Renewing an Approved Protocol

Brigham Young University–Hawaii

(Updated April 2014)

Please submit this form and any attachments as a *single* Word file to **boyd.timothy@byuh.edu** for pre-review by the IRB staff.

Protocol No. _____

Project Title: _____

Name(s) of Investigator(s): _____

E-mail Address: _____ Phone: _____

DESCRIPTION OF FORM:

The form asks you to check a box that describes the research you plan to conduct during the upcoming renewal period. Based on the box checked, you will complete either Section 1, 2, or 3 of the form. Section 4 provides instructions for requesting approval of anticipated changes in the research.

Please check one of the following:

[ ] I will be collecting data from human subjects during the upcoming renewal period. (Complete Section 1)
[ ] The research covered by this renewal will be limited to the analysis of data I collected under this protocol. (Complete Section 2)
[ ] The research covered by this renewal will be limited to the secondary analysis of data collected by someone else. (Complete Section 3)

Note: If the renewal must be reviewed by the convened IRB, you will be asked to provide additional information.

SECTION 1:

If you will collect data from research subjects during the upcoming renewal period, please provide the following:

- The total number of subjects accrued prior to this renewal: _____
- A copy of the consent form(s) used during the last renewal period.
- A response to one of the following, as appropriate:

    [ ] The assessment of potential risks to subjects, as described in the approved protocol, has not changed.
    [ ] Findings in this research, or research carried out by others, alter the risk assessment as described in the approved protocol. If new risks have been identified, please modify the protocol as described in Section 4.

- If an unanticipated problem involving risk to subjects occurred during the last renewal period, the date the problem was reported to the IRB: ___/___/__
- If either of the following events occurred during the last 12 months, please (1) check the box, and (2) provide information about the event without divulging private identifiable information about research subjects.

    [ ] Complaints from subjects
    [ ] Reports of suspected child abuse or neglect to NC authorities

SECTION 2:

If the research covered by this renewal will be limited to data analysis, please provide the following:

- The total number of subjects accrued prior to this renewal (if applicable): _____
- A copy of the consent form(s) used during the last renewal period (if applicable).
- If an unanticipated problem involving risk to subjects occurred during the last renewal period, the date the problem was reported to the IRB: ___/___/__
- If either of the following events occurred during the last 12 months, please (1) check the box, and (2) provide information about the event without divulging private identifiable information about research subjects.

    [ ] Complaints from subjects
    [ ] Reports of suspected child abuse or neglect to NC authorities

SECTION 3:

If your research is limited to the **secondary analysis of existing data collected by someone else**, please provide the following information:

- If an unanticipated problem involving risks to subjects occurred during the last renewal period, such as an inadvertent disclosure of private identifiable information, the date the problem was reported to the IRB: ___/___/__

- If any of the following events occurred during the last renewal period, please (1) check the box, and (2) provide information about the event without divulging private identifiable information.

    [ ] Any deviations from the approved confidentiality procedures
    [ ] Unanticipated identification of subjects

SECTION 4: Requesting Approval of Anticipated Changes

To request approval of changes to the currently approved protocol, in addition to providing the materials described in Section 1, 2, or 3 above, attach:

1. A memo describing the proposed changes.
2. A copy of the most recently approved protocol with changes in bold-face type. Note: Do not delete any portions of the protocol. Annotate the protocol as needed so that it will be clear to the reviewers if activities described in the protocol will no longer be conducted.

INVESTIGATOR'S SIGNATURE

Please check one and supply the appropriate information:

[ ] I (We) hereby affirm that the research will be conducted in accordance with the currently approved protocol, including approved amendments.

[ ] I am (We are) submitting changes to the currently approved protocol.

_____ Date: _____
Signature of Principal Investigator

_____ Date: _____
Signature of Faculty Advisor (if applicable)

FOR IRB USE ONLY:

Approved _____ Date: _____
IRB Member or Human Subjects Program Director