ADVERSE EVENT REPORTING
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I. INTRODUCTION

This chapter provides the clinics and networks with information regarding study policy on adverse event reporting. It is expected that few, if any, adverse events related to the study protocol will occur throughout the exam period. However, if such an event occurs, the following guidelines will assist the clinics in proper handling and reporting of the incident.

II. ADVERSE EVENTS

An adverse event is defined as both an expected side effect that is of a serious nature or an unexpected side effect/event regardless of severity. In the case of the Type 1 Diabetes Genetics Consortium (T1DGC), the expected risks associated with the study are related to the blood collection. Inserting a needle for blood sampling can be associated with some discomfort and bruising and, although very rarely, with inflammation and infection of the arm veins. These risks are considered to be minimal and are addressed in the protocol and the informed consent forms.

Pre-specified adverse events that must be reported include: excessive bleeding at the phlebotomy site; excessive bruising at the phlebotomy site; infection attributed to the phlebotomy; and thrombophlebitis attributed to the phlebotomy

There may be other adverse events associated with the clinic visit (*e.g.*, falling or other injury) that also should be reported if they meet the definition provided above. An incident that occurs prior to, during, or after the blood collection that is considered a "normal" occurrence of such a procedure (*e.g.,* fainting, nausea, etc.) is not documented as an adverse event and the form need not be completed.

III. ADVERSE EVENT GRADING

All adverse events that occur are graded both by attribution and severity of the incident. Attribution of the event is graded by its relation to the study protocol and is designated as one of the following: (1) unrelated to the protocol; (2) possibly related to

the protocol; (3) probably related to the protocol; or (4) definitely related to the protocol. Any event that is reported to either the Principal Investigator or his/her designated research staff by the participant or medical staff caring for the participant is evaluated and graded by the Principal Investigator and/or research staff according to one of these categories. Once relation to the protocol is determined, it is documented as such on the *T1DGC Adverse Event Report* that is completed at the clinic.

Adverse events are also graded based on the severity of the event. They are graded as being (1) mild; (2) moderate; or (3) severe. The following descriptions are used to determine the severity of the adverse event:

- Mild: The symptom or event did not require treatment.
- Moderate: The symptom or event resolved with treatment.
- Severe: The symptom or event resulted in the inability to carry on normal activities and required professional medical attention.

IV. ADVERSE EVENT REPORTING

Regardless of the severity, all adverse events reported to the clinic staff or Principal Investigator are documented, and the *T1DGC Adverse Event Report* is completed and submitted to the clinic's Internal Review Board (IRB) and/or Ethics Committee (EC), the Regional Network Center and the Coordinating Center. The report includes a description of the event, when and how it was reported, as well as any official chart records or documentation to corroborate the event or the reporting of the event. Clinics must know and follow the adverse event reporting policies of the local IRB or EC. (The *T1DGC Adverse Event Report* is located on the web site. Instructions for completing the report are located in Appendix A of this chapter.)

Any severe and/or unanticipated adverse event should immediately be reported to the safety officers and IRB or EC at the local clinic, the Regional Network Center and the Coordinating Center. All other adverse events are reported in a timely fashion to the safety officers and IRB or EC (*i.e.*, within 2 weeks of the date of the event). All adverse

events are summarized annually and submitted to the IRB or EC at the local clinic, Regional Network Center and Coordinating Center.

The Coordinating Center reports any action resulting in temporary or permanent suspension of this study (*e.g*., IRB or EC actions or actions by the investigators or co-investigators) to the NIDDK Project Officer.

APPENDIX A
ADVERSE EVENT REPORT:
INSTRUCTIONS FOR COMPLETION

CLINIC INSTRUCTIONS:

1. Place the participant's bar-coded ID label in the box designated "Participant ID Number."

2. Record the clinic ID and the clinic staff ID number in the designated boxes.

3. Record the date that the adverse event occurred. Date is recorded with day first, month second (month written out), and year third.

4. Record the location at which the adverse event occurred (*e.g.,* the clinic or at home).

5. Mark "Yes" if a physician was required, and in the space below, record the name of the physician who responded. Mark "No" if a physician was not required. The name of the physician is left blank if "No" is recorded.

6. Mark "Yes" if the participant was able to continue with the study interview/exam after the adverse event. Mark "No" if the adverse event prevented the participant from continuing the exam.

7. In the space provided for "Summary and Outcome of Adverse Event", describe the adverse event in a clear and concise manner. Provide specific details (*e.g.*, where, when, why, etc.) as well as the outcome of the event. Related documentation may be included if necessary.

8. Determine relation of the adverse event to the study protocol (*i.e.,* unrelated, possibly related, probably related, and definitely related) and mark the appropriate box.

9. Grade the severity of the adverse event as mild, moderate or severe, according to the descriptions listed below (from this chapter), and mark the appropriate box.
    - Mild: The symptom or event did not require treatment.
    - Moderate: The symptom or event resolved with treatment.
    - Severe: The symptom or event resulted in the inability to carry on normal activities and required professional medical attention.

10. Make a copy of the completed form and send to the Regional Network Center for review.

REGIONAL NETWORK INSTRUCTIONS:

11. The Regional Network Center records the date when the report is received under the section “For Regional Network Center Use”.

12. The Regional Network Center reviews and signs the report, records the date it is sent to the Coordinating Center and forwards a copy of the report to the Coordinating Center for final review.

COORDINATING CENTER INSTRUCTIONS:

13. The Coordinating Center records the date on the form when the report is received under the section “For Coordinating Center Use”. The form is reviewed and signed. “Yes” is marked if an action is required and “No” if no action is required. If “Yes” is marked, a summary of the action taken is recorded.

14. The Coordinating Center keeps a copy and returns the completed form to the Regional Network Center, who retains a copy of the completed form and forwards the original back to the clinic.