

EPIDEMIOLOGY OF DIABETES INTERVENTION AND COMPLICATIONS

Notification of Transfer to Inactive Status

This form must be completed whenever a Principal Investigator seeks to transfer a patient to inactive status. Transfer to inactive status implies a temporary or permanent moratorium on all efforts to involve the patient in any EDIC activities whatsoever. The clinical center must notify the Data Coordinating Center at the time of any potential transfer to inactive status. The Follow-Up Committee will also review all transfers to inactive status. The original of this form is to be sent to the Data Coordinating Center in the monthly forms mailing. Retain a copy in the clinic files.

A. IDENTIFYING INFORMATION

1. Clinic Number 2. CLINIC _ _
2. Patient ID Number 3. PATIENT _ _
3. Patient's Initials 4. INITIALS _ _
4. Date form completed 5. FORM DATE
Month Day Year

B. INFORMATION ON TRANSFER TO INACTIVE STATUS

1. Specify the reason for the notification of transfer to inactive status: (CHECK ALL THAT APPLY)

- a) Judgement of Principal Investigator and Study Coordinator that any manner of participation in the study could no longer be considered informed or would be directly injurious to the patient's well-being
- b) Catastrophic injury or illness leading to coma, dementia, blindness, or inability to participate in EDIC testing procedures
- c) Complete inaccessibility to monitoring of outcomes (for example, long term imprisonment)
- d) Patient has withdrawn consent for continued participation
- e) Other (specify in Question 2)

(1) 6. NDBIA

(1) 7. NDBIB

(1) 8. NDBIC

(1) 9. NDBID

(1) 10. NDBIE

Patient ID _____

2. Explain in detail reason for notification of transfer. (USE EXTRA SHEET IF NECESSARY)

3. On what date would the proposed transfer to inactive status become effective? (IF IMMEDIATELY, ENTER TODAY'S DATE.)

Month Day Year 11. NDB3DAT

If uncertain, check here:

(1) 12. NDB3A

C. PLANS FOR FUTURE CONTACT

1. Do you anticipate that you will attempt to contact the patient in the future?

No Yes Uncertain
(1) (2) (3) 13. NDC1

If NO, give reason(s): _____

2. Do you believe that the patient would be willing and able to return to an EDIC clinic for at least some outcome evaluations?

No Yes Uncertain
(1) (2) (3) 14. NDC2

If YES or UNCERTAIN, specify plans for future patient followup:

3. Who will be delivering the patient's diabetes care? (Specify names, addresses and phone numbers if known)

Signature of Principal Investigator:

15. WEEKNO