

SPECIMEN TRACKING AND INVENTORY SYSTEM
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I. INTRODUCTION

The purpose of this chapter is to provide detailed instructions to the DNA Repositories and the Autoantibody and Storage Laboratories for the specimen shipping and tracking system used in the Type 1 Diabetes Genetics Consortium (T1DGC). Instructions for the HLA Genotyping Laboratories are available in **Chapter XIII**, *HLA Genotyping Laboratory System*. The information that follows also will be useful to clinic and Regional Network Center staff and should guide staff at each critical point in the specimen tracking process. It is crucial to the success of the T1DGC that all staff involved, directly or indirectly, follows the outlined tracking procedures. (Appendix A provides an overview of the specimen tracking process.)

II. T1DGC DATA ENTRY WEB SITE

Laboratory staff will access the T1DGC data entry web site for entry of the T1DGC shipping forms. Instructions for logging in and steps to be taken in the event of forgetting the password are also explained below.

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. The username will always be the first initial of the user's name and entire last name. If the user's 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 application interface for the Type 1 Diabetes Genetics Consortium. At the top, there is a teal header bar with the text "TYPE 1 DIABETES GENETICS CONSORTIUM" in white. To the left of the header is a logo consisting of a stylized tree with a black node. To the right is a small icon of two people. Below the header, there 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 fields is a "Login" button.

Figure 1. Login window for T1DGC data entry system.

B. Forgot Password

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.

C. Locked Account

If the user unsuccessfully enters his/her username and password three consecutive times, the system will lock the user out of the web site. In this event, 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.

III. SHIPMENTS FROM CLINICS TO LABORATORIES

A. Types of Specimen Shipments

1. There are two types of specimen shipments from the clinics:
 - (a) cell line samples (green or yellow top tubes) and cell pack samples from the EDTA plasma tubes (purple top tubes); and
 - (b) serum (red top) and plasma (purple top) samples for autoantibody analysis in the proband, affected sibling and case participants (serum sample) and long-term storage samples for all participants (serum and plasma).

2. Cell line and cell pack samples are shipped at ambient temperature for arrival at the DNA Repository within 24 hours of collection (or as close to this time as possible, given geographic constraints). Green top (sodium heparin) tubes are used in all networks, with the exception of the United Kingdom Network where

yellow top (CPDA) tubes are used to collect the cell line samples. The cell pack that remains after aliquoting the EDTA plasma is recapped and shipped with the cell line samples the same day at ambient temperature to the DNA Repository for DNA extraction.

3. Serum samples (maximum of 5 per participant) and plasma samples (maximum of 4 per participant) are placed in storage boxes (with a 10x10 grid) and frozen; the frozen samples are shipped monthly from the clinic to the Autoantibody and Storage Laboratory.
4. The Autoantibody and Storage Laboratory staff is responsible for selecting one serum sample for each proband (purple-striped label), affected sibling(s) (green-striped labels) and case (orange-striped label) included in the shipment. The selected serum samples are analyzed for autoantibodies. All other serum and plasma samples included in the shipment are placed into a freezer for storage in the boxes in which they were shipped.

B. Completing Clinic Shipping Forms at the Clinics

1. The clinic staff completes two *T1DGC Clinic Shipping Forms* when shipping specimens to the laboratories: the *Face Sheet* and the *Contents Sheet*. Both forms are completed for each specimen shipment and are included in the shipping container. (The T1DGC data forms are located on the T1DGC web site: www.t1dgc.org).
2. The clinic staff affixes a bar-coded shipping ID label on the *Face Sheet* and the shipping container. Shipping IDs identify each unique shipment and are associated with a set of participant IDs through the *Contents Sheet*. Shipping IDs are 11-digit numbers that begin with the network identifier (*i.e.*, 1=Asia-Pacific; 2=European; 4=North American; and 5=United Kingdom). **The system for entry of the *Shipping Forms* cannot be accessed without a shipping ID label on the *Face Sheet*.**

3. The clinic staff completes the upper portion of the *Face Sheet* with the following information:
 - (a) full address of the clinic and the laboratory;
 - (b) shipping ID label in the designated space on the form (and a second identical shipping ID label on the shipping container);
 - (c) courier or shipping company used (e.g., Federal Express or World Courier) and the reference or tracking number;
 - (d) type of samples included in the shipment (i.e., cell line and cell pack **or** autoantibody/storage); and
 - (e) name of the clinic contact and his/her phone number.

4. The clinic staff completes the left side of the lower portion of the *Face Sheet* with the following information:
 - (a) clinic ID;
 - (b) date and time the shipment was packed at the clinic;
 - (c) total number of samples packed, confirmed by both counting samples and adding the numbers in the "number vials" column on the contents sheets;
 - (d) number of **contents** pages included; and
 - (e) ID of person packing the samples and completing the shipping forms.

5. The clinic staff completes the *Contents Sheet* by affixing a unique, bar-coded participant ID label that matches the bar-coded participant ID label on the specimen(s) included in the shipment.

6. More than one *Contents Sheet* may be included in each shipment, depending on the number of samples included. The number of pages attached and each page number should be recorded at the top of the contents pages by the clinic staff (e.g., Page 1 of 6, Page 2 of 6, etc.).

7. The clinic staff records the number of each type of sample included in the shipment (e.g., red cap=serum sample; purple cap or top=EDTA plasma sample

OR cell pack; green/yellow top=sodium heparin or CPDA cell line sample). The clinic staff also indicates whether the serum and/or plasma samples were hemolyzed by marking the appropriate check boxes in the column labeled "Comments on Samples".

8. The clinic staff makes two copies of each completed *Face Sheet* and *Contents Sheet*. The original set of shipping forms is included with the samples shipped to the laboratory. One copy is retained at the clinic. The second copy is forwarded from the clinic to the Regional Network Center.

C. Completing Clinic Shipping Forms at the Laboratories

1. When the shipment is received at the laboratory, the laboratory staff will verify contents of the shipment and record the specified information on the lower right portion of the *Face Sheet*. The following items are recorded by the person receiving the shipment:
 - (a) laboratory ID;
 - (b) date and time the shipment arrived at the laboratory;
 - (c) total number of samples received, confirmed by both counting samples and adding the numbers in the "number vials" column on the *Contents Sheets*;
 - (d) number of contents pages received; and
 - (e) initials of person receiving the samples and completing the shipping forms.
2. Complete the *Contents Sheet* by counting and recording the number of samples of each vial color in the column labeled "Arrived" for inventory purposes and acknowledgment of arrival.
3. In the column labeled "Comments on Samples", mark the following selections to indicate discrepancies in the number of samples shipped and the condition of samples in the shipment:

- (a) Tube(s) broken: if the green or yellow top tubes for cell lines are broken or the EDTA cell pack tube is broken. If a tube (or tubes) broke during shipment, record the number of **un**broken tubes received.
- (b) Samples thawed: if sample shipment is thawed upon receipt at the laboratory. If samples thawed, record the total number of samples received.
- (c) Samples missing: if the number of samples “Sent” by the clinic is not the same number of samples received at the laboratory.
- (d) Other: if none of the above indicates the problem with the shipment. Record any specific comments in the margin of the form.

Any discrepancies noted on the *Face Sheet* and *Contents Sheet* between number sent and number received (*i.e.*, content pages, samples) should be corrected. Network laboratory staff should contact the clinic and Regional Network Center coordinator to verify the number sent. If the discrepancy lies with the clinic, the laboratory staff should request a corrected clinic shipping form. The corrected clinic shipping form should be filed with the original shipping form received with the samples at the laboratory.

D. Data Entry of Clinic Shipping Forms at Laboratories

1. Depending on the laboratory with which the user is associated, the user is directed to the DNA Lab Home Page (Figure 4) or the Autoantibody Lab Home Page (Figure 5) after successful login. The first option on both of these menus is the “Clinic Shipping Form.”
2. Select “Clinic Shipping Form” from the lab home page menu.
3. The user is directed to the home page to “scan or enter a shipping ID” (Figure 6).

T1DGC DNA Lab System

- [Clinic Shipping Form](#)
- [DNA Shipping Form to HLA Genotyping Laboratory](#)
- [DNA Shipping Form to Rutgers \(DNA Sample Shipments\)](#)
- [DNA Shipping Form to CIDR](#)
- [DNA Shipping Form to Rutgers \(Cell Line Shipments\)](#)
- [DNA Shipping Form to NIDDK Central BioSample Repository \(Fisher\)](#)
- [DNA Shipping Form to Contributing Investigator](#)
- [DNA Shipping Form to Consortium Members](#)
- [DNA Shipping Form to MHC Fine Mapping Laboratory](#)
- [DNA Shipping Form to Diabetes and Inflammation Laboratory \(DIL\)](#)
- [DNA Shipping Form to Rapid Response Laboratory](#)
- [DNA Shipping Form PBMC to NIDDK Central BioSample Repository \(Fisher\)](#)
- [DNA Shipping Form PBMC to University of Virginia \(UVA\)](#)
- [DNA Shipping Form Cell Pack to University of Virginia \(UVA\)](#)
- [DNA Shipping Form Cell Line DNA to University of Virginia \(UVA\)](#)
- [DNA Shipping Form Whole Genome Amplified DNA to NIDDK Central Repository \(Fisher\)](#)
- [DNA Yield and Aliquot Inventory Upload](#)
- [Cell Line Transformations Upload](#)
- [DNA Shipping Form for HLA QC Exercise](#)
- [AP DNA Repository: Expended & Remaining DNA Stores](#)
- [AP QC DNA Tables 4a, 4b, 7b - Cell Line Detail](#)
- [AP AR0003-0007 AR0009-0010 Shipping Manifest](#)
- [AP AR0013 Shipping Manifest](#)
- [AP DNA Aliquots to Central Repository](#)
- [AP Access Sample Backlog Manifest](#)
- [AP CIDR 2008 Shipping Manifest](#)
- [Asia-Pacific T1DGC Analytic-ID Key](#)
- [AP Residual DNA Aliquots to Central Repository](#)

Figure 4. DNA lab home page.

T1DGC Autoantibody Lab System

- [Clinic Shipping Form](#)
- [Autoantibody Results Reporting Upload](#)
- [Autoantibody laboratory shipping form to McKesson](#)
- [Autoantibody Laboratory Shipping Form: Shipments to Denver](#)

Figure 5. Autoantibody lab home page.

News and Notes
1. The Data Entry website is back online. If you experience any issues please email Dustin Williams at dtwillia@wfubmc.edu

Scan or Enter a Family ID:

SUBMIT

Scan or Enter a Case/Control ID:

SUBMIT

Scan or Enter a Shipping ID:

SUBMIT

Figure 6. T1DGC data entry home page (scan or enter a shipping ID).

4. Position the cursor in the box titled “Scan or Enter a Shipping ID” (Figure 6). Scan the bar-coded shipping ID label from the *Face Sheet*.
5. If the shipping form has not been entered, this will take the user to a data entry screen for the *Face Sheet* (Figure 7). Data enter the entire form (except the fields at the top of the page) and press the “Save” button at the bottom of the page.

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

TO: _____ FROM: _____

SHIPPING ID LABEL: TYPE OF SAMPLES ENCLOSED:

COURIER/SHIPPING COMPANY: _____
TRACKING NUMBER: _____

NAME OF CLINIC CONTACT: _____ PHONE: _____

	COMPLETED BY CLINIC	COMPLETED BY LABORATORY
ID:	1. CLINIC <input type="text"/>	7. LABORATORY <input type="text"/>
DATE:	2. SAMPLES PACKED <input type="text"/> - <input type="text"/> - <input type="text"/> Day Month Year	8. SAMPLES ARRIVED <input type="text"/> - <input type="text"/> - <input type="text"/> Day Month Year
TIME:	3. SAMPLES PACKED <input type="text"/> : <input type="text"/> 24-hour clock	9. SAMPLES ARRIVED <input type="text"/> : <input type="text"/> 24-hour clock
SAMPLES:	4. NUMBER PACKED <input type="text"/>	10. NUMBER RECEIVED <input type="text"/>
CONTENT PAGES:	5. NUMBER INCLUDED (excludes this sheet) <input type="text"/>	11. NUMBER RECEIVED <input type="text"/>
	6. PERSON PACKING SAMPLES (ID) <input type="text"/>	12. PERSON RECEIVING SAMPLES (INITIALS) <input type="text"/>

Figure 7. T1DGC Clinic Shipping Form – Face Sheet.

6. 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 (Figure 8). Informational messages, warnings and error messages will appear if data entered are out of “expected” ranges or fields are left blank for all forms. See **Chapter XI, Data Entry System**, for more details about informational messages, warnings and errors. If any messages are displayed, confirm that the data on the form matches that entered on the web page. If errors (red dots) are displayed, the form **will not** save. If warnings and informational messages are displayed, press the “Save with Warnings” button to continue with entry of the forms.

Form Submission Errors
 -ENCL) Type of Samples Enclosed can not be missing
 01) Clinic ID cannot be missing, and must be a 4-digit number
 02) Packed date cannot be missing
 05) Pages included can not be missing
 07) Lab ID 1st digit must start between '1' and '5'
 07) Lab ID can not be missing, and must consist of a 3 digit-number
 07) Lab ID must end in '01' or '02'
 08) Arrived date can not be missing

Form Submission Warnings
 - Label) Shipping ID begins with '9' and is for test purposes, please confirm
 03) Packed time is missing or incomplete
 04) Number packed is missing
 09) Arrived time is missing or incomplete
 10) Number received is missing
 11) Pages received is missing

Form Submission Info
 06) ID code is missing
 12) Initials are missing

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

TO:	FROM:
SHIPPING ID LABEL: 9999999995	TYPE OF SAMPLES ENCLOSED: [Dropdown Menu]
COURIER/SHIPPING COMPANY:	
TRACKING NUMBER:	
NAME OF	

Figure 8. T1DGC Clinic Shipping Form – Face Sheet (with informational messages, warnings, and errors).

- After a successful save of the *Face Sheet*, the system displays the *T1DGC Clinic Shipping Form – Contents Sheet* (Figure 9).

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

Page:

T1DGC PARTICIPANT ID	Vial Cap	Number of Vials		Comments on Samples (MARK ALL THAT APPLY.)
	Color(s)	Sent	Arrived	
1	Red <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Red samples hemolyzed <input type="checkbox"/>
	Purple <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Purple samples hemolyzed <input type="checkbox"/>
	Green/Yellow <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Tube(s) broken <input type="checkbox"/>
2	Red <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Samples thawed <input type="checkbox"/>
	Purple <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Samples missing <input type="checkbox"/>
	Green/Yellow <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Other <input type="checkbox"/>
3	Red <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Red samples hemolyzed <input type="checkbox"/>
	Purple <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Purple samples hemolyzed <input type="checkbox"/>
	Green/Yellow <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Tube(s) broken <input type="checkbox"/>

Figure 9. T1DGC Clinic Shipping Form – Contents Sheet.

8. Data enter the entire page and press the “Save” button at the bottom of the page. Warning and error messages will appear if data entered are out of “expected” range as discussed previously for *Face Sheet*.
9. The *Contents Sheet* included with the shipment may be more than one page, depending on the number of samples included in the shipment. That is, if specimens for more than six participants are included in a shipment, one or more additional *Contents Sheets* will be associated with the *Face Sheet*. **The *Contents Sheets* are entered and saved one page at a time.**
10. After a successful save of a *Contents Sheet*, or, if a shipping form has previously been entered, the Shipping Form Selection page is displayed (Figure 10).
The user has three options from this page:
 - (a) “Start over with a new shipment” which returns the user to the screen with the box titled “Enter or Scan a Shipping ID”;
 - (b) “Add a shipping contents sheet” which opens up a blank *Contents Sheet*;
or
 - (c) “View a shipping form page” which displays previously entered shipping forms and what is currently saved in the database for the *Face Sheet* or any *Contents Sheet*.

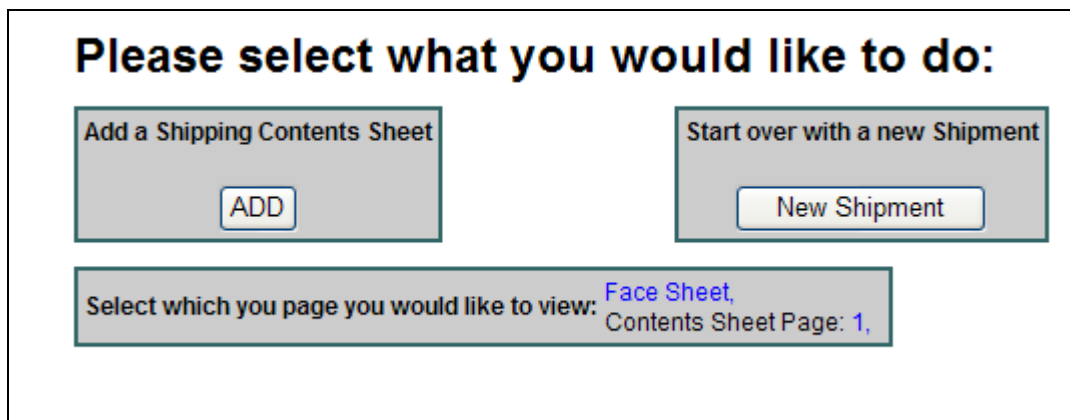


Figure 10. Shipping form selection page.

11. Once the receiving process and data entry for the shipment has been completed, make a copy of the forms for retention at the laboratory and forward the completed original shipping forms to the Regional Network Center as final documentation of the shipment. The original shipping forms can be batched weekly (or on a schedule specified by the Regional Network Center) via regular postal service. (Appendix B provides the contact and shipping information for the Network Coordinators.)

E. Verifying Shipping Form Data Entry at the Regional Network Center

1. Each sample shipment generates two versions of each shipping form at the Regional Network Center: (1) one forwarded by the clinic, indicating completion of the form when the shipment was sent (clinic version); and (2) the original from the laboratory, indicating completion of the form when the shipment was received (laboratory version).
2. The Regional Network Center must verify laboratory entry of *Shipping Forms* for all clinic shipments. The Regional Network Center will contact laboratories regarding any shipping forms received from the clinics that do not appear in the Specimen Tracking system. See **Chapter XI, Data Entry System**, for step-by-step procedures for checking entry of the *T1DGC Shipping Forms*.
3. The Regional Network Center also is responsible for verifying that all information has been entered correctly. The Regional Network Center staff can modify the shipping form at any point in the shipping process if information has been entered incorrectly, but must communicate with the laboratory and the clinic about any changes. **Changes must be reflected on all copies of the shipping forms (clinic, laboratory and Regional Network Center) as follows: mark through the incorrect data with two horizontal lines, record and circle the correct data, and initial and date the correct response.**

4. The *T1DGC Blood Collection Forms* received from the clinics are data entered at the Regional Network Center. These data form the basis for a comparison of samples collected in the clinic with samples that were shipped from the clinic and received at the laboratory (obtained from the shipping forms).
5. Discrepancies between blood collection and shipping forms are communicated to Regional Network Center staff via dynamic reports available on the T1DGC web site or as a direct communication from the Coordinating Center. Regional Network Center staff will resolve discrepancies with the clinics and/or receiving laboratories.

IV. DNA REPOSITORY SHIPMENTS TO OTHER LABORATORIES

A. Overview

The DNA Repository is responsible for generating bar-coded ID labels and a shipping record for cell line and/or DNA samples shipped elsewhere. The bar-coded labels for such samples are either the T1DGC participant ID (preferred), T1DGC analytic ID (for some shipments), or a local laboratory ID that is associated with the participant ID in a database available to the Coordinating Center.

The Coordinating Center provides a web-based application for recording all IDs for samples shipped from the DNA Repository for receipt at other locations. The Coordinating Center also provides the DNA Repository with the shipping ID labels to be used for all shipments from the repository to another facility or laboratory.

The T1DGC DNA Repository Flow Chart in Appendix C provides an overview of this process. Sample shipments from the DNA Repository to other sites include the following:

- (a) DNA sample to the Network HLA Genotyping Laboratory;
- (b) DNA sample to Center for Inherited Disease Research (CIDR)
- (c) DNA sample to MHC Fine Mapping Laboratory;
- (d) DNA sample to Rapid Response Laboratory;

- (e) DNA sample to Diabetes and Inflammation Laboratory (DIL);
- (f) cell line and/or DNA sample to the NIDDK Central Genetics Repository (Rutgers University, New Brunswick, NJ, USA);
- (g) cell line and/or DNA sample for participants contributed by a specific investigator;
- (h) DNA sample to investigators with approval from the T1DGC Access Committee;
- (i) PBMC, cell line and/or DNA sample to University of Virginia (Charlottesville, VA, USA); and
- (j) DNA sample to other DNA Repositories within the T1DGC.

Appendix D provides contact information and shipping addresses for all of the T1DGC HLA Genotyping Laboratories. Appendix E provides contact information and shipping addresses for laboratories receiving samples for T1DGC genotyping projects as well as the NIDDK Central Sample Repositories.

B. Completing DNA Shipping Forms for Shipments to Other Laboratories

1. The DNA Repository staff completes two *T1DGC DNA Shipping Forms* when shipping specimens to other laboratories: the *Face Sheet* and the *Contents Sheet*. Both forms are completed for each specimen shipment and are included in the shipping container. (Data forms are on the T1DGC web site: www.t1dgc.org).
2. The DNA Repository staff affixes a bar-coded shipping ID label on the *Face Sheet* and the shipping container. Shipping IDs identify each unique shipment and are associated with a set of participant IDs through the *Contents Sheet*. Shipping IDs are 11-digit numbers that begin with the network identifier (*i.e.*, 1=Asia-Pacific; 2=European; 4=North American; and 5=United Kingdom). **The system for entry of the *Shipping Forms* cannot be accessed without a shipping ID label on the *Face Sheet*.**

3. The DNA Repository completes the upper portion and the left side of the lower portion of the *Face Sheet*.
4. The *Contents Sheet* can be printed from the T1DGC data entry web site after all participant IDs have been scanned into the system.
5. The DNA Repository staff makes two copies of each completed *Face Sheet* and *Contents Sheet*. The original set of shipping forms is sent to the Coordinating Center. One copy is included with the samples shipped to the receiving laboratory. One copy is retained at the DNA Repository.

C. Data Entry of Shipping Forms at DNA Repositories

Data entry of the DNA Repository shipping forms follows primarily the same steps for all shipments to other facilities.

1. Select the appropriate shipping form from the DNA Lab Home Page.
2. The user is directed to “enter or scan a DNA shipping ID” (Figure 11). Scan the bar-coded shipping ID label from the *Face Sheet*.

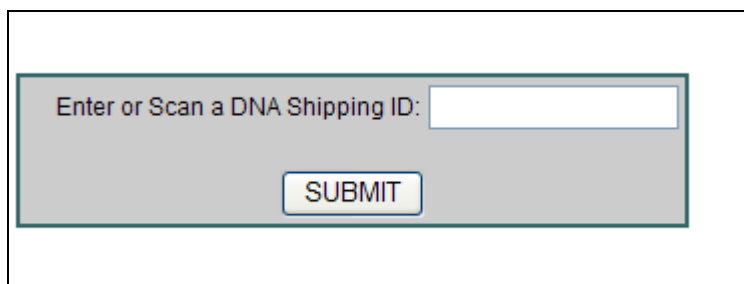
The image shows a screenshot of a web form. At the top, there is a text label "Enter or Scan a DNA Shipping ID:" followed by a white rectangular input field. Below the input field, centered, is a button with the word "SUBMIT" in capital letters. The entire form is enclosed in a thin black border.

Figure 11. Enter or scan a DNA shipping ID.

3. If the shipping form has not been entered, this will take you to a data entry screen for the *Face Sheet* (Figure 12). Data enter the entire form (except the fields at the top of the page) and press the “Save” button at the bottom of the page. Note that for some forms (*i.e.*, *DNA Shipping Form – Shipments to HLA*

Genotyping Laboratory) only the left side of the form is entered by the shipping DNA Repository.

**TYPE 1 DIABETES GENETICS CONSORTIUM
DNA REPOSITORY SHIPPING FORM - FACE SHEET
SHIPMENTS TO RUTGERS (DNA Sample Shipments)**

TO:	FROM:
SHIPPING ID LABEL: <input style="width: 100px;" type="text" value="99999999992"/>	USE THIS FORM ONLY FOR CELL LINE DNA SAMPLE SHIPMENTS TO RUTGERS. SELECT TYPE OF SHIPMENT: <input style="width: 100px;" type="text"/>
COURIER/SHIPPING COMPANY: SHIPMENTS TO RUTGERS.	
NAME OF DNA REPOSITORY CONTACT:	PHONE:
COMPLETED BY DNA REPOSITORY	
ID:	1. DNA REPOSITORY <input style="width: 100px;" type="text"/>
DATE:	2. SAMPLES PACKED <input style="width: 40px;" type="text"/> - <input style="width: 40px;" type="text"/> - <input style="width: 40px;" type="text"/> Day Month Year
TIME:	3. SAMPLES PACKED <input style="width: 40px;" type="text"/> : <input style="width: 40px;" type="text"/> 24-hour clock
SAMPLES:	4. NUMBER PACKED <input style="width: 100px;" type="text"/>
INITIALS:	5. PERSON PACKING SAMPLES <input style="width: 100px;" type="text"/>
	6. NIDDK CENTRAL REPOSITORY <input style="width: 100px;" type="text"/>
<input type="button" value="SAVE"/>	

Figure 12. T1DGC DNA Repository Shipping Form: Shipments to Rutgers (DNA Samples) – Face Sheet.

4. 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. Informational messages, warnings and error messages will appear if data entered are out of “expected” ranges or fields are left blank for all forms. If any messages are displayed, confirm that the data on the form matches that

entered on the web page. If errors (red dots) are displayed, the form **will not** save. If warnings and informational messages are displayed, press the “Save with Warnings” button to continue with entry of the forms.

- After a successful save of the *Face Sheet*, the system displays the *T1DGC DNA Shipping Form – Contents Sheet* (Figure 13).

**DNA REPOSITORY SHIPPING FORM - CONTENTS SHEET
SHIPMENTS TO RUTGERS (DNA Sample shipments)**

CLICK "SAVE" ONLY ONCE AFTER ALL SAMPLE IDs HAVE BEEN SCANNED INTO THE SYSTEM.
CLICKING "SAVE" DURING PROCESSING INSERTS DUPLICATE RECORDS.
PLEASE NOTIFY THE COORDINATING CENTER OF ANY PROCESSING ERRORS IMMEDIATELY!

<input type="button" value="Save"/>	
Analytic ID:	100 mcg aliquot sent
	1
	1
	1
	1
	1
	1
	1
	1
	1
	1
	1
	1
	1
	1
	1
	1
	1
	1
<input type="button" value="Save"/>	

Figure 13. T1DGC DNA Shipping Form – Contents Sheet.

6. Scan the bar-coded labels on each of the tubes, and if required, data enter the number of aliquots sent. Press the “Save” button at the bottom of the page. Warning and error messages will appear if data entered are out of “expected” range as discussed previously for *Face Sheet*.
7. After a successful save of a *Contents Sheet*, or, if a shipping form has previously been entered, the Shipping Form Selection page is displayed (Figure 14).
The user has three options from this page:
 - (a) “Start over with a new shipment” which returns the user to the screen with the box titled “Enter or Scan a Shipping ID”;
 - (b) “View a DNA shipping form page” which allows the user to review and update previously entered information; or
 - (c) “Print DNA shipping contents sheet” which allows the user to print a printer-friendly contents sheet for inclusion with the shipment.

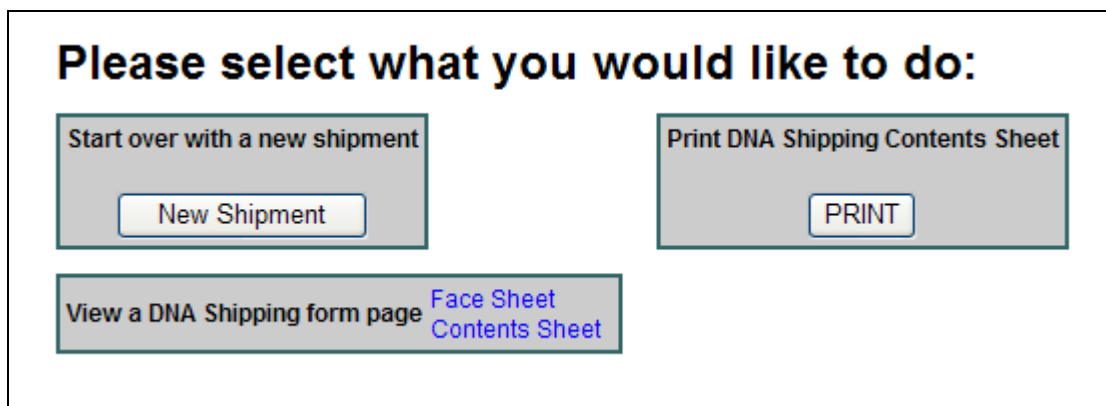


Figure 14. DNA shipping form selection page.

8. Once the shipping process and data entry for the shipment has been completed, make a copy of the forms for retention at the laboratory and forward the completed original to the Coordinating Center as final documentation of the shipment. A copy of the completed shipping forms should be included with the shipment. The original shipping forms can be batched weekly (or on a schedule specified by the Coordinating Center) via regular postal service.

V. AUTOANTIBODY LABORATORY SHIPMENTS TO OTHER LABORATORIES

A. Overview

The Autoantibody and Storage Laboratory is responsible for generating a shipping record for plasma and/or serum samples shipped elsewhere. The bar-coded labels for such samples contain the T1DGC participant ID.

The Coordinating Center provides a web-based application for recording all IDs for samples shipped from the Autoantibody and Storage Laboratory for receipt at other locations. The Coordinating Center also provides the Autoantibody and Storage Laboratory with the shipping ID labels to be used for all shipments from a Network Repository to another facility or laboratory.

Sample shipments from the Autoantibody and Storage Laboratory to other sites include the following:

- (a) plasma and serum samples to the NIDDK Central Biosample Repository (Germantown, MD, USA); and
- (b) residual serum samples to the Network Autoantibody and Storage Laboratory (Denver, CO, USA).

B. Completing Autoantibody Shipping Forms for Shipments to Other Laboratories

1. The Autoantibody and Storage Laboratory staff completes two *T1DGC Autoantibody Shipping Forms* when shipping specimens to other laboratories: the *Face Sheet* and the *Contents Sheet*. Both forms are completed for each specimen shipment and are included in the shipping container. (Data forms are on the T1DGC web site: www.t1dgc.org).
2. The Autoantibody and Storage Laboratory staff affixes a bar-coded Shipping ID label on the *Face Sheet* and the shipping container. Shipping IDs identify each unique shipment and are associated with a set of participant IDs through the *Contents Sheet*. Shipping IDs are 11-digit numbers that begin with the network

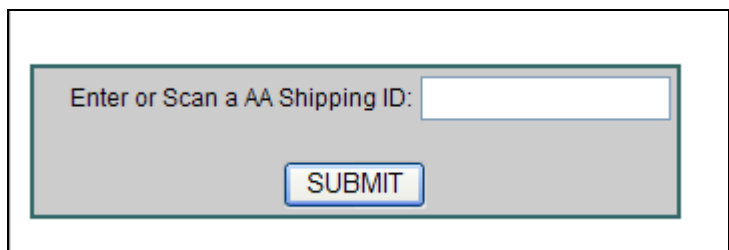
identifier (*i.e.*, 1=Asia-Pacific; 2=European; 4=North American; and 5=United Kingdom). **The system for entry of the *Shipping Forms* cannot be accessed without a Shipping ID label on the *Face Sheet*.**

3. The Autoantibody and Storage Laboratory completes the upper portion and the left side of the lower portion of the *Face Sheet*.
4. The *Contents Sheet* can be printed from the T1DGC data entry web site after all participant IDs have been scanned into the system.
5. The Autoantibody and Storage Laboratory staff makes two copies of each completed *Face Sheet* and *Contents Sheet*. The original set of shipping forms is sent to the Coordinating Center. One copy is included with the samples shipped to the receiving laboratory. One copy is retained at the Autoantibody and Storage Laboratory.

C. Data Entry of Shipping Forms at Autoantibody and Storage Laboratories

Data entry of all of the Autoantibody and Storage Laboratory Shipping Forms follows primarily the same steps.

1. Select the appropriate shipping form from the Autoantibody Lab Home Page.
2. The user is directed to “scan or enter an AA shipping ID” (Figure 15). Scan the bar-coded Shipping ID label from the *Face Sheet*.



The image shows a screenshot of a web form. At the top, there is a text label "Enter or Scan a AA Shipping ID:" followed by a white rectangular input field. Below the input field, centered, is a blue button with the word "SUBMIT" in white capital letters. The entire form is enclosed in a thin black border.

Figure 15. Enter or scan an autoantibody shipping ID.

- If the shipping form has not been entered, this will take you to a data entry screen for the *Face Sheet* (Figure 16). Data enter the entire form (except the fields at the top of the page) and press the “Save” button at the bottom of the page. Note that for some forms (*i.e., Autoantibody Shipping Form – Shipments to Denver*) only the left side of the form is entered by the shipping Autoantibody and Storage Laboratory staff.

TYPE 1 DIABETES GENETICS CONSORTIUM AUTOANTIBODY LABORATORY SHIPPING FORM - FACE SHEET SHIPMENTS TO MCKESSON			
TO:	FROM:		
SHIPPING ID LABEL: <input type="text" value="99999999994"/>	INCLUDE SERUM AND PLASMA SAMPLES ONLY IN SHIPMENTS TO NIDDK CENTRAL REPOSITORY (McKESSON).		
COURIER/SHIPPING COMPANY: TRACKING NUMBER:			
NAME OF AUTOANTIBODY LABORATORY CONTACT:	PHONE:		
COMPLETED BY LABORATORY			
ID:	<table style="width: 100%;"> <tr> <td style="width: 50%;">1. AUTOANTIBODY LABORATORY <input type="text"/></td> <td style="width: 50%;">7. NIDDK CENTRAL REPOSITORY <input type="text"/></td> </tr> </table>	1. AUTOANTIBODY LABORATORY <input type="text"/>	7. NIDDK CENTRAL REPOSITORY <input type="text"/>
1. AUTOANTIBODY LABORATORY <input type="text"/>	7. NIDDK CENTRAL REPOSITORY <input type="text"/>		
DATE:	2. SAMPLES PACKED <input type="text"/> - <input type="text"/> - <input type="text"/> <small>Day Month Year</small>		
TIME:	3. SAMPLES PACKED <input type="text"/> : <input type="text"/> <small>24-hour clock</small>		
SAMPLES:	4. NUMBER PACKED <input type="text"/>		
PATICIPANTS:	5. NUMBER OF UNIQUE IDS IN SHIPMENT <input type="text"/>		
INITIALS:	6. PERSON PACKING SAMPLES <input type="text"/>		
<input type="button" value="SAVE"/>			

Figure 16. T1DGC Autoantibody Laboratory Shipping Form: Shipments to Fisher – Face Sheet.

- 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. Informational messages, warnings and error messages will appear if data entered are out of “expected” ranges or fields are left blank for all forms. If any messages are displayed, confirm that the data on the form matches that entered on the web page. If errors (red dots) are displayed, the form **will not**

save. If warnings and informational messages are displayed, press the “Save with Warnings” button to continue with entry of the forms.

5. After a successful save of the *Face Sheet*, the system displays the *T1DGC Autoantibody Laboratory Shipping Form – Contents Sheet* (Figure 17).

**AUTOANTIBODY LABORATORY SHIPPING FORM - CONTENTS SHEET
SHIPMENTS TO MCKESSON**

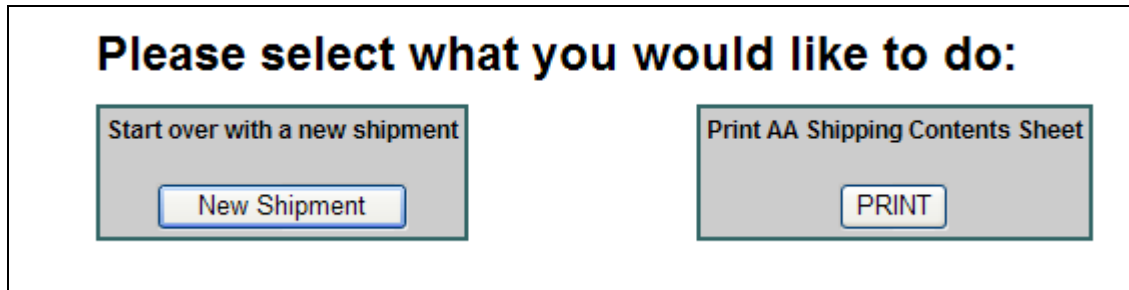
CLICK "SAVE" ONLY ONCE AFTER ALL SAMPLE IDs HAVE BEEN SCANNED INTO THE SYSTEM.
CLICKING "SAVE" DURING PROCESSING INSERTS DUPLICATE RECORDS.
PLEASE NOTIFY THE COORDINATING CENTER OF ANY PROCESSING ERRORS IMMEDIATELY!

Participant ID:	Red Top (serum) aliquot(s) sent:	Purple Top (plasma) aliquot(s) sent:
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

Figure 17. T1DGC Autoantibody Shipping Form – Contents Sheet.

6. Scan the bar-coded labels on each of the tubes, and if required, data enter the number of aliquots sent. Press the “Save” button at the bottom of the page. Warning and error messages will appear if data entered are out of “expected” range as discussed previously for *Face Sheet*.
7. After a successful save of a *Contents Sheet*, or, if a shipping form has previously been entered, the Shipping Form Selection page is displayed (Figure 18).
The user has two options from this page:
 - (a) “Start over with a new shipment” which returns the user to the screen with the box titled “Enter or Scan a Shipping ID”; or

- (b) “Print AA Shipping Contents Sheet” which allows the user to print a printer-friendly *Contents Sheet* for inclusion with the shipment.



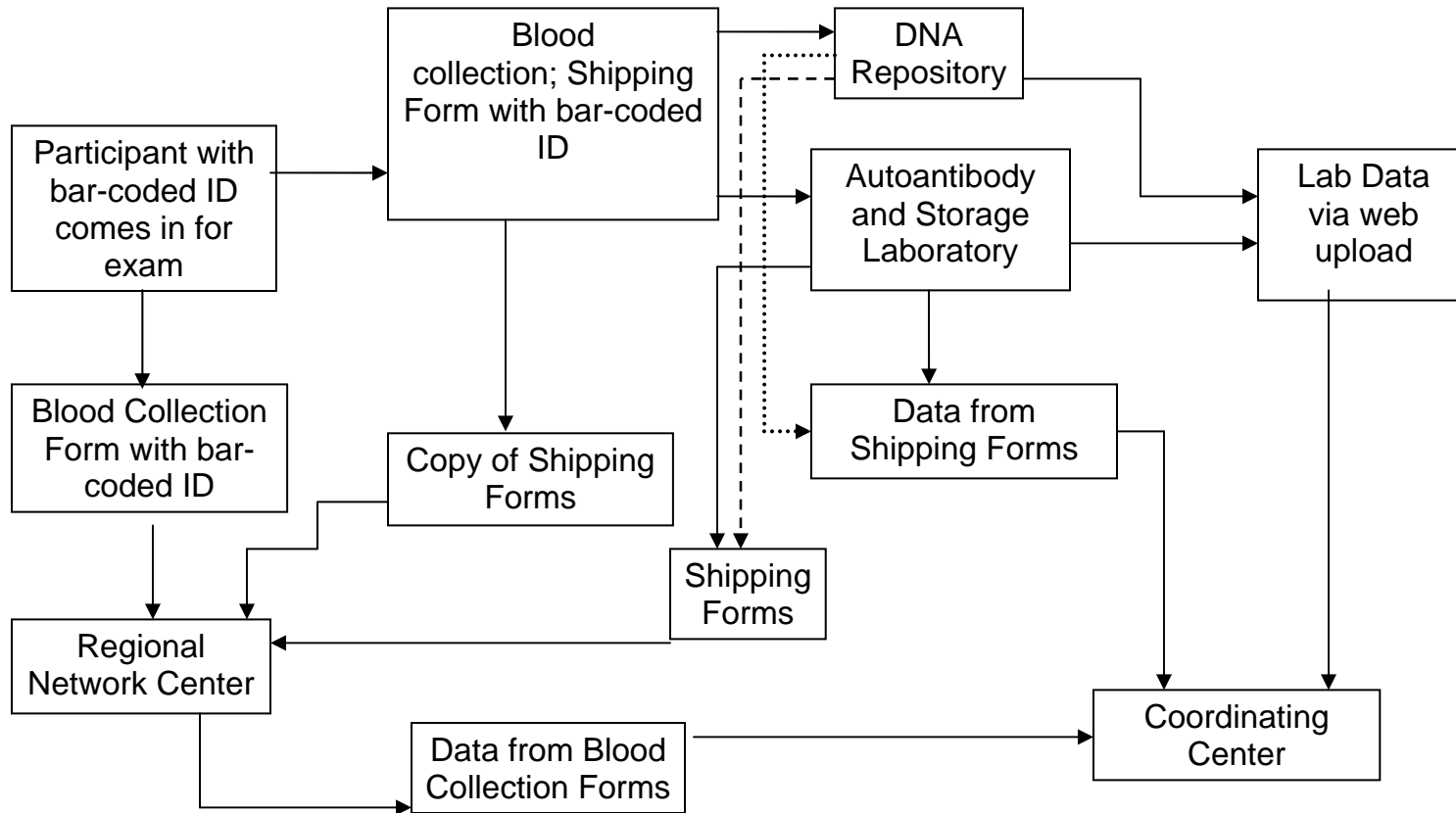
Please select what you would like to do:

Start over with a new shipment <input type="button" value="New Shipment"/>	Print AA Shipping Contents Sheet <input type="button" value="PRINT"/>
---	--

Figure 18. Autoantibody shipping form selection page.

8. Once the shipping process and data entry for the shipment has been completed, make a copy of the forms for retention at the laboratory and forward the completed original to the Coordinating Center as final documentation of the shipment. A copy of the completed shipping forms should be included with the shipment. The original shipping forms can be batched weekly (or on a schedule specified by the Coordinating Center) via regular postal service.

APPENDIX A
T1DGC SPECIMEN TRACKING FLOW CHART



APPENDIX B
T1DGC NETWORK COORDINATORS

Asia-Pacific Network:

Amanda Loth
Burnet Clinical Research Unit
Walter & Eliza Hall Institute of Medical Research
Gate 1
Royal Melbourne Hospital, Victoria 3050
Australia
Phone: +61-3-9345-2601
FAX: +61-3-9345-2318
E-mail: Amanda.Loth@mh.org.au

European Network:

Lotte Albret
Steno Diabetes Center
Niels Steensensvej 1
DK-2820 Gentofte
Denmark
Phone: +45-4443-9389
FAX: +45-4443-7313
E-mail: lwis@hagedorn.dk

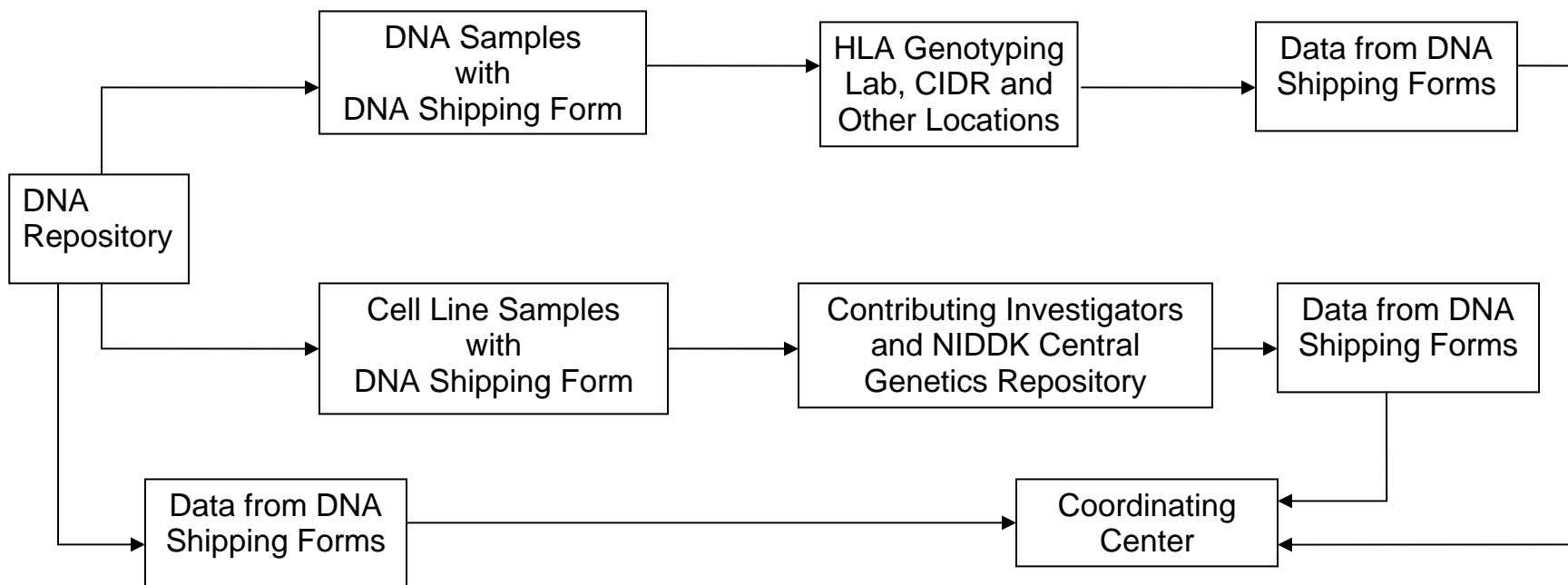
North American Network:

Angela Dove
Benaroya Research Institute at Virginia Mason
1201 9th Avenue
Seattle, WA 98101
Phone: (206) 223-7608
FAX: (206) 515-5239
E-mail: adove@benaroyaresearch.org

United Kingdom Network:

Heather Withers
JDRF/WT Clinical Resource Office
University Dept of Paediatrics, Box 116
Addenbrooke's Hospital
Hills Road
Cambridge, England
CB2 2QQ United Kingdom
Phone: +44-01223-763132
FAX: +44-01223-336996
E-mail: hw258@cam.ac.uk

APPENDIX C
T1DGC SPECIMEN TRACKING:
DNA REPOSITORY FLOW CHART



APPENDIX D
T1DGC HLA GENOTYPING LABORATORIES

Asia-Pacific Network:

Mike Varney, PhD
Victorian Transplantation and Immunogenetics Services (VTIS)
Australian Red Cross Blood Service
C/O Royal Melbourne Hospital
Rotary Bone Marrow Research Centre
Royal Parade
Parkville 3050
Phone: 61 3 9348 1966
FAX: 61 3 9348 1278
E-mail: mvarney@arcbs.redcross.org.au

European/United Kingdom Networks:

Joyce Carlson, MD, PhD
DNA Genotyping Lab
SWEGENE Resource Center for Profiling
Polygenic Disease and DNA Extraction Facility
National Biobanking Platform Clinical Chemistry
Entrance 71
University Hospital MAS
SE-205 02 Malmo Sweden
Phone: 46 40 33 14 93
FAX: 46 40 33 62 86
E-mail: joyce.carlson@klkemi.mas.lu.se

North American Network:

Janelle Noble, PhD
Children's Hospital Oakland Research Institute
5700 Martin Luther King, Jr. Way
Oakland, CA 94609
Phone: 510-450-7657
FAX: 510-450-7910
E-mail: jnoble@chori.org

APPENDIX E
T1DGC GENOTYPING PROJECT LABORATORIES
AND NIDDK CENTRAL SAMPLE REPOSITORIES

Center for Inherited Disease Research (CIDR)

Corinne Boehm
Center for Inherited Disease Research
Johns Hopkins Bayview Research Campus
Triad Technology Center
333 Cassell Drive, Suite 2000
Baltimore, MD 21224

MHC Fine Mapping Laboratory

Sarah Nutland
JDRF/WT Diabetes & Inflammation Lab
Cambridge Institute for Medical Research
University of Cambridge
Wellcome Trust/MRC Building
Addenbrooke's Hospital
Cambridge, CB2 2XY
United Kingdom

Rapid Response Laboratory

Kathryn Irenze
Broad Institute of MIT & Harvard
Seven Cambridge Center
Cambridge, MA 02142

Diabetes and Inflammation Laboratory (DIL)

Helen Stevens
Lab 4.19
JDRF/WT Diabetes & Inflammation Lab
Cambridge Institute for Medical Research
University of Cambridge
Wellcome Trust/MRC Building
Addenbrooke's Hospital
Cambridge, CB2 2XY
United Kingdom

NIDDK Central Genetics Repository: Rutgers

Carrie Virgilio/Dana Witt
NIDDK Communications Coordinator
Rutgers University Cell & DNA Repository
604 Allison Road, Nelson Labs C112
Piscataway, NJ 08854

NIDDK Central Biosample Repository: Fisher

Heather Higgins

Fisher Bioservices Corporation

20301 Century Blvd, Bldg 6, Suite 400

Germantown, MD 20874

University of Virginia

Jo Wright

University of Virginia

Center for Public Health Genomics

Old Med School Room 3817

Lane Road Loading Dock

21 Hospital Drive

Charlottesville, VA 22908