Final Review of Human Subjects Research Investigation

Required for All Human Subjects Research Studies

Study Title: 

Principal Investigator: 

IRB Protocol Number: 

1) Please confirm the status of your project?
   - All research-related activities are complete and I want to close the study.

2) Provide the following information about subject enrollment:
   - Number of subjects approved for enrollment by the IRB
   - Number of subjects who provided informed consent to participate in the study since initial approval
   - Number of subjects terminated from study (lost to follow-up, terminated by PI, withdrew consent, etc.)
   - Number of subjects who provided informed consent to participate in the study during the most recent approval period
   - Number of subjects that have completed all study procedures and follow-up visits
   - Number of subjects currently participating in study-related activities
      (If this number is greater than 0, you must submit a continuing review or annual progress report to keep the study open).

3) Please include a statement indicating whether any complaints were received about the research study (if none, enter NONE):
4) Provide a list of all study-related adverse events and summarize any study-related adverse events that resulted in changes to the protocol or informed consent documents.

5) Describe any other unanticipated problems involving risks to subjects, withdrawal of subjects from the research due to non-compliance, or any issues with recruitment, enrollment and/or retention of subjects.
6) Please provide a succinct narrative (no more than 2 paragraphs) about the study’s results and findings.
7) Has any data from this study been disseminated by the investigator in a peer-reviewed forum (e.g., conference, abstract, publication, etc.)?
   □ No.
   □ Yes. If so, please provide an appropriate citation of the work.

Name of PI: ____________________ Signature: ____________________ Date: __________