Human Subjects in Research (IRB)

Keene State College Policies and Procedures

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Keene State recognizes the need for investigations in which human beings serve as research subjects. The College is also cognizant of its responsibility for ensuring that the privacy, safety, health and welfare of subjects are adequately protected. An Institutional Review Board (IRB) has been established to review and approve the adequacy of human subject protection. Additionally, the College has established a Federal Wide Assurance with regard to the conduct of human subjects research.

The policies of the College, with respect to research involving human subjects are guided by *The Belmont Report*, a federal government document that charges each investigator who is conducting human subject research with the responsibility of demonstrating respect for persons, beneficence (maximizing benefits minimizing risks), and justice.

The policies are based on the following principles:

- Participation in any research project must be voluntary;
- The risks of participation must be acceptable when measured against the possible benefits to the participant or by the importance of the knowledge gained,
- Research and training activities involving human subjects must be supervised by a qualified person,
- All research programs that involve human subjects must be reviewed and approved by the IRB prior to initiation of the protocol.
- Per Federal Regulations, all continuing research must be reviewed on an annual basis.
- **This applies to all research involving humans, not just clinical research and regardless of whether or not the research is funded.**

Keene State College's full IRB policy and procedure manual is available here.

Submission Guidelines

Investigators need to select and submit the appropriate document electronically to the IRB at this address (irb@keene.edu).

Request for Initial Review and Approval

Request for Continuing Review and Approval

Request for Protocol Amendment

Request for IRB Course Approval

Incident Report Form

Additionally, each IRB protocal submission must be accompanied by proof of satisfactory completion of the CITI Human Subjects IRB training (a certificate is generated upon completion-please include this with your materials). Per Keene State College policy, no IRB protocol can be approved without proof of training. For instructions on completing the training please visit our CITI page.

If the research involves children (under 18), vulnerable populations (e.g. prisoners, pregnant women, the disabled), sensitive questions, deception, or potentially harmful interventions, a full board review will be required. For children, the consent form must have a signature line for the child's assent and the parent's consent.

If the research involves adults (age 18 or older), secondary data analysis, non-sensitive questions, or routine educational or cognitive tests, an expedited review is possible, handled by the IRB chair, without need of a full review.

Instructions for Extramural Researchers

Extramural investigators desiring to conduct human subject research at Keene State College, either by using the College's facilities or by recruiting members of the College's community as participants, are expected to demonstrate compliance with all relevant federal and state human subject regulations, including review and approval by their sponsoring or affiliated IRBs. To demonstrate said compliance, extramural researchers should submit a copy of the protocol submitted to their IRB along with a copy of the IRB's Record of Review indicating that the protocol was approved. Submit these items electronically to the Keene State College IRB at this address (irb@keene.edu). Approval by an extramural IRB does not necessarily replace review by Keene State College's IRB, however, which may elect to do its own full review of the protocol.

Members of the Keene State College IRB are expected to keep all information and documentation disclosed during the IRB review process confidential. These confidentiality requirements continue indefinitely.

Meeting Dates and Submission Deadlines

The IRB Committee typically meets once per month during the fall and spring semesters, and on an as needed basis during the summer.

Timeline for Receiving Initial and Ongoing Approval Note: You must not begin your research until the IRB has given your research protocol full approval. Review of exempt or expedited protocols can usually be completed within a few days. The review process for protocols submitted for full board review can take up to a month or longer to complete.

Anticipated Time-line for 2014-2015:

Protocol Submission Deadline is 3 weeks prior to Convened Meeting	**Full IRB Committee receives materials for review is 1 week prior to Convened Meeting**	**Convened Meeting Date**	**Outcome of Review Communicated to Applicant is 1 week following Convened Meeting**
September 23, 2014	October 7, 2014	October 14, 2014	October 21, 2014
October 28, 2014	November 11, 2014	November 18, 2014	November 25, 2014
January 20, 2015	February 3, 2015	February 10, 2015	February 17, 2015
April 7, 2015	April 14, 2015	April 28, 2015	May 5, 2015

*Note, protocols may be submitted at any time. If they are eligible for expedited review, they will be processed and reviewed on a rolling basis. The above dates, however, give you an idea of the "lengthiest" review timeline to expect, in instances where full board review is required. Please be aware that protocols that result in questions during the review process that must be addressed with the investigator may take longer to resolve.

You should include sufficient time in your research plan as allowance for any IRB-required changes to the research protocol. Minor revisions may be reviewed by the chair alone, or by a subcommittee of the full IRB. Substantive revisions usually return to the full board for review at a regularly scheduled meeting.

What happens to my protocol, once I submit it?

Per federal regulations, any ongoing project that has received IRB approval must seek re-approval at least annually. It is the investigator's responsibility to submit renewal protocols in a timely fashion. No human subjects research may be conducted without a current IRB approval in place.

The KSC IRB Committee

Stephen Clark, Psychology, Chair
Fitni Destani, Physical Education, Member
Chitra Akkoor, Communication, Member (non-scientist)
Yi Gong, Education, Member
Robert Schultz, Member (non-affiliated)

Sample Informed Consent Forms (Templates)

Below you will find two templates for consent forms, one for children, and one for adults.

Informed Consent Form for Adults

Informed Consent Form for Children

Types of Review

There are three levels of IRB review:

1. Exempt

"Exempt" means a protocol does not require extensive initial regulatory review. It does not mean the protocol is exempt from IRB review. To qualify as exempt, research must fall into any of six (6) regulated exemption categories. The categories represent a low potential for risk to subjects. Risk is reduced through anonymity of responses, use of existing or publicly available data, or through the use of non-invasive paradigms that will not harm subjects.

Exempt reviews are conducted by designees of the full IRB. Some commonexamples of Exempt research:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as 1) research on regular and special educational instructional strategies, 2) research on the effectiveness of, or the comparison among instructional techniques, curricula, or classroom management methods.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures or the observation of public behavior, unless: a. information is recorded in such a manner that human subjects can be identified b. any disclosure of the human subjects responses outside the research could place subjects at risk of criminal or civil liability, or be damaging to the subject's financial standing, employability, or reputation.
- Research involving the collection of existing data, if these sources are publicly available, or if the data is collected in such a way that the subjects cannot be identified.

Important: The likelihood that a proposal of this kind will be found exempt does not relieve you of the responsibility to submit your proposal to the IRB chair and have him or her decide if the proposal is in fact exempt.

For more information see the full IRB Policy and Procedure Manual.

2. Expedited

To qualify for expedited review, research must fall into one of the regulated expedited categories. "Expedited" categories involve collection of samples and data in a manner that is not anonymous and that involves no more than minimal risk to subjects.

Expedited reviews are conducted by a subcommittee of the full IRB. Some common examples of expedited research:

- studies including blood samples taken from healthy volunteers
- studies including moderate exercise by healthy volunteers
- analyses of voice recordings (such as those taken in the investigation of speech defects)
- studies of existing data or pathological specimens that include patient identifiers

For more information see the full IRB Policy and Procedure Manual.

3. Full Board

Proposed human subject research that does not qualify for exemption or expedited review must be reviewed by the full IRB. Protocols sent to the full board represent more than minimal risk to subjects, and are, therefore, reviewed rigorously for compliance with all applicable federal, state, local and university regulations. Some common examples of research requiring full IRB review:

- Research on Substance Abuse
- Research on Sexual and Physical Abuse
- Research on Depression and Suicide
- All Research Involving Children and Adolescents
- Research on Sexuality and Gender
- All research involving subjects with diminished capacity
- All institutionalized subjects (e.g., prisoners, state hospital patients)

For more information see the full IRB Policy and Procedure Manual.

I still have questions, who can help?

You may e-mail or call the IRB chair, Steve Clark at 603-358-2899

Helpful links:

- IRB FAQ's

- Office of Human Research Protections (OHRP)
- OHRP Database for Registered IORGs and IRBs, and Approved FWAs (including Keene State College)

For Additional Information Contact SusanEricson-West, Office of Sponsored Projects & Research (603-358-2046)