Sitting Bull College Institutional Review Board

Application Review Procedure

Introduction

Title 45 Code of Federal Regulations Part 46 (45 CFR 46) Protection of Human Subjects specifies federal regulations for the conduct of research involving human subjects.

An institution involved in biomedical or behavioral research should have in place a set of principles and guidelines that govern the institution, its faculty, and staff, in the discharge of its responsibilities for protecting the rights and welfare of human subjects taking part in research conducted at, or sponsored by the institution, regardless of the source of funding [Federal Policy §__.103(b)(1)].

Summary of Procedures

- The Institutional Review Board at Sitting Bull College convenes every **two (2)** months of the calendar year.
- Board meetings to discuss, comment, and review IRB applications will be held:
    - In person on the SBC campus
    - Online if further discussions are required on applications, or if a quorum cannot be reached to make binding decisions at a seating meeting.
    - Due to COVID-19, ALL meetings will transition to the online meeting platform.
- Upon receipt of the proposal, the IRB will verify and make sure the packet is complete. Applications should be submitted at least a week prior to the next scheduled meeting.
- Then the chair will forward the application to designated reviewers or the entire board who will examine the documents, and determine if the project is eligible for approval or disapproval.
- A decision will be rendered by the committee at the next scheduled meeting based on review comments and after any requests and clarification demands about the project have been addressed by the PI.
- A majority decision will be rendered on an application after review and deliberation.

- Review Procedures are based on the type of application sort: Full, Exempt, and Expedited

- Review timeline:
    - For exempt projects and projects qualifying for expedited review (no foreseeable risk), the researcher(s) and, if applicable, the faculty sponsor, will be notified within five working days after necessary information is received by the IRB Chair.
    - For projects requiring full IRB review, notice of the Board's decision will be mailed within seven working days after the IRB meeting.

Types of IRB Review Applications:

1. Exempt Review: An exempt review procedure consists of a review of research involving human subjects by the Chair or Member of the IRB.
    a. Research conducted in established or commonly accepted education settings, involving normal education practices, such as (a) research on regular and special education strategies; or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
    b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers liked to the subjects.
    c. Research involving survey or interview procedures, except where the following conditions exist: (a) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; (b) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and (c) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. 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.
    d. Research involving the observation (including observation by participants) of public behavior, except where the conditions named in number three above exist.
    e. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.

2. Expedited Review: An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110. For full list of categories, see Appendix A.
    a. Clinical studies of drugs and medical devices only when certain conditions are met.
    b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
    c. Prospective collection of biological specimens for research purposes by noninvasive means.
    d. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
    e. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the

protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

f. Collection of data from voice, video, digital, or image recordings made for research purposes.
g. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
h. Continuing review of research previously approved by the convened IRB.
i. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3. Regular Review: A regular or full review procedure consists of a review of research involving human subjects by the full IRB.
    a. Any research involving the use of vulnerable subjects. A vulnerable subject is defined as follows: "Vulnerability refers to the risks that researchers request their subjects to undertake in relation to the ability of the subjects to make fully informed consent. Populations routinely considered to be vulnerable include: children; prisoners; pregnant women; non-English speaking people; the mentally handicapped; those subjects engaged in illegal activities; people who are under medical treatment for an illness that is relevant to the risk they are being asked to assume by the researcher; and subjects who may risk retribution by a person with authority over them as a consequence of participation or non-participation in the study.
    b. Any research involving more than minimal risk, either mental or physical to the subject. Examples of protocols of this type may include surveys or questionnaires that solicit information regarding personal or sensitive aspects of the subject's behavior, including sexual practices, studies that solicit information regarding instances of child or sexual abuse suffered by the subject, criminal activities and for studies regarding eating disorders. Examples of studies that involve more than minimal physical risk to the subject include stress testing, drug and alcohol use by the subjects and studies where subjects are asked to do more than moderate physical exercise that could result in injury to the subject. This should not be considered an exhaustive list of studies that may involve more than minimal risk to the subject. The investigator should include a comprehensive statement of the potential risk/benefit ratio to the subject for consideration by the committee.