

Please attach the completed form to your IRBNet package. If you have any questions please contact Karen Dudley at russok@arcadia.edu or 267-620-4111.

Date form Completed:

Date project is to be closed:

1. Project Status*:

Project is completed—No Further Contact with Human Subjects is planned: no subjects are, or will be, treated or followed, all data are gathered and analyzed, and there are no further sponsor reports or forms to submit to the IRB.

Project terminated by the investigator (Please give reason below)

Project terminated by the sponsor. If by the sponsor, please attach documentation.

Project Never Initiated--No human subjects were recruited. Work will not be done at this time.

IRB Initiated Closure

Other:

If terminated by the investigator, why?

2. Expiration Status:

2.1. Has IRB approval for this project expired?

Yes, complete 2.2.

No, skip to Section 3

2.2. Was any research activity conducted after approval expired? ***Attach a description and summary of all research that has been conducted since the project expired, including subject recruitment, data collection, data analysis**, and any other research-related activities.***

Yes, complete 2.3.

No, skip to Section 3

2.3. Was approval granted by the IRB Chair for the continuation of study procedures?

Yes

No

If YES, please provide a copy of documentation supporting this approval.

If NO, please explain why.

3. Enrolled Subjects*:**

3.1. Total number of subjects/samples/charts approved for enrollment/to be studied in this project:

3.2. Were more subjects enrolled than were approved?

Yes

No

If YES, please explain.

*All pending issues must be resolved prior to closure of the project.

**Data analysis may require maintaining an active IRB protocol. In cases where there is no further contact with research subjects, and the available data has been de-identified, investigators can analyze data without an active IRB. If contact with subjects continues, or the available data contains information that allows identification of subjects, investigators will need to file a renewal.

***Enrolled subjects are those who signed consent forms and are participating in (or completed) the study. (Participating = e.g., filling out questionnaires, answering questions, taking drugs, having surgery, being called on the telephone, having data collected.) Enrollment is a finite number usually dictated by the sponsor or by statistical methods.