IV. STUDY POLICIES

A. INTRODUCTION

This chapter includes copies of the following approved Type 1 Diabetes Genetics Consortium (T1DGC) study documents and policies:

1. T1DGC Agreement

2. T1DGC Confidentiality Certification

3. T1DGC Publication and Presentations Policies

4. T1DGC Policy Governing Access to Study Repository Samples and Data

5. Guidelines for T1DGC Members Using Their Own Biological Samples

6. Intellectual Property

B. TYPE 1 DIABETES GENETICS CONSORTIUM AGREEMENT (Approved June 14, 2004)

Background

The international Type 1 Diabetes Genetics Consortium (T1DGC) is a collaborative group formed to facilitate the genetic analysis of type 1 diabetes (T1D) via the sharing of reagents, methods, strategies, samples, knowledge and data at all levels of the research effort, from individual groups to existing and future collaborative networks. The T1DGC will help both researchers and funding agencies monitor progress, and formulate, plan and assess the most informative and cost-effective strategies. It will help motivate researchers, peer reviewers and lay people to push forward the identification of genes and mechanisms in T1D. It will encourage sample and data sharing while maintaining the environment for new initiatives, both small and large, across the wide spectrum of approaches and technologies required in genetic analysis of complex diseases.

This initiative is undertaken in order to help increase consensus in the field, to provide an opportunity to collate data from a variety of studies for combined analyses and to increase clarity for future initiatives. A major role for the T1DGC will be to act as a repository for data and samples, to support scientists worldwide and to encourage new ideas for research in Type 1 diabetes.

Activities of the Consortium

T1DGC has the following activities:

1. The Consortium will provide an integrated map and new analysis of the combined data set of affected sib-pair (ASP) families (n ~ 1200). The combined data set includes genome-scan data from a combined US-UK collection (*AJHG* 2001, 69:820-830), and from a Scandinavian collection (*AJHG* 2001, 69:1301-1313). This analysis is ongoing. The data will be made available to all investigators on request when the manuscript has been accepted.
2. The Consortium will transmit samples from approximately 600 ASP families already collected by various investigators to the Center for Inherited Disease Research (CIDR) for whole-genome scan analysis. This submission has already occurred.
3. The Consortium will organize and collect an additional 2800 ASP families throughout the world. In order to conduct this recruitment, the Consortium has been organized into regional Networks. These families will provide DNA, plasma and serum samples, and phenotypic and medical history information. Family members will also be asked to allow immortalized cell lines to be made. A whole genome-scan analysis will be conducted on the DNA from recruited families. All samples (DNA, plasma, serum, cell lines) will eventually be deposited in a central NIDDK repository and be made available to the scientific community.
4. The Consortium has received funding to identify genes under the five (5) most promising linkage peaks identified by the analysis. The Steering Committee will develop specific procedures for this identification.
5. Such procedures in the future could include association studies and genetic analyses of diverse ethnic groups, using trios and cases and controls.

Steering Committee of T1DGC

The T1DGC will be guided by a Steering Committee (SC), the membership of which is as follows:

Member	Institution	Location	Country
Beena Akolkar	NIDDK	Bethesda, MD	USA
Pat Concannon	University of Virginia	Charlottesville, VA	USA
Henry Erlich	Roche Molecular Systems	Pleasanton, CA	USA
Cecile Julier	Inserm UMR, Faculté de Médecine Denis-Diderot	Paris	France
Grant Morahan	Western Australia Institute for Medical Research	Perth	Australia
Jorn Nerup	Hagedorn Research Institute	Gentofte	Denmark
Flemming Pociot	Hagedorn Research Institute	Gentofte	Denmark
Stephen Rich (Chair)	University of Virginia	Charlottesville, VA	USA
John Todd	Cambridge University	Cambridge	UK

Under the terms of funding, the NIDDK Program Officer is a full member of the Steering Committee.

Decisions are made by the Steering Committee by majority vote of a quorum of its membership. SC Voting Members are: Akolkar, Concannon, Erlich, Julier, Morahan, Nerup, Pociot, Rich, and Todd. Seven SC members constitute a quorum empowered to conduct T1DGC business. A simple majority vote (4/7 or 5/8 or 5/9) is considered binding.

The SC has established several committees to help with the functioning of the Consortium. These committees are: Access; Bioinformatics; Ethical, Legal and Social Issues (ELSI); Molecular Technology; Network Coordinators; Phenotyping/ Recruitment; Publications and Presentations; and Quality Control.

The Coordinating Center for T1DGC has been established at Wake Forest University Health Sciences (Winston-Salem, NC, USA).

The T1DGC has funding from the National Institutes of Health (NIDDK) and the Juvenile Diabetes Research Foundation (JDRF) to initiate a worldwide collection of affected sib-pair (and other pedigree types) families for on-going linkage studies and future association studies.

Network Organization

The T1DGC framework will support and foster Regional Networks. The Network PIs, working with physicians in local clinics, will be responsible for recruiting T1D subjects and families and for upholding local ethical conditions, informed consent and compliance.

The Regional Networks and Principal Investigators (PI) are:

Network	PI	Institution	Country
Asia-Pacific	Grant Morahan	Western Australia Institute for Medical Research	Australia
	Peter Colman	Walter & Eliza Hall Institute	Australia
European	Jorn Nerup	Hagedorn Research Institute	Denmark
	Flemming Pociot	Hagedorn Research Institute	Denmark
North American	Carla Greenbaum	Benaroya Research Institute	USA
United Kingdom	John Todd	Cambridge University	UK

Network investigators will be subject to national and regional laws and regulations in force. This includes appropriate ethical review and approval. Study subjects will have the right to request that their samples and information are destroyed at any time in the future. The details of the procedure for this request will be determined by Network policy.

Consortium Member Rights and Responsibilities

Investigators who choose to participate in the Consortium agree to abide by the following principles:

1. Each participating group will indicate their willingness to participate in the consortium effort and to abide by the principles outlined in this Consortium Agreement by providing a signed copy of this Consortium Agreement. By signing this Agreement, the investigator will receive Member access to the T1DGC Web site (http://www.t1dgc.org).

2. There are several ways to participate in the Consortium. These include:
   - participating in the recruitment of new collections for and on behalf of the Consortium using Consortium resources
   - providing genotyping or other research resources to the Consortium
   - participating in the activities of Consortium committees
   - participating in the analysis of aggregate Consortium data

3. Some investigators have provided previously-collected samples for submission to CIDR, as indicated in activity *2*, above. In this case, the contributing investigator has agreed:
- to be eligible to receive access to the data derived from the analysis of the samples they contributed to the Consortium, including HLA, *INS* and *CTLA4* typing and genome scan data;
- to retain the right to analyze and publish their own data, with no non-scientific restrictions on timing or content;
- to retain any intellectual property rights deriving from their separate analysis and/or publication of their own data;
- to participate in any joint analyses conducted by the Consortium, and to keep any interim results of such analyses confidential;
- to be recognized in publications to be co-authored by "The Type 1 Diabetes Genetics Consortium".

4. An investigator may choose to participate in the Consortium by helping to recruit families for the Consortium collection indicated as activity *2*, above. A group that contributes to the recruitment of new collections for and on behalf of the Consortium agrees to the following:

- to participate in the discussions leading to the establishment of Consortium standards for collection, and to abide by those standards;
- to obtain signed informed consent from volunteers according to high ethical and legal standards;
- to provide the Consortium-determined quantities of blood, serum, plasma and other samples, and to send these biological samples to Consortium-designated laboratories;
- to obtain phenotype and medical history information from volunteers, and to report this information to a Consortium-designated Center;
- to inform the Consortium if there are any ancillary studies being conducted while recruiting for the Consortium. An investigator agrees to provide the set of data and samples required by the Consortium.
- Laboratory results may be returned to the investigator, depending on Network policy. It is up to the discretion of the investigator to share this information with the subject, according to individual data collection site requirements. It is the responsibility of the Network to develop any statements about the interpretation of data, and to request that this statement be shared with participants.
- In the case where site requirements mean no laboratory results will be returned to the subject, and the subject makes an explicit request for this information, a second sample will be sent to another laboratory designated by the subject. The subject will pay for this testing and results.
- Investigators must agree to destroy any samples and information when subjects have requested withdrawal from the study. Investigators must notify their Regional Network of any request for destruction of samples and information. The details of the procedure for this request will be determined by Network policy.

5. A group that contributes to recruitment for and on behalf of the Consortium has the following rights:

- The Consortium is committed to providing data to contributors. It is the responsibility of the contributing investigator to obtain the appropriate ethical and privacy board review and approvals for receiving coded data and materials from the Consortium. Contributors may be required to provide these assurances prior to data and/or materials release.
- Contributors will receive access to data derived from the analysis of the samples they contributed to the Consortium, including HLA, *INS* and *CTLA4* typing and genome scan data. For NIH purposes, the T1DGC Coordinating Center (CC) must track who requests data and where it goes. Therefore, all investigators have to make written requests for data; email is acceptable. Contributors can request immediate access to the genome scan data for their own analysis, and the CC will provide that data as soon as the data are received.
- Contributing investigators have the right to receive DNA and/or immortalized cell line aliquots of samples they contributed to the Consortium.
- Contributing investigators retain the right to analyze and publish their own data, with no non-scientific restrictions on timing or content.
- Contributors retain any intellectual property rights deriving from their separate analysis of and/or publication of their own data.

- Contributors have the right to participate in any joint analyses including the data from their samples conducted by the Consortium, and agree to keep any interim results of such analyses confidential.
- Contributors agree to acknowledge the Consortium in publications and presentations, according to the policies determined by the Consortium Publication and Presentation Committee.
- Contributors will be recognized in publications to be co-authored by "The Type 1 Diabetes Genetics Consortium".
- Contributors will be eligible to apply for access to Consortium resources for additional analyses, according to policies and timetables established by the Consortium Steering Committee.

Consortium Responsibilities

1. The Consortium agrees to the following:

- to establish mechanisms for interested groups to participate in the activities of the Consortium;
- on request, to return the results of analysis of samples provided by contributing investigators;
- on request, to provide an aliquot of DNA and/or immortalized cell lines made from samples provided by contributors;
- on request, to notify the NIDDK Central Repository of any request to destroy contributed samples and information;
- to recognize the right of contributors to analyze and publish their own data, with no non-scientific restrictions on timing or content;
- to establish mechanisms for contributors to participate in any joint analyses including the data from their samples conducted by the Consortium;
- to recognize the contributing groups and individuals in publications to be co-authored by "The Type 1 Diabetes Genetics Consortium".

2. The Consortium will transmit collected DNA samples to the Center for Inherited Disease Research (CIDR) for whole-genome scan analysis. Because the samples will be assembled from a worldwide recruitment, the Consortium expects samples to be ready in a staggered schedule. Approximately 800 families will be provided in each of three submissions to CIDR. Each Network will have samples in each submission to CIDR.

An anticipated schedule for submissions to CIDR, receipt of data from CIDR and data releases is according to the following **approximate** timetable:

Submission to CIDR	Data received from CIDR	Expected release of aggregate data analysis*
Jan 2003	Oct 2003	+ 6 months
Dec 2004	Aug 2005	+ 6 months
Dec 2005	Aug 2006	+ 6 months
Dec 2006	Aug 2007	+ 6 months

*The Consortium expects to release the results of the aggregate analysis incorporating the samples from each submission according to the approximate schedule above.

On request from contributing investigators, the Consortium will provide whole-genome scan data on the contributed samples as soon as it is received.

The Consortium will undertake quality-control analysis of the data and will also begin linkage analysis on the aggregate data. Linkage analysis will be done only on the aggregate data set, and according to policies determined by the Steering Committee. Contributors have the right to participate in any joint analyses that includes data from their samples that are conducted by the Consortium. Contributors agree to keep any interim results of such analyses confidential.

The Consortium will release the genotypic data to Consortium Members from each submission 6 months after receipt of the data from CIDR.

At the conclusion of the study, the Consortium will create a database for the NIDDK Central Repository, according to the requirements of the Repository. Access to Consortium data will then be governed by policies determined by the NIDDK Central Repository.

The Consortium has no expectation that patentable information or material will result from the combined or aggregate Consortium database, and the Consortium will not assert or claim any such intellectual property (IP) rights. It may be possible for individual investigators who follow up the linkage results to generate patentable information or material, but they will need to decide themselves whether to claim any such potential intellectual property.

3. The Consortium agrees to provide resources for genetic analyses to the scientific community. The Consortium has received funding to identify genes under the five (5) most promising linkage peaks identified by the analysis. The Steering Committee will develop specific procedures for this identification. For additional research in the genetics of Type 1 diabetes, the following working model is being developed:

a) Investigators interested in identifying genes may apply for access to Consortium samples.
b) Applications would be reviewed by an Initial Review Group (IRG) acting according to policies drawn up by the Access Committee, and ratified by the Steering Committee.
c) The IRG would include *ad hoc* reviewers, outside scientists (with expertise not in diabetes), and representatives of the funding agencies.
d) Multiple applications may result in recommendation that collaborations be implemented. This would ensure that high-cost, labor-intensive positional cloning would be done with minimum overlap among labs.
e) IP issues would be negotiated between or among investigators working on a particular region.
f) When publication is in press, the data would be provided to the Consortium. The Consortium would make the data available after publication. All the data will become known and available to the scientific community.
g) Investigators who receive samples and information provided by the Consortium must agree to destroy those samples and information when notified by the T1DGC Coordinating Center or by the NIDDK Central Repository.
h) The Consortium would be recognized in publications in the author line, footnote, or acknowledgement, according to policies developed by the Publications and Presentations Committee. These issues could be sorted out during the review of the application.

4. Samples provided to the Consortium will, at least initially, be deposited in a regional Network repository. Regional Network repositories will initially store samples of DNA, cell lines, plasma, and serum. At timed intervals, and according to a schedule agreed by the Steering Committee and NIDDK, regional Network repositories will ship DNA, cell lines, plasma, and serum samples to the NIDDK Central Repository. Network repositories have a right to retain a cell line aliquot for samples deposited in the Network repository.

All samples (DNA, plasma, serum, cell lines) will eventually be deposited in the NIDDK Central Repository. These samples will be made available to the scientific community according to policies and a timetable to be determined by the Steering Committee and agreed with NIDDK. Contributing investigators will have an opportunity to provide input as these policies are developed. At the conclusion of the study, access to T1DGC materials will be governed by policies determined by the NIDDK Central Repository.

Study subjects will have the right to request that their samples and information are destroyed at any time in the future. The details of the procedure for this request will be determined by Network policy. The general outline is as follows: the T1DGC Coordinating Center at Wake Forest University will be responsible for notifying the NIDDK Central Repository to destroy requested samples and information. At the end of the study, each regional Network will be responsible for notifying the NIDDK Central Repository to destroy samples and information when subjects request withdrawal from the study.

Investigators who receive samples and information provided by T1DGC must agree to destroy those samples and information when subjects request withdrawal from the study and upon notification by the T1DGC Coordinating Center or NIDDK Central Repository.

The Consortium will not commercialize the DNA or data deposited with the Consortium. No individual or group will own or claim intellectual property rights to the combined or aggregate Consortium database, other than copyright or similar rights to control use and access to the database or the publication of information and findings generated by the Consortium.

5. The Steering Committee will examine educational and other activities as part of its commitment to establish mechanisms for all interested groups to participate in the activities of the Consortium.

6. The Steering Committee will establish procedures to evaluate opportunities to extend the results of research to develop methods of risk prediction, prevention and therapy in Type 1 diabetes. All interested investigators will have an opportunity to provide input as these procedures are developed.

Consortium Agreement

I have read the provisions of this Consortium Agreement, and I agree to be bound by its principles.

_____
Investigator Name

_____
Investigator Signature

_____
Date

_____
Network PI Signature

_____
Date

C. POLICY FOR COMPLETION OF TYPE 1 DIABETES GENTICS CONSORTIUM CONFIDENTIALITY CERTIFICATION (Approved September 22, 2004)

All individuals with any access to Type 1 Diabetes Genetics Consortium (T1DGC) data must sign a Confidentiality Certification. This includes, but is not limited to, the following groups of individuals:

- Principal Investigators
- Co-Investigators and Investigators
- Coordinating Center staff, including any data entry, data management, data analysis and support staff
- Regional Network staff and support staff
- Field Center staff and support staff
- Laboratory staff and support staff
- Data analysts (on-site and off-site)
- Fellows and students
- Consultants
- Ancillary study investigators

Each individual with access to T1DGC data must read, sign and date the Confidentiality Certification. The Network Principal Investigator must also sign the certification and keep the original copy on file at the Coordinating Center. A copy is retained at the Regional Network Center of the completed certification.

The Principal Investigators (Field Centers, Regional Networks and Coordinating Center) are responsible for ensuring that all individuals currently affiliated with the T1DGC Study through their site sign the Confidentiality Certification. The Coordinating Center is specifically responsible for ensuring that all subcontractors and consultants to the Study through the Coordinating Center contract, including laboratory investigators and staff, sign the Confidentiality Certification. The Principal Investigators are responsible for ensuring that all individuals who become affiliated with the T1DGC Study through employment or consulting in the future sign the Confidentiality Certification at the time he/she joins the Study.

TYPE 1 DIABETES GENETICS CONSORTIUM
CONFIDENTIALITY CERTIFICATION

As an employee of, consultant to, or fellow/student involved with the Type 1 Diabetes Genetics Consortium (T1DGC) Study funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), I am aware of the confidential nature of data on research participants maintained by the Study, and the necessity of maintaining that confidentiality.

I agree not to **transfer** or **disclose** any confidential data, nor any information about individual T1DGC Study participants, except as necessary for data/safety monitoring or programmatic management, in the course of my responsibilities at work nor in private, either during or after my affiliation with the T1DGC Study. I agree not to transfer **any** T1DGC data or biological specimens to individuals outside the T1DGC Study Group without the written permission of the T1DGC Steering Committee. Further, I agree to return all T1DGC data to the Principal Investigator or delete/destroy all T1DGC data upon termination of my affiliation with the Study.

I understand that as an employee of, consultant to, or fellow/student involved with the T1DGC study, I am subject to the provisions of laws and regulations related to confidentiality of study data in the country where the work is performed.

Name (print): _____

Signature: _____

Date: _____

T1DGC Site: _____

Principal Investigator's Signature: _____

Date: _____

D. T1DGC PUBLICATION AND PRESENTATIONS POLICIES (Approved October 8, 2008)

Goals

The goals of the Publications and Presentations (P&P) Committee are to:

1. assure and expedite orderly and timely presentations and publications;
2. assure that all members have the opportunity to participate and be recognized in the study-wide presentation of T1DGC papers;
3. establish procedures for timely review of proposed T1DGC publications and presentations;
4. assure that press releases, interviews, presentations, and publications of T1DGC material are accurate, objective, and do not compromise the scientific integrity of this collaborative study;
5. maintain a complete up-to-date list of T1DGC presentations and publications, and distribute such lists to all T1DGC members on a regular basis; and
6. assure that studies utilizing T1DGC resources appropriately acknowledge the T1DGC.

Roles and Responsibilities

Role of the Publications and Presentations Committee. The T1DGC P&P Committee will act as a primary body to oversee the publication and release of T1DGC information. The P&P Committee functions to set the T1DGC presentations and publications policy, encourage timely publication of T1DGC related material, and mediate any disputes arising over the publication or presentation of T1DGC results. The recommendations of the P&P Committee are reported to the Steering Committee. All Regional Network Centers and the Coordinating Center will have a member representative on the P&P Committee at all times. Appointment of other P&P committee members will be made by the Steering Committee and will be limited to T1DGC members. In order to facilitate efficient and timely review of presentations and publications, P&P Committee membership will be limited to 8 unless mandated otherwise by the Steering Committee. The P&P Committee will coordinate its activities with the Access Committee to avoid situations where T1DGC resources are committed for projects where publications with substantially overlapping content might result.

Role of the T1DGC Coordinating Center. The T1DGC Coordinating Center at Wake Forest University Health Sciences will act as a clearinghouse for all information related to T1DGC that is released to the public domain, including publications, abstracts, presentations and press releases. All such material must be submitted to the Coordinating Center for inclusion in the central T1DGC database. The Coordinating Center will also maintain a list of manuscripts in preparation that will be available in the T1DGC members' portion of the web site. The Coordinating Center will assist the P&P Committee with collection of all relevant material required for adhering to the policies of the P&P guidelines. Finally, the Coordinating Center will serve as the initial site for submission of all abstracts, presentations, manuscripts and press releases for P&P committee review.

Role of the Lead Author. Upon completion of the study the lead author will be charged with preparation of the planned abstract, manuscript, or presentation. The lead author is charged with coordinating the presentation of the planned material.

Basic Principles

In accepting biological reagents, data, or other material assistance from the T1DGC, investigators agree to abide by the T1DGC Publications and Presentations policies with regard to all manuscripts, abstracts, presentations, and press releases that incorporate any information obtained through the use of these resources and to acknowledge the role of the T1DGC in their provision.

1. Presentations utilizing T1DGC resources require review and approval.

These T1DGC policies recognize five classes of presentations that report findings generated with the use of consortium resources: (1) manuscripts submitted for publication in electronic or print journals; (2) abstracts submitted to meetings for either oral or poster presentation; (3) oral presentations that may, or may not, involve the prior submission of an abstract; (4) theses or dissertations for the satisfaction of an educational or degree requirement; and (5) press releases. All such presentations require the prior approval of the P&P Committee.

Manuscripts will fall into one of two categories. Major papers will report the findings of studies that utilize substantial T1DGC resources and are largely, or exclusively, supported by, and represent the major effort of, the consortium. Such papers would include, for example, reports of the results of overall analyses of linkage data for the consortium or consortium directed fine mapping in candidate regions. The topics, scope and goals of major papers will be defined by the P&P Committee in consultation with the T1DGC Steering Committee. All other papers will be developed from written proposals submitted to the P&P Committee for approval. In general, these papers will utilize fewer consortium resources than major papers and the studies reported will not have been supported by the consortium beyond the provision of data or biological samples.

It is essential that the P&P Committee, in its oversight role, be able to ascertain what data are included in a presentation and that the representations made are consistent with T1DGC goals and policies. To this end, the committee may employ outside reviewers in instances where a manuscript is submitted in a language other than English. The T1DGC places no restriction on language of publication.

2. Authorship must reflect the efforts of Consortium investigators.

The T1DGC is committed to the concept that the efforts of all consortium investigators involved in the collection, analysis, and maintenance of T1DGC resources be recognized in publications that utilize these resources. Accordingly, a collective consortium authorship, "The Type 1 Diabetes Genetics Consortium", will be defined that will include all investigators who have a signed consortium agreement on file at the Coordinating Center. Names of the individual members who make up this consortium authorship will be included as a footnote, acknowledgement, or on a supplementary web page depending on journal policy. The

consortium will be included as an author on all major papers as defined above. In addition to this collective consortium authorship, significant contributions to major papers by specific investigators will be recognized by including those investigators as individually named authors. For manuscripts falling into the "other" category, as well as for abstracts the P&P Committee will determine whether inclusion of the consortium among the authors is required on a case by case basis. In general, these decisions will be based on the extent of consortium resource utilization in specific studies.

3. Support of the T1DGC must be acknowledged.

All presentations that report findings obtained through the use of any T1DGC resources (data and/or samples) must acknowledge the T1DGC as the source of those resources and the agencies that supported their development. For manuscripts, the following statement should appear within the acknowledgments section:

"This research utilizes resources provided by the Type 1 Diabetes Genetics Consortium, a collaborative clinical study sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute of Allergy and Infectious Diseases (NIAID), National Human Genome Research Institute (NHGRI), National Institute of Child Health and Human Development (NICHD), and Juvenile Diabetes Research Foundation International (JDRF) and supported by U01 DK062418."

Oral presentations and posters do not have to adhere to this exact language, but must acknowledge the T1DGC and the listed funding agencies.

4. All T1DGC publications must comply with the NIH Public Access Policy.

The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central *upon acceptance for publication* (http://www.ncbi.nlm.nih.gov/pubmed/). To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication. (Appendix A provides details of how to comply with the NIH Public Access Policy.)

The Law
The NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008) which states:

SEC. 218. The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, *That the NIH shall implement the public access policy in a manner consistent with copyright law.*

Specific Issues:

1. Major Papers

1.a. In addition to the consortium authorship defined above, individual investigators will be specifically named in the authorship. These named authorships on major papers will be assigned by the P&P Committee to assure equitable distribution of investigators. Generally, there will be a representative from each Regional Network Center named on each paper. Network Center Principal Investigators (PIs) are invited to bring to the attention of the P&P Committee other investigators at their site who have made unique or significant contributions to a specific study to warrant their inclusion as named co-authors. Senior (last) authorship on major papers will rotate among the T1DGC Steering Committee members. The first and last author will usually not be from the same site. When appropriate, senior authorship may be switched among manuscripts.

1.b. Once an investigator accepts responsibility for a major paper, he/she should submit to the P&P Committee for approval a one to two page description of the paper, including the hypotheses, study sample, variables to be examined, and analytic methods.

1.c. Additional investigators may request to join the writing team for a major paper by arranging with the lead investigator for that project or by applying to the chair of the P&P Committee. A listing of papers currently in progress and the lead investigators will be available on the members' side of the T1DGC web site.

1.d. The progress of these papers will be closely monitored by the P&P Committee. Authors will be responsible for developing a projected time frame for manuscript preparation and submission and this plan will need to be approved by the P&P Committee. Among the major papers, some may be designated as "urgent," if publication is essential for the success of the study or for the publication of subsequent papers. The P&P Committee will query lead authors regularly for assurance that major papers are proceeding on schedule. The goal of this effort will be to work with the lead authors to insure adequate progress on major papers. In the event that a major paper falls well behind schedule, the P&P Committee will issue a written warning to the lead author requesting an explanation. If the situation continues, the P&P Committee may elect to reassign the manuscript to either a new lead author or a new writing team.

2. Other Papers

2.a. Written proposals for papers in the "Other" category may be submitted to the P&P Committee for approval for development, with authorship determined initially by the interested writers. The written proposals serve to minimize overlap between papers and will follow a standard format. They must include a description of the hypotheses of the paper, a one or two page description of the paper, including a description of variables, and the general statistical approach.

2.b. The P&P Committee can accept, reject, or ask for a re-submission with modifications for any paper proposal. In the event that two authors submit very similar proposals for papers, the P&P Committee will ask the authors to work together to develop a joint proposal.

2.c. Once a topic for an Other paper is approved by the P&P Committee, the Coordinating Center will list it on the study web site. Individual members will have responsibility to inform and recruit co-authors at his or her center for participation on writing teams. Additional investigators who wish to participate on an approved Other paper should contact the first author within a reasonable time frame (usually within 1 month). Lead authors will be responsible for keeping the P&P Committee updated as to the membership of the writing team and likely identities, but not necessarily order, of authors on the proposed manuscript.

2.d. It is anticipated that authorship on most papers will include a limited number of members from each of multiple institutions, in keeping with the consortium concept. The P&P Committee may request specific justifications for manuscripts that include disproportionately large numbers of named authors from a single institution.

2.e. The same person cannot be first author on more than two "other" papers simultaneously. However, there is no overall limit on the eventual number of first author papers any investigator may publish, and no limit on the number of different first authors from any group.

3. Review and approval of manuscripts

3.a. Prior to submitting a paper to a journal, the final draft, including all figures and ancillary material as it is to be submitted, must be approved by the T1DGC P&P Committee. Lead authors should communicate with the Coordinating Center in advance of their anticipated date for submission of a manuscript for P&P review so that there is adequate time to schedule a conference call for review.

3.b. Final manuscripts should be received by the Coordinating Center to allow distribution of the manuscript at least one week in advance of the P&P conference call on which it will be considered for approval.

3.c. Approval requires a majority of the voting members in attendance on the conference call to vote "approval".

3.d. The first author may be invited to attend the conference call in order to listen to the comments of the committee members. He/she may be asked to disconnect at the time of the vote. In some cases, the author will receive a written summary of P&P committee comments.

3.e. The P&P Committee will have the final authority to approve the manuscript.

4. Abstracts and Presentations

4.a. Abstracts do not need to be preceded by a paper proposal. An approved abstract can be submitted as a paper proposal, if so desired.

4.b. All abstracts for presentation of new data from the T1DGC must be approved by the P&P Committee. Abstracts must be received by the P&P Committee at least two weeks prior to the submission deadline unless an exception is granted by the P&P Committee.

4.c. The P&P Committee may request all slides and posters for any presentation of new (*i.e.,* unpublished) T1DGC data. The materials will be reviewed for content, interpretation and conclusions, but not necessarily for appearance, layout, or grammar. Usually, reviews of abstracts and presentation will be carried out by e-mail and the chair of the P&P committee will transmit any specific comments to the author in writing.

4.d. In the event of disagreements between investigators on a particular abstract, the P&P Committee will serve as mediator. If an agreement cannot be reached, the T1DGC Steering Committee will serve as the final arbiter.

4.e. When a T1DGC investigator is invited to present T1DGC data that are not yet published, the presenter should obtain permission to show the data from the first author of the pending paper. Disagreements between the first author and a presenter may be submitted to the P&P Committee for resolution.

5. Theses or Dissertations

5.a. Theses and dissertations are considered as publications and should be submitted to the P&P Committee as manuscript proposals. The applicant may use any data set that is generally available to consortium members.

6. Press Releases

6.a. Press releases related to publications, important new developments or findings from the T1DGC will be reviewed by the P&P Committee and, upon approval, released from the T1DGC Coordinating Center.

6.b. Individual centers may wish, in some cases, to personalize T1DGC press releases to highlight their role in the consortium. The P&P Committee will develop standard language that can be appended without specific review to T1DGC press releases to acknowledge the role of specific institutions. Any further editing of T1DGC press release text will require P&P Committee review and approval prior to release. Recognizing that in some cases there may be limited time for such review or approval, the chair of the P&P Committee may offer an expedited review process that will include consultation with at least the PI of the Steering Committee and representatives of National Institutes of Health (NIH) and Juvenile Diabetes Research Foundation (JDRF).

7. Miscellaneous Issues

7.a. In order to coordinate publications with access to T1DGC resources, the Chair of the P&P committee will receive copies of all applications to the Access Committee and will provide feedback to the Access Committee on possible overlap with existing projects.

7.b. The P&P Committee shall have the authority and responsibility to rank the priority of papers for progress.

7.c. In the case of a grievance regarding authorship, the party with the grievance should contact the P&P Committee. The committee will review the disagreement and make a recommendation to the Steering Committee. The Steering Committee shall make the final decision for all grievances.

7.d. If the NIDDK or JDRF Project Officer is included as a co-author on any manuscript or abstract, institutional clearance is required.

7.e. Individual PIs are responsible for assuring that their co-investigators abide by the guidelines set forth in this document.

APPENDIX A
How to Comply with the NIH Public Access Policy

Address Copyright

Before you sign a publication agreement or similar copyright transfer agreement, make sure that the agreement allows the paper to be submitted to NIH in accordance with the Public Access Policy.

Submit Papers

Authors may submit a paper to the journal of their choice for publication. There are four methods to ensure that a manuscript is submitted to PubMed Central in compliance with the NIH Public Access Policy.

Method A: Publish in a journal that deposits *all* NIH-funded final published articles in PubMed Central (PMC) without author involvement.
Method B: Make arrangements to have a publisher deposit a *specific* final published article in PubMed Central.
Method C: Deposit the final peer-reviewed manuscript in PMC yourself via the NIH Manuscript Submission System (NIHMS).
Method D: Complete the submission process for a final peer-reviewed manuscript that the publisher has deposited in the NIH Manuscript Submission System (NIHMS).

These methods vary in the version of the paper submitted, and the actions undertaken by the author and publisher. Please see Submission Methods for more information.

Cite Papers

When citing their NIH-funded papers in NIH applications, proposals or progress reports, authors must include the PubMed Central reference number for each paper.

Important Dates

- **April 7, 2008**
  As of April 7, 2008, final peer-reviewed manuscripts arising from NIH funds must be submitted to PubMed Central upon acceptance for publication.

- **May 25, 2008**
  As of May 25, 2008, NIH applications, proposals, and progress reports must include the PubMed Central reference number when citing a paper that falls under the policy and is authored or co-authored by the investigator, or arose from the investigator's NIH award. This policy includes applications submitted to the NIH for the May 25, 2008 due date and subsequent due dates.

Submission Methods

There are four methods to ensure that an applicable paper is submitted to PubMed Central (PMC) in compliance with the NIH Public Access Policy. Authors may use whichever method is most appropriate for them and consistent with their publishing agreement.

Method A: Publish in a journal that deposits *all* final published articles in PubMed Central (PMC) without author involvement.

Some journals automatically deposit all NIH-funded final published articles in PubMed Central, to be made publicly available within 12 months of publication, without author involvement. See the list of these journals at http://publicaccess.nih.gov/submit_process_journals.htm.

Method B: Make arrangements to have the publisher deposit a *specific* final published article in PubMed Central.

Some publishers will deposit an individual final published article in PubMed Central upon author request, and generally for a fee. See the list of publishers at http://publicaccess.nih.gov/select_deposit_publishers.htm.

Method C: Deposit the final peer-reviewed manuscript in PubMed Central yourself via the NIH Manuscript Submission System (NIHMS).

Submitting a final peer-reviewed manuscript to PubMed Central (PMC) via the NIHMS involves three tasks, as explained below. Task 1 may be done by an author or by someone in the author's organization (e.g., an assistant or a librarian). *Tasks 2 and 3 must be done by the author.*

Task 1: Deposit Manuscript Files and Link to NIH Funding

Upload a copy of the accepted final peer-reviewed manuscript and associated files (e.g., Microsoft Word document and figures) via the NIHMS. At the same time, identify the NIH funding associated with the manuscript. It usually takes less than 10 minutes to complete this task.

Task 2: Authorize NIH to Process the Manuscript

The author designates the number of months after publication when the manuscript may be made publicly available in PMC. The author then signs off, via the NIHMS, on a statement that confirms that the deposit of the manuscript is consistent with any publication and copyright agreements, and that NIH may begin processing the manuscript for use in PMC.

Task 3: Approve the PMC-formatted Manuscript for Public Display

The NIHMS will convert the deposited files into a standard PMC format, and email the author to approve the PMC-formatted manuscript for public display. The author reviews and approves the PMC-formatted manuscript via the NIHMS. Corrections to the manuscript, if necessary,

may be requested at this time.

Following completion of task 3, PMC will automatically make the paper publicly available after the designated delay period has expired.

Notes:

- Tasks 1 and 2 can be done at the same time, if the person performing them is an author of the manuscript.
- Tasks 2 and 3 may be done *only* by an author who logs into the NIHMS with an eRA Commons or NIH employee account.
- In many cases, the author who completes tasks 2 and 3 will be the Principal Investigator (PI) on the associated NIH award. When the author is not the PI, the NIHMS will notify the PI that a manuscript has been linked to the NIH award, upon completion of Task 2.
- The NIHMS offers extensive online instructions.

Method D: Complete the submission process for a final peer-reviewed manuscript that the publisher has deposited in the NIH Manuscript Submission System (NIHMS).

In a variation of Method C, some publishers deposit the manuscript files in the NIHMS for an author and designate the number of months after publication when the paper may be made publicly available in PMC.

The NIHMS will notify the author when the manuscript files are received from the publisher. At that point, the author must complete all of the tasks outlined for Method C, except for the file deposit part of Task 1 above.

E. TYPE 1 DIABETES GENETICS CONSORTIUM POLICY GOVERNING ACCESS TO STUDY REPOSITORY SAMPLES AND DATA (Approved October 9, 2008)

This document is a revised version of the previous Access Policy, Version 6 (February 12, 2007). Primary revisions in this version include:

- Non-member applications for access to T1DGC data and/or samples will be submitted to and approved by the NIDDK Central Repository.
- Procedures for review of applications for non-renewable resources have been modified, including specific criteria for the evaluation of such applications.

This Access Policy applies to T1DGC Contributing Investigators and Consortium Members until the end of the T1DGC study (NIH#U01DK062418). At that time, requests for access to T1DGC samples and data will be governed by policies determined by the NIDDK Central Repository, as specified in the T1DGC Consortium Agreement. **All requests from non-members are governed by NIDDK Central Repository policies.**

- The study database is frozen on a quarterly basis (January 1, April 1, July 1 and October 1); cumulative data sets can be requested following each freeze, as outlined in this policy and according to the timetable below.
- Samples can be requested by T1DGC investigators twice a year (January-February and July-August).

TIMETABLE:

Samples and data may be requested (for each participant provided) by Contributing Investigators.

6 months later →

Access to samples/data may be requested by T1DGC members.

12 months later →

Access to samples/data may be requested by non-members.

ACCESS INVESTIGATOR CATEGORIES

The T1DGC recognizes two groups of investigators: *T1DGC members*, who have submitted a signed Consortium Agreement to one of the T1DGC Network Centers or the Coordinating Center (including both T1DGC Contributing Investigators and T1DGC investigators who do not contribute samples) and *non-members*, who have not submitted a Consortium Agreement.

- All T1DGC member requests for access to samples or data (excluding requests for participants provided by Contributing Investigators) will be handled by the T1DGC Access Committee.

- All non-member requests for access to samples or data will be handled by application to the NIDDK Central Repository.
- Preference for access to T1DGC holdings is accorded to T1DGC members. T1DGC members may request access to T1DGC samples and data 12 months before non-members may submit similar requests.
- T1DGC members will receive preferential receipt of samples and data.
- The T1DGC web site will be used to notify investigators of samples and data available for access applications.

CONTRIBUTING INVESTIGATORS

Investigators who have contributed samples to T1DGC have the right to request data and samples for each participant provided.

- Requests for quarterly data freezes may be submitted to the investigator's Regional Network Center at any time.
- Requests for samples may be submitted to the investigator's Regional Network Center in January-February and July-August.
- Procedures detailed in the "Contributing Investigator Request for Samples and Data," section of the T1DGC web site must be followed.
- Contributing Investigators have priority access to data and samples for each participant they provide. T1DGC will bear the cost for transferring samples to Contributing Investigators.
- Contributing Investigators will have priority receipt of samples and data.

NON-CONTRIBUTING INVESTIGATORS (T1DGC Members)

T1DGC members may request access to data and samples on individuals they did not contribute to the T1DGC six months after these become available to the Contributing Investigator.

INVESTIGATORS NOT MEMBERS OF THE T1DGC (Non-Members)

Investigators who are not members of the T1DGC may request access to data and samples (through an application to the NIDDK Central Repository) twelve months after these become available to T1DGC members, or eighteen months after these become available to the Contributing Investigator.

RENEWABLE AND NON-RENEWABLE RESOURCES

There are two types of Consortium resources: renewable and non-renewable. Data and DNA aliquots obtained from cell lines are considered *renewable resources*. Whole-genome amplified DNA, plasma, and serum are considered *non-renewable resources*.

DATA

Data, referring to information obtained or generated as a result of Consortium activities, is considered a *renewable resource*. Examples of such data include medical information (*e.g.*, age-at-onset), immunological information (*i.e.*, $IA2_{ic}$, GAD65 autoantibodies), and genetic information (*e.g.*, genome scan linkage data, HLA genotype data, *INS*, *CTLA4*). T1DGC databases include results from T1DGC-directed genetic analyses, laboratory assays of serum and plasma specimens, and data collected on T1DGC forms.

SAMPLES

Samples, referring to biological materials obtained from blood, include cell lines, genomic DNA, whole genome amplified DNA, plasma and serum.

- Only Contributing Investigators are entitled to receive a cell line aliquot from samples that they submit, and only for use that is consistent with any restrictions arising from informed consent. Cell lines will not otherwise be distributed by the T1DGC.
- There are different criteria for access to renewable versus non-renewable samples. There are also different review and approval procedures (see below).
- Because access depends on sample availability, requests for access to samples may be made only according to a determined schedule. This applies to both renewable and non-renewable sample resources.
- Access to each sample will be governed by the provisions of its associated informed consent form. This means that some samples may be restricted to non-commercial use. Ordinarily, investigators who receive access to samples will also receive access to the data associated with those samples. However, data may become available to the investigator on a different time schedule than the samples.
- The timing of release of non-renewable sample resources is likely to be different from the timing of release of renewable samples.
- The investigator who receives access to T1DGC samples will bear the costs for sample transfer.

APPLYING FOR ACCESS TO RENEWABLE AND NON-RENEWABLE RESOURCES

To apply for access to T1DGC samples and/or data, you should complete the Access Application form posted in the "Application for Access to T1DGC Data and Sample," section of the T1DGC web site. NOTE: The Access Application form is Appendix A of this document (.pdf version) and is also posted on the T1DGC web site (.doc version).

Applications must be submitted to the Access Committee via the web-based Access System. A Confidentiality Certification (Appendix B) for all individuals with access to the data or samples should be completed and submitted to your Regional Network Center or Coordinating Center (for T1DGC members).

The timetable for applying for access to specified T1DGC resources depends on T1DGC membership (see TIMETABLE above and/or in Appendix C).

GENERAL GUIDELINES

- All applications will be reviewed by the Access Committee for concordance with the aims of the T1DGC and security.
- The Coordinating Center will keep confidential records of all applications and will provide the Steering Committee regular summary reports of its activities. For non-renewable applications, the evaluation forms from each Access Member and the written critique from the Access Committee Chair will be the sole record of the deliberations.
- Access is conditional on availability of samples and/or data, and agreement to abide by T1DGC policies related to publication, specimen disposal, custodianship, ethical approval and informed consent, patenting, and confidentiality.

- Access to each sample will be governed by the provisions of its associated informed consent form. Access to samples from particular countries is subject to the laws pertaining to those countries; individuals requesting access to samples will be required to sign an agreement acknowledging that they understand and will comply with any country-specific restrictions associated with certain samples. A plan for compliance will be required for the application requesting access to restricted samples.
- Access to T1DGC samples and/or data is conditional on the investigator agreeing to submit results to the NIDDK Central Repository for incorporation among the T1DGC data holdings, which enhances the scientific value of these samples and extends opportunities for collaborative research. This reporting must occur within one year after receipt of the samples and/or data.
- The Access Request system will simultaneously notify the Coordinating Center of all successful applications so that it can begin the process of data and/or sample transfer. Transfer will be accompanied by documentation related to sample collection and storage. Transfer of required data from the T1DGC database will be negotiated directly with the applicants. The Coordinating Center will regularly report to the Access Committee on the status of sample and data transfers.
- Unsuccessful applicants may revise their application and re-apply to the Access Committee. If the application is denied a second time, the unsuccessful applicant may appeal the decision. An appeal will be considered only if the review process was flawed. The Chair of the Steering Committee will determine if the review was flawed and, if so, the Steering Committee will constitute a separate review group to handle the appeal and review the application.
- The T1DGC Publications and Presentations Committee will track publications derived from T1DGC samples and data. Investigators granted access to samples and data will be requested to provide updated information on such publications to that Committee. Study publications policy (set by the T1DGC Publications and Presentations Committee) will govern the citation and release of this information to the general public.
- The T1DGC Coordinating Center maintains summary reports of its databases on the password-protected study web site. These include, in aggregate, distributions of genetic and phenotypic characteristics of the study cohort and data related to the collection and processing of these samples. The nature and content of these reports are determined by T1DGC committees, its sponsors, and its External Advisory Committee.

APPROVAL PROCESS FOR RENEWABLE RESOURCES

For *renewable* sample resources, the main criterion for approval of applications is **scientific appropriateness**.

- Applications for renewable samples will be considered approved if approved by majority vote of 6 members of the Access Committee. Applications will be decided within four weeks of receipt. The Access Committee Chair will notify applicants of the final decision.

- Approval for access to subsequent versions of the T1DGC database may be requested through an extension of the original access request. Extension of a data request is permissible only if the specific aims of the original request have not changed since the time of the initial submission. If the specific aims have changed, a new access request must be submitted.

APPROVAL PROCESS FOR NON-RENEWABLE RESOURCES

For *non-renewable* sample resources, the main criterion for approval of applications is **scientific merit;** additional criteria considered by the Access Committee are outlined below.

- The Access Committee (which includes a representative from the Coordinating Center and the funding agencies) will review each application for access to non-renewable samples, using the form developed for this purpose (Appendix D). In addition, one outside reviewer will be appointed by the Chair of the Access Committee. A primary reviewer will be appointed in each review panel, using the NIH model. The T1DGC Coordinating Center representative will be responsible for evaluating the logistical needs of the application and confirming the availability of the requested samples.

- Factors considered in the review of applications for non-renewable specimens include the **scientific merit** of the application, its uniqueness and potential contribution, synergy with the goals of the T1DGC, and the research experience of the applicant. Overlapping applications may result in recommendation that collaborations be implemented.

- Applications for non-renewable resources should:

    - clearly state the hypothesis to be tested and the number of samples needed to achieve this (*i.e.,* power calculations);
    - state precisely what assays will be undertaken, by what methods and the amount of sample required for each;
    - contain an undertaking not to use the sample for any other purpose without prior authorization;
    - include an undertaking to return all unused sample by a given deadline; and.
    - explain why T1DGC samples are needed (*i.e.,* why no other resources can address the hypothesis).

- Applications for non-renewable samples will be considered approved if approved by a two-thirds majority of the Access Committee (including the external reviewer). Applications will be decided within twelve weeks of receipt. The review panel will develop a written critique of each application and a rationale for its decision. The Access Committee Chair will notify applicants of the final decision.

APPENDIX A
T1DGC APPLICATION FOR ACCESS TO DATA AND SAMPLES

Date of submission:

Resource Requested: (Mark all that apply.)

Renewable Resources:

☐ **DNA (5mcg aliquot)**

☐ **Data (Specify requested data set[s]:_____)**

NOTE: Data set name is a required field. See list of "Available Data Sets and Samples" under "Access to T1DGC Data and Samples" link on www.t1dgc.org.

Non-Renewable Resources:

☐ **Whole Genome Amplified DNA (5mcg aliquot)**

☐ **Serum (0.5 ml aliquot)**

☐ **Plasma (0.5 ml aliquot)**

Project title:

Corresponding investigator and full contact information:

Name:

Address:

Telephone:

FAX:

E-mail:

Name(s), affiliation(s) and address(es) of major co-investigator(s) and/or collaborator(s):

Name(s), affiliation(s) and address(es) of project analyst(s):
Abstract (250 words or less):
Specific aims:
Previous peer review of the project. Indicate whether the genetic components of the project have undergone previous peer review, and by whom. Indicate the outcome of the review. If an application is currently pending at the NIH, provide details about the study section and institute assignment, if known.
Source(s) of funds for the project. If no new funds are required, this should be stated. If funded by the NIH, list the sponsoring institute and the dates of support. If approval is sought conditional on the applicant's success in obtaining funding, a specific timeline for this must be provided.

Number of samples to be analyzed and the projected timeline for obtaining the samples from T1DGC. (For non-renewable resources, a formal justification for the requested number of samples must be provided, including power analyses. This is critical for access to the limited plasma and serum samples.)
Brief outline of the plan for the next phase of the project if linkage or association is found (if applicable). Include specific plans for isolating the locus (loci) and name the individuals responsible for each step. Attach letters of collaboration from these individuals.
Description of core data required from the T1DGC central databases, including process and phenotypic data.
Measures to ensure the security of specimens and data. In addition, plans for disposal of any unused specimens and data must be described.
Background information about the disease/trait including the rationale for carrying out this particular study. Describe any unique features about the disease/trait that would single out this project for special consideration.

Analysis strategy for the resulting information and choice of analytic methods and software. If collaborations are established for analytical services, include letters of collaboration.

Assurance that the project has been reviewed for human subject protection by an appropriate Institutional Review Board (IRB) or Ethics Committee (EC).

Description of any commercial aims and likely benefits ensuing from the project. Details of pending or granted patents relevant to the application must be provided.

If samples are requested, please provide shipping contact information.
Name of Contact:

Shipping Address:

E-mail Address:

Phone Number:

Have all of co-investigators and collaborators approved the final version of this application? ☐ YES ☐ NO

Is there a deadline for submission of this material to an external agency? ☐ YES ☐ NO

If yes, what is the deadline and when would you like comments back? _____/_____/_____
DD/ MM/ YYYY

I have read and agree to abide by the T1DGC Access Policy, the T1DGC Publications and Presentations Policy, and the consent guidelines conferred by study participants.
☐ YES ☐ NO
I have signed and submitted the T1DGC Confidentiality Certification to my Network Center or the Coordinating Center.
☐ YES ☐ NO

All individuals who will have access to the data and/or samples have submitted the T1DGC Confidentiality Certification to the Network Center or Coordinating Center.
☐ YES ☐ NO
I agree to submit all results from analysis of these samples to the NIDDK Central Repository for incorporation among the T1DGC data holdings (including information on quality control methods).
☐ YES ☐ NO
I understand that some samples will be restricted to non-commercial use only.
☐ YES ☐ NO

Applications for non-renewable resources must include submission of the following items:

- **CV(s) for key personnel involved in the project (NIH format required)**
- **Letter(s) of support/commitment from major collaborator(s) and/or co-investigator(s)**
- **Essential reprints or preprints (no more than 3)**

Submission of these items is optional for applications for renewable resources.

APPENDIX B.
T1DGC CONFIDENTIALITY CERTIFICATION

All individuals with any access to Type 1 Diabetes Genetics Consortium (T1DGC) data must sign a Confidentiality Certification. This includes, but is not limited to, the following groups of individuals:

- Principal Investigators
- Co-Investigators and Investigators
- Coordinating Center staff, including any data entry, data management, data analysis and support staff
- Regional Network staff and support staff
- Field Center staff and support staff
- Laboratory staff and support staff
- Data analysts (on-site and off-site)
- Fellows and students
- Consultants
- Ancillary study investigators

Each individual with access to T1DGC data must read, sign and date the Confidentiality Certification. The Network Principal Investigator must also sign the certification and keep the original copy on file at the Coordinating Center. A copy is retained at the Regional Network Center of the completed certification.

The Principal Investigators (Field Centers, Regional Networks and Coordinating Center) are responsible for ensuring that all individuals currently affiliated with the T1DGC Study through their site sign the Confidentiality Certification. The Coordinating Center is specifically responsible for ensuring that all subcontractors and consultants to the Study through the Coordinating Center contract, including laboratory investigators and staff, sign the Confidentiality Certification. The Principal Investigators are responsible for ensuring that all individuals who become affiliated with the T1DGC Study through employment or consulting in the future sign the Confidentiality Certification at the time he/she joins the Study.

TYPE 1 DIABETES GENETICS CONSORTIUM
CONFIDENTIALITY CERTIFICATION

As an employee of, consultant to, or fellow/student involved with the Type 1 Diabetes Genetics Consortium (T1DGC) Study funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), I am aware of the confidential nature of data on research participants maintained by the Study, and the necessity of maintaining that confidentiality.

I agree not to **transfer** or **disclose** any confidential data, nor any information about individual T1DGC Study participants, except as necessary for data/safety monitoring or programmatic management, in the course of my responsibilities at work nor in private, either during or after my affiliation with the T1DGC Study. I agree not to transfer **any** T1DGC data or biological specimens to individuals outside the T1DGC Study Group without the written permission of the T1DGC Steering Committee. Further, I agree to return all T1DGC data to the Principal Investigator or delete/destroy all T1DGC data upon termination of my affiliation with the Study.

I understand that as an employee of, consultant to, or fellow/student involved with the T1DGC study, I am subject to the provisions of laws and regulations related to confidentiality of study data in the country where the work is performed.

Name (print): _____

Signature: _____

Date: _____

T1DGC Site: _____

Principal Investigator's Signature: _____

Date: _____

APPENDIX C.
TIMETABLE FOR T1DGC SAMPLE AND DATA AVAILABILITY

SAMPLES

Available to:

Contributing Investigators	**T1DGC Members**	**Non-Members**
July-Aug 2005	Jan-Feb 2006	~~Jan-Feb 2007~~
Jan-Feb 2006	July-Aug 2006	~~July-Aug 2007~~
July-Aug 2006	Jan-Feb 2007	~~Jan-Feb 2008~~
Jan-Feb 2007	July-Aug 2007	~~July-Aug 2008~~
July-Aug 2007	Jan-Feb 2008	~~Jan-Feb 2009~~
Jan-Feb 2008	July-Aug 2008	~~July-Aug 2009~~
July-Aug 2008	Jan-Feb 2009	~~Jan-Feb 2010~~
Jan-Feb 2009	July-Aug 2009	~~July-Aug 2010~~
July-Aug 2009	Jan-Feb 2010	~~Jan-Feb 2011~~
Jan-Feb 2010	~~July-Aug 2010~~	~~July-Aug 2011~~

QUARTERLY DATA FREEZE

Available to:

Contributing Investigators	**T1DGC Members**	**Non-Members**
July 2005	Jan 2006	~~Jan 2007~~
Oct 2005	April 2006	~~April 2007~~
Jan 2006	July 2006	~~July 2007~~
April 2006	Oct 2006	~~Oct 2007~~
July 2006	Jan 2007	~~Jan 2008~~
Oct 2006	April 2007	~~April 2008~~
Jan 2007	July 2007	~~July 2008~~
April 2007	Oct 2007	~~Oct 2008~~
July 2007	Jan 2008	~~Jan 2009~~
Oct 2007	April 2008	~~April 2009~~
Jan 2008	July 2008	~~July 2009~~
April 2008	Oct 2008	~~Oct 2009~~
July 2008	Jan 2009	~~Jan 2010~~
Oct 2008	April 2009	~~April 2010~~
Jan 2009	July 2009	~~July 2010~~
April 2009	Oct 2009	~~Oct 2010~~
July 2009	Jan 2010	~~Jan 2011~~
Oct 2009	~~April 2010~~	~~April 2011~~
Jan 2010	~~July 2010~~	~~July 2011~~

NOTE: ~~Strikethrough~~ means outside the life of T1DGC funding (for T1DGC members); applications for requests to be submitted to and adjudicated by NIDDK Central Repository.

APPENDIX D.

T1DGC Evaluation Form: Non-Renewable Resource Request
Access Request Number: AR_____

Please rate items 1-5 as "Acceptable" or "Not Acceptable". All comments will be forwarded to the investigator submitting the request.

1. Importance of the scientific question to type 1 diabetes research:

Acceptable ____ Not Acceptable ____
Comments:

2. Unique requirement for samples requested:

Acceptable ____ Not Acceptable ____
Comments:

3. Quality and thoroughness of the proposal in outlining the specific hypotheses and methods:

Acceptable ____ Not Acceptable ____
Comments:

4. Number of samples and amount of sample required:

Acceptable ____ Not Acceptable ____
Comments:

5. Plan for sharing data results with other investigators:

Acceptable ____ Not Acceptable ____
Comments:

6. Additional comments or questions:

Request Approved: ____ Request Not Approved: ____

F. GUIDELINES FOR T1DGC MEMBERS USING THEIR OWN BIOLOGICAL SAMPLES (Approved January 9, 2007)

T1DGC investigators may request cell lines and DNA from the participants they contributed to the study. This document summarizes T1DGC policy about the permissible uses of these biological samples, based on the informed consent form, the consortium agreement, and other existing documents. *Please be reminded that the consent form is the primary document that governs the use of these samples, and that the provisions in that document should be honored.*

1) Oversight. These samples were collected under the T1DGC consent form approved by your local ethics committee (or IRB). Your use of these samples remains subject to restrictions in this consent form and the oversight of your local ethics committee.

2) Uses. The standard consent form allows these samples to be used only to study type 1 diabetes, its complications, and other autoimmune diseases. Any use different than this must be approved by your local ethics committee (or IRB), and may require additional consent.

3) Sharing with Others. Your local ethics committee (or IRB) may authorize you to share these samples with other researchers. If so, other researchers must use the samples under the same rules that apply to you.

4) Selling Samples. You may not sell the samples or charge someone to use them. Selling or charging means to make a profit. It is permissible to request payment only to cover the costs of storing or distributing the samples. Payment to cover the costs of acquiring these samples is not appropriate because those costs were paid for by the T1DGC Consortium.

5) Destroying Samples. If participants request to withdraw from the T1DGC study, you must be able to destroy their samples and information, including any samples or information that you might give to others.

For North American Network Investigators Only

6) Identifying Samples. These samples were collected under the understanding that they would be stored and studied anonymously. Therefore, unless you receive different permission from your local IRB, you may not attempt to identify these samples or link them to information that could identify the participants they come from.

G. INTELLECTUAL PROPERTY

Although there is no formal written Intellectual Property (IP) policy, the T1DGC theoretical guiding principle regarding this topic is summarized below.

The Consortium has no expectation that patentable information or material will result from the combined or aggregate Consortium database, and the Consortium will not assert or claim any such IP rights. Therefore, no individual or group will own or claim IP rights to the combined or aggregate Consortium database, other than copyright or similar rights to control use and access to the database or the publication of information and findings generated by the Consortium.

Individual investigators retain any IP rights deriving from their separate analysis of and/or publication of their own data. Thus, it may be possible for individual investigators who follow up the Consortium's analyses to generate patentable information or material, but they will need to decide themselves whether to claim any such potential IP.