples inconsistent | Must be corrected |
| Blood Redraw | | Plasma samples inconsistent | Must be corrected |
| Blood Redraw | | Clinic ID inconsistent | RNC, Clinic |
| Blood Redraw | | Samples inconsistent | Must be corrected |
| Consent Summary | 1 | Consent date appears out of | Must be corrected |

| | | | |
|----------------------------------|------|--|-------------------|
| | | range | |
| Consent Summary | 2 | Consent date appears out of range | Must be corrected |
| Consent Summary | 3 | Consent date appears out of range | Must be corrected |
| Consent Summary | 4 | Consent date appears out of range | Must be corrected |
| Consent Summary | 5 | Consent date appears out of range | Must be corrected |
| Consent Summary | 6 | Consent date appears out of range | Must be corrected |
| Consent Summary | 7 | Consent date appears out of range | Must be corrected |
| Consent Summary | 8 | Consent date appears out of range | Must be corrected |
| Consent Summary | 9 | Consent date appears out of range | Must be corrected |
| Consent Summary | | Consent date after exam date | Must be corrected |
| Elig Additional Affected Sibling | 35 | Appears out of range | RNC, Clinic |
| Elig Guardian | 14 | Time of diagnosis earlier than proband | RNC, Clinic |
| Elig Guardian | 27 | Should be missing, check Q26 | RNC, Clinic |
| Elig Guardian | | Clinic ID inconsistent | RNC, Clinic |
| Elig Proband | 9 | Appears out of range | RNC, Clinic |
| Elig Proband | 13 | Appears out of range | RNC, Clinic |
| Elig Proband | 13 | Time of diagnosis earlier than proband | RNC, Clinic |
| Elig Proband | 23 | Appears out of range (less than elder sib) | RNC, Clinic |
| Elig Proband | 29 | Appears to be before interview date | RNC, Clinic |
| Elig Proband | | Clinic ID inconsistent | RNC, Clinic |
| Exam Affected | 7a | Should be no or not applicable | Must be corrected |
| Exam Affected | | Clinic ID inconsistent | RNC, Clinic |
| Exam Parent | 5 | Appears out of range | RNC, Clinic |
| Exam Parent | 6a | Should be no or not applicable | Must be corrected |
| Exam Parent | 9b | Onset day is missing | RNC, Clinic |
| Exam Parent | 16a | Appears out of range | RNC, Clinic |
| Exam Parent | 16d | Appears out of range | RNC, Clinic |
| Exam Parent | 16d | Appears out of range | RNC, Clinic |
| Exam Parent | | Clinic ID inconsistent | RNC, Clinic |
| Exam Proband | 7a | Should be no or not applicable | Must be corrected |
| Exam Proband | 12c1 | Appears out of range | RNC, Clinic |
| Exam Proband | 12c4 | Appears out of range | RNC, Clinic |

| | | | |
|-------------------|----|---|-------------------|
| Exam Proband | 13 | Appears to be out of range | RNC, Clinic |
| Exam Proband | | Clinic ID inconsistent | RNC, Clinic |
| Exam Unaffected | 8 | Should be no | Must be corrected |
| Exam Unaffected | | Clinic ID inconsistent | RNC, Clinic |
| Shipping (Clinic) | 3 | Appears out of range | RNC, Clinic |
| Shipping (Clinic) | 4 | Appears out of range | RNC, Clinic |
| Shipping (Clinic) | 5 | Appears out of range | RNC, Clinic |
| Shipping (Clinic) | 8 | Arrived date 2 more than packed date | RNC, Clinic |
| Shipping (Clinic) | 10 | Number received not equal to number sent | Must be corrected |
| Shipping (Clinic) | 11 | Pages received not equal to number included | Must be corrected |
| Shipping (Clinic) | | Clinic ID inconsistent | RNC, Clinic |
| Shipping (Clinic) | | Pages packed greater than pages entered | Must be corrected |
| Shipping (Clinic) | | Arrived doesn't match number sent or comments | Must be corrected |
| Shipping (Clinic) | | Number received not equal to number sent | Must be corrected |
| Shipping (Clinic) | | Cell line samples inconsistent | Must be corrected |
| Shipping (Clinic) | | Cell pack samples inconsistent | Must be corrected |
| Shipping (Clinic) | | Plasma samples inconsistent | Must be corrected |
| Shipping (Clinic) | | Serum samples inconsistent | Must be corrected |
| Shipping (Clinic) | | QC Cell pack samples inconsistent | Must be corrected |
| Shipping (Clinic) | | QC Plasma samples inconsistent | Must be corrected |
| Shipping (Clinic) | | QC Serum samples inconsistent | Must be corrected |
| Shipping (Clinic) | | Cell line samples received above limit | Clinic |
| Shipping (Clinic) | | Cell pack samples received above limit | Clinic |
| Shipping (Clinic) | | Serum samples received above limit | Clinic |
| Shipping (Clinic) | | Plasma samples received above limit | Clinic |
| Shipping (Clinic) | | Green arrived appears out of range | Must be corrected |
| Shipping (Clinic) | | Purple arrived appears out of range | Must be corrected |
| Shipping (Clinic) | | Red arrived appears out of range | Must be corrected |
| Shipping (Clinic) | | Samples inconsistent | Must be corrected |
| Shipping (Clinic) | | Tubes broken, shouldn't be checked | Must be corrected |