**STUDY CLOSE-OUT**

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## I. INTRODUCTION

Close-out for the Type 1 Diabetes Genetics Consortium (T1DGC) will occur in phases. When individual clinics notify the Regional Network Centers of completion of recruitment and their plan to end enrollment, this will comprise the first phase of close-out. The Regional Network Center will notify the Coordinating Center and initiate close-out for that clinic. The Regional Network Centers may also identify clinics that are no longer actively recruiting and elect to initiate close-out at those sites prior to the overall study close-out. Finally, when enrollment of the affected sibling pair (ASP) families, trios, cases and controls is completed, the overall study close-out will be initiated.

Close-out of the Regional Network Centers and Network laboratories (Autoantibody and Storage Laboratory, DNA Repository, and HLA Genotyping Laboratory) will occur after all clinics within the network have been closed. Specific tasks may be able to be completed prior to all clinics being closed. After all Regional Networks Centers and Network laboratories are closed, close-out of the T1DGC Coordinating Center will be initiated. It may be possible that specific tasks can be completed prior to all Regional Network Centers and Network laboratories being closed.

## II. CLINIC CLOSE-OUT

Once a clinic has notified the Regional Network Center of its intention to end enrollment and close (or the Regional Network Center has notified a clinic to initiate close-out, or overall close-out is initiated), each clinic should complete, edit and forward all family data forms to the Regional Network Centers within 60 days of the last family's entry into the study. The Regional Network Centers will work with each clinic to: (1) identify all remaining families needing completion; (2) provide regular communication regarding the status of data irregularities; and (3) generally assist the clinics to complete close-out in a timely fashion.

After the clinic initiates close-out, while final participant visits and re-collections are being completed, the clinic and the Regional Network Center will communicate regularly via phone and e-mail to review all reports, data queries, sample discrepancies

and discuss procedures for incomplete families/participants, withdrawal of consent, and discuss record storage procedures.

When all of the close-out procedures have been accomplished, the clinic and the Regional Network Center will have a final close-out conference call to ensure that the clinic has completed all needed tasks and to confirm that the clinic is ready to close. Any remaining concerns and issues should be discussed and resolved at this time.

## A. Recruitment Close-out

Clinics will cease recruitment and initiate close-out when the Principal Investigator and Clinic Coordinator have ascertained that there are no additional participants to be enrolled, when the Regional Network Center notifies the clinic to end recruitment, or when the Coordinating Center notifies the Regional Network Center that the study is officially closed to recruitment. Once the last participant has been seen, the clinic should complete, edit and forward all data forms to the Regional Network Centers within 60 days of that date.

## B. Staff Preparation

The Clinic Coordinator will coordinate staff preparation for final close-out of the clinic by notifying all support staff of the plans and timeline for ceasing enrollment and submitting final data collection forms to the Regional Network Center. Staff will need to insure that there are sufficient supplies to complete sample collection and complete any re-collections that may be requested. If the study or part of the study is conducted at the institution's General Clinical Research Center (GCRC), its management should be advised of close-out plans. The Clinic Coordinator should maintain regular contact with the Regional Network Center as the close-out procedures are implemented.

## C. Final Data Collection

At the beginning of the final data collection phase, the Regional Network Center staff will provide various reports that show incomplete families and outstanding data/samples for that clinic. The Clinic Coordinator should review these reports with the

Regional Network Center staff. Reports that should be sent to the clinic include the following:

1. Data Entry/Samples Status
2. Outstanding Data/Sample Collection
3. Irregularities
4. QC Samples
5. Incomplete Minority Trio Families (if applicable)

From the Data Entry/Samples Status report, the Clinic Coordinator should identify families with outstanding family members that possibly could be enrolled and plan to re-contact such individuals and encourage their participation within the time period designated by the Regional Network Center. Clinic staff may need to re-contact families and participants that are not identified as "completed close-out."

Families that the Clinic Coordinator is certain will not be completed should be handled as specified in Section II.D below ("Procedures for Handling Outstanding Participants") and the proper procedures for that particular family member or member(s) should be initiated. Any questions about these procedures should be directed to the Regional Network Center for further information or clarification.

From the Outstanding Data/Sample Collection report, the Clinic Coordinator can likewise identify specific data and/or samples that need to be collected and initiate the collection of these in order to complete these families/participants whenever possible. At close-out, no incomplete families, outstanding data/sample collection, or irregularities should remain on any of the reports.

**D. Procedures for Handling Outstanding Participants**

Because the study design requires the presence of at least the proband and affected sibling to complete the core ASP family, and the presence of the father, mother, and proband to complete the trio family, procedures for dealing with non-participating family members differ based on the family type and the individual's

particular status in the family. Since cases and controls are collected as individuals there are no procedures for non-participating family members.

The T1DGC investigators would like to encourage participation of the full ASP family whenever possible. To this end, the clinics are encouraged to enroll all eligible members of ASP families. After the initial enrollment has occurred, it may become evident that not all members of the family will participate.

After consultation with the Regional Network Center staff for additional suggestions to encourage a particular family member to participate, and, if every effort has been exhausted to complete the family, the following procedures should be utilized for each type of family member.

**1. ASP Families**

*a. Proband or Affected Sibling Will Not Participate*

If it is determined that the proband (AS1, -03) or affected sibling (AS2, -04) will not complete the study after every effort has been made to enroll these individuals into the study, after a reasonable amount of time (> 6 months) has elapsed, and a third affected sibling is not participating, the family is deemed ineligible. In this event, the following steps should be implemented:

*Clinic:*

i. Notify the Regional Network Center (RNC) in writing that this family is no longer eligible. The clinic should provide the Regional Network Center with the participant IDs for all family members; if samples have been collected for any family member, the clinic must notify the Regional Network Center of the number of samples and the location of the samples.

ii. Place a copy of the notification or a statement in the family's clinic file, indicating the date that the Regional Network Center was notified.

iii. If needed, the Coordinating Center will send the *Notification to Destroy Samples* form(s) for each family member. If samples are still located at the

clinic, the clinic should complete the clinic sections, send completed forms to the Coordinating Center and retain a copy of the form(s) in the clinic file.

*Regional Network Center:*

i. Notify the Coordinating Center of this change in eligibility in writing, including all participant IDs.
ii. Request that a *Notification to Destroy Samples* form(s) be initiated if samples were collected; include the number of samples and the location of samples.
iii. Promptly complete the Regional Network Center portion of the *Notification to Destroy Samples* form(s) when received from the Coordinating Center and forward back to the Coordinating Center.
iv. Place a completed copy of the *Notification to Destroy Samples* form(s) in the family's file upon receipt from the Coordinating Center.

*Coordinating Center:*

i. Initiate the *Notification to Destroy Samples* form(s) for each family member as needed.
ii. Send a copy of the completed *Notification to Destroy Samples* form(s) to the Regional Network Center for their files.
iii. Enter the *Notification to Destroy Samples* form(s) into the data entry system.
iv. Data previously entered into the study database will be marked as ineligible; this family will no longer be included in subsequent enrollment and data management reports.

*b. Mother or Father Will Not Participate*

If every effort has been made to complete a family by obtaining the participation of the mother and/or father and the clinic staff determines that either the mother and/or the father will not participate (when previously the *T1DGC ASP Exam Form* indicated that he/she would participate), this does not affect the eligibility of the remaining family members. The following steps should be implemented:

*Clinic:*

i. Re-contact the participant that originally completed the *T1DGC ASP Exam Form* to obtain information for the parent who is not going to participate. This information is obtained from question 3.

ii. On the *T1DGC ASP Exam Form,* questions 11 and/or 12 should be changed to "no" if the father and/or the mother will not participate and Q11 a, b, c, and/or Q12 a, b, c should be completed.

iii. Make the changes using the method of correction outlined in **Chapter V,** *Interviewing Instructions.*

iv. Promptly notify the Regional Network Center and sent the *T1DGC ASP Exam Form* pages with the new information.

v. File the updated *T1DGC ASP Exam Form* pages in the participant's file with the original forms.

*Regional Network Center:*

i. Enter the new information provided on the updated *T1DGC ASP Exam Form* into the data entry system and save the new information.

c. *Other Siblings Will Not Participate*

If the clinic determines that an additional affected sibling (AS4, -07; AS5, -08; or AS6, -09) or any unaffected sibling (UN1, -05 or UN2, -06) will not participate (when previously the *T1DGC ASP Eligibility Form* (Administered to Guardian) or *T1DGC Application for Additional Affected Sibling* indicated that he/she would participate), the eligibility of the remaining family members is not affected. For additional affected siblings with a completed *T1DGC Application for Additional Affected Sibling*, the clinic should notify, in writing, the Regional Network Center, who will notify the Coordinating Center. The Coordinating Center will mark the data for the additional affected sibling as ineligible, so that this participant will no longer be included in subsequent enrollment and data management reports. For unaffected siblings or situations in which the *T1DGC Application for Additional Affected Sibling* has not been collected, no action is required by the clinic, Regional Network Center or Coordinating Center.

## 2. Trio Families

By definition, a trio family requires enrollment of the proband, mother and father. To minimize the possibility that a trio family is deemed ineligible, clinics are strongly urged to initiate enrollment of a trio family only when the proband, mother, and father are present at the enrollment visit. If it becomes evident that not all members of the trio family will participate, the family is ineligible.

If every effort has been made to get either the proband (AS1, -03), father (FA, -01), or mother (MO, -02) into the study and a reasonable amount of time has elapsed (> 6 months) it is determined that the proband will not complete the study, the family is deemed ineligible.

At institutions that have Institutional Review Board (IRB) or Ethics Committee (EC) approval to participate in the case-control collection, if either the mother and/or father will not complete the study, the proband can be converted to a case participant without re-labeling any forms or blood samples. The *Conversion to Case Form* should be used to convert the proband to a case and the form should be initiated by the clinic. See Appendix A for comprehensive instructions (Q x Qs) for the *T1DGC Conversion to Case Form*. The following steps should be implemented:

*Clinic:*

i. At clinics that are not participating in the case-control collection, notify the Regional Network Center in writing that the trio family is no longer eligible, including the participant IDs for all family members. If samples have been collected for any family members, the clinic must notify the Regional Network Center of the number of samples and the location of the samples.
ii. Place a copy of the notification or a statement in the file indicating the date that the Regional Network Center was notified.
iii. If needed, the Coordinating Center will send the *Notification to Destroy Samples* form(s) for each family member. If samples are still at the clinic, the clinic should complete the clinic sections, send completed forms to the

Coordinating Center, and retain a copy of the form(s) in the clinic file.

iv. At clinics that are participating in the case-control collection, complete the *Conversion to Case Form* for the proband and send it to the Regional Network Center for processing. This form can be pre-filled based on the information from the *Eligibility Form*. (See Section II.E, "Conversion to Case" below.) Notify the Regional Network Center in writing that the trio family is no longer eligible, including the participant IDs for all family members. If samples have been collected for any family members, the clinic must notify the Regional Network Center of the number of samples and the location of the samples. The Coordinating Center will complete any necessary *Notification to Destroy Samples* form(s) for the mother and/or father.

*Regional Network Center:*

i. Notify the Coordinating Center of this change in eligibility in writing, including all participant IDs and the request that a *Notification to Destroy Samples* form(s) be initiated, if samples were collected, including the number of samples and the location of the samples.

ii. Promptly complete the Regional Network Center portion of the *Notification to Destroy Samples* form(s) when received from the Coordinating Center and forward back to the Coordinating Center.

iii. When a completed copy of the *Notification to Destroy Samples* (if required) form is received, place it in the family's file.

iv. If the proband is being converted to a case participant, the *Conversion to Case Form* is entered into the data entry system at the Regional Network Center in order for this proband to be identified as a case.

*Coordinating Center:*

i. Initiate the *Notification to Destroy Samples* forms for each family member, as needed.

ii. Send a copy of the completed *Notification to Destroy Samples* form(s) to the Regional Network Center for their files.

iii. Enter the *Notification to Destroy Samples* form(s) into the data entry system.

iv. Data previously entered in the data entry system will be marked as ineligible and this family will no longer be included in data management reports.

v. If a proband is converted to a case, the forms pertaining to this individual will remain in the data entry system.

## E. Conversion to Case

The *T1DGC Conversion to Case Form* will be used in situations where only one affected child was recruited or in cases where other family members have been deemed to be ineligible. This form can be used only in specified populations where case participants were recruited (*i.e.,* African American and Mexican American in the North American Network, Cameroon in the European Network, or India in the Asia-Pacific Network). The form can be completed primarily by the clinic or Regional Network Center, based upon the participant's response to the questions from the *Eligibility Form* and the *Exam Form.* The exception to this is Question 12 on the *Conversion to Case Form* where the region in which the participant lives is recorded; this is only answered for case collections in Cameroon and India. In these instances, it may be necessary to contact the participant for this information. See Appendix A for comprehensive instructions (Q x Qs) for the *T1DGC Conversion to Case Form*.

## F. Re-collection of Blood Samples

Clinic Coordinators should check family/participant records to determine if there are any participants from whom samples were not collected at the initial clinic visit or from whom adequate samples could not be obtained. This is especially important for the members of the family that make the family eligible: proband and affected sibling for the ASP family; mother, father, proband for the trio family; and all cases and controls. Participants should be re-contacted and a re-collection appointment scheduled for the outstanding family member(s). If the participant is some distance away, the Clinic Coordinator may contact the Regional Network Center to determine if a remote collection for this participant is possible. The Regional Network Center staff can also advise the clinics of any participants who did not have an initial collection completed.

It is critical that the Regional Network Centers notify the Coordinating Center when a clinic is closing, so that the Coordinating Center can work with the regional DNA Repositories to ensure successful cell line transformations for each participant collected by the clinic that is closing. The DNA Repositories will prioritize DNA extraction and cell line transformation from samples collected from that clinic. The Coordinating Center Project Manager will work with the Regional Network Center to identify pending or failed cell lines that should be re-collected prior to close-out of the clinic.

Throughout the study, the Regional Network Center will notify a clinic when a re-collection is needed for reasons including the following: (1) a viable cell line could not be produced; (2) a shipment failure occurred; or (3) a low DNA yield from the EDTA cell pack occurred. As clinic closure approaches, it is crucial to obtain these re-collections as soon as possible. The Regional Network Center staff will keep each clinic informed of the re-collections requested and Clinic Coordinators should make every effort to have the participants return to the clinic for this blood collection. If the blood collection will not be possible, the Clinic Coordinator should notify the Regional Network Center Coordinator who will subsequently notify the Coordinating Center Project Manager.

## G. Final Data Correction and Clean-up

Several times prior to clinic close-out, the Clinic Coordinator should review the clinic's irregularities report (provided by the Regional Network Center) that lists missing, conflicting and/or inconsistent data with the Regional Network Center staff and discuss methods for resolving these data issues.

1. Missing Data: The initial focus should be on obtaining missing data. This will be accomplished by:
    a. reviewing the family/participant records to determine whether the data are available via medical or hospital records; and/or
    b. re-contacting the family/participant to obtain the additional information.
2. Conflicting Data and/or Inconsistent Data: If the information recorded on the various data forms for a participant does not agree, the conflicting data will need to be resolved by re-contacting the participant, if needed.

The Regional Network Center will assist the clinic in identifying any other conflicting data or data inconsistencies that are reported and help resolve these. The overall goal is for as many of the missing data or data inconsistencies to be completed and/or corrected as possible to provide the most complete and accurate sets of data possible for each enrolled participant.

When the Clinic Coordinator and the Regional Network Center staff have determined that all outstanding issues regarding missing data and/or data inconsistencies have been resolved, the irregularities and outstanding data reports for that clinic should have no families or participants listed.

## H. Internal Review Board (IRB)/Ethics Committee (EC) Approvals and Renewals

The local Principal Investigator should retain the Internal Review Board (IRB) or Ethics Committee (EC) approval document and submit the renewal as needed to keep the study approval active until the clinic is officially closed. It is important that there be IRB/EC approval during the time that data clean-up is in progress and any re-collections are being obtained.

Any Principal Investigator who is a consortium member and plans to obtain data and/or samples for future research should review the approval/renewal status with the local institutional IRB/EC to ensure that there is adequate coverage for additional research that will occur after the closure of participant enrollment, re-collections and data clean-up. This local IRB/EC may require that a renewal application following the end of participant enrollment be filed or that the current approval be amended to reflect that participant enrollment has ended but research is continuing.

If required by the local institution, the Clinic Coordinator should notify the local IRB/EC that participant recruitment and enrollment have ended and/or of the closure of the study clinic and forward this notification to the Regional Network Center, and subsequently to the Coordinating Center.

## I. Retention of Study Documents, Materials, and Supplies

Table 1 provides an overview of the disposition of all study documents, materials, and supplies. Study documents, supplies and materials should be stored by the clinic, returned to the Regional Network Center, or destroyed/discarded. Some study documents will not be retained or archived after the clinic closes. Clinic Coordinators should discuss disposal of any study-related documents or materials with the Regional Network Centers staff prior to disposing to ensure that disposal is appropriate in all instances. The details for handling study documents, supplies and any other study-related materials are provided below.

**Table 1. Disposition of Study Documents, Materials, and Supplies**

| DOCUMENTS, SUPPLIES, MATERIALS | STORE | RETURNTO RNC | DESTROY, DISCARD |
|---|---|---|---|
| Certificates of Confidentiality | | | |
| Consortium Agreements | X | | |
| IRB/EC Approvals and Renewals | X | | |
| Laboratory Supplies | | X (If current) | X (If expired) |
| Protocol, Manual of Operations | X | | |
| Study Records | X | X | |
| Equipment Purchased by T1DGC | | X (If directed by RNC) | |
| Mailing Labels/ Shipping Labels | | X (If directed by RNC) | X (If directed by RNC) |
| Unused Participant Labels Packets | | X (If clinic closes prior to overall close-out) | X (If directed by RNC) |
| Unused Data Forms | | | X |

### 1. Certificates of Confidentiality

The clinic's copies of the Certificates of Confidentiality, signed by everyone associated with the study, should be retained with the IRB/EC documents after close-out. The original signed certificates should have been forwarded to the Regional Network Center.

## 2. Consortium Agreements

The clinic's copies of the Consortium Agreements signed by local Principal Investigators and staff should be retained with the IRB/EC documents following close-out. The original signed agreements should have been forwarded to the Regional Network Center.

## 3. IRB/EC Approvals and Renewals

The local Principal Investigator should keep the original IRB/EC approvals/renewals on file for a minimum of five years following the close-out of the overall study (per National Institute of Health requirements). Each Clinic Coordinator should check with the local IRB/EC to determine if the local institution requires a longer period of retention.

## 4. Laboratory Supplies Purchased by T1DGC

Any clinic closing before the overall study closure should discuss the disposition of remaining laboratory supplies with the Regional Network Center staff. Because these were purchased with T1DGC funds, the clinic will be required to ship remaining items to the Regional Network Center for dispersal to clinics still recruiting participants. This supply status will be evaluated for each individual clinic based on the type of supplies remaining, expiration dates, and needs at other clinics.

## 5. Protocol, Manual of Operations

One copy of the Manual of Operations and one copy of the Protocol should be archived with the study records. All others may be destroyed, following the local institution's policies for discarding study-related materials.

## 6. Study Records

Study forms consist of the completed T1DGC data forms for each participant, the signed consent forms, as well as any additional records/information associated with the family/participant. T1DGC study forms must be retained for a minimum

of five years following the close-out of the overall study (per National Institute of Health requirements). Each Clinic Coordinator should check with the local IRB/EC to determine if the local institution requires a longer period of record retention. Study forms should be retained for the longer period of time.

Due to the number of clinics, the wide variety of locations and storage capability at each location, the preferred method for long-term storage of the original data forms is that they be sent to the Regional Network Center. This will provide for a more central storage of the T1DGC data forms for the length of time required and relieve the individual clinics of the long-term storage responsibility. When the original records are received at the Regional Network Center, the copies of the study forms will be shipped to the clinic for retention.

The preparation of records for storage includes:

a. Separation of personal identifying information from each set of participant forms. Personal identifying information includes: (1) signed consents; (2) any tracking information such as names, addresses, phone numbers, and other contacts; or (3) any other personal identifiers. These should be retained in an orderly fashion, but stored separately so that they may not be linked to the specific participant set of T1DGC data forms. Any master list that includes the T1DGC unique ID and the participant's or family's name should be kept separate from the T1DGC data forms.
b. The removal of any extra labels remaining in the participant's files. These may be destroyed following the local institution's policies for discarding study-related materials.
c. Organization of the completed T1DGC data forms in an orderly fashion and placing them in labeled boxes/containers prior to storage.
d. A plan for shipment of the records to the Regional Network Center.

For any clinic whose IRB/EC committee will not allow the centralized storage of study records, an alternative plan for storage of the study records must be

developed and discussed with the Regional Network Center prior to clinic close-out.

Any local plan will require implementation of steps a-c above and the determination of a secure location for the retention of the T1DGC study forms and other records for the period of time required. The records should be located in locked storage or may be archived with an archival company, depending on the local institution's policies for study record storage. Wherever the records are stored, they should be accessible to the T1DGC, if needed.

**7. Equipment Purchased by T1DGC**

Any equipment purchased with T1DGC funds for the conduct of the study, (*e.g.*, centrifuges, computers) should be returned to the Regional Network Center, if directed to do so. Clinics that have equipment purchased with study funds should contact the Regional Network Center for instructions for returning the equipment.

**8. Mailing Labels/Shipping Labels**

Once the clinic has shipped the last shipment to the laboratories and the Regional Network Center, any remaining address/shipping labels or airbills may be destroyed or returned to the Regional Network Center.

**9. Unused Participant Labels Packets**

Once the clinic is certain that no additional participants will be seen, any remaining unused label packets should be returned to the Regional Network Center for distribution to other active centers. If the Regional Network Center notifies the clinic of the overall study closure, then unused label packets may be destroyed following the local institution's policies for discarding study-related materials.

### 10. Unused Data Forms

Extra photocopies of the blank data collection forms may be destroyed following the local institution's policies for discarding study-related materials.

## J. Future Contact Information

The clinic should provide the Regional Network Center staff with the complete contact information of the responsible person who will be available should future contact with the clinic and/or participants be required. This is usually the clinic Principal Investigator or his/her designated representative.

The clinic's IRB/EC contact information should also be provided to the Regional Network Center. This is the entity that is listed on the participant consent forms as point of contact for the participant should they have questions or be unable to reach the Principal Investigator or other designated contacts. The Clinic Principal Investigator or Clinic Coordinator should follow-up with their IRB/EC as to how the institution wants to handle potential participant queries regarding the study following the closure of the clinic and subsequently the closure of the Regional Network Center and the Coordinating Center. The IRB/EC is ultimately responsible for the study records and remains the point of contact for any participant who has questions or concerns after study closure.

# III. REGIONAL NETWORK CENTER CLOSE-OUT

The Regional Network Center will be instrumental in helping initiate close-out of the study clinics in their network. Through the use of regular e-mails, telephone calls and mailings, the Regional Network Center will work closely with the clinics to implement the final data/sample collection, re-draws, data clean-up and close-out procedures.

## A. Clinic Close-out Form

The Regional Network Center will complete items 1-15 on the *Clinic Close-out Form* for each clinic in the network as the various steps of close-out are completed at that clinic. The Regional Network Center will enter these forms into the data entry

system on a regular basis (see **Chapter XI,** *Data Entry System*, for complete instructions), so that the status of each clinic's close-out process can be monitored at the Coordinating Center. This will serve as the documentation that all steps in the close-out process have been reviewed and completed and provide contact information for key personnel after close-out of the Regional Network Center and Coordinating Center is complete. See Appendix B for comprehensive instructions (Q x Qs) for the *T1DGC Clinic Close-out Form*

**B. Clinic Close-out Conference Call**

In addition to regular communications with the clinic during close-out, the Regional Network Center will schedule a final close-out conference call with each study clinic in the network. A template conference call agenda is provided in Appendix C.

The main purpose of the call is to establish the date that final data (after clean-up and correction) is due to the Regional Network Center. A final review of all reports regarding data, samples and procedures for record storage, withdrawal of consents after clinic closure and any other remaining details will be discussed during this call.

Once this call is completed and the *Clinic Close-Out Form* Items 1-15 have been completed by the Regional Network Center, the Coordinating Center will review all reports, data queries, and sample discrepancies a final time to ensure that all are in order and complete. The Coordinating Center will then notify the Regional Network Center that the clinic is officially closed.

The Coordinating Center will complete and data enter the final items on the *Clinic Close-Out Form* and the Regional Network Center will update their copy of the form from this entry and print the completed form to retain in that clinic's records.

The Regional Network Center will notify the clinic that charges for supplies with Sarstedt or shipping with World Courier and Federal Express will no longer be accepted on the T1DGC master account and that any subsequent charges will be re-billed to the

clinic. After receiving the closure notification from the Coordinating Center, the Regional Network Center will notify the clinic that it is officially closed.

### C. Final Review of Reports/Families

The T1DGC is a genetic study, and, as such, information may be discovered through various genotyping projects suggesting that individuals reported to be related are actually not related. This information is not to be shared with the participant or family; however, in some instances this may cause a participant or entire family to be deemed ineligible. The Coordinating Center, in conjunction with the Regional Network Centers, will identify these individuals, verify that sample collections were performed accurately, organize re-collections as needed, and perform the necessary notifications to destroy samples if these individuals are deemed to be unrelated to other family members. (See Section II.D, "Procedures for Handling Outstanding Participants.") Prior to Regional Network Center close-out, all reports will be reviewed and should be clear of outstanding participants and issues.

Reports that should be sent to the clinic include the following:

1. Dynamic reports (from the T1DGC data entry web site):
    a. Clinic Summary
    b. Outstanding Data/Sample Collection
    c. Irregularities
    d. QC Samples (missing and stray)
    e. Incomplete Minority Trio Families
2. Final Review of Query System (including final approval by the Coordinating Center Project Manager)
3. Redraw Report
4. Duplicate Data Entry Discrepancies
5. Reports Specific to Close-out (including all data from Network Laboratories and Central Repositories):
    a. Invalid IDs
    b. Incomplete Families and Participants

c. Outstanding Notification to Destroy Samples (NTDS)

d. Inventory

e. Case Parents

f. QC Samples

## D. Retention of Study Documents, Materials, and Supplies

Following the close-out of all of the clinics in the network, the Regional Network Center will begin its own close-out procedures. The procedures for the Regional Network Center regarding handling study records, supplies and any other study-related materials/documents that must be retained are very similar to those for the clinic close-out in terms of what records are retained and what items can be discarded. The details for handling study documents, supplies and any other study-related materials are listed below.

The Regional Network Center will have study documents that will not need to be retained or archived after the study closes. Before disposing of any study-related documents or materials, the Regional Network Coordinators should discuss disposal with the Coordinating Center Project Manager to ensure that disposal is appropriate in all instances.

### 1. Certificates of Confidentiality

The Regional Network Centers should have received the original signed Certificates of Confidentiality from each clinic. All original signed Certificates of Confidentiality should have been forwarded to the Coordinating Center. A copy of the signed documents should be retained at the Regional Network Center with the IRB/EC approvals/renewals after close-out.

### 2. Consortium Agreements

The Regional Network Centers should have received the original signed Consortium Agreements from each clinic. The original signed agreements should be retained with the IRB/EC approvals/renewals following close-out.

## 3. IRB/EC Approvals and Renewals

Each Regional Network Center's Principal Investigator should retain the original IRB/EC approvals and renewals on file for a minimum of five years following the close-out of the overall study (per National Institute of Health requirements). The Regional Network Center Coordinator should check with the institution's IRB/EC to determine if a longer period of record retention is required. All archived study documents should be retained for the longer period of time.

## 4. Laboratory Supplies Purchased by T1DGC

Any network closing before the overall study closure should discuss the disposition of remaining laboratory supplies with the Coordinating Center staff. Because these were purchased with T1DGC funds, the network may be required to ship remaining items to another Regional Network Center for dispersal to clinics still recruiting participants. This supply status will be evaluated for each individual network based on the type of supplies remaining, expiration dates, and needs at other clinics.

Following the closure of the overall study, the Regional Network Center may dispose of any remaining laboratory supplies by putting them into their laboratory inventory where appropriate or by discarding any supplies that have expired or are no longer needed.

## 5. Protocol, Manual of Operations

One copy of the Manual of Operations and one copy of the Protocol should be archived with the study records. All others may be destroyed, following the local institution's policies for discarding study-related materials.

## 6. Study Records

Each Regional Network Center should have the original participant records for the T1DGC sent from each clinic for consolidated storage. If the clinic's IRB/EC did not allow the originals to be sent to the Regional Network Center, the

Regional Network Center should retain the copies of each data collection form sent. All records must be saved for a minimum of five years following the close-out of the overall study (per National Institute of Health requirements).

Each Regional Network Center Coordinator should check with the local IRB/EC to determine if the local institution requires a longer period of retention. Study forms must be retained for the longer period of time.

Study records at the Regional Network Center consist of the completed T1DGC data forms for each participant from each clinic, the signed consent forms, as well as any additional records/information associated with the family/participant.

The Regional Network Center is responsible for determining that the records were appropriately prepared for storage (as outlined in Section II.I.6 of this chapter) and complete this preparation if it was not carried out by the clinic. The records should be located in locked storage or may be archived with an archival company, depending on the local institution's policies for study record storage. Wherever the records are stored, they should be accessible to the T1DGC, if needed.

**7. Equipment Purchased by T1DGC**

Any equipment purchased by T1DGC funds for the conduct of the study, such as centrifuges, computers, etc. should be returned to the Coordinating Center. The Regional Network Center Coordinator should contact the Coordinating Center for instructions for returning the equipment.

**8. Mailing Labels/Shipping Labels/Participant Label Packets/Data Forms**

At the time of close-out, any remaining address/shipping labels or airbills may be destroyed. All unused label packets and unused data collection forms may be destroyed following the local institution's policies for discarding study-related materials.

## E. Administrative Tasks for Regional Network Center Close-Out

In addition to ensuring that all families/participants are complete and edited, all clinics are closed and all study documents, materials and supplies have been properly redistributed, stored or destroyed, tasks may arise on a network-specific basis. These include, ensuring proper IRB/EC documentation and consent review has been completed by the NIDDK, verifying all web site users have signed a Confidentiality Certificate, distributing thank you certificates and mugs to all T1DGC staff, entering the final Contributing Investigator requests for data and samples, confirming the individuals to be included in the T1DGC acknowledgment list and preparing the final invoice.

The Regional Network Center Principal Investigator should designate the responsible person who will be available should future contact with the center be required and provide complete contact information to the Coordinating Center. The Regional Network Center should also provide the institution's IRB/EC contact information to the Coordinating Center.

When the Regional Network Center has completed all of the necessary activities for data verification and cleaning, record retention and close-out, the Regional Network Center Coordinator or Principal Investigator should notify their IRB/EC of the closure of the study.

## F. Coordinating Center Tasks for Regional Network Center Close-Out

The Coordinating Center will conduct a final site visit at each Regional Network Center to review the final close-out activities and to ensure that all data verification and cleaning, record retention and other required closure activities have been completed. A sample agenda for this close-out site visit is provided in Appendix D.

Throughout the close-out process, the Coordinating Center will itemize remaining tasks and work with the Regional Network Center to develop the appropriate timeline. Examples of the close-out documents can be found in Appendix E.

When the Regional Network Center has completed all of the necessary activities for data verification and cleaning, record retention and close-out, access to the T1DGC data entry web site will be removed for all Regional Network Center staff. After all tasks have been completed, the Coordinating Center will notify the Project Office and Regional Network Center that the network is closed.

## IV. AUTOANTIBODY AND STORAGE LABORATORY CLOSE-OUT

The Network Autoantibody and Storage Laboratories will receive plasma and serum samples throughout the duration of recruitment. They are responsible for performing the autoantibody assays on the samples collected from probands, affected siblings and case participants. Ultimately, all storage samples will be transferred to the NIDDK Central Biosample Repository located at Fisher Bioservices (Germantown, MD, USA). Close-out tasks consist of ensuring that all assays have been completed, all paperwork has been correctly entered and stored and all samples have been shipped to the final location. Specifics about each of these tasks are described below.

### A. Final Receipt of Clinic Shipments and Documentation

The Regional Network Centers will work with the clinics and the Network Autoantibody and Storage Laboratory to ensure that all shipments of plasma and serum samples have been shipped and received by the laboratory.

In conjunction with the Regional Network Centers, it is the responsibility of the Autoantibody and Storage Laboratory to ensure that receipt and entry of all clinic shipping forms is complete and accurate. The original clinic shipping forms should be shipped to the Regional Network Center, with copies retained at the Autoantibody and Storage Laboratory. (See Section IV.G, “Retention of Study Documents, Materials, and Supplies.”)

Prior to clinic close-out and before review of laboratory close-out specific reports, all reports will be reviewed and should be clear of outstanding participants and issues. The reports to be reviewed include:

1. Dynamic reports (from the T1DGC data entry web site):
    a. Clinic Summary
    b. Outstanding Data/Sample Collection
    c. Irregularities
    d. QC Samples (missing and stray)
    e. Incomplete Minority Trio Families
2. Final Review of Query System
3. Redraw Report
4. Reports Specific to Family/Participant Close-out (including all data from Network Laboratories and Central Repositories):
    a. Invalid IDs
    b. Incomplete Families and Participants
    c. Outstanding Notification to Destroy Samples (NTDS)
    d. Inventory
    e. Case Parents
    f. QC Samples
5. Reports Specific to Laboratory Close-out:
    a. Inventory: Plasma from clinic to network laboratory
    b. Inventory: Serum from clinic to network laboratory
6. QC Report: AA Table 2.1: Clinic Discrepancies

All outstanding queries related to the number of samples collected and number of samples shipped and received must be resolved prior to clinic close-out. Queries from all clinics must be resolved prior to close-out of the Autoantibody and Storage Laboratory.

**B. Final Upload of Results**

Prior to Autoantibody and Storage Laboratory close-out, autoantibody results from each proband, affected sibling and case participant must be uploaded to the Coordinating Center. The Coordinating Center will work with the network laboratories to identify individuals for whom results are missing.

After all results have been uploaded, the final quality control reports will be run and posted on the T1DGC web site. The laboratories will have the opportunity to identify any QC sample pairs where they believe one sample may have been mislabeled upon receipt. These pairs should be reported to the Coordinating Center, and if necessary, two separate set of quality control reports will be run: the first will assess the quality of the overall collection (from clinic to laboratory) and the second set will assess the laboratory quality.

## C. Final Shipments to Other Autoantibody Laboratories and NIDDK Central Repositories

At time of final laboratory close-out, all T1DGC samples that originally resided in the Autoantibody and Storage laboratory must either have been shipped to another location or destroyed. Specific details related to inventory are described below.

### 1. Shipments to North American Autoantibody and Storage Laboratory

The residual serum used for analyses purposes in the Autoantibody and Storage Laboratories located in Melbourne, Australia and Bristol, United Kingdom must be shipped to the Autoantibody and Storage Laboratory located in Denver, Colorado, USA for additional assaying. The Coordinating Center will work with the laboratories to ensure that all residual serum has been sent and received by the Denver laboratory. The “Shipments to Denver” reports will help to identify samples that have not yet been shipped to their final location.

### 2. Shipments to NIDDK Central Repository: Fisher

All serum and plasma samples (with the exception of the residual serum used for analyses purposes) should be sent to the NIDDK Central Biosample Repository (Fisher Bioservices; Germantown, MD, USA). The Coordinating Center will work with the laboratories to ensure that all serum and plasma samples have been sent and received by the NIDDK Central Repository. The “Shipments to Fisher” reports will help to identify samples that have not yet been shipped to their final location.

## D. Final Review of Shipping Forms and Resolution of Discrepancies

Throughout the duration of the study, all original Autoantibody and Storage Laboratory shipping forms will be forwarded to the Coordinating Center for review and comparison to the T1DGC specimen tracking system. At the time of close-out, the Coordinating Center will notify the Autoantibody and Storage Laboratory of all outstanding forms and discrepancies between the paper copies and the T1DGC specimen tracking system. This includes the *Autoantibody Laboratory Shipping Form: Shipments to Fisher* and the *Autoantibody Laboratory Shipping Form: Shipments to Denver*. For shipments to Denver, the Coordinating Center must have two originals of each shipping form; one completed by the shipping laboratory and one completed by the receiving laboratory (Denver). The Coordinating Center will review the *Face Sheets* and *Contents Sheets* of all shipping forms. All discrepancies between the paper copies and the specimen tracking system must be corrected prior to close-out.

## E. Final Review of Reports/Families

The T1DGC is a genetic study, and as such, information may be discovered through various genotyping projects suggesting that individuals reported to be related are actually not related. This information is not to be shared with the participant or family; however, in some instances this may cause a participant or entire family to be deemed ineligible. If it is confirmed through re-collections or the individual's identity is unable to be confirmed, it may be necessary for samples that were collected to be destroyed. The Coordinating Center will work with the Autoantibody and Storage Laboratory to determine samples that should be destroyed. (See Section II.D, "Procedures for Handling Outstanding Participants.")

Prior to Autoantibody and Storage Laboratory close-out, all reports will be reviewed and should be clear of outstanding participants and issues. The reports to be reviewed include:

1. Reports specific to laboratory close-out:
    a. Shipments to Fisher: Approved samples
    b. Shipments to Fisher: Not approved samples

c. Shipments to Denver: Approved samples

d. Shipments to Denver: Not approved samples

e. Inventory: Plasma from clinic to network laboratory

f. Inventory: Serum from clinic to network laboratory

g. Inventory: Plasma from network laboratory to Fisher/Denver

h. Inventory: Serum from network laboratory to Fisher/Denver

2. QC Reports

a. AA Table 2.1: Clinic Discrepancies

b. AA Table 10.1: Fisher Discrepancies

## F. Final Inventory Review

At the conclusion of the study, the Autoantibody and Storage Laboratory should have shipped all samples to their final location. Remaining samples will be destroyed.

At the conclusion of recruitment, an e-mail from the Coordinating Center will direct the laboratory to destroy all pilot samples. E-mail confirmation that all pilot samples have been destroyed should be sent from the Autoantibody and Storage Laboratory Principal Investigator to Joan Hilner (jhilner@wfubmc.edu) and Letitia Perdue (lperdue@wfubmc.edu). This will serve as study documentation that these samples have been destroyed.

At the time of close-out, the Autoantibody and Storage laboratory should provide a file of all residual serum samples. An e-mail from the Coordinating Center will request that all residual serum samples to be destroyed. E-mail confirmation that all residual serum samples have been destroyed should be sent from the Autoantibody and Storage Laboratory Principal Investigator to Joan Hilner (jhilner@wfubmc.edu) and Letitia Perdue (lperdue@wfubmc.edu). This will serve as study documentation that these samples have been destroyed.

A final inventory may be requested. After all remaining close-out activities have been completed, the Autoantibody and Storage Laboratory Principal Investigator must send an e-mail to Joan Hilner (jhilner@wfubmc.edu) and Letitia Perdue

(lperdue@wfubmc.edu) confirming that no T1DGC samples remain at the facility. This will serve as study documentation that all samples have been shipped or destroyed.

## G. Retention of Study Documents, Materials, and Supplies

The details for handling study documents, supplies and any other study-related materials are listed below. The Autoantibody and Storage Laboratory will have some study documents that will not need to be retained or archived after the study closes. The Autoantibody and Storage Laboratory staff should discuss disposal of any study-related documents or materials with the Coordinating Center prior to disposing to ensure that disposal is appropriate in all instances.

### 1. Protocol, Manual of Operations

One copy of the Manual of Operations and one copy of the Protocol should be archived with the study records. All others may be destroyed following the local institution's policies for discarding study-related materials.

### 2. Study Records

Each Autoantibody and Storage Laboratory should have copies of the clinic and autoantibody shipping forms for the T1DGC. All records must be saved for a minimum of five years following the close-out of the overall study (per National Institute of Health requirements). Each Autoantibody and Storage Laboratory should check with the local IRB/EC to determine if the local institution requires a longer period of retention. Study forms must be retained for the longer period of time.

The Autoantibody and Storage Laboratory is responsible for determining that the records are appropriately prepared for storage (as outlined in Section II.I.6 of this chapter). The records should be located in locked storage or may be archived with an archival company, depending on the local institution's policies for study record storage. Wherever the records are stored, they should be accessible to the T1DGC, if needed.

### 3. Equipment Purchased by T1DGC

With few exceptions, any equipment purchased by T1DGC funds for the conduct of the study, such as freezers, may be retained by the Autoantibody and Storage Laboratory. The Autoantibody and Storage Laboratory should contact the Coordinating Center to ensure this is permissible, under direction from the funding agencies.

### 4. Mailing Labels/Shipping Labels/ Data Forms

At the time of close-out, any remaining address/shipping labels or airbills may be destroyed. All unused data forms may be destroyed following the local institution's policies for discarding study-related materials.

## H. Administrative Tasks for Autoantibody and Storage Laboratory Close-Out

In addition to ensuring that all documentation is correct, all study results have been received, all samples have been shipped to their final location, and all study documents, materials and supplies have been properly redistributed, stored or destroyed, tasks may arise on a laboratory-specific basis. These include confirming the individuals to be included in the T1DGC acknowledgment list and preparing the final invoice.

The Autoantibody and Storage Laboratory Principal Investigator should designate the responsible person who will be available should future contact with the laboratory be required and provide complete contact information to the Coordinating Center.

When the Autoantibody and Storage Laboratory has completed all of the necessary activities for data verification and cleaning, record retention and close-out, the Autoantibody and Storage Laboratory staff or Principal Investigator should notify their IRB/EC of the closure of the study.

## I. Coordinating Center Tasks for Autoantibody Laboratory Close-Out

The Coordinating Center will conduct a final site visit at each Autoantibody and Storage Laboratory to review the final close-out activities and to ensure that all data verification and cleaning, record retention and other required closure activities have been completed. The agenda for this close-out site visit is in Appendix F.

Throughout the close-out process, the Coordinating Center will itemize remaining tasks and work with the Autoantibody and Storage Laboratory to develop the appropriate timeline. Examples of close-out documents can be found in Appendix G.

When the Autoantibody and Storage Laboratory has completed all of the necessary activities for data verification and cleaning, record retention and close-out of the Autoantibody and Storage Laboratory, access to the T1DGC data entry web site will be removed for all Autoantibody and Storage Laboratory staff. After all tasks have been completed, the Coordinating Center will notify the Project Office and Autoantibody and Storage Laboratory that the laboratory is closed.

## V. DNA REPOSITORY CLOSE-OUT

The DNA Repositories will receive green top tubes and cell pack DNA samples throughout the duration of recruitment. They are responsible for growing the cell line and extracting DNA from the cell pack and cell line sample. DNA samples will be shared with various genotyping projects throughout the duration of the T1DGC project. Ultimately, all storage samples will be transferred to the NIDDK Central Genetics Repository located at Rutgers University (New Brunswick, NJ, USA) and the NIDDK Central Biosample Repository located at Fisher Bioservices (Germantown, MD, USA). Close-out tasks consist of ensuring that all cell lines have been grown successfully, DNA aliquots have been aliquoted for all participants, DNA aliquots have been supplied appropriately to the various study directed genotyping projects, all paperwork has been correctly entered and stored and all samples have been shipped to the final location. Specifics about each of these tasks are described below.

## A. Final Receipt of Clinic Shipments and Documentation

The Regional Network Centers will work with the clinics and the Network DNA Repository to ensure that all shipments of green top tubes and cell pack DNA samples have been shipped and received by the laboratory.

In conjunction with the Regional Network Centers, it is the responsibility of the DNA Repository to ensure that receipt and entry of all clinic shipping forms is complete and accurate. The original clinic shipping forms should be shipped to the Regional Network Center, with copies retained at the DNA Repository. (See Section V.H, "Retention of Study Documents, Materials, and Supplies.")

Prior to clinic close-out and before review of laboratory close-out specific reports, all reports will be reviewed and should be clear of outstanding participants and issues. The reports to be reviewed include:

1. Dynamic Reports (from the T1DGC data entry web site):
    a. Clinic Summary
    b. Outstanding Data/Sample Collection
    c. Irregularities
    d. QC Samples (missing and stray)
    e. Incomplete Minority Trio Families
2. Final Review of Query System
3. Redraw Report
4. Generated Reports Specific to Family/Participant Close-out (including all data from Network Laboratories and Central Repositories):
    a. Invalid IDs
    b. Incomplete Families and Participants
    c. Outstanding Notification to Destroy Samples (NTDS)
    d. Inventory
    e. Case Parents
    f. QC Samples

5. QC Reports:
    a. DNA Table 2.1: Clinic Discrepancies (cell lines)
    b. DNA Table 5.1: Clinic Discrepancies (cell packs)

All outstanding queries related to the number of samples collected and number of samples shipped and received must be resolved prior to clinic close-out. Queries from all clinics must be resolved prior to close-out of the DNA Repository.

**B. Final Upload of Results**

Prior to DNA Repository close-out, all cell lines must be grown up, where appropriate, and DNA must be extracted from all cell lines, cell packs and green top tubes, where appropriate. The Coordinating Center will work with the Network laboratories to identify individuals for whom results are missing. Prior to close-out, the Coordinating Center and Network DNA Repository will ensure that reports reflecting that the following have been completed are clear:

1. Cell Line Transformation Spreadsheet
    a. All participants with a green top tube sent and who agreed to have a cell line grown up are represented on the spreadsheet
    b. Cell line transformation has been initiated on all participants for whom a sample was received.
2. No cell line transformation in process (*i.e.,* designated as pending)
3. DNA Yield Spreadsheet
    a. All applicable participants with either a green top tube or cell pack tube represented on the spreadsheet
    b. DNA extracted from all green top tubes (cell lines)
    c. DNA extracted from all green top tubes (whole blood)
    d. DNA extracted from all cell packs

After all results have been uploaded, the final quality control reports will be run and posted on the T1DGC web site.

## C. Final Shipments to Contributing Investigators, Genotyping Facilities and and NIDDK Central Repositories

At time of final laboratory close-out, all T1DGC samples that originally resided in the DNA Repository must either have been shipped to another location or destroyed. Specific details related to inventory are described below.

### 1. Shipments to Contributing Investigators

The Regional Network Center is responsible for ensuring that Contributing Investigators are notified in a timely fashion that they may request data and samples (one cell line aliquot and/or one DNA aliquot) from the participants they contributed to the T1DGC. The Coordinating Center will supply the requested data to the Contributing Investigators and prepare the manifest for the samples the Network DNA Repository will ship to the investigator. The Coordinating Center will work with the laboratories to ensure that all cell line and/or DNA samples have been sent to the requesting Contributing Investigator.

### 2. Shipments to Consortium Members

Prior to the initiation of the NIDDK Central Genetics Repository, the Network DNA Repositories are responsible for shipments of DNA aliquots to Consortium Members with approved access requests. The Coordinating Center will prepare the manifests for the samples the Network DNA Repository will ship to the investigator. The Coordinating Center will work with the laboratories to ensure that all DNA samples have been sent to the requesting Consortium Members.

### 3. Shipments to Genotyping Facilities

The Network DNA Repositories are responsible for shipments to multiple genotyping facilities, including Network HLA Genotyping Laboratories, the Center for Inherited Disease Research (CIDR), the MHC Fine Mapping Laboratory, the Rapid Response Laboratory, the Genome Wide Association Laboratory (DIL), and the CNV Laboratory (University of Virginia). Multiple shipments will be sent to the University of Virginia (UVA), including residual cell line DNA, cell pack

DNA, and PBMC samples.

The Coordinating Center will supply instructions and create manifests for shipments to all genotyping facilities. The Coordinating Center will work with the laboratories to ensure that all samples have been sent and received by the appropriate genotyping facility. The "Shipments to HLA" reports; genotyping data sets received from CIDR, MHC, Rapid Response and the DIL; and the UVA inventory will help to identify samples that have not yet been shipped to their final location.

## 4. Shipments to NIDDK Central Repositories

Cell line aliquots and DNA samples will be sent to the NIDDK Central Repositories located at Rutgers University (New Brunswick, NJ, USA) and Fisher Bioservices (Germantown, MD, USA). Renewable resources (*i.e.*, cell lines and cell line DNA) will be sent to Rutgers and non-renewable resources (*i.e.*, cell pack DNA, whole blood DNA) will be sent to Fisher.

### *a. Cell line shipments*

Each T1DGC participant should have at least one viable cell line aliquot sent to Rutgers. After the initial shipment of each individual's cell line aliquot, Rutgers will grow up the cell line and determine viability status. Samples that are deemed to be not viable, or have not yet been assessed for viability, will require a replacement cell line sample to be sent to Rutgers. Up to three replacement samples may be sent. The Coordinating Center will work with the laboratories to ensure that all cell line samples have been sent and received by the NIDDK Central Repository. The "approved cell line" and "not approved cell line" reports, in conjunction with the quality control reports, will help to identify samples that have not been shipped to Rutgers or have not been deemed as viable by Rutgers.

*b. DNA shipments*

The Network DNA Repository is responsible for shipping up to three cell line DNA aliquots to Rutgers, up to two cell pack DNA samples to Fisher and up to two whole blood DNA samples to Fisher. DNA samples of each of these types may not be available for each participant. The Coordinating Center will work with the laboratories to ensure that all applicable DNA samples have been sent and received by the NIDDK Central Repository. The "approved DNA aliquots" and "not approved DNA aliquots" reports, in conjunction with the quality control reports, will help to identify samples that have not been shipped to the NIDDK Central Repositories.

## D. Final Review of Shipping Forms and Resolution of Discrepancies

Throughout the duration of the study, all original DNA Repository shipping forms will be forwarded to the Coordinating Center for review and comparison to the T1DGC specimen tracking system. At the time of close-out, the Coordinating Center will notify the DNA Repository of all outstanding forms and discrepancies between the paper copies and the T1DGC specimen tracking system. This includes the following shipping forms: (1) *DNA Repository Shipping Form: Shipment to HLA Genotyping Laboratory*; (2) *DNA Repository Shipping Form: Shipment to CIDR*; (3) *DNA Repository Shipping Form: Shipment to MHC Fine Mapping Laboratory*; (4) *DNA Repository Shipping Form: Shipment to Rapid Response Laboratory*; (5) *DNA Repository Shipping Form: Shipment to DIL*; (6) *DNA Repository Shipping Form: Shipment to Rutgers (DNA samples)*; (7) *DNA Repository Shipping Form: Shipment to Rutgers (cell line samples)*; (8) *DNA Repository Shipping Form: Shipment to Fisher (DNA samples)*; (9) *DNA Repository Shipping Form: Shipment to Fisher (WGA samples)*; (10) *DNA Repository Shipping Form: Shipment to Contributing Investigators*; (11) *DNA Repository Shipping Form: Shipment to Consortium Members*; (12) *DNA Repository Shipping Form: Shipment to UVA (cell pack samples)*; (13) *DNA Repository Shipping Form: Shipment to UVA (PBMC samples)*; and (14) *DNA Repository Shipping Form: Shipment to UVA (cell line DNA samples)*.

For shipments to the HLA Genotyping Laboratories, the Coordinating Center must have two originals of each shipping form; one completed by the shipping laboratory (DNA Repository) and one completed by the receiving laboratory (HLA Genotyping Laboratory). The Coordinating Center will review the *Face Sheets* and *Contents Sheets* of all shipping forms. All discrepancies between the paper copies and the specimen tracking system must be corrected prior to close-out.

## E. Final Review of Discrepancies between DNA Repositories and UVA

The Coordinating Center will work with the UVA facility in order to ensure that all samples shipped from the Network DNA Repositories have been received. The UVA facility will be responsible for ensuring that the shipping forms and manifest match the samples received for all shipments, including cell pack DNA, cell line DNA and PBMC samples. The Coordinating Center will communicate any discrepancies between the samples shipped and received to the Network DNA Repository. All discrepancies must be resolved prior to close-out.

## F. Final Review of Reports/Families

The T1DGC is a genetic study, and as such, information may be discovered through various genotyping projects suggesting that individuals reported to be related are actually not related. This information is not to be shared with the participant or family; however, in some instances this may cause a participant or entire family to be deemed ineligible. If it is confirmed through re-collections or the individual's identity is unable to be confirmed, it may be necessary for samples that were collected to be destroyed. The Coordinating Center will work with the DNA Repository to determine samples that should be destroyed. (See Section II.D, "Procedures for Handling Outstanding Participants.")

Prior to DNA Repository close-out, all reports will be reviewed and should be clear of outstanding participants and issues. The reports to be reviewed include:

1. Generated Reports Specific to Laboratory Close-out (including all data from Network Laboratories and Central Repositories)

a. Cell line shipments to Rutgers: Approved samples
b. Cell line shipments to Rutgers: Not approved samples
c. Replacement cell line shipments to Rutgers
d. DNA shipments to Rutgers: Approved samples
e. DNA shipments to Rutgers: Not approved samples
f. Cell pack DNA shipments to Fisher: Approved samples
g. Cell pack DNA Shipments to Fisher: Not approved samples
h. Whole blood DNA shipments to Fisher: Approved samples
i. Whole blood DNA Shipments to Fisher: Not approved samples
j. Upload discrepancies: Cell line transformation sheet
k. Upload discrepancies: DNA yield sheet

2. QC Reports:
   a. DNA Table 2.1: Clinic Discrepancies (cell lines)
   b. DNA Table 5.1: Clinic Discrepancies (cell packs)
   c. DNA Table 7.1: Rutgers Discrepancies (cell lines)
   d. DNA Table 8.1: Rutgers Discrepancies (cell line DNA aliquots)
   e. DNA Table 9.1: Fisher Discrepancies (cell pack DNA aliquots)
   f. DNA Table 10.1: Fisher Discrepancies (whole blood DNA aliquots)
   g. DNA Table 11.a: Assessment of cell line viability at Rutgers (ASP)
   h. DNA Table 11.b: Assessment of cell line viability at Rutgers (Trio)
   i. DNA Table 11.c: Assessment of cell line viability at Rutgers (Case)
   j. DNA Table 11.d: Assessment of cell line viability at Rutgers (Control)

## G. Final Inventory Review

At the conclusion of the study, the DNA Repository should have shipped all samples to their final location. Remaining samples (not associated with an approved Access Request for a network repository) will be destroyed. (See Section V.J., “Establishment of Network Repositories”)

At the conclusion of recruitment, an e-mail from the Coordinating Center will direct the laboratory to destroy all pilot samples. E-mail confirmation that all pilot samples have been destroyed should be sent from the DNA Repository Principal Investigator to Joan Hilner (jhilner@wfubmc.edu) and Letitia Perdue (lperdue@wfubmc.edu). This will serve as study documentation that these samples have been destroyed.

After genotyping has been completed at the respective genotyping facilities, DNA samples and/or plates may be shipped back to the Network DNA Repository. The Network DNA Repository should confirm receipt of the samples via e-mail. An e-mail from the Coordinating Center will request that all residual DNA samples be destroyed. E-mail confirmation that all residual DNA samples from the various genotyping projects have been destroyed should be sent from the DNA Repository Principal Investigator to Joan Hilner (jhilner@wfubmc.edu) and Letitia Perdue (lperdue@wfubmc.edu). This will serve as study documentation that these samples have been destroyed.

At the time of close-out, the DNA Repository should provide a file of all residual cell lines, DNA aliquots (cell pack, cell line and whole blood) and PBMC samples. An e-mail from the Coordinating Center will request that all residual samples be destroyed. E-mail confirmation that all residual samples have been destroyed should be sent from the DNA Repository Principal Investigator to Joan Hilner (jhilner@wfubmc.edu) and Letitia Perdue (lperdue@wfubmc.edu). This will serve as study documentation that these samples have been destroyed.

A final inventory may be requested. After all remaining close-out activities have been completed, the DNA Repository Principal Investigator must send an e-mail to Joan Hilner (jhilner@wfubmc.edu) and Letitia Perdue (lperdue@wfubmc.edu) confirming that no T1DGC samples remain at the facility. This will serve as study documentation that all samples have been shipped or destroyed.

## H. Retention of Study Documents, Materials, and Supplies

The details for handling study documents, supplies and any other study-related materials are listed below. The DNA Repository will have some study documents that will not need to be retained or archived after the study closes. The DNA Repository staff should discuss disposal of any study-related documents or materials with the Coordinating Center prior to disposing to ensure that disposal is appropriate in all instances.

### 1. Laboratory Supplies Purchased by T1DGC

The Coordinating Center centrally purchased all fetal bovine serum (FBS) for cell line transformations in the DNA Repositories throughout the study. Any repository closing before the overall study closure should discuss the disposition of remaining FBS with the Coordinating Center staff. Because the FBS was purchased with T1DGC funds, the repository may be required to ship remaining items to another repository that is still transforming cell line samples. The remaining FBS status will be evaluated for each individual repository, based on expiration dates and needs at other repositories. Following the closure of the overall study, the laboratory may dispose of any remaining FBS by placing it into their laboratory inventory where appropriate or by discarding any FBS that has expired or is no longer needed.

### 2. Protocol, Manual of Operations

One copy of the Manual of Operations and one copy of the Protocol should be archived with the study records. All others may be destroyed following the local institution's policies for discarding study-related materials.

### 3. Study Records

Each DNA Repository should have copies of the clinic and DNA shipping forms for the T1DGC. All records must be saved for a minimum of five years following the close-out of the overall study (per National Institute of Health requirements). Each DNA Repository should check with the local IRB or EC to determine if the

local institution requires a longer period of retention. Study forms must be retained for the longer period of time.

The DNA Repository is responsible for determining that the records were appropriately prepared for storage (as outlined in Section II.I.6 of this chapter) and complete this preparation. The records should be located in locked storage or may be archived with an archival company, depending on the local institution's policies for study record storage. Wherever the records are stored, they should be accessible to the T1DGC, if needed.

### 4. Equipment Purchased by T1DGC

With few exceptions, any equipment purchased by T1DGC funds for the conduct of the study, such as freezers, may be retained by the DNA Repository. The DNA Repository should contact the Coordinating Center to ensure this is permissible, under direction from the funding agencies.

### 5. Mailing Labels/Shipping Labels/Participant Label Packets/Data Forms

At the time of close-out, any remaining address/shipping labels or airbills may be destroyed. All unused label packets and unused data forms may be destroyed following the local institution's policies for discarding study-related materials.

## I. Additional Tasks

Additional tasks related to samples considered part of the T1DGC existing collection may be required prior to DNA Repository close-out. The United Kingdom DNA Repository is responsible for ensuring that all cell line and DNA samples from the UK GRID collection have been shipped and received by Rutgers. Replacement samples may be required for samples deemed as non-viable by Rutgers. The whole genome amplified (WGA) samples from the Danish, Joslin and Sardinian existing collection cohorts will be shipped to the NIDDK Repository at Fisher Bioservices. The Coordinating Center, will work with the UK DNA Repository to ensure that all samples have been sent and received by the appropriate Central Repository.

The UK DNA Repository serves the dual purpose of also being responsible for the GWAS Genotyping Project. As such, this genotyping facility will be responsible for shipping residual DNA sent as part of this project to UVA for future study-directed genotyping projects.

## J. Establishment of Network Repositories

In several networks, the Regional Network Center Principal Investigator may request to retain the residual cell line aliquots that would otherwise be destroyed prior to close-out. In these cases, the Network Principal Investigator must submit a T1DGC Access Request through the T1DGC Access System. The Contributing Investigator must agree that their samples can be retained as part of this request. If the request is approved, as part of the final inventory reconciliation prior to close-out of the Network DNA Repository, the Coordinating Center will work with the Network DNA Repository to identify the samples that may be retained as part of the network repository.

Once the final inventory has been received at the Coordinating Center, the Coordinating Center will identify participants from the clinics whose Contributing Investigator agreed to have their samples be retained as part of the network repository. Any samples for participants for which the Contributing Investigator did not agree will be destroyed. Confirmation of destruction will follow the steps described above in regards to close-out of remaining samples.

The final inventory of samples retained as part of the approved Access Request and network repository should be sent to the Coordinating Center. This will serve as study documentation for the location of these samples.

## K. Administrative Tasks for DNA Repository Close-Out

In addition to ensuring that all documentation is correct, all study results have been received, all samples have been shipped to their final location, and all study documents, materials and supplies have been properly redistributed, stored or destroyed, tasks may arise on a laboratory-specific basis. These include confirming the

individuals to be included in the T1DGC acknowledgment list and preparing the final invoice.

The DNA Repository Principal Investigator should designate the responsible person who will be available should future contact with the laboratory be required and provide complete contact information to the Coordinating Center.

When the DNA Repository has completed all of the necessary activities for data verification and cleaning, record retention and close-out, the DNA Repository staff or Principal Investigator should notify their IRB/EC of the closure of the study.

### L. Coordinating Center Tasks for DNA Repository Close-Out

The Coordinating Center will conduct a final site visit at each DNA Repository to review the final close-out activities and to ensure that all data verification and cleaning, record retention and other required closure activities have been completed. The agenda for this close-out site visit is provided in Appendix H.

Throughout the close-out process, the Coordinating Center will itemize remaining tasks and work with the DNA Repository to develop the appropriate timeline. Examples of the close-out documents can be found in Appendix I.

When the DNA Repository has completed all of the necessary activities for data verification and cleaning, record retention and close-out of the DNA Repository, access to the T1DGC data entry web site will be removed for all DNA Repository staff. After all tasks have been completed, the Coordinating Center will notify the Project Office and DNA Repository that the laboratory is closed.

## VI. HLA GENOTYPING LABORATORY CLOSE-OUT

The Network HLA Genotyping Laboratories will receive DNA aliquots throughout the duration of recruitment. These laboratories are responsible for performing the HLA genotyping on all participants. Ultimately, all residual DNA aliquots will be destroyed.

Close-out tasks consist of ensuring that all genotyping has been completed, all paperwork has been correctly entered and stored, and all samples have been destroyed. Specifics about each of these tasks are described below.

## A. Final Receipt of Shipments and Documentation

The Coordinating Center will work with the Network DNA Repository and the Network HLA Genotyping Laboratory to ensure that all shipments of DNA samples have been shipped and received by the HLA Genotyping Laboratory.

Prior to clinic close-out and before review of laboratory close-out specific reports, all reports will be reviewed and should be clear of outstanding participants and issues. The reports to be reviewed include:

1. Dynamic Reports (from the T1DGC data entry web site):
    a. Clinic Summary
    b. Outstanding Data/Sample Collection
    c. Irregularities
    d. QC Samples (missing and stray)
    e. Incomplete Minority Trio Families
2. Final Review of Query System
3. Redraw Report
4. Generated Reports Specific to Family/Participant Close-out:
    a. Invalid IDs
    b. Incomplete Families and Participants
    c. Inventory
    d. QC Samples
5. Generated Reports Specific to Laboratory Close-out:
    a. Outstanding HLA samples
6. QC Reports:
    a. QC Report: HLA 1a.1: DNA Discrepancies: Existing Collection
    b. QC Report: HLA 1b.1: DNA Discrepancies: Current Collection

Queries from all clinics must be resolved prior to close-out of the HLA Genotyping Laboratory. The Coordinating Center will work with the Regional Network Centers and the DNA Repositories to ensure that samples have been shipped for all T1DGC participants. Each participant should have at least one DNA aliquot that has been sent for HLA genotyping. Results should be provided for all participants.

**B. Final Upload of Results**

Prior to HLA Genotyping Laboratory close-out, genotyping results from each participant should be uploaded to the Coordinating Center. The Coordinating Center will work with the laboratories to identify individuals for whom results are missing. All plates must be uploaded through the T1DGC HLA Genotyping System, including any re-dos that are required.

After all results have been uploaded, the final quality control reports will be generated and posted on the T1DGC web site. The laboratories will have the opportunity to identify any QC sample pairs where they believe one sample may have been mislabeled. These pairs should be reported to the Coordinating Center, and, if necessary, two separate set of quality control reports will be run: the first will assess the quality of the overall collection (from clinic to laboratory) and the second set will assess the laboratory quality.

**C. Final Shipments to Other HLA Genotyping Laboratory**

The Network HLA Genotyping Laboratories will be responsible for shipping specified samples for the 454 project to the HLA Genotyping Laboratory at Children's Hospital Oakland Research Institute (CHORI; Oakland, CA, USA). The Coordinating Center will work with the laboratories to ensure that all requested residual samples have been sent and received by the CHORI laboratory. The "Shipments to CHORI" reports will help to identify samples that have not yet been shipped.

## D. Final Review of Shipping Forms and Resolution of Discrepancies

Throughout the duration of the study, all original HLA genotyping shipping forms will be forwarded to the Coordinating Center for review and comparison to the T1DGC specimen tracking system. At the time of close-out, the Coordinating Center will notify the HLA Genotyping Laboratory of all outstanding forms and discrepancies between the paper copies and the T1DGC specimen tracking system. This includes the *DNA Repository Shipping Form: Shipments to HLA Genotyping Laboratories* and the *HLA Genotyping Laboratory Shipping Form: Shipments to CHORI*. The Coordinating Center must have two originals of each shipping form; one completed by the shipping laboratory and one completed by the receiving laboratory. The Coordinating Center will review the *Face Sheets* and *Contents Sheets* of all shipping forms. All discrepancies between the paper copies and the specimen tracking system must be corrected prior to close-out.

## E. Final Review of Reports/Families

The T1DGC is a genetic study, and as such, information may be discovered through various genotyping projects suggesting that individuals reported to be related are actually not related. This information is not to be shared with the clinic. Prior to HLA Genotyping Laboratory close-out, all discovered Mendelian inheritance errors (MIEs) must be resolved either through re-collections or confirmation of unrelatedness. The Coordinating Center will work with the laboratories to determine the cause of the error. Quality control report HLA 4.a and 4.b should show no unresolved MIEs prior to close-out of the HLA Genotyping Laboratory.

Prior to HLA Genotyping Laboratory close-out, all reports will be reviewed and should be clear of outstanding participants and issues. The reports to be reviewed include:

1. Generated Reports Specific to Laboratory Close-out):
    a. Outstanding HLA samples
2. QC Reports:
    a. QC Report: HLA 1a.1: DNA Discrepancies: Existing Collection

b. QC Report: HLA 1b.1: DNA Discrepancies: Current Collection

c. QC Report: HLA 4a.1: MIEs: Existing Collection

d. QC Report: HLA 4b.1: MIEs: Current Collection

## F. Final Inventory Review

At the conclusion of the study, the HLA Genotyping Laboratory will destroy al residual samples. At the time of close-out, the HLA Genotyping laboratory may be requested to provide a file of all residual samples. An e-mail from the Coordinating Center will request that the residual DNA and plates be destroyed. In some cases, the Network HLA Laboratory may be requested to ship all residual DNA or shipped to the Network DNA Repository. E-mail confirmation that all residual DNA samples have been destroyed (or shipped) should be sent from the HLA Genotyping Laboratory Principal Investigator to Joan Hilner (jhilner@wfubmc.edu) and Letitia Perdue (lperdue@wfubmc.edu). This will serve as study documentation that these samples have been destroyed.

A final inventory may be requested. After all remaining close-out activities have been completed, the HLA Genotyping Laboratory Principal Investigator must send an e-mail to Joan Hilner (jhilner@wfubmc.edu) and Letitia Perdue (lperdue@wfubmc.edu) confirming that no T1DGC samples remain at the facility. This will serve as study documentation that these samples have been destroyed.

## G. Retention of Study Documents, Materials, and Supplies

The details for handling study documents, supplies and any other study-related materials are listed below. The HLA Genotyping Laboratory will have some study documents that will not need to be retained or archived after the study closes. The HLA Genotyping Laboratory staff should discuss disposal of any study-related documents or materials with the Coordinating Center prior to disposing to ensure that disposal is appropriate in all instances.

## 1. Laboratory Supplies Purchased by T1DGC

Any laboratory closing before the overall study closure should discuss the disposition of remaining reagents and genotyping strips with the Coordinating Center staff. Because these were purchased with T1DGC funds, the laboratory may be required to ship remaining items to another laboratory for dispersal to laboratories that are still genotyping samples. This supply status will be evaluated for each individual laboratory based on the type of supplies remaining, expiration dates, and needs at other laboratories.

Following the closure of the overall study, the laboratory may dispose of any remaining laboratory supplies by putting them into their laboratory inventory where appropriate or by discarding any supplies that have expired or are no longer needed.

## 2. Protocol, Manual of Operations

One copy of the Manual of Operations and one copy of the Protocol should be archived with the study records. All others may be destroyed following the local institution's policies for discarding study-related materials.

## 3. Study Records

Each HLA Genotyping Laboratory should have copies of the clinic and HLA shipping forms for the T1DGC. All records must be saved for a minimum of five years following the close-out of the overall study (per National Institute of Health requirements). Each HLA Genotyping Laboratory should check with the local IRB or EC to determine if the local institution requires a longer period of retention. Study forms must be retained for the longer period of time.

The HLA Genotyping Laboratory is responsible for determining that the records were appropriately prepared for storage (as outlined in Section II.I.6 of this chapter). The records should be located in locked storage or may be archived with an archival company, depending on the local institution's policies for study

record storage. Wherever the records are stored, they should be accessible to the T1DGC, if needed.

**4. Equipment Purchased by T1DGC**

With few exceptions, any equipment purchased by T1DGC funds for the conduct of the study, such as Bee Blot machines and scanners, may be retained by the HLA Genotyping Laboratory. The HLA Genotyping Laboratory should contact the Coordinating Center to ensure this is permissible, under direction from the funding agencies.

**5. Mailing Labels/Shipping Labels/Participant Label Packets/Data Forms**

At the time of close-out, any remaining address/shipping labels or airbills may be destroyed. All unused label packets and unused data forms may be destroyed following the local institution's policies for discarding study-related materials.

## H. Administrative Tasks for HLA Genotyping Laboratory Close-Out

In addition to ensuring that all documentation is correct, all study results have been received, all samples have been shipped to their final location, and all study documents, materials and supplies have been properly redistributed, stored or destroyed, tasks may arise on a laboratory-specific basis. These include confirming the individuals to be included in the T1DGC acknowledgment list and preparing the final invoice.

The HLA Genotyping Laboratory Principal Investigator should designate the responsible person who will be available should future contact with the laboratory be required and provide complete contact information to the Coordinating Center.

When the HLA Genotyping Laboratory has completed all of the necessary activities for data verification and cleaning, record retention and close-out, the HLA Genotyping Laboratory staff or Principal Investigator should notify their IRB/EC of the closure of the study.

## I. Additional Tasks

Additional tasks related to the 454 ambiguity analysis must be completed by the North American HLA Genotyping Laboratory prior to close-out. This includes receipt of all samples, genotyping and analysis of all samples, and upload of results to the Coordinating Center. The residual DNA after this genotyping has been completed will be destroyed as part of close-out procedures.

## J. Coordinating Center Tasks for HLA Genotyping Laboratory Close-Out

The Coordinating Center will conduct a final site visit at each HLA Genotyping Laboratory (if needed) to review the final close-out activities and to ensure that all data verification and cleaning, record retention and other required closure activities have been completed.

Throughout the close-out process, the Coordinating Center will itemize remaining tasks and work with the HLA Genotyping Laboratory to develop the appropriate timeline. Examples of the close-out documents can be found in Appendix J.

When the HLA Genotyping Laboratory has completed all of the necessary activities for data verification and cleaning, record retention and close-out of the HLA Genotyping Laboratory, access to the T1DGC data entry web site will be removed for all HLA Genotyping Laboratory staff. After all tasks have been completed, the Coordinating Center will notify the Project Office and HLA Genotyping Laboratory that the laboratory is closed.

# VII. COORDINATING CENTER CLOSE-OUT

The Coordinating Center will be closed-out after all clinics, Regional Network Centers and laboratories are closed. Close-out tasks consist of ensuring that all facilities are closed appropriately as described above, creation of the final data sets, updating all source documents, updating the web site, close-out of all fiscal accounts, dissemination of information to the NIDDK Central Repositories, and archive of data and source documentation. Specifics about each of these tasks are described below.

## A. Close-out of All Facilities

The Coordinating Center will work with all Regional Network Centers and laboratories to ensure the proper steps have been completed regarding close-out. Close-out site visits and close-out conference calls will be completed on a frequent basis during the close-out procedure. The Coordinating Center will not be closed until all facilities have been closed.

## B. Final Data Sets

The Coordinating Center is responsible for the final data capture. This includes a thorough review of all family and participant data, ensuring all samples reside in their final location and completion of an inventory of the location of all T1DGC samples and creation of a “golden pedigree” and catalog of all T1DGC data and samples.

The “golden pedigree” consists of determining the appropriate family structure, using all genotyping results available and confirmation about familial relationship from the clinics, if possible. After the “golden pedigree” has been established, all genotypic and phenotypic data sets will be created for the final data sets.

After the final data sets have been created, all reports will be re-run and reviewed a final time.

## C. Final Source Documents

All T1DGC source documents will be updated at the time of close-out in order to ensure that all are up-to-date. The final documents will be posted to the T1DGC web site and made available to the NIDDK Central Repositories for release to the scientific community.

## D. Web Site Updates

At the time of close-out, access to the T1DGC data entry web site will be restricted to only those Coordinating Center personnel directly involved with close-out procedures. After study close-out, the T1DGC data entry system will be deactivated

and archived at Wake Forest University.

The Coordinating Center is responsible for updating information on the public web site to represent that the study is closed. Final data sets and documentation will be made available via the web site for three months. Prior to close-out, all data set links will be removed from the public T1DGC web site. The public T1DGC web site will remain accessible indefinitely, with the links to any data sets disabled. However, the T1DGC Coordinating Center will not update or maintain the web site after close-out.

## E. Fiscal Accountability

The T1DGC Coordinating Center is responsible for payment of final invoices to all subcontractors. At the conclusion of recruitment, the master accounts will be closed. It is the responsibility of the Coordinating Center to prepare the final report to the funding agencies, including the final fiscal report, final recruitment numbers and list of achievements. The final fiscal report must be sent to the funding agencies within 90 days of the close of the funding period.

## F. Dissemination of Information to the NIDDK Central Repositories

After the T1DGC Coordinating Center is closed, the NIDDK Central Repositories will be responsible for all requests for data and samples. To this end, it is critical that the NIDDK Central Repositories understand the study and have all necessary information and documentation. Staff from the Coordinating Center will visit the NIDDK Central Repositories to resolve any issues early on. A final close-out visit consisting of representatives from the Coordinating Center, Project Office and all NIDDK Central Repositories (Genetics, Biosample, and Data) will allow all individuals the opportunity to clarify any outstanding issues.

The T1DGC Coordinating Center will create a checklist of all materials to be transferred to the NIDDK Central Data Repository (Appendix K). The NIDDK Central Data Repository will sign off that they have received and reviewed the data.

## G. Archive of Data and Source Documentation

The T1DGC Coordinating Center is responsible for retaining study records for a minimum of five years following the close-out of the overall study (per National Institute of Health requirements). If the Coordinating Center IRB/EC has a longer period of retention, study records will be retained for the longer period of time. Records must be appropriately prepared for storage (as outlined in Section II.I.6 of this chapter). The records should be located in locked storage or may be archived with an archival company, depending on the local institution's policies for study record storage. Wherever the records are stored, they should be accessible to the T1DGC, if needed.

In addition to study records, the Coordinating Center will archive the database, phenotypic and genotyping data sets, and the data entry web site for the requisite period of time.

## H. Miscellaneous Tasks

Additional tasks may arise for the Coordinating Center associated with close-out. The Coordinating Center will maintain the IRB approval for two years after the study is closed-out in order to answer questions as they arise and finalize all archiving.

# VII. T1DGC CLOSE-OUT

Close-out of the T1DGC will be an ongoing process until all sites and facilities are closed. After the T1DGC Coordinating Center and Steering Committee have ceased to exist, responsibility for the T1DGC data and samples will reside with the NIDDK Central Repositories.

# APPENDIX A
# CONVERSION TO CASE FORM:
# QUESTION BY QUESTION INSTRUCTIONS

These instructions are meant to assist the interviewer and to provide answers to any questions from a participant or clinic staff member.

This form is administered to the case or to the case's guardian (*i.e.,* the biological mother, the biological father, or other legal guardian). Only one person is interviewed, although more than one can be present. The interviewer reads the questions to the participant and marks or records appropriate answers. For some questions the interviewer reads all the choices listed to the participant and marks affirmative responses.

Information in all capital letters is an instruction to the interviewer and is not read to the participant.

Please complete all parts of the form. Note that certain individual items may be marked "Don't know" and with an asterisk. In these cases, continue completing the form and contact the appropriate individuals within 10 days in order to collect information not known at the time of the initial exam. The participant may need to contact his/her physician or other family members in order to obtain information. Items should be followed-up, but forms should be forwarded to the Regional Network Center when it has become apparent that this information will not be found.

All dates are written as day first, month second, and year third. The day is recorded numerically. If the day is a single-digit number, a "0" is recorded in the first box. The month is written out in its entirety (*e.g.,* January, February). The year is recorded numerically, with all four digits of the year included (*e.g.,* 1950). Any single digit numerical response is recorded with a leading "0" (*e.g.,* if participant is 5 years old, record "05").

**Question by Question Instructions**

The interviewer affixes the case's Participant ID Label in the box shown in the upper right hand corner. A label is affixed on every page.

The interviewer records the clinic ID for his/her individual clinic. This number is assigned by the Regional Network Center and it is recorded on every page.

The interviewer records the secondary ID for the participant. The secondary ID is "AS1" for the proband, or "AS2," "AS3," "AS4," or "AS5" for an affected sibling. The secondary ID is recorded on every page.

**1. Case was previously a:**

The interviewer selects the type of participant that the individual was previously considered. If the participant was originally a member of a trio family, the interview marks "Trio Proband." If the participant was originally a member of an ASP family, the individual selects either "Minority ASP Proband" or "Minority ASP Affected Sibling."

**2. Interview Date**

This is the date the interview takes place or the date the form was completed. Record the date of the interview in the appropriate boxes. For some clinics, the information on the form is abstracted from other sources and transferred onto this form. In this case, the interviewer records the date the information is abstracted and the form is completed. **This form should never be completed until the participant has signed the *Informed Consent*.**

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

The interviewer marks all sources from which information is gathered about the participant. If information is obtained by calling a participant before he/she comes into the clinic, mark "Phone interview." If the participant comes into the clinic and is interviewed in person, the interviewer marks "Face-to-face interview." If information is abstracted from other sources (*e.g.,* other forms, pulling medical records), the

interviewer marks “From existing records.” The interviewer marks all applicable answers.

**4. Who is completing this form? CASE IS THE PERSON/CHILD DIAGNOSED WITH TYPE 1 DIABETES. IF GUARDIAN COMPLETING FORM, READ ITALICIZED TEXT. ONLY ONE GUARDIAN IS INTERVIEWED.**

The interviewer marks “Case” if the participant is answering questions about himself/herself. If a guardian is answering the questions, the interviewer determines the relationship the guardian has with the case. The interviewer may ask the guardian his/her relationship to the child, if it is not already known. The interviewer marks “Biological Father” if the man completing the interview believes himself to be the biological father of the case. The interviewer marks “Biological Mother” if the woman completing the interview gave birth to the case. The interviewer marks “Other Guardian” if the guardian completing this form is neither biological parent of the case. Only one guardian answers the questions, however more than one guardian can be present at the interview. The interviewer should be aware of the relationship the guardian has to the child while administering this questionnaire. If the form is administered to the guardian, the italicized text in parentheses is read. Versions of questions may differ based upon the relationship to the case.

**5. Is your *(your child’s)* origin of birth, or primary ethnic origin one of the following? READ CHOICES AND RECORD PARTICIPANT’S RESPONSE.**

In Asia-Pacific or European Networks read the categories listed in the first section of the question: Cameroon, India or Thailand. If the participant answers “None of the above,” stop completing this form; this participant is ineligible.

In the North American Network, read the choices listed under the second section of the question: Mexican American, African American or both. If the participant answers “None of the above,” stop completing this form; this participant is ineligible.

**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.**

**QUESTION 6 REFERS TO THE CASE'S CHILDREN.**

**6. Do you *(Does your child)* have any children? Exclude any adopted children or stepchildren.**

The participant responds "Yes" if he/she, or the child, has any biological children and continues to Question 6a. Both living and deceased children are included. Stepchildren and adopted children are not included. The participant responds "No" if he/she, or the child, does not have any children, but the case is old enough to have children. The interviewer skips to Question 7. The interviewer marks "Question not asked" if the case is not old enough to have children and the interviewer does not ask the question and skips to Question 7. If the participant does not know this information, but the case is old enough to have children, mark the "Don't know" box and skip to Question 7.

**6a. How many children do you *(does your child)* have?**

The participant responds by giving the number of biological children he/she, or the child, has.

**6b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.**

The participant responds by giving the number of biological children he/she, or the child, has who have been diagnosed with type 1 diabetes, as defined by the T1DGC.

**6c. How many of them have another type of diabetes?**

The participant responds by giving the number of biological children he/she, or the child, has who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

**6d. How many of them are not affected or you don't know if they are affected with any type of diabetes?**

The participant responds by giving the number of biological children he/she, or the child, has without any form of diabetes, or is unsure of the children's diabetes status. The interviewer performs a quick check to be certain the answers to Questions 6b, 6c, and 6d add up to the answer given in Question 6a.

**QUESTIONS 7a – 7c REFER TO THE CASE'S MATERNAL RELATIVES**

**7a. Which of your *(your child's)* following biological relatives have been diagnosed with type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.**

The interviewer can expect a "Yes" or "No" answer to each choice. The participant only answers "Yes" if the family member has been diagnosed with type 1 diabetes, as defined by the T1DGC. If the participant answers "Don't know" to any of the questions, continue with the form.

**7b. Which of your *(your child's)* following biological relatives have been diagnosed with another type of diabetes?**

The interviewer can expect a "Yes" or "No" answer to each choice. If the participant answers "Don't know" to any of the questions, continue with the form.

**7c. Do you *(Does your child)* have any full aunts and uncles on your *(child's)* mother's side?**

The participant responds "Yes" if he/she, or the child, has any biological full aunts and uncles on his/her mother's side. These are the biological mother's full siblings.

Both living and deceased aunts and uncles are included. Step-aunts, step-uncles, adopted aunts, adopted uncles, aunts-in-law and uncles-in-law are not included. If the participant answers "No" or "Don't know," the interviewer skips to Question 8. If the participant answers "Don't know," continue with the form. If the participant answers, "Yes," continue to Question 7c1.

**7c1. How many full aunts and uncles on your *(child's)* mother's side do you *(does your child)* have?**

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her mother's side.

**7c2. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.**

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her mother's side that have been diagnosed with type 1 diabetes, as defined by the T1DGC.

**7c3. How many of them have another type of diabetes?**

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her mother's side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

**7c4. How many of them are not affected or you don't know if they are affected with any type of diabetes?**

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her mother's side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain that the answers to Questions 7c2, 7c3, and 7c4 add up to the answer given in Question 7c1.

**QUESTIONS 8a – 8c REFER TO CASE'S PATERNAL RELATIVES**

**8a. Which of your *(your child's)* following biological relatives have been diagnosed with type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.**

The interviewer can expect a "Yes" or "No" answer to each choice. The participant only answers "Yes" if the family member has been diagnosed with type 1 diabetes, as defined by the T1DGC. If the participant or guardian answers "Don't know" to any of the questions, continue with the form.

**8b. Which of your *(your child's)* following biological relatives have been diagnosed with another type of diabetes?**

The interviewer can expect a "Yes" or "No" answer to each choice. If the participant answers "Don't know" to any of the questions, continue with the form.

**8c. Do you *(Does your child)* have any full aunts and uncles on your *(child's)* father's side?**

The participant responds "Yes" if he/she, or the child, has any biological full aunts and uncles on his/her father's side. These are the biological father's full siblings. Both living and deceased aunts and uncles are included. Step-aunts, step-uncles, adopted aunts, adopted uncles, aunts-in-law and uncles-in-law are not included. If the participant answers "No" or "Don't know," the interviewer skips to Question 9. If the participant answers "Don't know," continue with the form. If the participant answers, "Yes," continue to Question 8c1.

**8c1. How many full aunts and uncles on your *(child's)* father's side do you *(does your child)* have?**

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her father's side.

**8c2. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.**

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her father's side that have been diagnosed with type 1 diabetes, as defined by the T1DGC.

**8c3. How many of them have another type of diabetes?**

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her father's side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

**8c4. How many of them are not affected or you don't know if they are affected with any type of diabetes?**

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her father's side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 8c2, 8c3, and 8c4 add up to the answer given in Question 8c1.

**9. Do you (*Does your child)* have any full brothers and sisters? Full brothers and sisters are those that have the same biological mother and the same biological father.**

The participant responds "Yes" if he/she, or the child, has any full brothers or sisters. Both living and deceased brothers and sisters are included. Step-siblings, adopted siblings and half-siblings are not included. If the participant answers "No" or "Don't know," the interviewer skips to Question 10. If the participant answers "Don't know," continue with the form. If the participant answers "Yes," continue to Question 9a.

**9a. How many?**

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has. Both living and deceased brothers and sisters are included in this count. Step-siblings, adopted siblings and half siblings are not included.

**9b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.**

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has who have been diagnosed with type 1 diabetes, as defined by the T1DGC.

**9c. How many of them have another type of diabetes?**

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

**9d. How many of them are not affected or you don't know if they are affected with any type of diabetes?**

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 9a, 9b, and 9c add up to the answer given in Question 9.

**10. Do you *(Does your child)* have any half siblings with the common parent being your *(child's)* mother?**

The participant responds "Yes" if he/she, or the child, has any half brothers and sisters on his/her mother's side; the interviewer continues to Question 10a. Both living and deceased half brothers and sisters are included. Step-siblings and adopted siblings are not included. If the participant answers "No" or "Don't know," skip to Question 11.

**10a. How many half brothers and sisters do you *(does your child)* have with common parent being your *(child's)* mother?**

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side.

**10b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.**

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side that have been diagnosed with type 1 diabetes, as defined by the T1DGC.

**10c. How many of them have another type of diabetes?**

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

**10d. How many of them are not affected or you don't know if they are affected with any type of diabetes?**

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 10b, 10c, and 10d add up to the answer given in Question 10a.

**11. Do you *(Does your child)* have any half siblings with the common parent being your *(child's)* father?**

The participant responds "Yes" if he/she, or the child, has any half brothers and sisters on his/her father's side; the interviewer continues to Question 11a. Both living and deceased half brothers and sisters are included. Step-siblings and adopted siblings

are not included. If the participant answers “No” or “Don’t know,” skip to Question 12.

**11a. How many half brothers and sisters do you *(does your child)* have with common parent being your *(child’s)* father?**

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father’s side

**11b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.**

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father’s side that have been diagnosed with type 1 diabetes, as defined by the T1DGC.

**11c. How many of them have another type of diabetes?**

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father’s side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

**11d. How many of them are not affected or you don’t know if they are affected with any type of diabetes?**

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father’s side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 11b, 11c, and 11d add up to the answer given in Question 11a.

**12. In what region do you live, or to what tribe do you belong? IN INDIA OR CAMEROON, HAND PARTICIPANT CUE CARD AND RECORD RESPONSE.**

In India or Cameroon, the participant chooses one region or tribe. The interviewer hands (or reads) the participant the cue card containing a list of regions or tribes to choose from. If a participant chooses more than one region or tribe, the interviewer asks which region or tribe he/she most identifies with and records that choice. Record the appropriate code(s) in the boxes. In North America, the region or tribe is not applicable; the interviewer marks "Not Applicable."

**Questions 13-14 are directed toward clinic staff and are completed as the activity occurs (*i.e.,* after interviewing and after editing).**

**13. Interviewer ID**

The interviewer records his/her five-digit assigned code in the appropriate boxes after completion of the *T1DGC Conversion to Case Form*.

**14. ID of person editing**

This is not completed until a clinic staff member reviews the form to ensure completion and accuracy. The person editing and reviewing the form records his/her five-digit assigned code in the appropriate boxes.

## APPENDIX B
## CLINIC CLOSE-OUT FORM:
## QUESTION BY QUESTION INSTRUCTIONS

These instructions are meant to assist the person completing the *Clinic Close-Out Form* and to provide answers to any questions from a Regional Network Coordinator or a clinic staff member.

This form is completed by the Regional Network Coordinator for each clinic as they are closed out. The information will likely be collected in stages as each step of close-out is completed and the form may be accessed multiple times for data entry. The form is located on the T1DGC Data Entry Web Site, under the Administration section. Select the Network ID from the drop down box and then enter the Clinic ID number and "submit" to enter the form. For subsequent entries, repeat this process and the original form will open again.

The Regional Network Coordinator may obtain this information from the clinic via e-mail, phone call or by sending a list of the information that the clinic can provide and asking them to complete the list and return the information to the Regional Network.

All dates are written as day first, month second, and year third. The day is recorded numerically. If the day is a single-digit number, a "0" is recorded in the first box. The month is written out in its entirety (*e.g.,* January, February). The year is recorded numerically, with all four digits of the year included (*e.g.,* 1950). All single digit numerical responses are recorded with a leading "0" (*e.g.,* if participant is 5 years old, record "05").

The "Not applicable" check box should be utilized only when the information was not collected due to a clinic's closing prior to the implementation of the close-out form, or when the particular question does not apply to that clinic.

**Question by Question Instructions**

The Regional Network Coordinator records the Network ID and clinic ID for the individual clinic. These two items are recorded on every page.

**1. Date final participant seen**

This is the date the final participant was seen and is provided by the Clinic Coordinator. Record the date in the appropriate boxes.

**2. Date final form received at Regional Network Center**

When the Regional Network Coordinator has determined that the final participant has been seen at the clinic, they should request that the final forms be submitted to the Regional Network Center within 60 days of the final participant's enrollment. Record the date in the appropriate boxes.

**3. Date final form entered at Regional Network Center**

When the data entry of the final form set is complete, record the date in the appropriate boxes.

**4. Date last shipment received at Network DNA Repository**

The clinic will provide the Regional Network Center with the date the last shipment for the DNA Repository is shipped. Record this date in the appropriate boxes.

**5. Date last shipment received at Network Autoantibody and Storage Laboratory**

The clinic will provide the Regional Network Center with the date the last shipment for the Autoantibody Laboratory is shipped. Record this date in the appropriate boxes.

**6. Please mark all that have been completed.**

As each of the tasks listed below are completed, indicate their completion by checking the box beside each entry:

a. Status for each family assessed with Regional Network Center and clinic

b. All irregularities resolved or confirmed

c. All queries resolved or confirmed

d. All re-collections resolved or confirmed

"Not applicable" should be checked only if the clinic did not begin enrollment of participants into the study.

**7. Date original data collection forms received at Regional Network Center**

After the clinic forwards the last of the original data collection forms to the Regional Network Center; complete question 7 by filling in the date the last form sets were received. "Not applicable" is checked only for clinics whose IRB does not allow the original data forms to be sent to the Regional Network Center or if there were no data forms collected at this center because no participants were enrolled.

**8. Date copies of all data collection forms shipped to clinic**

The Regional Network Center will ship copies of all of the original data forms to the clinics once all of the originals have been received and the date the forms are shipped is recorded here. "Not applicable" is checked only for clinics that will retain the originals (thus no copies are shipped) or if there were no data forms collected at the center because no participants were enrolled.

**9. Date lab supplies received at Regional Network Center**

Any unexpired laboratory supplies should be sent back to the Regional Network Center to allow them to be distributed to centers still actively recruiting. The date that these supplies are received at the Regional Network Center is recorded in the spaces provided. "Not applicable" is checked only if there were no supplies returned to the clinic due to their expiration or if there were no supplies remaining.

**10a. Extra label sets destroyed or redistributed?**

Indicate whether the extra label sets were destroyed or returned to the Regional Network Center for re-distribution. If at all possible, any useable labels should be returned to the Regional Network Center.

**10b. Date label sets were destroyed or received at Regional Network Center for redistribution**

Record the appropriate date for destruction or receipt at Regional Network Center in the spaces provided. If the clinic closed before labels were destroyed or returned, if there were no labels remaining at the clinic, or if no labels were ever distributed to the clinic, "Not applicable" should be checked.

**11. Description of procedures for storage of forms at clinic**

- **a.** Answer one of the three options: (1) originals stored; (2) copies stored; or (3) no forms stored at clinic. If no forms are stored, skip to question 12.
- **b.** Indicate whether the forms are stored onsite (within institution) or at an offsite storage facility.
- **c.** **Location of stored forms**: provide an explanation of the location of the stored forms so that at a later date if forms needed to be accessed, someone from the institution could locate them.
- **d.** **Security of stored forms:** provide a description of the security provided for the storage of the forms.
- **e.** **Person(s) with authorization for access to stored forms:** list the person who will have access to the data forms in the future should further use of the forms be required. This is normally the Principal Investigator or his/her designated representative.
- **f.** **Identifying personal information separated from form sets** Answer "yes" or "no" depending on whether the clinic has indicated if the personal information has been separated from the data forms or not.
- **g.** **Location of personal information:** Provide a brief description of the location of the personal information for the participants of the study

h. **Security of stored personal information**: provide a description of the security provided for the storage of personal information at the clinic.

i. **Person(s) with authorization for access to personal information:** list the person who will have access to the personal information in the future should further contact with individual participants be required. This is normally the Principal Investigator or his/her designated representative.

**12. Will originals be available until at least August 31, 2013?**

Select one of three answers: yes, no, not applicable. "Not applicable" should be used if originals are stored at the Regional Network Center, not at the clinic, or if no forms were collected at this clinic.

**13a. Future contact if participant withdraws from study:**

List the name, e-mail address and phone number for the person who should be contacted in the event that a participant requests to withdraw from the study after the closure of the clinic. "Not applicable" should be selected only if no participants were enrolled at this clinic.

**13b. IRB/Ethics Committee contact if participant withdraws from study:**

List the name, institution, e-mail address and phone number for the IRB/Ethics Committee contact who should be contacted in the event that a participant requests to withdraw from the study after the closure of the clinic. "Not applicable" should be selected only if no participants were enrolled at this clinic.

**14. Date local IRB/Ethics Committee notified of end of study at clinic:**

Complete the date once the clinic informs the Regional Network Center that the Clinic Coordinator has notified their IRB/EC notification of study closure. If possible, the clinic should forward a copy of the closure letter/notification to the Regional Network Center for the study records. "Not applicable" should be selected only in the event that the clinic closed without properly notifying the Regional Network Center of the components of their close-out procedures.

**15. Date clinic closed (60 days from date final participant seen):**

Enter the date when the close-out form information has been completed and the clinic is closed by the Regional Network Center.

**Items 16 – 19 are completed by the Coordinating Center.**

Regional Network Center staff should periodically review the Close-Out Report for their network posted on the data entry web site in their network's list of reports to determine when all fields have been completed. At that point, print a copy of the close-out form and store with the clinic's records.

## APPENDIX C

## CLINIC CLOSE-OUT CONFERENCE CALL AGENDA

1. Review timeline for completion of close-out based on data final participant seen in the clinic (*i.e.,* date final forms are expected, date last shipments to Network DNA Repository and Network Autoantibody and Storage laboratories are anticipated).
2. Review data irregularities and queries that must be resolved.
3. Review any sample discrepancies including the re-draws required; a plan to handle these should have been implemented.
4. Review procedures for families with members not participating to be able to close-out these families. This should be merely a formality as the clinics should have already implemented these.
5. Review all *Notification to Destroy Samples* forms and ensure that they are complete.
6. Determine if there are laboratory supplies that should be shipped to Regional Network Center.
7. Determine if there are extra label sets to be returned to Regional Network Center for re-distribution elsewhere.
8. Determine record storage procedures:
    a. Plan for sending originals to Regional Network Center and date this will be done.
    b. If IRB/EC will not allow originals to be sent to the Regional Network Center, review the clinic's plan for storage that will enable access by T1DGC (if needed) after study center closes.
    c. Date copies will be sent from Regional Network Center to clinic.
9. Review procedures for dealing with withdrawal of consents (current and future).
10. Review consent form issues. (In North America, there may be sites that state need to re-consent when minor participant reaches age 18)
11. Discuss date when local IRB/EC will be notified of end of recruitment or study closure.

12. Inform clinic of date after which no shipments can be charged to T1DGC master accounts with Sarstedt, World Courier, and Federal Express.
13. Inform clinic that official closure complete (after notification by Coordinating Center).

## APPENDIX D

## AGENDA FOR REGIONAL NETWORK CENTER CLOSE-OUT VISIT

I. Review of Remaining Data Entry/ Edits
   - A. Missing Data
   - B. Duplicate Data Entry Corrections
   - C. Query System – Items Still to Be Verified
   - D. Review of Reports
     1. Irregularities
     2. Outstanding Families
     3. Re-draw Report
   - E. Summary and Plan for Completion

II. Review of Plans and Execution for Archival Long-term Storage
   - A. Network Copies of Data Collection Forms from Clinics
   - B. Layered Portion of Informed Consent Forms
   - C. IRB
   - D. Informed Consents – Case-Control Consents
   - E. Shipping Forms from Laboratories
   - F. Consortium Agreements
   - G. Certificates of Confidentiality
   - H. Contributing Investigator Requests for Data and/or Samples
   - I. Logs
     1. Daily Freezer Temperature Log
     2. Discarded ID Log
     3. Participant and QC Selection Log/Adequacy of QC Sampling
     4. Data Editing Log
     5. Other Network Center or Clinic Logs (*e.g.*, Staff IDs, Clinic IDs)
   - J. Manual of Operations
   - K. Protocol
   - L. Clinic Close-out Forms

III. Discard and/or Destruction Plan at Network Center
   - A. Remaining T1DGC Label Sets
   - B. Blood Collection Supplies
   - C. Other Items That Can Be Discarded/Destroyed
     1. Extra copies of blank data forms
     2. Extra copies of blank consent forms
     3. Pre-printed World Courier/FedEx shipping bills

IV. Miscellaneous
   - A. Communication
     1. Future Regional Network Center Contact Person(s)
     2. Coordinating Center
   - B. Contributing Investigator Requests – Procedures and Deadline
   - C. Notification to Destroy Samples – Final Paperwork
   - D. Complete List of Investigators and/or Staff for Publications
   - E. Certificates of Appreciation/Mugs
   - F. Final Reimbursement/ Invoicing

## APPENDIX E

## REGIONAL NETWORK CENTER

## CLOSE-OUT TASKS

I. All families and participants listed as completed close-out
II. Resolution of all duplicate data entry discrepancies
III. All reports clear
    A. Dynamic Reports
        i. Clinic Summary (and detail)
        ii. Outstanding Data/Sample Collection
        iii. Irregularities
        iv. QC Samples (missing and stray)
        v. Incomplete Minority Trio Families
    B. Query System
        i. All reviewed and verified
        ii. All okayed by CoC
    C. Excel Reports on the shared drive
        i. Redraw report
        ii. Bad.ids (close-out report)
        iii. Incomplete (close-out report)
        iv. NTDS (close-out report)
        v. Inventory (close-out report)
        vi. Case parents (close-out report)
        vii. QC samples (close-out report)
IV. Resolution of consent not approved by NIDDK
V. All notifications complete
VI. All conversion to case forms complete --- any additional non-paternities
VII. All clinic close-out forms complete
VIII. Thank-you certificates mailed to all Network staff
IX. Archival of data and forms at Network Center
X. Anyone who did not sign the Certificate of Confidentiality removed from web site
XI. All Contributing Investigator requests for data/samples entered
XII. All Contributing Investigators requests for genotyping data sets entered
XIII. Final Invoice

## APPENDIX F

## AGENDA FOR AUTOANTIBODY AND STORAGE LABORATORY CLOSE-OUT VISIT

9:00 Introductions/ Review Agenda

9:10 Receipt of Samples
- Outstanding (missing/incomplete) clinic shipping forms
- Resolution of shipping discrepancies
- Storage of shipping forms

9:30 Sample Assays
- Issues with any of the assays (particularly last two that were added)
- Review split duplicate (QC) results
- Outstanding initial assay results
    - GAD65
    - IA2
    - TPO
    - TG
    - 21-hydroxylase
    - H/K ATPase
- List of exhausted samples to be ordered from Fisher
- Timeline for completion of all assays

10:30 Shipments to NIDDK Central Repository (Fisher)
- Summary of samples shipped vs received
- All shipping forms (for shipments to Fisher) received at Coordinating Center
- Resolution of shipping discrepancies

11:00 Review Remaining Close-Out Tasks

11:45 Final Invoice

12:00 Lunch

1:00 Tour of the Laboratory (including sample receiving area and freezer storage)

1:30 Discussion of Additional Manuscripts

2:00 Action Items and Timelines/ Adjourn

## APPENDIX G

## AUTOANTIBODY AND STORAGE LABORATORY

## CLOSE OUT TASK LIST

I. Shipments to Fisher
   A. Not Approved List Clear
   B. Approved List Clear

II. All QC reports clear
   A. AA 2.1 – Clinic Discrepancies
   B. AA 5.1 – Fisher Discrepancies
   C. AA 6 – Summary of shipping status to Fisher
   D. Full inventory – from blood collection to Network AA to Fisher
      i. Plasma from clinic to network
      ii. Plasma from network to Fisher
      iii. Serum from clinic to network
      iv. Serum from network to Fisher

III. Shipping Forms
   A. Receipt of all original AA to Denver
   B. Receipt of all original AA to Fisher
   C. Coordinating Center review of all shipping forms
   D. Resolve any discrepancies between paper copies and system

IV. Discrepancy Review
   A. Shipments to Denver from Melbourne
   B. Shipments to Denver from Bristol

V. Autoantibody results on all participants
   A. All participants received on upload sheet and results for all participants given
   B. QC checks – e-mail from Lab about any that he believes could be mislabeling, so that these can be removed from the reports (2 versions of reports will be run)

VI. Inventory
   A. All notifications to destroy samples complete
   B. Final inventory received at CoC
   C. Destruction of any residual samples
   D. Confirmation e-mail that no samples remain at facility

VII. Final Invoice

VIII. Deactivate staff from the T1DGC data entry web site

## APPENDIX H

## AGENDA FOR DNA REPOSITORY

## CLOSE-OUT VISIT

9:00 Introductions/ Review Agenda

9:10 Review Current Status of Samples Received and Processed – Transformation of Peripheral Blood Cells, Isolation of DNA

- Numbers of samples received and number of samples transformed and DNA extracted: review data reports (based on data uploaded on February 28, 2010)
- Outstanding samples and data management issues: review backlog of samples and specific problems with data contained in spreadsheets uploaded monthly

9:30 Shipments

- Outstanding entry of shipping forms with incomplete data or shipments without shipping forms.

10:00 Transformation of Peripheral Blood Mononuclear Cells

- Review transformation rates
- Completion of current workload

10:30 DNA Extraction: Cell Pack and Peripheral Blood Mononuclear Cells

- Review extraction rates
- Completion of current workload

11:00 Review Remaining Tasks

- Shipments to Contributing Investigators: DNA Aliquots and Cell Lines
- Shipments to NIDDK Central Repository (Rutgers): DNA Aliquots and Cell Lines
- Shipments to NIDDK Central repository (Fisher): PBMCs and Cell Pack DNA
- Receipt and destruction of residual DNA samples from HLA Genotyping Lab
- Residual cell lines

12:00 Specific Action Items and Timeline

- Review Close-Out Spreadsheet and Estimate Completion Dates

**APPENDIX I**

**DNA REPOSITORY**

**CLOSE-OUT TASK LIST**

I. Cell line shipments to Rutgers
   - A. Final shipment of original samples
     - i. Check approved list clear
     - ii. Check not approved list clear
     - iii. Received status (success or failure from Rutgers) on all original
   - B. Replacement shipment
     - i. List of replacement created
     - ii. Replacements for samples that have been destroyed
     - iii. All replacements sent
     - iv. Received status (success or failure from Rutgers) on all replacements
     - v. Send additional replacement sample on all failed replacements
   - C. Confirm cell line shipped for all applicable participants

II. Residual cell line DNA to Rutgers/UVA
   - A. Provide an inventory of remaining aliquots, including volume and concentration
   - B. Re-label all samples with analytic IDs and complete and return manifest
   - C. Complete shipping form face sheets (one per box) and notify CoC of shipping IDs
   - D. CoC import IDs into contents sheet
   - E. Ship samples

III. All QC reports clear
   - A. DNA 2/2.1/6/6.1 – Clinic Discrepancies (cell lines, cell packs)
   - B. DNA 3a/4a/4b – No cell line transformation in process/no cell line culture started
   - C. DNA 7b – Cell lines without DNA extracted
   - D. DNA 8 and 9 – Rutgers discrepancies (cell lines, DNA)
   - E. DNA 11a – Summary of shipping status to Rutgers
   - F. DNA 13 – Assessment of cell line viability at Rutgers

IV. Shipping Forms
   - A. Receipt of all DNA Shipping Forms
   - B. Coordinating Center review of all shipping forms
   - C. Resolve any discrepancies between paper copies and system

V. Lab Upload
    A. Cell Line Transformation Spreadsheet
        i. All applicable participants received on upload sheet
        ii. Success or failure confirmed for all participants
    B. DNA Yield Spreadsheet
        i. All applicable participants received on upload sheet
        ii. DNA extracted from all cell lines, all cell pack, all whole blood (as applicable)
VI. Establishment of the NA Repository at UVA
    A. Access Application submitted and approved
    B. Shipment to UVA
    C. Receipt of inventory from UVA and/or resolution of discrepancies
VII. Inventory
    A. All notifications to destroy samples complete
    B. Destruction of CIDR plates
    C. Receipt and destruction of residual DNA from HLA Lab
    D. Final inventory received at CoC
    E. Destruction of any residual samples
    F. Confirmation e-mail that no samples remain at facility
VIII. Final Invoice
IX. Deactivate laboratory staff from the T1DGC data entry web site

## APPENDIX J

## HLA GENOTYPING LABORATORY

## CLOSE-OUT TASKS AND TIMELINE

I. All plates complete
   - A. Checked for MIEs
   - B. All MIEs resolved
   - C. Review of QC samples

II. All QC reports clear
   - A. HLA 1b.1 – DNA shipment discrepancies
   - B. Approved and not approved NA clear

III. Shipping Forms
   - A. Receipt of all original DNA to HLA
   - B. Receipt of all original HLA to CHORI
   - C. Coordinating Center review of all shipping forms
   - D. Resolve any discrepancies between paper copies and system

IV. Discrepancy Review
   - A. Shipments from DNA Repository
   - B. Shipments from other HLA Laboratories

V. HLA results on all participants
   - A. All participants received by DNA Repository
   - B. All participants received as part of the 454 experiment

VI. 454 Testing
   - A. Analysis of second run
   - B. Completion of third run
   - C. Analysis of third run
   - D. Additional samples on another plate with other samples – completion
   - E. Analysis of remaining samples

VII. 454 Results
   - A. Transfer of data to Coordinating Center
   - B. Determine changes to be made to the database (implemented at CoC)

VIII. Inventory
   - A. Final inventory received at CoC
   - B. Destruction of any residual samples
   - C. Confirmation e-mail that no samples remain at facility

IX. Final Invoice

# APPENDIX K

# CHECKLIST OF DATA AND DOCUMENTS

# FOR TRANSFER TO NIDDK CENTRAL DATA REPOSITORY

| | RTI Receipt of Files (initials) | RTI Receipt Date (mm/dd/yy) | RTI Review of Files (initials) | RTI Review Date (mm/dd/yy) | RTI Sign Off on Files (initials) | RTI Sign Off Date (mm/dd/yy) | | |
|---|---|---|---|---|---|---|---|---|
| **T1DGC.2011.03_CIDR_Microsatellite.zip** | | | | | | | | |
| | | | | | | | | |
| ***Analyses Files*** | | | | | | | | |
| ***Genotypic Data*** | | | | | | | | |
| T1DGC.2011.03_CIDR_Microsatellite_chr<chrom#>.ped | | | | | | | | |
| T1DGC.2011.03_CIDR_Microsatellite_chr<chrom#>.allele | | | | | | | | |
| ***Map Files*** | | | | | | | | |
| T1DGC.2011.03_CIDR_Microsatellite_chr<chrom#>.par | | | | | | | | |
| T1DGC.2011.03_CIDR_Microsatellite_Map.xls | | | | | | | | |
| ***Phenotypic Data*** | | | | | | | | |
| T1DGC.2011.03_CIDR_Microsatellite_Phenotypic_Existing.csv | | | | | | | | |
| | | | | | | | | |
| ***Data Set Documentation*** | | | | | | | | |
| ***Genotypic*** | | | | | | | | |
| T1DGC.2011.03_CIDR_Microsatellite_Genotypic_Summary_Description.pdf | | | | | | | | |
| T!DGC.2011.03_CIDR_Microsatellite_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_CIDR_Microsatellite_Duplicates_List.csv | | | | | | | | |
| T1DGC.2011.03_CIDR_Microsatellite_Family_Summary.pdf | | | | | | | | |
| T1DGC.2011.03_CIDR_Microsatellite_Pedigree_Summary.pdf | | | | | | | | |
| T1DGC.2003.10_CIDR_Microsatellite_Project_Release_Summary.pdf | | | | | | | | |
| ***Phenotypic*** | | | | | | | | |
| Annotated Lab & Repository Spreadsheets (folder) | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Race_Ethnicity_and_Tribal_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_CIDR_Microsatellite_Phenotypic_Descriptive_Statistics.pdf | | | | | | | | |
| T1DGC.2011.03_CIDR_Microsatellite_Phenotypic_Existing_Collection_ID_Key.xls | | | | | | | | |
| | | | | | | | | |
| T1DGC.2011.03._Required_Acknowledgement_Statement.pdf | | | | | | | | |

| | RTI Receipt of Files (initials) | RTI Receipt Date (mm/dd/yy) | RTI Review of Files (initials) | RTI Review Date (mm/dd/yy) | RTI Sign Off on Files (initials) | RTI Sign Off Date (mm/dd/yy) | | |
|---|---|---|---|---|---|---|---|---|
| **T1DGC.2011.03_CIDR_6K.zip** | | | | | | | | |
| | | | | | | | | |
| ***Analyses Files*** | | | | | | | | |
| ***Genotypic Data*** | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_chr<chrom#>.ped | | | | | | | | |
| ***Map Files*** | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Chr<chrom#>.map | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Map.csv | | | | | | | | |
| ***Phenotypic Data*** | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Phenotypic_Current_Forms.csv | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Phenotypic_Current_HLA.csv | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Phenotypic_Current_Labs.csv | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Phenotypic_Current_Repository.csv | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Phenotypic_Existing_.csv | | | | | | | | |
| | | | | | | | | |
| ***Data Set Documentation*** | | | | | | | | |
| ***Genotypic*** | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Genotypic_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Duplicates_List.csv | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Family_Summary.pdf | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Pedigree_Summary.pdf | | | | | | | | |
| T1DGC.2006.03_CIDR_6K_Project_Release_Summary.pdf | | | | | | | | |
| T1DGC.2006.03_CIDR_6K_Locus_Information.pdf | | | | | | | | |
| T1DGC.2007.07_CIDR_6K_Project_Release_Summary.pdf | | | | | | | | |
| T1DGC.2007.07_CIDR_6K_Locus_Information.pdf | | | | | | | | |
| T1DGC.2009.04_CIDR_6K_Project_Release_Summary.pdf | | | | | | | | |
| T1DGC.2009.04_CIDR_6K_Locus_Information.pdf | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Converting AB Calls to Nucleotide Calls.pdf | | | | | | | | |
| ***Phenotypic*** | | | | | | | | |
| Data Collection Annotated Forms (folder) | | | | | | | | |
| Annotated Lab & Repository Spreadsheets (folder) | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Race_Ethnicity_and_Tribal_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Other_Study_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Phenotypic_Descriptive_Statistics.pdf | | | | | | | | |
| T1DGC.2011.03_CIDR_6K_Phenotypic_Existing_Collection_ID_Key.xls | | | | | | | | |
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| T1DGC.2011.03._Required_Acknowledgement_Statement.pdf | | | | | | | | |

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| **T1DGC.2011.03_MHC.zip** | | | | | | | | |
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| ***Analyses Files*** | | | | | | | | |
| ***Genotypic Data*** | | | | | | | | |
| T1DGC.2011.03_MHC_OPA1.ped | | | | | | | | |
| T1DGC.2011.03_MHC_OPA2.ped | | | | | | | | |
| T1DGC.2011.03_MHC_deCODE.ped | | | | | | | | |
| ***Map Files*** | | | | | | | | |
| T1DGC.2011.03_MHC_OPA1_Map_B34.tsv | | | | | | | | |
| T1DGC.2011.03_MHC_OPA2_Map_B34.tsv | | | | | | | | |
| T1DGC.2011.03_MHC_Integrated_Map_B34-36.tsv | | | | | | | | |
| T1DGC.2011.03_MHC_deCODE_MSAT_B34-36.tsv | | | | | | | | |
| ***Phenotypic Data*** | | | | | | | | |
| T1DGC.2011.03_MHC_Phenotypic_Current_Forms.csv | | | | | | | | |
| T1DGC.2011.03_MHC_Phenotypic_Current_HLA.csv | | | | | | | | |
| T1DGC.2011.03_MHC_Phenotypic_Current_Labs.csv | | | | | | | | |
| T1DGC.2011.03_MHC_Phenotypic_Current_Repository.csv | | | | | | | | |
| T1DGC.2011.03_MHC_Phenotypic_Existing_.csv | | | | | | | | |
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| ***Data Set Documentation*** | | | | | | | | |
| ***Genotypic*** | | | | | | | | |
| T1DGC.2011.03_MHC_Genotypic_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_MHC_Duplicates_List.xls | | | | | | | | |
| T1DGC.2011.03_MHC_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_MHC_Family_Summary.pdf | | | | | | | | |
| T1DGC.2011.03_MHC_Pedigree_Summary.pdf | | | | | | | | |
| T1DGC.2011.03_MHC_Summary of Sample Failures.pdf | | | | | | | | |
| T1DGC.2011.03_MHC_Summary_of_Redundant_Markers.xls | | | | | | | | |
| T1DGC.2011.03_MHC_SNP_Genotyping_QC_Sanger.pdf | | | | | | | | |
| T1DGC.2011.03_MHC_Microsatellite_Genotyping_QC_deCODE.pdf | | | | | | | | |
| ***Phenotypic*** | | | | | | | | |
| Data Collection Annotated Forms (folder) | | | | | | | | |
| Annotated Lab & Repository Spreadsheets (folder) | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Race_Ethnicity_and_Tribal_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Other_Study_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_MHC_Phenotypic_Descriptive_Statistics.pdf | | | | | | | | |
| T1DGC.2011.03_MHC_Phenotypic_Existing_Collection_ID_Key.xls | | | | | | | | |
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| T1DGC.2011.03._Required_Acknowledgement_Statement.pdf | | | | | | | | |

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| **T1DGC.2011.03_RR.zip** | | | | | | | | |
| | | | | | | | | |
| ***Analyses Files*** | | | | | | | | |
| ***Genotypic Data*** | | | | | | | | |
| T1DGC.2011.03_RR_SQNM.ped | | | | | | | | |
| T1DGC.2011.03_RR_ILMN.ped | | | | | | | | |
| ***Map Files*** | | | | | | | | |
| T1DGC.2011.03_RR_SQNM_ILMN_Combined_Map.csv | | | | | | | | |
| ***Phenotypic*** | | | | | | | | |
| T1DGC.2011.03_RR_Phenotypic_Current_Forms.csv | | | | | | | | |
| T1DGC.2011.03_RR_Phenotypic_Current_HLA.csv | | | | | | | | |
| T1DGC.2011.03_RR_Phenotypic_Current_Labs.csv | | | | | | | | |
| T1DGC.2011.03_RR_Phenotypic_Current_Repository.csv | | | | | | | | |
| T1DGC.2011.03_RR_Phenotypic_Existing_.csv | | | | | | | | |
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| ***Data Set Documentation*** | | | | | | | | |
| ***Genotypic*** | | | | | | | | |
| T1DGC.2011.03_RR_Genotypic_Summary_Description.pdf | | | | | | | | |
| T1DG.2011.03_RR_Duplicates_List.csv | | | | | | | | |
| T1DGC.2011.03_RR_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_RR_Family_Summary.pdf | | | | | | | | |
| T1DGC.2011.03_RR_Pedigree_Summary.pdf | | | | | | | | |
| T1DGC.2011.03_RR_Summary_of_Sample_Failures.pdf | | | | | | | | |
| T1DGC.2011.03_RR_Sample_Intake.pdf | | | | | | | | |
| T1DGC.2011.03_RR_SQNM_QC_Procedures_Part1.pdf | | | | | | | | |
| T1DGC.2011.03_RR_SQNM_QC_Procedures_Part2.pdf | | | | | | | | |
| T1DGC.2011.03_RR_ILMN_QC_Procedures.pdf | | | | | | | | |
| T1DGC.2011.03_RR_QC_Concordance_Report.pdf | | | | | | | | |
| ***Phenotypic*** | | | | | | | | |
| Data Collection Annotated Forms (folder) | | | | | | | | |
| Annotated Lab & Repository Spreadsheets (folder) | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Race_Ethnicity_and_Tribal_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Other_Study_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_RR_Phenotypic_Descriptive_Statistics.pdf | | | | | | | | |
| T1DGC.2011.03_RR_Phenotypic_Existing_Collection_ID_Key.xls | | | | | | | | |
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| T1DGC.2011.03._Required_Acknowledgement_Statement.pdf | | | | | | | | |

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| **T1DGC.2011.03_RR2.zip** | | | | | | | | |
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| ***Analyses Files*** | | | | | | | | |
| ***Genotypic Data*** | | | | | | | | |
| T1DGC.2011.03_RR2_BROAD.ped | | | | | | | | |
| T1DGC.2011.03_RR2_Sanger.ped | | | | | | | | |
| ***Map Files*** | | | | | | | | |
| T1DGC.2011.03_RR2_BROAD_Map.csv | | | | | | | | |
| T1DGC.2011.03_RR2_SANGER_Map.csv | | | | | | | | |
| ***Phenotypic Data*** | | | | | | | | |
| T1DGC.2011.03_RR2_Phenotypic_Current_Forms.csv | | | | | | | | |
| T1DGC.2011.03_RR2_Phenotypic_Current_HLA.csv | | | | | | | | |
| T1DGC.2011.03_RR2_Phenotypic_Current_Labs.csv | | | | | | | | |
| T1DGC.2011.03_RR2_Phenotypic_Current_Repository.csv | | | | | | | | |
| T1DGC.2011.03_RR2_Phenotypic_Existing_.csv | | | | | | | | |
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| ***Data Set Documentation*** | | | | | | | | |
| ***Genotypic*** | | | | | | | | |
| T1DGC.2011.03_RR2_Genotypic_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_RR2_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_RR2_BROAD_Duplicates_List.csv | | | | | | | | |
| T1DGC.2011.03_RR2_SANGER_Duplicates_List.csv | | | | | | | | |
| T1DGC.2011.03_RR2_BROAD_Family_Summary.pdf | | | | | | | | |
| T1DGC.2011.03_RR2_BROAD_Pedigree_Summary.pdf | | | | | | | | |
| T1DGC.2011.03_RR2_SANGER_Family_Summary.pdf | | | | | | | | |
| T1DGC.2011.03_RR2_SANGER_Pedigree_Summary.pdf | | | | | | | | |
| ***Phenotypic*** | | | | | | | | |
| Data Collection Annotated Forms (folder) | | | | | | | | |
| Annotated Lab & Repository Spreadsheets (folder) | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Race_Ethnicity_and_Tribal_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Other_Study_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_RR2_Phenotypic_Descriptive_Statistics.pdf | | | | | | | | |
| T1DGC.2011.03_RR2_Phenotypic_Existing_Collection_ID_Key.xls | | | | | | | | |
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| T1DGC.2011.03._Required_Acknowledgement_Statement.pdf | | | | | | | | |

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| **T1DGC.2011.03_TAQMAN.zip** | | | | | | | | |
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| ***Analyses Files*** | | | | | | | | |
| ***Genotypic Data*** | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Case_Control.ped | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Family.ped | | | | | | | | |
| ***Map File*** | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Map.xls | | | | | | | | |
| ***Phenotypic Data*** | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Phenotypic_Current_Case_Control_Forms.csv | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Phenotypic_Current_Case_Control_HLA.csv | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Phenotypic_Current_Case_Control_Labs.csv | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Phenotypic_Current_Case_Control_Repository.csv | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Phenotypic_Current_Family_Forms.csv | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Phenotypic_Current_Family_HLA.csv | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Phenotypic_Current_Family_Labs.csv | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Phenotypic_Current_Family_Repository.csv | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Phenotypic_Existing_Case_Control.csv | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Phenotypic_Existing_Family.csv | | | | | | | | |
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| ***Data Set Documentation*** | | | | | | | | |
| ***Genotypic*** | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Genotypic_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Duplicates_List.csv | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Duplicates_List_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Family_Summary.pdf | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Pedigree_Summary.pdf | | | | | | | | |
| ***Phenotypic*** | | | | | | | | |
| Data Collection Annotated Forms (folder) | | | | | | | | |
| Annotated Lab & Repository Spreadsheets (folder) | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Race_Ethnicity_and_Tribal_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Other_Study_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Phenotypic_Cases_Controls_Descriptive_Statistics.pdf | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Phenotypic_Family_Descriptive_Statistics.pdf | | | | | | | | |
| T1DGC.2011.03_TAQMAN_Phenotypic_Existing_Collection_ID_Key.xls | | | | | | | | |
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| T1DGC.2011.03._Required_Acknowledgement_Statement.pdf | | | | | | | | |

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| **Current Collection (T1DGC.2011.03_Phenotypic_Current.zip)** | | | | | | | | |
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| ***Analyses Files*** | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current.v8x | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Forms.csv | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_HLA.csv | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Labs.csv | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Repository.csv | | | | | | | | |
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| ***Data Set Documentation*** | | | | | | | | |
| General Documentation (folder) | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Race_Ethnicity_and_Tribal_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Other_Study_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Current_Descriptive_Statistics.pdf | | | | | | | | |
| | | | | | | | | |
| T1DGC.2011.03._Required_Acknowledgement_Statement.pdf | | | | | | | | |
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| **Existing Collections (T1DGC.2011.03_Phenotypic_Existing.zip)** | | | | | | | | |
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| ***Analyses Files*** | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing. v8x | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing.csv | | | | | | | | |
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| ***Data Set Documentation*** | | | | | | | | |
| Annotated Lab & Repository Spreadsheets (folder) | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Race_Ethnicity_and_Tribal_Codes.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Phenotypic_Existing_Descriptive_Statistics.pdf | | | | | | | | |
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| T1DGC.2011.03._Required_Acknowledgement_Statement.pdf | | | | | | | | |

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| **T1DGC.2011.03_Golden_Pedigree.zip** | | | | | | | | |
| | | | | | | | | |
| T1DGC.2011.03_Catalog.pdf | | | | | | | | |
| *Includes brief description of T1DGC (summary of T1DGC, description of genotyping projects, appropriate acknowledgements, how to order data and samples)* | | | | | | | | |
| *Legend of drawings* | | | | | | | | |
| | | | | | | | | |
| T1DGC.2011.03_Resources.csv | | | | | | | | |
| T1DGC.2011.03_Resources_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Resources_Data_Dictionary.pdf | | | | | | | | |

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| **T1DGC.2011.03_Study_Documents.zip** | | | | | | | | |
| | | | | | | | | |
| T1DGC.2011.03_Manual_of_Operations.pdf | | | | | | | | |
| T1DGC.2011.03_Protocol.pdf | | | | | | | | |
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| ***Data Collection Annotated Forms*** | | | | | | | | |
| 01_T1DGC_Trio_Pre-Eligibility_Form.pdf | | | | | | | | |
| 02_T1DGC_Layered_Consent.pdf | | | | | | | | |
| 03_T1DGC_ASP_Consent_Summary.pdf | | | | | | | | |
| 04_T1DGC_ASP_Eligibility_Form_Proband.pdf | | | | | | | | |
| 05_T1DGC_ASP_Eligibility_Form_Parent.pdf | | | | | | | | |
| 06_T1DGC_ASP_Application_for_Additional_Siblings.pdf | | | | | | | | |
| 07_T1DGC_ASP_Trio_Application_to_Eligibility_Committee.pdf | | | | | | | | |
| 08_T1DGC_ASP_Exam_Form_Proband.pdf | | | | | | | | |
| 09_T1DGC_ASP_Exam_Form_Affected_Sibling.pdf | | | | | | | | |
| 10_T1DGC_ASP_Exam_Form_Parent.pdf | | | | | | | | |
| 11_T1DGC_ASP_Exam_Form_Unaffected.pdf | | | | | | | | |
| 12_T1DGC_ASP_Trio_Blood_Collection_Form.pdf | | | | | | | | |
| 13_T1DGC_ASP_Trio_Blood_Collection_Form_Recollection.pdf | | | | | | | | |
| 14_T1DGC_Trio_Consent_Summary.pdf | | | | | | | | |
| 15_T1DGC_Trio_Eligibility_Form_Proband.pdf | | | | | | | | |
| 16_T1DGC_Trio_Eligibility_Form_Parent.pdf | | | | | | | | |
| 17_T1DGC_Trio_Exam_Form_Proband.pdf | | | | | | | | |
| 18_T1DGC_Trio_Exam_Form_Parent.pdf | | | | | | | | |
| 19_T1DGC_Case_Control_Consent_Record.pdf | | | | | | | | |
| 20_T1DGC_Case_Eligibility_Form_Case.pdf | | | | | | | | |
| 21_T1DGC_Case_Eligibility_Form_Parent.pdf | | | | | | | | |
| 22_T1DGC_Case_Application_to_Eligibility_Committee.pdf | | | | | | | | |
| 23_T1DGC_Case_Exam_Form.pdf | | | | | | | | |
| 24_T1DGC_Control_Eligibility_Form_Control.pdf | | | | | | | | |
| 25_T1DGC_Control_Eligibility_Form_Parent.pdf | | | | | | | | |
| 26_T1DGC_Case_Control_Blood_Collection_Form.pdf | | | | | | | | |
| 27_T1DGC_Case_Control _Blood_Collection_Form_Recollection.pdf | | | | | | | | |
| 28_T1DGC_Conversion_to_Case.pdf | | | | | | | | |
| 29_T1DGC_Clinic_Shipping_Form_Face_Sheet.pdf | | | | | | | | |
| 30_T1DGC_Clinic_Shipping_Form_Contents_Sheet.pdf | | | | | | | | |
| 31_T1DGC_Autoantibody_Shipping_Form_to_Fisher.pdf | | | | | | | | |
| 32_T1DGC_DNA_Shipping_Form_to_Rutgers_Cell_Line_Samples.pdf | | | | | | | | |
| 33_T1DGC_DNA_Shipping_Form_to_Rutgers_DNA_Samples.pdf | | | | | | | | |
| 34_T1DGC_DNA_Shipping_Form_to_Fisher_DNA_Samples.pdf | | | | | | | | |
| 35_T1DGC_DNA_Shipping_Form_to_Fisher_WGA_DNA_Samples.pdf | | | | | | | | |
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| | RTI Receipt of Files (initials) | RTI Receipt Date (mm/dd/yy) | RTI Review of Files (initials) | RTI Review Date (mm/dd/yy) | RTI Sign Off on Files (initials) | RTI Sign Off Date (mm/dd/yy) | | |
|---|---|---|---|---|---|---|---|---|
| ***Study Data Management Forms*** | | | | | | | | |
| T1DGC_Clinic-Close-Out.pdf | | | | | | | | |
| T1DGC_Notification_to_Destroy_Samples_Form.pdf | | | | | | | | |
| T1DGC_Contributing_Investigator_Request_for_Quarterly_Data_and_Samples.pdf | | | | | | | | |
| T1DGC_Contributing_Investigator_Request_for_Genotyping_Data_Sets.pdf | | | | | | | | |
| T1DGC_Adverse_Event_Report.pdf | | | | | | | | |
| T1DGC_Discarded_ID_Log.pdf | | | | | | | | |
| T1DGC_Data_Edititing_Log.pdf | | | | | | | | |
| T1DGC_Participant_and_QC_Selection_Log.pdf | | | | | | | | |
| T1DGC_Daily_Freezer_Temperature_Log.pdf | | | | | | | | |
| T1DGC_ASP_Family_Contact_Sheet.pdf | | | | | | | | |
| T1DGC_Trio_Family_Contact_Sheet.pdf | | | | | | | | |
| T1DGC_ASP_Participant_Identification_Form.pdf | | | | | | | | |
| T1DGC_Trio_Participant_Identification_Form.pdf | | | | | | | | |
| T1DGC_DNA_Shipping_Form_to_HLA.pdf | | | | | | | | |
| T1DGC_DNA_Shipping_Form_to_CIDR.pdf | | | | | | | | |
| T1DGC_DNA_Shipping_Form_to_MHC_Fine_Mapping_Lab.pdf | | | | | | | | |
| T1DGC_DNA_Shipping_Form_to_Rapid_Response_Lab.pdf | | | | | | | | |
| T1DGC_DNA_Shipping_Form_to_DIL.pdf | | | | | | | | |
| T1DGC_DNA_Shipping_Form_to_Contributing_Investigators.pdf | | | | | | | | |
| T1DGC_DNA_Shipping_Form_to_Consortium_Members.pdf | | | | | | | | |
| T1DGC_DNA_Shipping_Form_to_UVA_Cell_Pack_Shipments.pdf | | | | | | | | |
| T1DGC_DNA_Shipping_Form_to_UVA_PBMC_Shipments.pdf | | | | | | | | |
| T1DGC_DNA_Shipping_Form_to_UVA_Cell_Line_DNA_Shipments.pdf | | | | | | | | |
| T1DGC_Autoantibody_Shipping_Form_to_Denver.pdf | | | | | | | | |
| T1DGC_HLA_Genotyping_Lab_ Shipping_Form_to_Chori.pdf | | | | | | | | |
| | | | | | | | | |
| ***Annotated Lab Spreadsheets*** | | | | | | | | |
| 36_T1DGC_Autoantibody_Lab_Upload_Forms.pdf | | | | | | | | |
| 37_T1DGC_DNA_Lab_Upload_Cell_Line_Transformation.pdf | | | | | | | | |
| 38_T1DGC_HLA_Lab_Upload_XML.pdf | | | | | | | | |
| 39_T1DGC_Rutgers_Lab_Upload_Cell Lines.pdf | | | | | | | | |
| 40_T1DGC_Rutgers_Lab_Upload_DNA.pdf | | | | | | | | |
| 41_T1DGC_Fisher_Lab_Upload.pdf | | | | | | | | |
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| ***Quality Control Reports*** | | | | | | | | |
| T1DGC.2011.03_QC_Reports_Autoantibody.pdf | | | | | | | | |
| T1DGC.2011.03_QC_Reports_DNA.pdf | | | | | | | | |
| T1DGC.2011.03_QC_Reports_HLA.pdf | | | | | | | | |
| T1DGC.2011.03_QC_Reports_Forms.pdf | | | | | | | | |

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|---|---|---|---|---|---|---|---|---|
| **T1DGC.2011.03_INTERNAL FILES.zip** | | | | | | | | |
| | | | | | | | | |
| **Sample Inventory** | | | | | | | | |
| T1DGC.2011.03_Sample_Inventory.v8x | | | | | | | | |
| | | | | | | | | |
| Data Collection Annotated Forms (folder) | | | | | | | | |
| Annotated Lab & Repository Spreadsheets (folder) | | | | | | | | |
| T1DGC.2011.03_Sample_Inventory_Summary_Description.csv | | | | | | | | |
| T1DGC.2011.03_Sample_Inventory_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Sample_Inventory_Data_Dictionary.pdf | | | | | | | | |
| | | | | | | | | |
| **Key** | | | | | | | | |
| T1DGC.2011.03_Key.csv | | | | | | | | |
| T1DGC.2011.03_Key.v8x | | | | | | | | |
| | | | | | | | | |
| T1DGC.2011.03_Key_Summary_Description.pdf | | | | | | | | |
| T1DGC.2011.03_Key_Data_Set_Listing.pdf | | | | | | | | |
| T1DGC.2011.03_Key_Data_Dictionary.pdf | | | | | | | | |
| T1DGC.2011.03_Current_Clinics.pdf | | | | | | | | |
| T1DGC.2011.03_Existing_Clinics.pdf | | | | | | | | |

| | RTI Receipt of Files (initials) | RTI Receipt Date (mm/dd/yy) | RTI Review of Files (initials) | RTI Review Date (mm/dd/yy) | RTI Sign Off on Files (initials) | RTI Sign Off Date (mm/dd/yy) | | |
|---|---|---|---|---|---|---|---|---|
| **T1DGC.2011.03_INTERNAL_STUDY DOCUMENTS.zip** | | | | | | | | |
| | | | | | | | | |
| ***Miscellaneous Study Documents*** | | | | | | | | |
| T1DGC.2011.03_Publications.pdf | | | | | | | | |
| Link to Public Website: https://www.t1dgc.org | | | | | | | | |
| ***Data and Sample Distribution*** | | | | | | | | |
| T1DGC.2011.03_ Data_and_Sample_Distribution_Reports.csv | | | | | | | | |
| T1DGC.2011.03_ Data_and_Sample_Distribution_Reports.pdf | | | | | | | | |
| | | | | | | | | |
| ***Presentations from T1DGC and NIDDK Central Repository Close-Out Meeting (March 15, 2011)*** | | | | | | | | |
| 01_T1DGC_2011.03_Study_Overview.pdf | | | | | | | | |
| 02_T1DGC_2011.03_Sample_Inventory.pdf | | | | | | | | |
| 03_T1DGC_2011.03_Data_and_Sample_Distribution.pdf | | | | | | | | |
| 04_T1DGC_2011.03_Phenotypic_Data_Sets.pdf | | | | | | | | |
| 05_T1DGC_2011.03_Genotypic_Data_Sets.pdf | | | | | | | | |
| 05_T1DGC_2011.03_Golden_Pedigree.pdf | | | | | | | | |
| 06_T1DGC_2011.03_NIDDK_Central_Data_Repository_Website.pdf | | | | | | | | |
| 07_T1DGC_2011.03_Coordinating_Center_Contacts.pdf | | | | | | | | |