

6. GOKIND FORMS COMPLETION AND MAILING OF FORMS

The GoKinD forms have been constructed to serve the following functions:

- 1) To provide the data required for a thorough evaluation of the eligibility of cases and controls.
- 2) To allow the audit and tracking of GoKinD specimens in a thorough format that is standard for all clinical centers.
- 3) To document that certain study procedures have been followed.
- 4) To request certification of new clinic staff.

This chapter will describe the study forms, how to complete, fax (when necessary), and mail them to COC. (See Appendix 2 for copies of all study forms.)

6.1 THE STUDY FORMS

The number of GoKinD forms has been kept to a minimum (see Table 6.1). This restriction of data collection reflects the policy of collecting only data useful in characterizing the cohort being studied, and ensuring successful tracking of specimens from the clinics to the CBL and to the CDC.

6.1 FORM SUPPLIES

Shortly after a clinic's certification, the COC will ship the GoKinD forms to the clinic. A prototype of the Informed Consent Form is included in the Protocol. Informed Consent Forms and additions to the informed consent documents for clinic use should be printed locally to reflect any changes requested by that institution's IRB.

Most GoKinD forms are printed on two-part No Carbon Required (NCR) paper consisting of a COC (white) copy and a clinical center (yellow) copy. Mailing lists are printed on three-part NCR paper consisting of a CBL (white) copy, a COC (yellow) copy, and a clinical center (pink) copy. Before mailing the white copy make sure that the entries on the yellow and pink copies of each page are readable. **Be sure to use a black ballpoint pen to complete the forms.**

During the study, resupply of GoKinD forms can be requested from COC using the Supply Reorder Form (Form 204GK).

6.2 FORM, PATIENT, AND VISIT IDENTIFYING INFORMATION

6.2.1 Form Number and Version Number

The number for each form consists of an integer and a decimal. The integer indicates the form number and the decimal indicates the version of the form. For example, GoKinD form number 200.1 indicates that the Checklist for Proband/Relatives is designated 200 and that the version is the first. The date on the upper right corner of the form indicates when this version was adopted. When a form is modified both the sequence number and the date will change.

6.2.2 Identifying Information

Before a patient arrives for a scheduled visit, all forms required for that visit should be assembled in that patient's folder and the identifying information sections should be filled out. On all forms, the following identifying information must be completed.

- 1) Clinic Number
- 2) Family ID Number
- 3) Proband/Relative Code
- 4) Proband/Relative's Initials

6.2.3 Clinic Number

Each of the GoKinD clinical centers is assigned a unique three-digit clinic number that is used on every study form. A list of GoKinD Centers is given in Table 6.2.

6.2.4 Family Identification Number and Proband/Relative Code

Each family is assigned a permanent eight-digit identification number (GoKinD ID). The first three digits of the family identification number refer to the clinical center at which the family was first screened for eligibility and the next five digits are a code assigned to the patient and the family during screening.

The proband/relative code is a two-digit number designating the relative (FA-01, MO-02, Proband-03, Oldest Sibling-04, Next Oldest Sibling-05, and so on).

At the COC, the family identification number and the proband/relative code will be combined to form a ten-digit identification number.

6.2.5 Proband/Relative's Initials

The patient's initials, comprising the patient's first, middle, and last initials, constitute a second patient identifier. **If the patient has no middle name or initial, an "X" is used as the middle initial.** The initials that are entered onto the Medical History and Physical Examination Form (Form 210GK) will be the initials used for the duration of GoKinD. Once the initials identifier has been determined for GoKinD, it will never be changed, even if the patient's name changes during the course of GoKinD.

6.2.6 Date of Visit

The date an examination is begun is regarded as the examination date. A number of procedures may be associated with each examination. An examination is not regarded as complete until all procedures have been completed. All dates should be recorded in month, day, and year order.

6.3 COMPLETING FORMS

Each form has been prepared such that all instructions required for properly completing the form are self-contained. **Forms should be filled out carefully using a ballpoint pen with black ink.** Changes should be made carefully and neatly. Please date and initial all changes. Extra notations should not be made if there is no space designated for them. If you find that there are inadequacies on a form, please notify the COC so that revisions can be considered.

Before the patient leaves the clinic, at the conclusion of the visit, the study coordinator should review each of the required forms for accuracy and completeness. The study coordinator should also ensure that all tests and questions required for that visit have been conducted and the appropriate forms completed.

6.4 BATCHING AND MAILING

Forms should be mailed to the COC every week using the GoKinD mailers. GoKinD form mailers will be distributed by the COC.

6.4.1 Inventorying Forms

On each Thursday, all forms completed during the preceding week should be collected and sorted by form number and by GoKinD ID number within form number. A copy of the Clinic Forms Inventory (Form 220GK), which requires specification of the form number, date, GoKinD ID number, and study week number, should be completed. A listing of study week numbers is given in Table 6.3. The copies of each study form that are being mailed to the COC are compared against the just completed Clinic Forms Inventory. The clinic's copies of the forms may then be re-sorted by GoKinD ID number and filed in each patient's clinic file.

Forms and the Clinic Forms Inventory are organized by form number in order to facilitate processing at COC, where the forms must be verified by form number.

6.4.2 Batching Forms

COC's copies of the forms (which are the original white copies for two-part NCR forms or the yellow copies for three-part NCR forms) will then be batched for mailing to COC. A copy of the Clinic Forms Inventory (Form 220GK) and the Forms Mailing List (Form 221GK) should be included with the batch. All forms within a weekly batch should first be sorted by number, i.e., all forms of a given type should be together in the batch. The study coordinator will inventory the batch of forms by completing the Forms Mailing List (Form 221GK). On this form, the number of each type of form included in the batch is listed. The entries on the mailing list should correspond to the total number of entries on the Clinic Forms Inventory.

6.4.3 Mailing Forms

A copy of the Forms Mailing List is faxed to the COC at 301-881-4471. This is done as a security measure; it helps insure that COC will become aware of a missing batch of forms.

The batch of forms, Clinic Forms Inventory, and Forms Mailing List should then be mailed in the GoKinD supplied mailer on Thursday afternoon.

The forms are placed in one or more study supplied pre-addressed, no-postage required envelopes and mailed to:

GoKinD Coordinating Center
The Biostatistics Center
6110 Executive Boulevard, Suite 750
Rockville, MD 20852

Canadian centers only should send their forms by FedEx using the COC FedEx number supplied to them.

When more than one envelope is required to mail a batch, the date of mailing should be written on each envelope, and each should then be numbered at the bottom as “1 of x,” “2 of x,” etc., where x is the total number of envelopes included in that mailing.

There may be some periods in which no forms have been completed. In this event, the clinic should complete the Forms Mailing List and check the box indicating that no forms are being sent. This form alone should then be faxed to the COC at 301-881-4471. (During the weeks where there are no forms to send, you will not need to mail a copy of the original form to the COC; please just send the faxed copy.)

6.5 RECEIPT OF FORMS

When forms arrive at the COC, the data control clerk will open the mail and reassemble the batch if multiple mailing envelopes were used. (Forms should arrive at the COC by the Monday following the Thursday mailing.) If a complete batch has not been received by the next Thursday, a trace will be initiated. The clinical center will also be contacted so that copies of any missing forms may be immediately mailed.

When the batch is reassembled, the clerk will count the number of forms received and compare the counts with those given on the Mailing List and the Inventory. If there are any discrepancies noted, the clinical center will be called immediately.

6.6 EDITING DATA ON FORMS

Each form is edited at the COC for missing data, inconsistencies, and values that are out of range. An error notice is printed which lists all the errors detected for a given form. An example of an error notice from GoKinD is presented in Figure 6.1. These notices are mailed monthly to the originating clinic for recording the correct information. The error notice is a “turn-around” document on which the corrections to the error notices are written by the coordinator and the original document returned to the COC. A copy of the edit message should be attached to the appropriate form.

An edit message should be returned to the COC in the next regular mailing, even if the data in question are correct.

An edit message consists of a table showing the form number, the clinic number, the GoKinD ID and initials, the date the form was completed and the study week it was mailed. Below this information is listed one or more error notices. Each error notice lists the form item

Number used and an abbreviated description of the item. The variable name for the datum in question (as used in the COC's edit and analysis programs) is printed next to the value of the variable. A message describing the reason for questioning the value is printed. A line labeled "new value" is provided for entering a response to the message. The possible responses include:

- 1) Entering a new value
- 2) Entering the word "missing" if the correct datum cannot be retrieved
- 3) Entering the word "okay" if the original value was correct
- 4) Entering another explanation

The edit program also prints a table of control totals for forms edited in that batch to compare with the data entry control totals. In addition, tables containing the number of forms edited and the number of errors per form are printed by form type and clinic. These edit summary tables can be used to monitor clinic performance.

There may be occasions when the clinic staff will realize they have made an error in completing a form, yet the nature of the error may be such that an edit program may not detect it. To make an unsolicited correction to a form, the clinic should:

- 1) Make a copy of page 1 of the form and the page(s) to be updated.
- 2) Write "correction" in red ink on page 1.
- 3) Indicate all needed changes in red ink. Initial and date the changes.
- 4) Send the pages to COC. Corrections may be sent with the regular mailing, but should be clearly separate from it and from any edit messages generated by COC's edit programs.

TABLE 6.1
GOKIND FORMS LISTING

New #	Current Date	Title
200.3GK	7/12/02	Checklist for Proband/Relatives
201.2GK	4/06/01	Consent Form
202.2GK	4/06/01	Personal Information on Proband/Relative
203.2GK	4/06/01	Notification of Death
204.5GK	10/15/02	Supply Reorder Form
205.3GK	10/22/01	CBL Supply Reorder Form
207.1GK	7/03/02	Notification of Transfer, Remote Site Collection, or Refusal to Participate
210.2GK	4/06/01	Medical History and Physical Examination
211.2GK	4/06/01	Current Medication Form
212.1GK	7/12/02	Historical Urine Value for Control Probands
220.2GK	4/06/01	Clinic Forms Inventory
221.3GK	7/08/02	Forms Mailing List
222.3GK	3/18/02	Genetic Specimen Mailing List
223.3GK	3/18/02	Hemoglobin A1c Specimen Mailing List
224.3GK	3/18/02	Lipid, Serum Creatinine, & Cystatin C Specimen Mailing List
225.3GK	3/18/02	Urine Specimen Mailing List
226.3GK	3/18/02	Hemoglobin A1c Quality Control Mailing List
227.3GK	3/18/02	Lipid, Serum Creatinine, & Cystatin C Quality Control Mailing List
228.3GK	3/18/02	Urine Quality Control Mailing List
229.3GK	3/18/02	Genetic Quality Control Mailing List
230.3GK	3/18/02	Saved Specimen Mailing List

System:

* GoKinD forms begin at 200.

200-209: Related to basic patient information (preliminary forms & updates)

210-219: Related to the physical examination

220-230: Related to mailing lists/inventories

TABLE 6.2
LIST OF GOKIND CENTERS AND CLINIC NUMBERS

GoKinD Center	Clinic Number
Joslin Diabetes Center	100
Medical University of South Carolina	102
MedStar Clinical Research Center	103
Mount Sinai Hospital, University of Toronto	104
New York Presbyterian Hospital, Cornell Medical Center	105
Northwestern University	106
St. Joseph's Health Care London, University of Western Ontario	107
University Hospital, University of Missouri	108
University of California, San Diego	109
University of Florida	110
University of Iowa	111
University of Maryland Medical System	112
University of South Florida	113
University of Tennessee Memphis	114
Virginia Mason Research Center, Northwest Clinical Center	115
St. Louis Children's Hospital, Washington University	116
University of Wisconsin	117
Vanderbilt University Medical Center	118
Sansum Medical Research Institute	119
University of Miami/Jackson Memorial Hospital	120
University of North Carolina at Chapel Hill	122
University of Minnesota	123
Mid-America Diabetes Associates, P.A.	124
Albany Medical College	126
Baylor University Medical Center	127
Loma Linda University Medical Center	128
St. Vincent's Medical Center	129
Diabetes Research Group	130
CTI Network, Inc.	131

TABLE 6.3
GOKIND STUDY WEEK NUMBERS FOR YEAR 1 THROUGH YEAR 3

WEEKNO	START	END
001	03/12/2001	03/18/2001
002	03/19/2001	03/25/2001
003	03/26/2001	04/01/2001
004	04/02/2001	04/08/2001
005	04/09/2001	04/15/2001
006	04/16/2001	04/22/2001
007	04/23/2001	04/29/2001
008	04/30/2001	05/06/2001
009	05/07/2001	05/13/2001
010	05/14/2001	05/20/2001
011	05/21/2001	05/27/2001
012	05/28/2001	06/03/2001
013	06/04/2001	06/10/2001
014	06/11/2001	06/17/2001
015	06/18/2001	06/24/2001
016	06/25/2001	07/01/2001
017	07/02/2001	07/08/2001
018	07/09/2001	07/15/2001
019	07/16/2001	07/22/2001
020	07/23/2001	07/29/2001
021	07/30/2001	08/05/2001
022	08/06/2001	08/12/2001
023	08/13/2001	08/19/2001
024	08/20/2001	08/26/2001
025	08/27/2001	09/02/2001
026	09/03/2001	09/09/2001
027	09/10/2001	09/16/2001
028	09/17/2001	09/23/2001
029	09/24/2001	09/30/2001
030	10/01/2001	10/07/2001
031	10/08/2001	10/14/2001
032	10/15/2001	10/21/2001
033	10/22/2001	10/28/2001
034	10/29/2001	11/04/2001
035	11/05/2001	11/11/2001
036	11/12/2001	11/18/2001
037	11/19/2001	11/25/2001
038	11/26/2001	12/02/2001
039	12/03/2001	12/09/2001
040	12/10/2001	12/16/2001
041	12/17/2001	12/23/2001
042	12/24/2001	12/30/2001

TABLE 6.3 (cont.)
GOKIND STUDY WEEK NUMBERS FOR YEAR 1 THROUGH YEAR 3

WEEKNO	START	END
043	12/31/2001	01/06/2002
044	01/07/2002	01/13/2002
045	01/14/2002	01/20/2002
046	01/21/2002	01/27/2002
047	01/28/2002	02/03/2002
048	02/04/2002	02/10/2002
049	02/11/2002	02/17/2002
050	02/18/2002	02/24/2002
051	02/25/2002	03/03/2002
052	03/04/2002	03/10/2002
053	03/11/2002	03/17/2002
054	03/18/2002	03/24/2002
055	03/25/2002	03/31/2002
056	04/01/2002	04/07/2002
057	04/08/2002	04/14/2002
058	04/15/2002	04/21/2002
059	04/22/2002	04/28/2002
060	04/29/2002	05/05/2002
061	05/06/2002	05/12/2002
062	05/13/2002	05/19/2002
063	05/20/2002	05/26/2002
064	05/27/2002	06/02/2002
065	06/03/2002	06/09/2002
066	06/10/2002	06/16/2002
067	06/17/2002	06/23/2002
068	06/24/2002	06/30/2002
069	07/01/2002	07/07/2002
070	07/08/2002	07/14/2002
071	07/15/2002	07/21/2002
072	07/22/2002	07/28/2002
073	07/29/2002	08/04/2002
074	08/05/2002	08/11/2002
075	08/12/2002	08/18/2002
076	08/19/2002	08/25/2002
077	08/26/2002	09/01/2002
078	09/02/2002	09/08/2002
079	09/09/2002	09/15/2002
080	09/16/2002	09/22/2002
081	09/23/2002	09/29/2002
082	09/30/2002	10/06/2002
083	10/07/2002	10/13/2002
084	10/14/2002	10/20/2002

TABLE 6.3 (cont.)
GOKIND STUDY WEEK NUMBERS FOR YEAR 1 THROUGH YEAR 3

WEEKNO	START	END
085	10/21/2002	10/27/2002
086	10/28/2002	11/03/2002
087	11/04/2002	11/10/2002
088	11/11/2002	11/17/2002
089	11/18/2002	11/24/2002
090	11/25/2002	12/01/2002
091	12/02/2002	12/08/2002
092	12/09/2002	12/15/2002
093	12/16/2002	12/22/2002
094	12/23/2002	12/29/2002
095	12/30/2002	01/05/2003
096	01/06/2003	01/12/2003
097	01/13/2003	01/19/2003
098	01/20/2003	01/26/2003
099	01/27/2003	02/02/2003
100	02/03/2003	02/09/2003
101	02/10/2003	02/16/2003
102	02/17/2003	02/23/2003
103	02/24/2003	03/02/2003
104	03/03/2003	03/09/2003
105	03/10/2003	03/16/2003
106	03/17/2003	03/23/2003
107	03/24/2003	03/30/2003
108	03/31/2003	04/06/2003
109	04/07/2003	04/13/2003
110	04/14/2003	04/20/2003
111	04/21/2003	04/27/2003
112	04/28/2003	05/04/2003
113	05/05/2003	05/11/2003
114	05/12/2003	05/18/2003
115	05/19/2003	05/25/2003
116	05/26/2003	06/01/2003
117	06/02/2003	06/08/2003
118	06/09/2003	06/15/2003
119	06/16/2003	06/22/2003
120	06/23/2003	06/29/2003
121	06/30/2003	07/06/2003
122	07/07/2003	07/13/2003
123	07/14/2003	07/20/2003
124	07/21/2003	07/27/2003
125	07/28/2003	08/03/2003
126	08/04/2003	08/10/2003

TABLE 6.3 (cont.)
GOKIND STUDY WEEK NUMBERS FOR YEAR 1 THROUGH YEAR 3

WEEKNO	START	END
127	08/11/2003	08/17/2003
128	08/18/2003	08/24/2003
129	08/25/2003	08/31/2003
130	09/01/2003	09/07/2003
131	09/08/2003	09/14/2003
132	09/15/2003	09/21/2003
133	09/22/2003	09/28/2003
134	09/29/2003	10/05/2003
135	10/06/2003	10/12/2003
136	10/13/2003	10/19/2003
137	10/20/2003	10/26/2003
138	10/27/2003	11/02/2003
139	11/03/2003	11/09/2003
140	11/10/2003	11/16/2003
141	11/17/2003	11/23/2003
142	11/24/2003	11/30/2003
143	12/01/2003	12/07/2003
144	12/08/2003	12/14/2003
145	12/15/2003	12/21/2003
146	12/22/2003	12/28/2003
147	12/29/2003	01/04/2004
148	01/05/2004	01/11/2004
149	01/12/2004	01/18/2004
150	01/19/2004	01/25/2004
151	01/26/2004	02/01/2004
152	02/02/2004	02/08/2004
153	02/09/2004	02/15/2004
154	02/16/2004	02/22/2004
155	02/23/2004	02/29/2004
156	03/01/2004	03/07/2004
157	03/08/2004	03/14/2004
158	03/15/2004	03/21/2004
159	03/22/2004	03/28/2004
160	03/29/2004	04/04/2004
161	04/05/2004	04/11/2004
162	04/12/2004	04/18/2004
163	04/19/2004	04/25/2004
164	04/26/2004	05/02/2004
165	05/03/2004	05/09/2004
166	05/10/2004	05/16/2004
167	05/17/2004	05/23/2004
168	05/24/2004	05/30/2004

TEMPORARY
Figure 6.1
GOKIND Edit Message Report

Page 1

F12.1GK PERSONAL INFORMATION ON STUDY VOLUNTEER

Date of Report: 11/08/00

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*=====*
*
* Clinic Number: 13          1 of 70 Fields in Error          Verified by: _____*
* Patient ID:    13356                                           *
* Initials: SLB      Overall Error Percentage Rate = 1.43%      Date:      _____*
* Form Date:      091800      (Total # Errors/Total # Fields)   *
* Week No:        913                                           *
*                                                           Source File: WK872S.ED1434 *
*=====*

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Page	Section	Label	Minimum	Maximum	Edit Level	Variable	Old Value	*	New Value
04	Z.1	'CERTIFICATION NUMBER'	101	4199	Required	CERTIF		*	

Additional Comments:

LAST PAGE OF EDITS FOR THIS FORM