3. GUIDELINES FOR OBTAINING INFORMED CONSENT

3.1 INFORMED CONSENT

In order to be eligible for the study each participant must be willing to sign a statement of informed consent prior to participation, in order to document that subjects understand the study and its procedures and agree to participate in the study activities. The Informed Consent must be signed and a copy returned to the Coordinating Center for a patient to be considered officially enrolled in the GoKinD study. The Informed Consent must be signed before any data may be collected on that patient. **The basic informed consent form and the informed consent for remote collection using CTI Network, Inc. are presented in Appendix 3.**

The basic elements of the informed consent are:

1. A straight forward statement that the study involves research and a clear explanation of the purpose of the study, including a description of the procedures to be followed in the examinations and the identification of experimental procedures, and the expected duration of the subject's participation.

2. A description of the outcome(s) of primary interest, the length and schedules of follow-up, and methods of locating and following up subject participants who transfer to inactive status.

3. A description of the attendant and reasonably foreseeable discomforts and risks, as well as a description of any reasonably expected benefits.

4. A disclosure of alternative procedures that might be advantageous for the subject.

5. A statement that participation is voluntary and the subject is free to refuse to participate or withdraw consent and to discontinue participation in the project or activity at any time without jeopardizing his/her medical care.

6. No exonerating language through which the subject is made to waive, or appear to waive, any legal rights, or to release the institution or its agents from liability for negligence.

7. A description of the measures taken to ensure confidentiality of subject information.

8. A description of the measures taken to ensure subject safety.

9. An explanation of a subject's rights to compensation for research related injuries and identification of specific individuals to contact regarding injury and/or questions related to rights as a research subject.

10. A description of subject responsibilities, including an explanation of the information that will be available during and at the conclusion of the study.

11. An offer to answer all inquiries concerning participation in the research including identification of specific individuals to contact for answers to pertinent questions about the research.

12. A statement that participation in the study may involve risks which are currently unforeseeable.

13. An explanation of circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

14. An explanation of the health consequences of a subject's decision to withdraw from the research and the need to orderly termination of participation.

15. A statement that significant new findings developed during the course of the study which may influence the subject's willingness to continue participation will be provided to the subject.

16. Each patient must be notified of the National Institutes of Health Privacy Act Notice. In preparation for the long-term follow-up of the GoKinD subjects it is important that a system of records be maintained centrally. The system, of course, must contain information that is personal and to some may be of a sensitive nature. In order for names, addresses, phone numbers, names of next-of-kin and social security numbers to be centrally stored, it is required by law that the subject be notified that the information will be collected, for what purpose, that it is voluntary and to whom it will be released.

17. Confidentiality of subject information is a major concern of the participating individuals and the organizations that oversee the use of human subjects in research and seek to set standards for that research. The concern is not only that personal information will get into the hands of third parties, such as employers and insurance companies, but also that genetic information may get into the hands of individuals who cannot benefit from the knowledge but can be harmed by it. Three types of data can be distinguished by their sources: data identifying individuals and characterizing their phenotypes that are collected by centers recruiting subjects; phenotypic data generated by the central laboratory; and genotype data generated by investigators using the DNA. The following policies will be implemented to protect confidentiality of this data. 1) Samples sent to the CBL and The Centers for Disease Control and Prevention will be coded to track samples but will not contain identifiers such as name, address, or social security number. 2) Databases compiled will be password protected. 3) Forms will be kept in locked file cabinets. 4) Identifying information maintained by The JDRF Coordinating Center will not be stored in the same place as other study data.

18. Study participants will receive the results of the standard tests on their blood and urine. They will <u>not</u> receive information about the results of studies of their DNA. All patients with diabetes may benefit if this project is successful in discovering the genes responsible for susceptibility to complications of diabetes. At some time in the future, there may be justification for informing the patients of the results of the tests of their DNA. The Executive Committee will have an ongoing responsibility for evaluating whether the patients would benefit from that information and, if they

decide there is sufficient justification, they will forward a specific proposal to the IRBs at institutions that provided patients.

In accordance with DHHS policy on informed consent, it is necessary to recognize that each subject's mental and emotional condition is important … and that in discussing the element of risk a certain amount of discretion must be employed consistent with full disclosure of facts necessary to any informed consent.

Individual sites may require that the recommended Informed Consent Form be amended to include additional statements or be reworded based on local institutional requirements.