SAMPLE STORAGE AND SHIPPING

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I. SAMPLE STORAGE AT CLINIC

A. Introduction

Shipment of T1DGC samples occurs daily and monthly, depending upon the type of sample. Whole blood for cell lines (one or two samples for each participant, depending on age) and the cell pack from the EDTA plasma sample are maintained at room temperature and shipped to the DNA Repository within 24 hours of collection. Autoantibody samples (one each for the proband, the affected sibling, and the case) and long-term storage samples (up to 5 serum and 4 plasma per participant) are stored in a freezer and shipped monthly.

B. Guidelines for Freezing Serum and Plasma Samples

1. All cryovials are to be frozen immediately after aliquoting; do not allow vials to sit out. The preferred freezer temperature is -70^{o}C, although -20^{o}C is acceptable for short-term sample storage (*i.e.*, one month).

2. Cryovials must be frozen upright in the storage boxes that will hold the samples when they are shipped to the laboratory.

3. Record time of freezing samples on the *T1DGC Blood Collection Form*. Samples must be placed in the freezer **within 90 minutes** of blood collection.

4. Update the shipping forms daily as samples are stored.

C. Procedure for Packing Serum and Plasma Samples for Storage

Each participant's serum samples (maximum of 5 with red cap) and plasma samples (maximum of 4 with purple cap) are stored and shipped **together**.

Each storage box has 100 spaces for samples. Before packing the boxes for long-term storage, wrap a length of freezer tape around the outside corners of the box's lid to reinforce it. When fully packed, the box may be slightly crowded.

Since each participant should have a total of 9 samples, all of the samples for as many as 10 participants can be stored in one box (*i.e.*, a total of 90 samples per storage box). **DO NOT DIVIDE A FAMILY'S SAMPLES ACROSS TWO BOXES.** Within a box, pack the samples in order of the date collected, from the upper left hand corner to the lower left hand corner.

Case, control and re-collection samples may be included in the boxes with the family samples and are placed in the boxes in the same manner. These samples should be placed at the end of a family's samples to so they do not divide the family's samples.

For each participant, pack the **serum** samples first and then pack the **plasma** samples. Begin at the first sample position on the first row of the box and place successive samples moving to the right and then moving down a row. Serum samples will occupy the first five spaces in each row. For all participants with a full set of storage samples (5 serum and 4 plasma), only the last space in the row will be empty (Figure 1). In this figure, all 10 participants have a full complement of vials.

If a participant has fewer than the maximum number of serum and plasma samples, begin filling in the row, leaving a blank space for any missing storage samples. Serum samples should occupy the first five spaces and plasma the next four spaces. In Figure 2, participant #2 has three serum samples and two plasma samples. Participant #5 has two serum and one plasma sample. Participant #7 has three serum samples and **no** plasma samples. Participant #9 has one serum sample and one plasma sample.

As a participant's samples are added to the storage box, place a vial label on the top of the box lid, starting in the upper left hand corner of the box. To the right of the label write **in ballpoint ink** the number of serum and plasma samples enclosed for the respective ID (*i.e.*, 5–S; 4–P). The ID labels should be placed on the lid as described here and illustrated in Figure 3. Vial labels for the first five participants' samples (*i.e.*, participants 1-5) should be in a column on the left side of the box lid and the vial labels for the second five participants' samples (*i.e.*, participants 6-10) should be in a column

on the right side of the box lid. If a vial label for the participant's samples is not available, write the **full 7-digit ID**, **in ballpoint ink**, in the location the label should occupy.

1st ppt's samples (Father: Family 1)	S	S	S	S	S	P	P	P	P	■
2nd ppt's samples (Mother: Family 1)	S	S	S	S	S	P	P	P	P	■
3rd ppt's samples (Proband: Family 1)	S	S	S	S	S	P	P	P	P	■
4th ppt's samples (Affected: Family 1)	S	S	S	S	S	P	P	P	P	■
5th ppt's samples (Unaffected: Family 1)	S	S	S	S	S	P	P	P	P	■
6th ppt's samples (Father: Family 2)	S	S	S	S	S	P	P	P	P	■
7th ppt's samples (Mother: Family 2)	S	S	S	S	S	P	P	P	P	■
8th ppt's samples (Proband: Family 2)	S	S	S	S	S	P	P	P	P	■
9th ppt's samples (Affected: Family 2)	S	S	S	S	S	P	P	P	P	■
10th ppt's samples (Unaffected: Family 2)	S	S	S	S	S	P	P	P	P	■

Figure 1. Packing diagram for storage samples. ("S" indicates a serum cryovial, "P" indicates an EDTA plasma cryovial and "■" indicates an empty space. "ppt's" = participant's. Color of letters indicates color of the cryovial cap.)

1st ppt's samples (Father: Family 1)	S	S	S	S	S	P	P	P	P	■
2nd ppt's samples (Mother: Family 1)	S	S	S	■	■	P	P	■	■	■
3rd ppt's samples (Proband: Family 1)	S	S	S	S	S	P	P	P	P	■
4th ppt's samples (Affected: Family 1)	S	S	S	S	S	P	P	P	P	■
5th ppt's samples (Unaffected: Family 1)	S	S	■	■	■	P	■	■	■	■
6th ppt's samples (Father: Family 2)	S	S	S	S	S	P	P	P	P	■
7th ppt's samples (Mother: Family 2)	S	S	S	■	■	■	■	■	■	■
8th ppt's samples (Proband: Family 2)	S	S	S	S	■	P	P	P	P	■
9th ppt's samples (Affected: Family 2)	S	■	■	■	■	P	■	■	■	■
10th ppt's samples (Unaffected: Family 2)	S	S	S	S	S	P	P	P	P	■

Figure 2. Packing diagram for storage samples where fewer than the maximum numbers have been collected for 2nd, 5th, 7th and 9th participants. ("S" indicates a serum cryovial, "P" indicates a plasma cryovial, and "■" indicates an empty space. "ppt's" = participant's. Color of letters indicates color of the cryovial cap.)

When a box has been filled, the labels affixed and the number of storage samples (serum and plasma) recorded for each participant, place a vertical strip of freezer tape over each column of labels on the top of the box. This will prevent the labels from falling off during long-term storage.

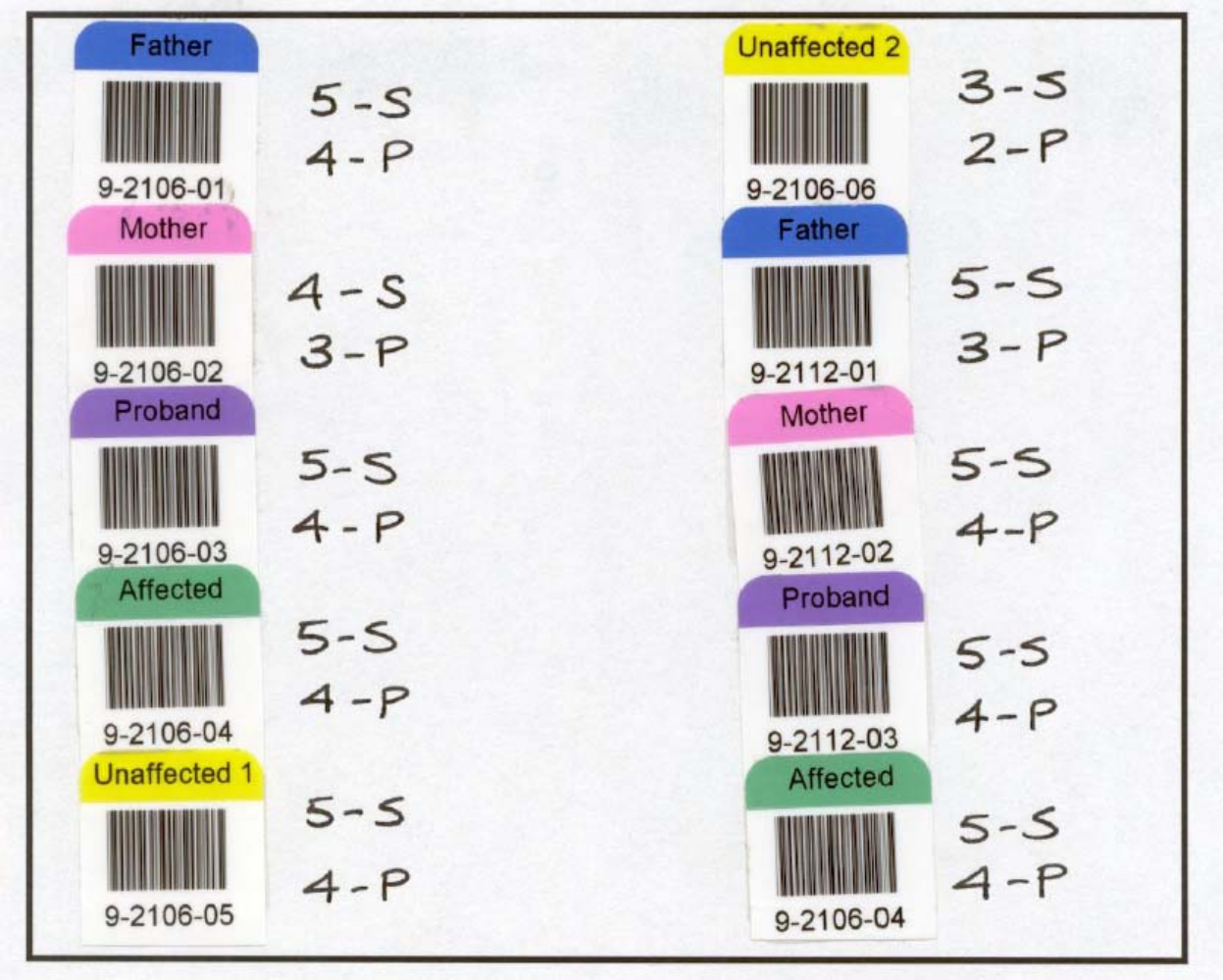

Figure 3. Placement of participant ID labels and sample counts on the top of the storage box lid.

D. Procedure for Quality Control Samples

The duplicate (i.e., quality control or QC) EDTA cell packs will be shipped daily (at ambient temperature) with the original cell pack and cell line samples. Serum and plasma QC samples will be shipped monthly with original samples (*i.e.*, in the same month as they are collected).

Samples should not be placed adjacent to the original samples; place QC samples at the end of the shipment (Figure 4). Each set of QC samples (serum or plasma) should occupy a separate row; do not combine samples from a QC-Red participant with those from a QC-Purple participant to fill an entire row. For a QC-Red participant, the first five spaces in the row will be filled and the remaining five spaces will

be empty. For a QC-Purple participant, the first five spaces in the row will be empty, the next four spaces will be filled with samples and the last space will be empty.

1st ppt's samples (Father: Family 1)	S	S	S	S	S	P	P	P	P	■
2nd ppt's samples (Mother: Family 1)	S	S	S	S	S	P	P	P	P	■
3rd ppt's samples (Proband: Family 1)	S	S	S	S	S	P	P	P	P	■
4th ppt's samples (Affected: Family 1)	S	S	S	S	S	P	P	P	P	■
5th ppt's samples (Father: Family 2)	S	S	S	S	S	P	P	P	P	■
6th ppt's samples (Mother: Family 2)	S	S	S	S	S	P	P	P	P	■
7th ppt's samples (Proband: Family 2)	S	S	S	S	S	P	P	P	P	■
8th ppt's samples (Affected: Family 2)	S	S	S	S	S	P	P	P	P	■
9th ppt's samples (QC-Red)	S	S	S	S	S	■	■	■	■	■
10th ppt's samples (QC-Purple)	■	■	■	■	■	P	P	P	P	■

Figure 4. Packing diagram for storage samples, with quality control samples included. ("S" indicates a serum cryovial, "P" indicates an EDTA plasma cryovial and "■" indicates an empty space. "ppt's" = participant's. Color of letters indicates color of the cryovial cap.)

II. SAMPLE SHIPPING

All T1DGC samples must be packaged and shipped in compliance with the 46th edition of the International Air Transport Association (IATA) *Dangerous Goods Regulations*. Samples for T1DGC are classified as Category B (diagnostic specimens

or clinical specimens) and must comply with the IATA Packing Instruction 650 (Appendix A). Effective January 1, 2005, packages containing diagnostic specimens must have a diamond-shaped label with "UN 3373" inside. Either "Diagnostic Specimens" or "Clinical Specimens" must be clearly marked on the package (adjacent to the UN 3373 label) and on the waybill.

A. Schedule for Shipping Cell Line and EDTA Cell Pack Samples

Daily shipments are required for green top (sodium heparin) or yellow top (CPDA) tubes and EDTA cell pack (purple top) samples. Blood should be received at the DNA Repository **within 24 hours** of collection (or as close to this time as possible, considering geographic and budgetary constraints). Overnight shipment to the laboratory is arranged via courier by clinic staff.

B. Cell Line and EDTA Cell Pack Sample Packaging and Shipment

Ship cell line and EDTA cell pack samples at room temperature in double-boxed styrofoam 8-slot tube holders. To help maintain room temperature, surround the box assembly with gel packs (**stored at room temperature between uses**) and place the assembly inside a larger styrofoam shipping container. **DO NOT REFRIGERATE GEL PACKS AS THIS WILL COMPROMISE THE VIABILITY OF THE SAMPLE! DO NOT USE DRY ICE AS FREEZING WILL DESTROY THE CELLS!**

C. Schedule for Shipping Autoantibody, Storage, and Serum and Plasma Quality Control Samples

Autoantibody, storage and serum and plasma quality control samples are shipped **monthly** to the Network Autoantibody and Storage Laboratory, preferably on a Monday or Tuesday. Samples should be held in clinic freezers for a **maximum** of 30 days to: (1) minimize loss of samples at the local level due to freezer failure; (2) minimize degradation of samples stored at less than -70^{o}C; and (3) ensure that autoantibody analysis remains current by providing a consistent flow of samples to the laboratory. To minimize the risk of catastrophic loss of samples, shipments should never exceed 500 samples.

Clinics are assigned a specific shipping date (*e.g.*, the first Monday of each month) and shipping dates will rotate so that network laboratories are receiving samples each week. Clinics should provide laboratories with 24 hours advance notice of intent to ship. Appendix B provides the laboratory contact information for each network.

D. Frozen Sample Packaging and Shipping

Packaging and shipping of frozen samples is the responsibility of each clinic.

1. Samples must be frozen for at least twenty-four hours before they are shipped.

2. Frozen samples are shipped in the storage boxes in which they have been stored in the freezers at the clinics.

3. The boxes with frozen samples must be placed so that samples are upright in the supplied insulated shipping container and surrounded with dry ice pellets. At least 10 pounds (4.5 kg) of dry ice is necessary to keep the samples frozen for up to 48 hours; 15-20 pounds (7-9 kg) is recommended.

4. Label each shipment with "CONTENTS TO REMAIN FROZEN".

E. Sample Packaging and Shipping

1. The two clinic shipping forms (*Face Sheet* and *Contents Sheet*) must be enclosed or attached with each shipment. Instructions for the completion of these forms are located in Appendix C. Use a separate *Face Sheet* for each shipping container of samples.

2. Samples must be shipped by air courier for arrival at the laboratory by the following morning. On the day of shipment, the primary nurse or technician should notify the laboratory that the samples have been shipped to arrive by air courier the following morning. (This will vary by network; due to differences in time zones, the technician may need to call the laboratory the morning that the shipment will be arriving.) The technician will also provide the laboratory with

the courier service used and the courier's reference number.

3. **If the shipment is not received by noon, the laboratory personnel should contact the Regional Network Center and the Clinic Coordinator of the pertinent clinic immediately. This permits the clinic to put a trace on the missing samples and, hopefully, locate them before the sample integrity is compromised.**

4. Shipments **MUST** be made according to the shipping schedule.

5. The clinics must request that laboratories return the containers as soon as possible, with expenses covered as determined by the Regional Network Center. Return need not be by air courier and the clinics should provide the laboratories with a return address shipping label.

III. DESTRUCTION OF T1DGC SAMPLES

T1DGC samples should be destroyed or discarded **only** with written instructions from the study Coordinating Center located at Wake Forest University. **All samples should be retained until the clinic and/or laboratories receive the *T1DGC Notification to Destroy Samples* form.** (Appendix D provides a copy of the form and instructions for its completion.) The Coordinating Center initiates the form after notification by the Regional Network Center Coordinator, or may be initiated at the Coordinating Center based upon results from study directed genotyping projects or inventory received from the NIDDK Central Repositories. The sample(s) to be destroyed are confirmed prior to forwarding the form to the appropriate clinic and/or laboratory.

Valid reasons for destroying or discarding samples include the following: (1) appropriate consent not obtained from participant at time of blood collection; (2) participant subsequently withdrew consent; (3) participant determined to be ineligible after blood collection; (4) consent not obtained for cell line; and (5) other miscellaneous reasons. The "Other" reasons category includes: (1) frozen samples that were lost or

delayed in transit and were received thawed; and (2) mislabeled tubes where identification of the sample is in question. The laboratory **should never** discard or destroy samples that arrive unlabeled without consulting the clinic staff, the Regional Network Coordinator, **AND** the Coordinating Center.

IV. SHIPPING SUMMARY

In summary, samples are shipped as outlined below:

Destination	Frequency	Tube or Vial	Mode
Original and Recollection Samples:			
DNA Repository	Daily	Green or yellow top tubes (cell line) EDTA tube (cell pack for DNA)	Ambient temperature
Autoantibody and Storage Laboratory	Monthly	5 2-ml cryovials (autoantibodies/serum storage) 4 2-ml cryovials (plasma storage)	Frozen
QC (Duplicate) Samples:			
DNA Repository	Daily (with original samples)	EDTA tube (cell pack for DNA)	Ambient temperature
Autoantibody and Storage Laboratory	Monthly (with original samples)	5 2-ml cryovials (autoantibodies/serum storage QC) 4 2-ml cryovials (plasma storage QC)	Frozen

APPENDIX A

IATA PACKING INSTRUCTION 650

PACKING INSTRUCTION 650

▲ OPERATOR VARIATIONS, AO-03, AS-08, CO-07, CS-07, FX-09, QF-03

General Requirements

Diagnostic specimens must be packed in good quality packagings, which must be strong enough to withstand the shocks and loadings normally encountered during transport, including trans-shipment between transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling.

Packagings must be constructed and closed so as to prevent any loss of contents when prepared for transport which might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity or pressure.

Primary receptacles must be packed in secondary packagings in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings must be secured in outer packagings with suitable cushioning material. Any leakage of the contents must not substantially impair the protective properties of the cushioning material or of the outer packaging.

Packages must be prepared as follows:

(a) **For liquids:**

- The primary receptacle(s) must be leak-proof and must not contain more than 500 mL.
- There must be absorbent material placed between the primary receptacle and the secondary packaging; if several fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated so as to prevent contact between them. The absorbent material, such as cotton wool, must be in sufficient quantity to absorb the entire contents of the primary receptacles and there must be a secondary packaging which must be leak-proof.
- The primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa in the range of -40°C to+55°C (-40°F to 130°F).
- The outer packaging must not contain more than 4 L.

(b) **For solids:**

- The primary receptacle(s) must be sift-proof and must not contain more than 500 g.
- If several fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated so as to prevent contact between them and there must be a secondary packaging which must be leak-proof.
- The outer packaging must not contain more than 4 kg.

☞ An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

☞ Each completed package must be capable of successfully passing the drop test described in 6.6.1 except that the height of the drop must not be less than 1.2 m.

- Packages consigned as freight must be at least 100 mm (4 in) in the smallest overall external dimension.

- Each package and the "Nature and Quantity of Goods" box of the air waybill must show the text "DIAGNOSTIC SPECIMEN PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650".

  With effect from 1 January 2004, each package must also be marked requirements in accordance with 7.1.5.8 to indicate that the shipper has determined that the packaging meets the applicable air transport. The marking must be applied adjacent to the words "Diagnostic Specimens".

  A Shipper's Declaration for Dangerous Goods is not required.

  Provided diagnostic specimens are packed in accordance with this Packing Instruction, no other requirements of these Regulations apply except for the definition in 3.6.2.1.4 and the reporting of dangerous goods accidents and incidents in 9.6.1.

- **Specific Requirements**
  Although exceptional cases (for example, the shipment of whole organs), may require special packaging, the great majority of diagnostic specimens can and must be packaged according to the following guidelines.

  Substances shipped at ambient temperatures or higher: Primary receptacles include those of glass, metal or plastic. Positive means of ensuring a leak-proof seal, such as heat seal, skirted stopper or metal crimp seal must be provided. If screw caps are used these must be reinforced with adhesive tape.

  Substances shipped refrigerated or frozen (wet ice, pre frozen packs, Carbon dioxide, solid [dry ice]): Ice, Carbon dioxide, solid (dry ice) or other refrigerant must be placed outside the secondary packaging(s) or alternatively in an overpack with one or more completed packagings. Interior support must be provided to secure the secondary packaging(s) or packages in the original position after the ice or Carbon dioxide, solid (dry ice) has been dissipated. If ice is used the packaging must be leak-proof. If Carbon dioxide, solid (dry ice) is used the outer packaging must permit the release of carbon-dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

  Substances shipped in liquid nitrogen: Plastic capable of withstanding very low temperatures must be used instead of glass receptacles. Secondary packaging must also withstand very low temperatures and in most cases will need to be fitted over individual primary receptacles. Requirements for shipment of liquid nitrogen must also be observed. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant used as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

  Lyophilized substances: Primary receptacles must be either flame-sealed glass ampoules or rubber-stoppered glass vials with metal seals.

APPENDIX B

NETWORK LABORATORY CONTACT

INFORMATION FOR SAMPLE SHIPMENTS

ASIA-PACIFIC NETWORK:

DNA Repository / Autoantibody and Storage Laboratory:

Attention: Nick Homatopoulos/ Ian Nicholson
Victorian Transplantation and Immunogenetics Service (or VTIS)
Australian Red Cross Blood Bank
Cnr Kavanagh and Balston Sts
Southbank
Victoria 3006
Australia

Contact via e-mail:

Michael Varney (mvarney@arcbs.redcross.org.au) with copies to:
Ian Nicholson (inicholson@arcbs.redcross.org.au) **and**
Nick Homatopoulos (nhomatopoulos@arcbs.redcross.org.au)

Phone: 61 3 9341 6309 (Mike Varney) or 61 3 9694 0242 (Ian Nicholson)

EUROPEAN NETWORK:

DNA Repository:

Bernhard O. Boehm, M.D.
Klinikum der Universität Ulm
Kliniken Oberer Eselsberg
Abteilung Innere Medizin I
Robert-Koch-Straße 8
89081 Ulm
Germany

Contact via e-mail:

Bernhard Boehm (bernhard.boehm@uniklinki-ulm.de) **and**
Tina Joss (tina.joss@uniklinki-ulm.de) **and**
Angelika Kurkhaus (angelika.kurkhaus@uniklinki-ulm.de) **and**
Silke Rosinger (silke.rosinger@uniklinki-ulm.de) **and**
(et1dgn.ulm-repository@uniklinki-ulm.de)

Phone: +49-731-500-44515
FAX: +49-731-500-44519

APPENDIX B (CONT.)

NETWORK LABORATORY CONTACT

INFORMATION FOR SAMPLE SHIPMENTS

Autoantibody and Storage Laboratory:

Alistair Williams
Diabetes and Metabolism
Medical School Unit
Southmead Hospital
Bristol BS10 5NB
UK

Contact via e-mail: antibody-IGC@bristol.ac.uk

Phone: +44 117 959 5337
FAX: +44 117 959 5336

NORTH AMERICAN NETWORK:

DNA Repository:

Fred Hutchinson Cancer Research Center (FHCRC)
1100 Fairview Ave. North, D2-346
P.O. Box 19024
Seattle, WA 98109-1024

Primary Contact: Heather Risbeck
Phone: 206-667-3756
E-mail: hrisbeck@fhcrc.org
FAX: 206-667-5255

Laboratory Director: John Hansen, MD
Phone: 206-667-5111
E-mail: jhansen@fhcrc.org
FAX: 206-667-5255

Shared E-mail: cgb@fhcrc.org

APPENDIX B (CONT.)

NETWORK LABORATORY CONTACT

INFORMATION FOR SAMPLE SHIPMENTS

Autoantibody and Storage Laboratory:

Barbara Davis Center
M20-4201C, Attn: Liping Yu
1775 Aurora Ct.
Aurora, CO 80010
Telephone: 303-724-6809

Contact: Liping Yu
Phone: 303-315-7108
E-mail: liping.yu@ucdenver.edu

UNITED KINGDOM NETWORK:

DNA Repository:

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

Contact via e-mail:

Helen Stevens (helen.stevens@cimr.cam.ac.uk)

Phone: 44(0)1223 762 106
FAX: 44(0)1223 762 102

Autoantibody and Storage Laboratory:

Alistair Williams
Diabetes and Metabolism
Medical School Unit
Southmead Hospital
Bristol BS10 5NB
UK

Contact via e-mail: antibody-IGC@bristol.ac.uk

Phone: +44 117 959 5337
FAX: +44 117 959 5336

APPENDIX C

CLINIC SHIPPING FORMS:

INSTRUCTIONS FOR USE

There are two clinic shipping forms: a *Face Sheet* and a *Contents Sheet*. Copies of these forms are located on the T1DGC web site.

Both forms must be included in any daily shipments (for cell line samples and EDTA cell packs) sent to the DNA Repository and in any monthly shipment (for autoantibody and storage samples) sent to the Autoantibody and Storage Laboratory.

Two copies of each of these forms are created from the originals. The original forms are sent to the laboratory with the sample shipment. Copy #1 is kept at the clinic and Copy #2 is sent to the Regional Network Center.

Both the clinic and the laboratory complete designated portions of the forms when processing the sample shipment. Data from both forms are entered into a web-based specimen tracking system at the laboratory when samples are received. The laboratory forwards the completed original forms to the Regional Network Center for final documentation of the shipment.

FACE SHEET:

1. The clinic completes the top half and the left side of the bottom half of the *Face Sheet*.

2. The full address of the clinic and the laboratory is printed or typed in the area allotted.

3. A Shipping ID Label is placed in the designated space on the form. A second identical Shipping ID Label is placed on the shipping container. Shipping IDs are 11-digit numbers, beginning with the network identifier. (NOTE: There are three shipping labels provided for each **unique** shipping ID. Only two labels are to be

used in any given shipment; one label is placed on the shipping form and one on the shipping container. The third label can be used in the event that one label tears. Alternatively, the third label can be used for local forms. However, the third label should never be used on a subsequent shipment.)

4. The courier or shipping company used (*e.g.*, Federal Express or World Courier) and the reference number ID is recorded on the form.

5. The type of samples included in the shipment (*i.e.*, cell line and/or cell pack **or** autoantibody/storage) is selected.

6. Record the name of the clinic contact and his/her phone number.

7. The following items are recorded on the left side on the bottom part of form by the person preparing the shipment:
   (1) clinic ID
   (2) date and time the shipment was packed at the clinic
   (3) total number of samples packed. The technician should confirm this total by both counting samples and adding the numbers in the "number vials" column on the contents sheets.
   (4) number of contents pages included. Number will vary depending on the number of vials in the shipment, since each contents page allows for 6 sample IDs. (NOTE: The *Face Sheet* is not included in the count of contents pages.)
   (5) ID of person packing the samples and completing the shipping forms.

8. The right side of the bottom part of the face sheet is to be completed by the laboratory personnel upon arrival of the shipment.

9. The following items are recorded by the person receiving the shipment:
   (1) Laboratory ID
   (2) date and time the shipment arrived at the laboratory
   (3) total number of samples received. The technician should confirm this total by

both counting samples and adding the numbers in the "number vials" column on the contents sheets.

(4) number of contents pages received.

(5) initials of person receiving the samples and completing the shipping forms.

CONTENTS SHEET

The second shipping form is the *Contents Sheet*. 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 filled in at the top of the contents pages by the clinic staff. This form should be completed as the samples are collected and stored. The form must be checked against the samples when packaged for shipment at the clinic and when the samples are received at the laboratory.

1. The clinic records the page numbers in the upper right corner of the form.

2. The clinic places one of the bar-coded large ID labels for each participant's samples on the form. This will reduce staff effort and prevent transcription errors at the clinics and laboratories. (NOTE: Each *Contents Sheet* will accommodate labels for 6 participant ID labels. Completely fill all 6 spaces, leaving no blank spaces, as the *Contents Sheet* is completed.)

3. The clinic records the type of samples by marking the vial cap colors for the samples (*e.g.*, red=serum; purple=plasma **or** EDTA cell pack; green/yellow= sodium heparin or CPDA tubes). Mark all that apply.

4. The clinic records the number of samples with that same color vial cap with the same ID in the column labeled "Sent".

5. In the column labeled "Comments on Samples", the clinic marks "Red samples hemolyzed" if serum samples were hemolyzed and/or "Purple samples

hemolyzed" if plasma samples were hemolyzed. These two selections are the only comments that should be marked by clinic staff; the remaining options are to be used by the laboratory upon receipt and inspection of the samples.

6. The laboratory counts and records the number of samples of each vial color in the column labeled "Arrived" for inventory purposes and acknowledgment of arrival. If a tube (or tubes) broke during shipment, record the number of **un**broken tubes received.

   If the number of samples sent does not equal the number of samples received, the laboratory staff must contact the clinic staff to resolve the discrepancy. This may involve the clinic sending a corrected version of the *Face Sheet* and/or *Contents Sheet*.

   The laboratory should copy the Regional Network Center and the Coordinating Center on all communications with the clinic regarding shipping problems or discrepancies with the shipment.

7. In the column labeled "Comments on Samples", the laboratory should mark the following selections to indicate discrepancies in the number of samples hipped 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
   b. Sample thawed: if sample shipment is thawed upon receipt at the laboratory
   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

APPENDIX D

T1DGC NOTIFICATION TO DESTROY SAMPLES: FORM AND INSTRUCTIONS FOR USE

T1DGC Notification to Destroy Samples

T1DGC Participant ID

COMPLETED BY COORDINATING CENTER

1. Date

Day - Month - Year

2. Reason for destroying samples

- Consent not obtained 1
- Withdrew consent 2
- Ineligible 3
- Consent not obtained for cell line 5
- Other 4

If other, provide additional information or explanation:

_____

3. Clinic ID associated with participant ID

Clinic ID

4. Type of samples to be destroyed (CHECK ALL THAT APPLY.)

- Serum aliquots 1
- Plasma aliquots 1
- Green top tubes 1
- Cell pack 1
- DNA aliquots 1
- Cell line aliquots 1

5. Number of each sample type to be destroyed **(NOTE: Reflects full inventory of all known participant samples across all laboratories and clinics.)**

Serum aliquots	*Green top tubes	***DNA aliquots
Plasma aliquots	**Cell pack	****Cell line aliquots

* For Network DNA Repositories, this reflects the number of green top tubes received; please destroy all PBLs LCLs and DNA aliquots associated with these samples UNLESS reason for destroying samples is "consent not obtained for cell line"; then, destroy all samples except PBMC.

** Please destroy all DNA aliquots extracted from the cell pack.

*** This reflects the total number of DNA aliquots shipped from Network DNA Repositories to other facilities.

**** For Rutgers or Contributing Investigator Requests, this reflects the number of cell line aliquots received.

T1DGC Participant ID

6. Authorized Coordinating Center signature

_____

7. Date sent to Regional Network Center ☐☐ - ☐☐☐ - ☐☐☐☐
Day Month Year

COMPLETED BY REGIONAL NETWORK CENTER

8. Regional Network decision
Approved ☐ 1
Not approved ☐ 2

9. Authorized Regional Network Center signature

_____

10. Date sent to Coordinating Center ☐☐ - ☐☐☐ - ☐☐☐☐
Day Month Year

COMPLETED BY COORDINATING CENTER

11. Notification sent to following T1DGC study sites (ID completed for applicable sites)

a. Clinic ID ☐☐☐☐

b. Shipping ID ☐-☐☐☐☐☐☐☐☐☐ Autoantibody and Storage Laboratory ID ☐☐☐

c. Shipping ID ☐-☐☐☐☐☐☐☐☐☐ DNA Repository ID ☐☐☐

Shipping ID ☐-☐☐☐☐☐☐☐☐☐

d. Shipping ID ☐-☐☐☐☐☐☐☐☐☐ HLA Genotyping Laboratory ID ☐☐☐

T1DGC Participant ID

COMPLETED BY COORDINATING CENTER

11. Notification sent to following T1DGC study sites (ID completed for applicable sites) (Continued)

e. Shipping ID ☐-☐☐☐☐☐☐☐☐☐☐ CIDR ID ☐☐☐

f. Shipping ID ☐-☐☐☐☐☐☐☐☐☐☐ MHC Laboratory ID ☐☐☐

g. Shipping ID ☐-☐☐☐☐☐☐☐☐☐☐ NIDDK Biosample Repository ID (Fisher) ☐☐☐

Shipping ID ☐-☐☐☐☐☐☐☐☐☐☐

h. Shipping ID ☐-☐☐☐☐☐☐☐☐☐☐ NIDDK Genetics Repository ID (Rutgers) ☐☐☐

Shipping ID ☐-☐☐☐☐☐☐☐☐☐☐

i. Shipping ID ☐-☐☐☐☐☐☐☐☐☐☐ Rapid Response Laboratory ID ☐☐☐

j. Other Shipping ID ☐-☐☐☐☐☐☐☐☐☐☐ Laboratory ID **OR** Clinic ID **OR** Request ID ☐☐☐☐

Other Shipping ID ☐-☐☐☐☐☐☐☐☐☐☐ Laboratory ID **OR** Clinic ID **OR** Request ID ☐☐☐☐

Reason for additional Shipping ID

_____

12. Date notification sent to T1DGC laboratory or clinic ☐☐ - ☐☐☐☐☐☐☐☐☐ - ☐☐☐☐

Day Month Year

T1DGC Participant ID

COMPLETED BY T1DGC LABORATORY OR CLINIC

13. T1DGC laboratory or clinic (COMPLETE ONLY ONE.)

Lab ID **OR** Clinic ID

14. Type of samples destroyed (CHECK ALL THAT APPLY.)

Serum aliquots 1
Plasma aliquots 1
Green top tubes 1
Cell pack 1
DNA aliquots 1
Cell line aliquots 1

15. Number of each sample type destroyed (Refer to Question 5 for number and type of sample(s) to be destroyed. Refer to Question 11 for the shipping ID associated with the sample(s) to be destroyed. COMPLETE ALL THAT APPLY TO YOUR FACILITY.)

Serum aliquots | *Green top tubes | ***DNA aliquots

Plasma aliquots | **Cell pack | ****Cell line aliquots

* For Network DNA Repositories, this reflects the number of green top tubes received; please destroy all PBLs LCLs and DNA aliquots associated with these samples UNLESS reason for destroying samples is "consent not obtained for cell line"; then, destroy all samples except PBMC.

** Please destroy all DNA aliquots extracted from the cell pack.

*** This reflects the total number of DNA aliquots shipped from Network DNA Repositories to other facilities.

**** For Rutgers or Contributing Investigator Requests, this reflects the number of cell line aliquots received.

16. Date samples destroyed

Day - Month - Year

17. Authorized laboratory or clinic signature

_____

COMPLETED BY COORDINATING CENTER

18. Date completed notification form received at Coordinating Center

Day - Month - Year

19. Date completed notification form FAXed to Regional Network Center

Day - Month - Year

T1DGC NOTIFICATION TO DESTROY SAMPLES:

INSTRUCTIONS FOR USE

The *T1DGC Notification to Destroy Samples* form will be used in cases where it is necessary to destroy study samples. This form is completed by the Coordinating Center and approved by the Regional Network Center prior to the Coordinating Center notifying the necessary laboratories and/or clinic that samples must be destroyed.

Each laboratory or clinic completes a section of the form outlining the samples they destroyed and sends the form to the Coordinating Center. This form is entered into a database at the Coordinating Center and a copy of the form is forwarded to the Regional Network Center.

Completed by Coordinating Center

1. The Coordinating Center records the T1DGC Participant ID on every form page.

2. The Coordinating Center records the date the form is completed in a day-month-year format (Question 1).

3. The Coordinating Center marks one response as to why samples are being destroyed. If the response category “Other” is marked, additional information or an explanation is included (Question 2).

4. The Coordinating Center records the Clinic ID associated with the participant (Question 3).

5. The Coordinating Center marks all types of samples to be destroyed. All applicable samples at all locations are marked (Question 4).

6. The Coordinating Center determines the number of each sample type to be destroyed. This number is based on the information the Coordinating Center has

as to how many samples are present across all laboratories and clinics (Question 5).

7. There must be an authorized Coordinating Center signature. Authorized Coordinating Center personnel include Joan Hilner, T1DGC Project Director, and Letitia Perdue, T1DGC Project Manager (Question 6).

8. The Coordinating Center completes the date the form is sent to the Regional Network center in a day-month-year format (Question 7).

Completed by Regional Network Center

9. The Regional Network Center approves or does not approve the destruction of the participant's samples and marks the correct response (Question 8).

10. There must be an authorized Regional Network Center signature. Authorized Regional Network Center personnel include the Principal Investigator and the Network Coordinator (Question 9).

11. The Regional Network Center completes the date the form is sent back to the Coordinating Center in a day-month-year format (Question 10).

Completed by Coordinating Center

12. The Coordinating Center records the laboratory and/or clinic ID for all applicable sites where participant samples are currently being held. The shipping ID containing the samples that are being destroyed is recorded in order to ensure the correct samples are destroyed. This form is sent to all applicable sites along with a cover letter from Joan Hilner, Project Director, or Letitia Perdue, Project Manager (Question 11).

13. The Coordinating Center completes the date the form is sent to the T1DGC laboratory or clinic in a day-month-year format (Question 12).

Completed by T1DGC Laboratory or Clinic

14. The T1DGC Laboratory or Clinic completes either the “Lab ID” box or the “Clinic ID” box with their laboratory or clinic ID (Question 13).

15. The T1DGC Laboratory or Clinic determines the number and type of each sample for this participant they currently have in their facility and destroys these samples.

16. All sample types destroyed at this facility are recorded on the form (Question 14).

17. The number of each sample type destroyed is recorded. If no samples were destroyed, a 0 is recorded in the box. The cover letter from the Coordinating Center will include the number and type of samples the facility has that need to be destroyed (Question 15).

18. The T1DGC Laboratory or Clinic completes the date the samples were destroyed in a day-month-year format (Question 16).

19. There must be an authorized Laboratory or clinic signature. Authorized Laboratory personnel include the Principal Investigator or the Laboratory Director. Authorized clinic personnel include the Principal Investigator (Question 17).

Completed by Coordinating Center

20. This form is forwarded to the Coordinating Center, and a staff member completes the date the form was received at the Coordinating Center in a day-month-year format (Question 18).

21. The Coordinating Center FAXes a copy of the form to the Regional Network Center and completes the date this was FAXed in a day-month-year format (Question 19).