BYU	SOP: IRB Communication			
	Number	Approved by	Effective date	Page
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1. OBJECTIVE

It is important that staff, subjects, and other interested parties have a means of communicating information about the conduct of a research project directly to the appropriate institutional officials. It is vital that IRB members, department heads, and other officials with responsibility for oversight of research have open and ready access to the highest levels of authority within the institution. The investigator and his/her research staff interact with subjects; therefore it is vital that open and frequent communication with the investigative team be maintained.

Specific Procedures

1.1 Investigator Notifications

1.1.1 Initial submission: The Investigator will be notified in writing of the IRB's decision as soon as possible after the meeting. If the approval is pending upon receipt and review of requested materials or responses from the Investigator or Sponsor, the IRB must receive the response within 30 days of the date of notification; however, this period may be extended if the Investigator/Sponsor communicates a need for an extension.

1.1.2 Renewals and revisions: Investigators will be notified in writing as soon as possible as to action taken by the IRB for any continuing reviews or revisions.

1.1.3 Notification of final approval: Investigators will be notified in writing of the final approval. The IRB-approved consent form will be dated with the period of approval and submitted to the Investigator with the final approval letter. Standard conditions for continued approval included, but are not necessarily limited to:

- Informed consent is obtained and documented.
- The IRB is notified of serious adverse events.
- Changes to the protocol, and deviations from the protocol are reported.
- Continuing review reports are submitted to the IRB.
- Documentation of FDA approval prior to study initiation.

1.1.4 Disapproval: correspondence will provide the reason(s) for disapproval and instructions to the Investigator for appeal of this decision.

1.2 Investigator Appeal of IRB Action

An investigator may appeal the revisions required by the IRB in the protocol and/or informed consent form. This appeal must be in writing and submitted to the IRB Administrator. Investigators may also appeal an IRB decision to disapprove a study. Any such appeal may be in writing or in person and must be reviewed by the full IRB at a convened meeting. If the appeal is denied and the study disapproved, the Investigator's institution cannot override the IRB's decision.

1.3 Noncompliance

Investigator noncompliance may often be the result of communication difficulties, therefore the IRB will attempt to resolve apparent instances of noncompliance without interrupting the conduct of the study, especially if the rights and welfare of subjects may be jeopardized.

However, if it appears that an investigator is intentionally in noncompliance, the IRB, through the IRB Chairperson will notify the Investigator in writing, detailing the alleged noncompliance, specifying corrective action, and stating the consequences. Copies of such correspondence shall also be sent, as circumstances merit, to the individual's Chair, Dean, and the AAVP over Research.

Should noncompliance continue, appropriate action will be determined at a convened meeting. Action by the IRB can include but is not limited to:

- Halting the research until the Investigator is in compliance. If the research is halted, OHRP will be notified if the research is funded by a government agency, and FDA will be notified if the research involves an FDA regulated product or agent.
- Requiring the Investigator to complete a training program.
- Barring the Investigator from conducting further research.
- Any other action deemed appropriate by the IRB.
- When unapproved research is discovered, the IRB and the institution will act promptly to halt the research, ensure remedial action regarding any breach of regulatory or institutional human subject protection requirements, and address the question of the Investigator's fitness to conduct future human subject research.

Serious or continuing noncompliance with federal policies on the protection of human subjects or the policies, procedures or determinations of the IRB must be reported promptly to the AAVP over Research as well as the appropriate department or agency head for funded proposals, to OHRP and/or FDA as appropriate.

The IRB's responsibility is to protect the rights and welfare of research subjects, which could be placed at risk if there is misconduct on the part of an investigator or any member of the investigative team. It is, therefore, the duty of the IRB to be receptive to and act on good faith allegations of misconduct. Allegations of misconduct in science should be referred to the AAVP over Research for handling under BRIGHAM YOUNG UNIVERSITY policies.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.109, 46.113
21 CFR 56.109, 56.113

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.