

Reporting form for

Continuing Review or Project Termination

NOTE: For exempt projects, continuing review materials should be submitted at least one week prior to the expiration date of the current approval period. For projects previously approved by expedited or full board review, continuing review materials should be submitted at least **four weeks** prior to the expiration date of the current approval period.

1. Contact and Study Information

Date of report: _____

Study Title: _____

IRB Number: _____

IRB Approval Date _____

Study Sponsor: _____

Principal Investigator: _____

Phone: _____ E-mail: _____

Person Responsible for
Regulatory Documents: _____

Phone: _____ E-mail: _____

Department and School: _____

Date of Training Certification: _____

Date of most recent approval for this study: _____

Does this study involve collection of biologic material for genetic study? Yes No

2. Project Status—Please check one of the following, as appropriate:

- Continuing *with no changes* in procedure, risks, or class of human subjects since the last review.
- Continuing *with changes* in procedure, risks, or class of human subjects since the last review. (List changes made)
- Never initiated. (Please sign the last page of this form and return it to the IRB Office.)
- Completed; no further contact with human subjects is planned and study closure is requested. If completed, date of project termination: _____

(Please complete this form, sign it, and return it to the IRB committee (electronically and/or hard-copy.)

3. Project Sites—This project is being conducted at the following Drake sites or Drake-affiliated sites.

- Drake University

Other (please specify): _____

4. Study Enrollment

Number of subjects enrolled in the study to date: _____

Number of subjects enrolled since the last review: _____

Is enrollment of subjects ongoing? Yes No

If YES, number of subjects yet to be enrolled: _____

5. Study Withdraw

a. Have any subjects withdrawn from the study since the project began? (Please report subjects who have withdrawn of their own choice and those who have been withdrawn by the investigator or sponsor.) Yes No

If YES, how many? _____

Why?

b. Have any subjects withdrawn since the date of the last approval? (Please report subjects who have withdrawn of their own choice and those who have been withdrawn by the investigator or sponsor.) Yes No

If YES, how many? _____

Why?

6. Serious Adverse Events

Have any *serious* adverse events been noted since the project began? (Report only those, which have occurred at Drake or Drake-affiliated sites.) Yes No

If YES, how many? _____

Please describe the nature of each serious adverse event.

7. Protocol Deviations or Violations

a. Have any *protocol deviations* been noted since the project began? (Report only those, which have occurred at Drake or Drake-affiliated sites.) Yes No

If YES, how many? _____

Please describe the nature of each deviation.

b. Have any *protocol violations* been noted since the project began? (Report only those, which have occurred at Drake or Drake-affiliated sites.) Yes No

If YES, how many? _____

Please describe the nature of each violation.

8. Progress Report

If you have sponsor progress reports, abstracts, or DSMB reports related to the research, please attach copies. Otherwise, please write a brief summary of the findings of the research thus far, even if you have only preliminary data to report.

9. Attachments

- a. Please attach a clean copy of the current consent/assent document(s) (electronic and/or hard-copy), if subjects are still being enrolled in the study (for date stamping purposes)
- b. Please attach a copy of the current protocol in use.
- c. Please have available upon request all copies of signed consent/assent forms used in the study so far.
- d. Submit a copy of this form electronically to the IRB (irb@drake.edu). Please note that if you do not have an electronic signature, hard copies of the signature page will need to be scanned then emailed to the IRB:

Principal Investigator's Assurance

I certify that the approved protocol and approved method for obtaining informed consent have been followed during the period covered by this progress report. I also certify that the information provided for continuing review is complete and accurate to the best of my knowledge.

Signature of Principal Investigator

Date