1. HOW TO GET STARTED AS A NEW SITE

1.1 INTRODUCTION

In order to begin participation in the GoKinD study, it is necessary for each site to be certified by the Coordinating Center (COC). To obtain certification, each site must receive Institutional Review Board (IRB) approval, identify a study coordinator, obtain storage space for study documents, sign the Letter of Agreement (LOA) with The George Washington University (GWU) and attend a training session.

1.2 IRB APPROVAL PROCEDURE

The process of obtaining IRB approval differs at institutions that do and do not hold a Multiple Project Assurance (MPA) of compliance from the Office of Human Research Protections (OHRP) located in the Office of the Secretary, Department of Health and Human Services (DHHS). Required procedures for these two circumstances are described in the following sections. The OHRP has simplified the assurance and IRB registration process. Existing assurances will remain in effect through their current expiration date.

1.2.1 IRB Procedure for Sites with Multiple Project Assurance (MPA)

As soon as the decision is made that a site will participate as a GoKinD center, the Principal Investigator (PI) of the center, or his/her designee, should submit the GoKinD protocol with the sample informed consent form to his/her IRB. It is important that the information contained in the sample informed consent also be in the site's final informed consent form. Additional local requirements may be included as needed. A copy of the IRB-approved informed consent form should be mailed to the COC, along with the letter of IRB approval, before the site begins screening patients and their parents. All sites with MPAs will be registered automatically.

1.2.2 IRB Procedure For Sites Without Multiple Project Assurance

Sites without an MPA number must file a new Federal Wide Assurance (FWA). The COC will provide guidance. Note that OHRP will not issue a Single Project Assurance (SPA) number after March 1, 2001. See Appendix 1 for procedure for filing FWAs. The new IRB identification numbers for the GoKinD Clinics are given in Table 1.1.

Once the process is complete, submit the GoKinD protocol and informed consent form. A copy of the IRB-approved informed consent form should be mailed to the COC, along with the letter of IRB approval before the site begins screening patients and their parents.

1.3 IDENTIFICATION OF STUDY COORDINATOR

One individual at each site should be identified as the primary study coordinator. In order for each site to function smoothly, it is critical that one responsible and resourceful individual be identified. The name, mailing address, FedEx address, telephone number, fax number, and E-mail address of this individual should be sent to the COC. For the start up of the

study, coordinator training sessions will be held. Attendance is mandatory and no site may begin recruitment until at least one coordinator attends a training session. Each study coordinator will receive a certification number that should be used in completing all future study forms on study subjects.

1.4 SPACE REQUIREMENT FOR STUDY COORDINATOR AND STUDY DOCUMENTS

The site should have an appropriate space for the study coordinator to interview patients and complete data forms. In this space or in an adjacent area there should be a locked cabinet for patient study forms, or the room may be locked. The forms should be kept on site until the COC stipulates that they can be disposed of according to study requirements and local regulations. In addition, space should exist to store blank study forms, patient brochures, and other study supplies.

1.5 OTHER EQUIPMENT REQUIREMENTS

A fax machine to receive information from the COC. For baseline blood and urine storage, a freezer (-70°c or -20°c) which is not an autodefrost model and a centrifuge are required.

1.6 LEGAL AGREEMENT WITH THE GEORGE WASHINGTON UNIVERSITY

In order to complete the contractual agreement with the Coordinating Center and be ready for the start of patient recruitment, each site must sign a LOA with GWU. Before this can be done, the following information must have been submitted to the COC:

- CVs of Principal Investigators
- OHRP'S IRB registration number
- Copy of the IRB approval letter and the name/affiliation of the IRB
- Copy of the IRB-approved informed consent form
- Name of the individual or institution with whom the LOA will be made
- Social security or tax identification number for U.S. clinics
- Certification that all work is to be performed in Canada for Canadian clinics
- Address to which payments should be sent
- Whether or not the institution is a small business

The LOA cannot be executed, and patient recruitment and payments cannot be initiated until all of the above information is received. Once the COC has received all necessary information from a site, the LOA with two signature pages will be generated at the COC. The

Principal Investigator of the COC and the Director of the Office of Sponsored Research will sign the letter to verify that the site has been approved as a GoKinD site. The LOA will then be mailed to the GoKinD site with an explanatory cover letter. The two signature pages will need to be countersigned by the site's Principal Investigator and an authorized official from the site's institution. One original copy of the signature page will be returned to the COC; the LOA and other original copy of the signature page are to be kept at the site. Once the COC has received the countersigned LOA and all other required documentation, the site will be eligible for certification.

1.7 CERTIFICATION PROCESS

When a study coordinator is eligible to be certified, the COC clinic monitor will send her/him a GoKinD certification quiz. Upon successful completion of the quiz (grade of 85% or higher), the study coordinator is assigned a certification number to be used when completing all GoKinD forms. If a grade of 85% or higher is not attained, the study coordinator will need to review the certification quiz by telephone with the COC clinic monitor. The study coordinator may be asked to ship specimens to the Central Biochemistry Laboratory if the coordinator does not regularly collect and ship laboratory specimens.

1.8 CERTIFICATION NUMBERS

The COC will issue a unique number to each of the site staff members through a certification process. Any new staff member subsequent to the site's certification will receive his/her certification number upon completion of this process also. These numbers are a means of assuring that only trained site staff are completing study forms. We will wish to describe the stability of clinic staff at the conclusion of the study. In the interim, on a random basis, the COC will monitor use of correct certification numbers by cross-checking the issued number with the name of the person assigned to that number.

1.9 CERTIFICATION OF NEW PERSONNEL AT A CERTIFIED SITE

GoKinD is projected to last through the year 2005. Certainly, new personnel may assume key positions in each and every site. The COC should be alerted to the changes in key personnel as well as to new phone numbers, fax numbers, and addresses. Ideally, the training of new personnel should be performed by the individual who is being replaced. If local training is not possible because of non-overlapping of staff, there are contingency plans for training at the COC.

New personnel should follow the appropriate procedures for certification described in the previous sections.

TABLE 1.1

FEDERALWIDE ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS

ORGANIZATION	ADDRESS	PRINCIPAL INVESTIGATOR	ASSURANCE NUMBERS
Joslin Diabetes Center Section on Genetics & Epidemiology	One Joslin Place Rm 368 Boston, MA 02115	Previous - John Rogus, ScD Current - James H. Warram, MD, ScD	**IRB00000371** **FWA00001535**
Medical University of South Carolina	96 Jonathan Lucas St. Rm 816 CSB PO Box 250624 Charleston, SC 29425	Previous - Maria Szpiech, MD Current - John A. Colwell, MD, PhD	**FWA00001888**
MedStar Clinical Research Center	650 Pennsylvania Ave , SE Suite 50 Washington, DC 20003	Robert E. Ratner, MD	**IRB00000598** **FWA00000504**
Mount Sinai Hospital University of Toronto	Room 5024 60 Murray St., Box 17 Toronto, Ontario Canada M5T 3L9	Bernard Zinman, MD	**IRB00001484** **FWA00000911**
New York Presbyterian Hosp. Weill Cornell Medical Center	Box 136 1300 York Avenue New York, NY 10021	David Brillon, MD	**FWA00000093**
Northwestern University Medical Center	303 E. Chicago Avenue Tarry 15-731 Chicago, IL 60611-3008	Mark E. Molitch, MD	**FWA00001549**
St. Joseph's Health Care, London University of Western Ontario	268 Grosvenor St. Rm E216 London, Ontario Canada N6A 4V2	Irene Hramiak, MD	**IRB00000940** **FWA00000200**
University of Missouri Hospital and Clinics	Diabetes & Endocrinology Center D110A 1 Hospital Drive Columbia, MO 65212	Stephen A. Brietzke, MD	**FWA00002876**
University of California, San Diego	Clinical Research Facility-0620 9500 Gilman Drive La Jolla, CA 92093-0620	Steven V. Edelman, MD	**FWA00004495**
University of Florida	Department of Medicine Box 100226 Gainesville, FL 32610	Lawrence Kennedy, MD	**IRB00000335** **FWA00005790**

ORGANIZATION	ADDRESS	PRINCIPAL INVESTIGATOR	ASSURANCE NUMBERS
University of Iowa	Division of Endocrine U. of Iowa, Internal Medicine E422 GH, 200 Hawkins Dr. Iowa City, IA 52242	William L. Sivitz, MD	**IRB00000099** **FWA00003007**
University of Maryland Medical System	22 South Greene Street Room N5E13 Baltimore, MD 21201	Debra Counts, MD	**FWA00007145**
University of South Florida	College of Medicine MDC Box 45 12901 Bruce B. Downs Blvd Tampa, FL 33612	John I. Malone, MD	**FWA00001669**
Benaroya Research Institute (V. Mason)	1201 9th Avenue Seattle, WA 98101	Carla Greenbaum, MD	**IRB00000057** **FWA00001995**
Washington University School of Medicine	660 South Euclid St. Louis, MO 63110	Neil H. White, MD	**IRB00000164** **FWA00002284**
Vanderbilt University Medical Center	305 Medical Arts Building Nashville, TN 37232-1229	Michael E. May, MD	**IRB00000476** **FWA00005756**
Sansum Diabetes Research Institute	2219 Bath Street Santa Barbara, CA 93105	Lois Jovanovic, MD	**IRB00000797** **FWA00001254**
University of Miami Jackson Memorial Hospital	Highland Professional Bldg 1801 NW 9th Ave., Ste. 521 Miami, FL 33136	George W. Burke III, MD	**FWA00002247**
University of North Carolina at Chapel Hill	Abdominal Transplantation and General Surgery 4023 Burnett-Womack Bldg 229 Campus Box 7211 Chapel Hill, NC 27599	Previous - Mark Johnson, MD Current - Kenneth Andreoni, MD	**IRB00000538** **IRB00000539** **FWA00004801**
University of Minnesota Pediatric Nephrology	MMC 491 420 Delaware Street, SE, Minneapolis, MN 55455	Michael Mauer, MD	**IRB00000439** **FWA00000312**
Mid-America Diabetes Associates, P.A.	200 S. Hillside Wichita, KS 67211	Richard A. Guthrie, MD	**IRB00001674** **FWA00001005**
Albany Medical Center	Division of Endocrinology & Metabolism, MC 141 47 New Scotland Avenue Albany, NY 12208	James Desemone, MD	**FWA00001314**
St. Vincent's Medical Center, National Institute of Transplantation	National Institute of Transplantation 2200 W. Third St., #100 Los Angeles, CA 90057	Robert Mendez, MD	**IRB00000913** **FWA00003778**