Operating Model for Research with Human Subjects
Brigham Young University–Hawaii

(Updated Jan 2015)

The purpose of this document is to outline the methods used in approving research involving human subjects at Brigham Young University–Hawaii in compliance with applicable Federal Law[1]

PART I – OVERVIEW

All research studies conducted by or participated in by BYUH faculty, stuff, or students which use human subjects are required to be reviewed by the University Institutional Review Board for Human Subjects (IRB) or the appropriate college/department human subjects review committee.

The college/department committees function as subcommittees of the University IRB. They are authorized to review student coursework research projects provided vulnerable subjects are not being used and external funding or agency support is not being sought. Student coursework research cannot use vulnerable subjects without such research being reviewed by the University IRB.

The IRB Chairperson, or a designee, will make the initial determination of whether a study should be reviewed by expedited or full board review. The following is an excerpt from the application guide from which part of this determination is made.

Number of Subjects: _____ **Gender of Subjects**: _____
Age of Subjects: _____

Vulnerability of Subjects:

Are the participants younger than 18 years of age? _____Yes _____No
Are the participants pregnant women? _____Yes _____No
Are the participants prisoners? _____Yes _____No
Are the participants institutionalized? _____Yes _____No
Are the participants cognitively impaired? _____Yes _____No

(If yes to any of the above, please explain rationale for selecting vulnerable subjects)

Is this research? _____Therapeutic? _____ Non-therapeutic?

Note: **Therapeutic research** includes study of the efficacy of a therapeutic or diagnostic assessment method when the intervention is designed solely to enhance the well being of the participant who is seeking a health benefit.

Non-therapeutic research has no likelihood or intent of producing a diagnostic, preventive, or therapeutic benefit to the participant.

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1 The University complies with the rules and regulations as outlined in the Federal Wide Assurance of Compliance with the Office of Human Research Protection (OHRP). Complete copies of all documents referred to herein are available from the Office of Research and Creative Activities, A-261, ASB.

The main purpose of the review of research, which uses human subjects, is to safeguard the rights and welfare of human research subjects. The University IRB assesses whether a protocol conforms to various ethical standards including reasonable balance of risks and benefits, adequate provisions for informed consent, and equitable selection of subjects. The committee only considers scientific design to the extent that if the research is so poorly designed that it wastes the subject's time or if the research would place the subjects at risk.

A research subject is considered vulnerable if the risk of the research is greater than the probability and magnitude of that ordinarily encountered in daily life, or during the performance of routine physical and psychological exams or tests. A portion of the application guide is reproduced on the first page of this model and is used in the following way:

If the subject is not healthy, hospitalized, not mentally competent, underage, pregnant, imprisoned, or institutionalized, he/she is vulnerable. This is not a comprehensive list but is representative of the kinds of criteria used.

PART II – CONFIGURATION OF IRB

IRB consist of a Chair, three to four faculty members, one off-campus representative, and one non-scientific representative. The off-campus representative and the non-scientific representative may be the same individual as allowed by federal regulations 45 CFR §46.107.

PART III – DEFINITIONS OF PROPOSAL TYPE

Exempt Research is research not requiring IRB action; to be monitored by college/department subcommittees, provided the following apply:

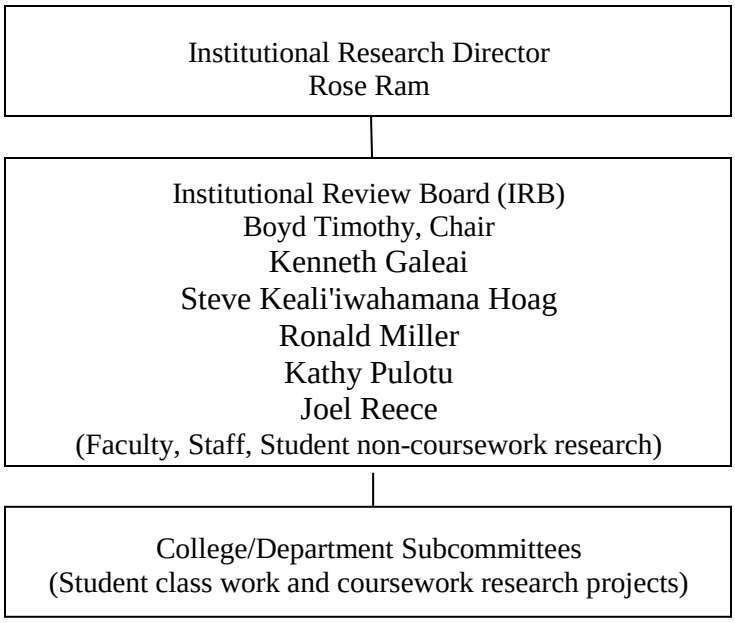
Research activities in which the ONLY involvement of human subjects will be in one or more of the following categories:

1) Research conducted in educational settings, involving research on instructional strategies, techniques, curricula, or classroom management methods where such research is a normal part of classroom instruction.
2) Research involving the use of educational tests, so long as the information is taken so that subjects cannot be identified directly or indirectly.
3) Surveys or interviews, or research involving observations of public behavior, are exempt for subjects 18 years of age and older UNLESS the following conditions exists:
    (a) Responses are recorded so that subjects can be identified.
    (b) If subjects' responses became known outside the research that there could be risk of either criminal or civil liability; or possible damage to the subjects financial, social, or employment standing.
    (c) If the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior or use of alcohol.
4) All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.
5) Research involving the collection or study of publicly available data, as long as the information is recorded in the research in a manner that the subject cannot be identified.

Expedited Review is research that does not require review before the full board and does not meet the criteria for exempt research above. The following must apply to meet expedited criteria:

Research proposals may be expedited if the proposed subjects are not vulnerable, and the research involves no more than minimal risk. The University IRB may also use the expedited procedure to review minor changes in previously approved research during the period for which the approval was authorized. The IRB chairperson and/or one or more of the members of the Board as designated by the Chair may carry out expedited review. The only possible outcomes of expedited reviews are either approval or full board review. A record of expedited proposals and actions will be kept.

For **Full-Board Review**, a quorum of the IRB meets to review all research involving human subjects not included in either exempt or expedited classifications. The requirements for the board are detailed in the Code of Federal Regulations 45 CFR §46.107. The configuration of the Board, responsibility, and a chart of the proposal flow are outlined below.



PART IV – RESPONSIBILITY

Institution: BYUH acknowledges that it is responsible for the lawful performance of all research involving human subjects and will comply with Federal, State, and local laws applicable to such research. In addition, BYUH requires that all such research will be conducted in a manner consistent with University standards of honor and conduct.

Research Investigator: As members of this Institution, each investigator accepts, as part of their own, the University's responsibilities for compliance with applicable laws, and compliance with University standards of honor and conduct. Applicable Federal regulations governing investigator responsibilities are lengthy. Complete copies of these regulations are summarized below.

- Each investigator acknowledges and accepts responsibility for protecting the rights

and welfare of human research subjects.

- Investigators must provide IRB approved consent documents to all subjects at the time of consent; unless waived by the IRB.

- Investigators will promptly report any changes in previously approved research.

- Investigators will promptly report any problems or injuries.

Research Subjects: The consent form must be easily understood and signed by each subject. If the subject is underage, a parent or guardian must also understand and sign the consent form. The subject must understand the confidentiality under which he/she will participate, as well as being made aware of all proposed safety considerations.

Each **off-campus investigator** (e.g., a private practice physician or researcher not otherwise an employee of this institution or who otherwise would not ordinarily be bound by the provisions of this Assurance) who is involved in human subject research with individuals affiliated with this Institution must obtain approval from the BYUH IRB.

PROCEDURE FOR ASSURING COMPLIANCE IN REGARDS TO EARLY TERMINATION OR SUSPENSION OF IRB APPROVAL

In accordance with Title 45 CFR Part 46, the BYUH IRB shall have authority to suspend or terminate a research project if it is found that one or more of the following conditions exist:

1. If the research is not being conducted in accordance with the IRB's requirements.

2. If unexpected and/or serious harm to subjects has occurred; or it unanticipated problems or risks for subjects develop.

3. Under conditions of fraud or misconduct on the part of any associated with a project.

Any Federal agency or department, which financially supports a research projects, also has authority to suspend or terminate that research if it finds the Institution has materially failed to comply with the terms of Title 45 CFR Part 46; or, if in the judgment of the agency/department the Institution materially failed to protect the rights of the human subjects.

Any suspension or termination of approval of the IRB shall include a statement of the reasons for the IRB's action. The action will be reported promptly to the Investigator, the Institutional research administration office, and the sponsoring Federal agency or department.

Under condition 3, and following the suspension or termination of the research, the IRB actions are governed by established University policy concerning faculty misconduct. As noted above the action of suspension or termination is reported to the Investigator, Institutional Research Administration office, and the sponsoring Federal agency or department. The IRB in conjunction with the Office of Research & Creative Activities then provide all evidence and other information concerning the alleged misconduct to the Associate Academic Vice President who will conduct an investigation under the direction of the Academic Vice President. The Academic Vice President's Council will review all information and take action, as they feel necessary