T1DGC ADVERSE EVENT REPORT

PARTICIPANT ID NUMBER: [ ]

CLINIC ID: [ ][ ][ ][ ] CLINIC STAFF ID NUMBER: [ ][ ][ ][ ][ ]

DATE OF ADVERSE EVENT: [ ][ ] - [ ] - [ ][ ][ ][ ]
Day Month Year

LOCATION OF ADVERSE EVENT: _____

WAS A PHYSICIAN SUMMONED? YES [ ] 1 NO [ ] 2

NAME OF PHYSICIAN: _____

DID PARTICIPANT CONTINUE EXAMINATION? YES [ ] 1 NO [ ] 2

SUMMARY AND OUTCOME OF ADVERSE EVENT:

_____

_____

_____

_____

RELATION OF ADVERSE EVENT TO PROTOCOL:

UNRELATED [ ] 1
POSSIBLY RELATED [ ] 2
PROBABLY RELATED [ ] 3
DEFINITELY RELATED [ ] 4

GRADE OF ADVERSE EVENT:

MILD [ ] 1
MODERATE [ ] 2
SEVERE [ ] 3

Pre-specified, adverse events that must be reported: (1) excessive bleeding at the phlebotomy site; (2) excessive bruising at the phlebotomy site; (3) infection attributed to phlebotomy; and (4) thrombophlebitis attributed to phlebotomy. Unspecified adverse events such as injury due to fall or accident in the clinic also should be reported.

For Regional Network Center Use:

Date Received at Regional Network Center: ☐☐ - ☐☐☐ - ☐☐☐☐
Day Month Year

Reviewed by: _____

_____

_____

Date Sent to Coordinating Center: ☐☐ - ☐☐☐ - ☐☐☐☐
Day Month Year

For Coordinating Center Use:

Date Received at Coordinating Center: ☐☐ - ☐☐☐ - ☐☐☐☐
Day Month Year

Reviewed by: _____

_____

_____

Any action required? YES ☐ 1 NO ☐ 2

If yes, provide summary of action(s):

_____

_____

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