DRAFT

INSTRUCTIONS FOR SUBMITTING PROPOSALS TO THE HASKELL INDIAN NATIONS UNIVERSITY INSTITUTIONAL REVIEW BOARD (HINU IRB)

February 20, 2003

Haskell Indian Nations University

Lawrence, Kansas

Email applications may be submitted. See page 10 of the instructions for details.

DRAFT

TABLE OF CONTENTS

WHO MUST APPLY FOR HINU IRB APPROVAL (AND WHY)?

The National Research Act of 1974/1983 (PL 93-348) dictates that, in order for institutions to be eligible for behavioral or biomedical research grants from federal sources (e.g., The Department of Health and Human Services and its various research institutes), an institutional Review Board (IRB) must be established and maintained to review research involving human subjects. The charge of this IRB is to protect the rights of those subjects participating in such research at this institution. The IRB for the Haskell Indian Nations University is the HINU IRB. The University must also have an approved Federalwide Assurance (FWA), which sets forth the responsibilities of the University, the researchers, and the IRB with respect to human subjects research. Our Federalwide Assurance (FWA) may be found at (insert URL if applicable) HINU IRB must review proposals for research involving human subjects if the research:

(1) is in any way sponsored by the University (e.g., affiliated with the University in name), or
(2) is conducted by, or under the direction of, any employee or agent of the University as part of their institutional responsibilities, or
(3) is conducted by, or under the direction of, any employee or agent of the University using University facilities or property, or
(4) involves the use of the institution's non-public information to contact or identify participants or prospective participants.

Investigators conducting research with human subjects that meet any of these conditions must prepare proposals of that research and submit them to HINU IRB for approval. HINU IRB's review of the proposals is guided by the Code of Federal Regulations (Title 45, Part 46), which sets the minimum standards for protection of human subjects.

WHEN TO SUBMIT

Proposals for HINU IRB approval can be submitted at any time. During the academic year, HINU IRB works continuously on the review of proposals and meets on a monthly basis, usually in the third week of each month. Research proposals that are received by the 15th of each month will be acted upon at the meeting that takes place during the following month.

For example, if a proposal needing a full committee review is submitted by October 15th, a committee decision concerning that proposal will be reached during the November meeting. A proposal submitted on the 16th of October, however, is not guaranteed committee action until the December meeting. Thus, the turnaround interval for committee action on a reviewed proposal can be as brief as three weeks, or as long as six weeks. Note that if the 15th of the month falls on a weekend or holiday, the deadline for receipt of a proposal is extended to 5:00 p.m. on the next full work day.

HINU IRB recommends that lead-time for committee approval be figured into the schedule for the conduct of research, especially since committee action (i.e., discussion and vote on approval of the project) is not necessarily equivalent to or a guarantee of committee approval. Furthermore, it should be noted that the same turnaround schedule cannot be guaranteed during the summer months, because some of the committee members are on nine-month University contracts, and are thus unavailable to review projects or attend meetings during the summer months.

WHAT TO SUBMIT

Proposals are submitted using the HINU IRB application form. The form is available from the Haskell Indian Nations University Office of Institutional Research and Sponsored Programs; 155 Indian Ave; Lawrence KS 66046 or can be emailed to you.

The most current version of the application will have "2/2003" typed on the upper left hand corner of the face page. Proposals submitted to HINU IRB typically consist of two parts.

Part 1: The HINU IRB application, which includes four pages (a face page, a checklist page, a description page, and an abstract page). A copy of the application follows the text of this manual. Send or bring a blank 3.5" diskette to the HINU IRB office and we will return it with the application in the format requested. HINU IRB can send you the Instructions and application via email upon your request.

Part 2: Appendices should also be submitted with the application. Appendices contain supplementary information regarding the application, which usually include (but are not limited to) a copy of the written consent form (if applicable) to be used in the conduct of the research, copies of any additional supplementary materials (surveys, questionnaires, assessment materials, etc.) that will be used in the conduct of the research and an institutional disclaimer statement. However, the Principle Investigator (PI) should feel free to include any materials that (s)he believes will assist the committee in evaluating the application.

Each of these two parts of an HINU IRB proposal is discussed in the sections that follow.

PART 1: THE HINU IRB APPLICATION

The HINU IRB application is attached at the end of this manual. Please use this form for any new submissions.

PAGE 1.

The face page contains the formalities of the HINU IRB application. The space for the HINU IRB application number at the top right of the face page should be left blank.

1. Name of Investigator(s). All investigators should be listed here. In projects with more than one investigator, correspondence about the proposal will be addressed to the investigator who signs as the first investigator. From here on, this person is referred to as the principal investigator (PI). The PI will be HINU faculty, student, or staff. If the PI is neither faculty nor staff, a HINU faculty supervisor or sponsor will be needed to sign off on the form (see item 5 on the next page). Students, therefore, need to have a faculty supervisor or sponsor. The faculty supervisor/sponsor is considered to be ultimately responsible for the proper conduct of the project with respect to the protection of human subjects.

   Tutorial: All researchers, including the faculty supervisor for a project, must complete the online tutorial for conducting research involving human subjects before the project can receive HINU IRB approval. You may access the tutorial at www.research.ukans.edu/tutor. (You may access our tutorial if you wish, or copy it and set it up on your server, or whatever the appropriate term to use is. I don't know much about this area David Hann)

2. Department Affiliation. Please indicate the campus department (if applicable) with which the PI is affiliated.

3. Campus or Home Mailing and E-mail Address. This is the address to which correspondence concerning the proposal will be sent. If possible, please give a campus address, so that HINU IRB may use campus mail for delivery of this correspondence. If you have an email address, you should provide that also as email correspondence allows much faster turnaround on project review and approval than surface mail.

4. Phone Number(s). Please provide a campus number (if applicable) and home telephone number at which the PI can be reached. These allow the coordinator to contact the PI in case there is a technical problem with the application.

5. Name of Faculty Member Responsible for Project. Research projects submitted to HINU IRB must have a faculty sponsor. If the PI is not a HINU faculty member or faculty-equivalent please indicate the faculty member who will be sponsoring the research.

6. Type of investigator and nature of activity. If the PI applying for HINU IRB approval is faculty or staff, the top part of this item should be filled out, indicating the status of the PI and whether the research is to be submitted for internal or external funding. If a HINU account number has been assigned to this project, please provide that number. If the PI is a student, fill out the bottom part of this item.

7. Title of investigation. Please give a brief title for the project. Brief titles facilitate correspondence and record keeping. If this is a funded project or an application for a funded project, is the HINU IRB project title the same as that submitted to the funding organization? If not, please give that title as well.

8. Individuals other than faculty, staff, or students at Haskell Indian Nations University. If applicable, check the box and indicate the names of other non-HINU personnel that may be participating in the conduct of this research.

9. Certifications. The PI and any other personnel involved in the conduct of the research should sign the bottom of the face page, thus affirming familiarity with the policies of HINU IRB and the professional codes of ethical conduct with respect to human subjects. This is an important step. HINU IRB cannot process applications that are not signed by the faculty sponsor and all participating investigators. Please note that by submitting the application via email or hard copy you are certifying that you have read, understand, and will comply with the policies and procedures of the Haskell Indian Nations University regarding human subjects in research and that you subscribe to the standards and will adhere to the policies and procedures of the HINU IRB.

PAGE 2

Please fill out the name of the PI and the proposal title at the top of this page. The space following the "HINU IRB #." is for office use and should be left blank.

10. Checklist. The checklist allows HINU IRB to rapidly screen applications for possible expedited or exempt conditions. Please read and answer "Yes" or "No" to items 10a to 10m carefully. Failure to do so accurately may result in delays in the processing or approval of your proposal. The section "Other Supporting Materials," should be noted if item 10.c., about cooperating institutions, is checked "yes." If item 10k is marked "yes," then copies of the instruments to be used in the research (or a detailed description of the instruments) must be attached as an appendix. These materials will be retained in HINU IRB files concerning this project.

Use of Audio and Video Recording

For projects in which audio and/or video recording is intended, your abstract and consent form should explain who will have access to the tapes, security measures you will take to protect the privacy of subjects recorded, and what you will do with the tapes upon completion of your project (e.g. erase them, retain them for future research, etc.).

Payment to subjects

Please note that if the research involves payment to subjects (i.e., if item 10b is marked "yes"), such payment is considered to be appropriate only if it is meant to compensate subjects for costs incurred as part of participation in the research. (e.g. travel, time, etc.) PIs should not use payment schemes that may be potentially coercive.

11. Approximate number of subjects to be involved in the research. Please indicate the number of subjects from whom you are planning to collect data.

PAGE 3.

Information about the project purpose, proposed subjects, and selection procedures helps the committee discern the potential benefits to be derived from the research, whether the proposed population is especially vulnerable or at risk, and whether the processes for subject selection are equitable and sensitive to issues of confidentiality and privacy.

12. Project Purpose(s). Please describe briefly, and without jargon, the purpose of the project described in the application. Please use only the space provided.

13. Describe the Proposed Subjects. Please indicate any special criteria for including or excluding subjects involved in the proposed research. For example, if subjects are to be included in the project only if they are from a particular age group, racial group, or gender, please indicate this here. Additionally, if there is some medical attribute (e.g., Alzheimer's Disease, heart disease, etc.) or physical (e.g., marathon runners, bicyclists, weight lifters) that characterizes the subjects to be included in the study, please indicate this here as well.

Subject Selection Considerations

14. Describe how the subjects are to be selected. Please indicate how you will gain access to, and recruit these subjects for participation in the project. That is, will you recruit participants through word-of-mouth, fliers or poster, newspaper ads, public or private membership or employee lists, etc. (If subjects are to be recruited from a cooperating institution, such as a clinic or other service organization be aware that subjects' names and other private information, such as medical diagnosis, may not be obtained without the subjects' written permission.) If subjects are to be recruited randomly (by mail or telephone), through one of the on-campus subject pools, through PSYCH. 104 mass screening, or through a cooperating institution, please indicate the particulars here. Please note that investigators who wish to recruit subjects who are clients of an organization (clinic, hospital, etc.) should have that organization ascertain subjects' interest rather than just obtain a list of client names from the organization without the consent of the clients. Investigators may ask the organization to distribute the consent form or introductory letter and have interested subjects contact the investigator directly or through the organization. This method protects the privacy of prospective subjects.

PAGE 4.

This is **an important part** of the application. Although proposals assigned to committee review will be read and considered in their entirety by only three members of HINU IRB, pages 2 to 4 of such proposals are distributed to all members of the committee prior to the monthly meeting. Thus, the abstract will be seen by all members of the committee and so it should be complete and provide an accurate description of the proposed project. Many of the problems the committee encounters in evaluating proposals arise from difficulties in understanding what is being proposed. Often, the committee must request clarification before reaching a final decision with respect to a proposal. With clear abstracts and generic language, many of these problems can be avoided.

15. Submitted abstract to funding agency of the proposed procedures. The abstract should be a succinct overview of the project. Please describe the procedures to be employed in the project. The HINU IRB committee is comprised of professionals from various academic and nonacademic fields. Therefore, it is important that the procedures be described in terms that can be understood by such an audience. Describe the procedures in the space provided, without jargon, abbreviations, or technical terminology. If you must use technical terms, please define or explain them so that someone not knowledgeable about your field can understand them.

PART 2: APPENDICES

Supplementary materials should be attached to the applications as appendices. These supporting materials often include the following items.

Copies of Research Instruments

If applicable (usually, if item 10k on the page 2 of the application has been checked "yes"), copies of instruments (assessments, scales, questionnaires, surveys, protocols, etc.) that are to be used in the proposed research are attached in appendices. If the instruments or protocols cannot be attached themselves, a detailed description of the instruments may suffice.

Informed Consent Form

If written informed consent is being used, a copy of the consent form that will be used in the research should be attached. According to the federal code of regulations (45 CFR 46), the consent form must include the following items when appropriate and applicable:

a. A statement of the purpose of the research and a brief description of procedures to be followed.
b. A description of any reasonably foreseeable discomforts or risks (psychological, sociological, or physical) to the subjects. If more than minimal risk is involved in the project, a statement concerning the Kansas Tort Claims Act should be included. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The Kansas Tort Claims Act reads as follows: "In the event of injury, the Kansas Tort Claims Act provides for compensation if it can

be demonstrated that the injury was caused by the negligent or wrongful act or omission of a state employee acting within the scope of his/her employment."

c. A description of the benefits for the subjects or others which may reasonably expected from the research.
d. A disclosure of alternative procedures that would be advantageous to the subject. (This is usually only applicable to research involving experimental medical treatments).
e. A statement that participation is voluntary. This should include an assurance that participation may be discontinued at any time, and that refusal to participate in, or withdraw participation from, the project will result in no penalty or loss of benefits to which the subject is otherwise entitled.
f. A statement describing the extent (if any) to which the confidentiality of records through which the subject can be identified will be protected.
g. An indication of the commitment in time required to participate in the study.
h. An offer to answer any inquiries concerning the project, and information concerning whom to contact in case questions arise after the data collection session is completed. This is usually done by providing the name of the PI, the departmental affiliation, and the telephone number(s) on the consent form.
i. Signatures
    1) The subject's signature, if appropriate (e.g., the subject is of legal age, the subject is competent to understand and provide informed consent). If individuals who are not of legal age (under 18 years) may be inadvertently recruited for participation in the project (e.g., when subjects are obtained from University subject pools), the following should appear below the signature: "With my signature, I affirm that I am at least 18 years of age."
    2) If the subject's signature is not appropriate, the signature of the parent or guardian (again, if of legal age), and the name of the subject.
j. Reference to any written explanations given to subjects to be followed if this explanation does not appear on the consent form.
k. An affirmation under the signature stating that, "With my signature I acknowledge that I have received a copy of this consent form to keep."
l. Add to the consent form/introductory letter the faculty supervisor's name, department, and department phone number.

Please note that, if the consent form is longer than a single page, then page numbers should be provided that indicate the entire length of the form on each of the pages (e.g., "Page 1 of 3," "Page 2 of 3," etc.). Copies of acceptable consent forms are provided for illustrative purposes with this packet.

If oral informed consent is being proposed for use, the PI should consult directions and regulations for documenting oral consent in the Federal Regulations (45 CFR 46.117.b.2). This typically involves submission of a text or script of the consent procedures, the presence of a witness, and a summary description of the research provided for subjects.

Assent Procedures

In research with children or other participants for whom the ability to give informed consent is otherwise compromised, it is usually appropriate to obtain some form of agreement, or "assent" to participation in the data collection sessions. For example, even though children or individuals with developmental disabilities cannot provide informed consent for participation in research, a researcher should still describe the procedures in language that can be understood by the subjects, and obtain their verbal "agreement" to participate. If an assent procedure is to be used, a prototype of the "script" of this procedure should be included in the appendices of the application.

Letters of Introduction - Surveys and Questionnaires

For mail surveys or questionnaires that are completely anonymous in nature, signed informed consent can often be waived. However, in the place of informed consent under such circumstances, an appropriate "letter of introduction" should accompany the survey. The letter of introduction should include the critical aspects of the informed consent form (e.g., risk- benefit statements, assurances of voluntary participation and confidentiality of responses, etc.). The letter should also include a statement that, by returning the questionnaire, the respondent indicates his or her consent to participate in the study. A copy of the letter of introduction should be included in the appendices.

If investigators wish to use the Internet or electronic mail to conduct surveys some extra precautions are necessary. Because respondents' electronic addresses are typically provided when they return such surveys by e-mail, PIs should devise a plan for stripping such information to maintain the confidentiality and anonymity of respondents' names. Also, it is possible that, through intent or accident, someone other than the intended recipient may see the subject's response. The investigator should therefore inform subjects that, while effort will be made to protect subjects privacy, security and confidentiality of participants' responses cannot be guaranteed.

Other Supporting Materials

Often, some of the concerns of the committee can be addressed by the inclusion of supporting letters from responsible individuals at institutions (schools, clinics, health care facilities, branches of law enforcement, etc.) that are involved or cooperating in the research. These letters might provide an indication of their willingness to cooperate in the conduct of the research, or their granting of permission to project personnel for access to subject populations located at such institutions. The letter may also indicate that such individuals have reviewed or (if applicable) have secured approval of the research protocol within that institution.

HOW MUCH TO SUBMIT

Investigators must submit: ONE copy of the entire completed HINU IRB application (pages 1-4) plus consent form(s) and all appendix materials.

WHERE TO SUBMIT

If submitting proposals by U.S. mail, send them to HINU Office of Institutional Research and Sponsored Programs - IRB, Haskell Indian Nations University, 155 Indian Ave., Lawrence, KS 66046. E-mail applications may be submitted. Student researchers must email their application to their faculty supervisor, who looks at the application then forwards it to: lhara@Haskell.edu. Please note that supporting materials that cannot be emailed must be provided to the HINU IRB office by hand delivery or surface mail.

Campus mail submissions may be addressed to Office of Institutional Research and Sponsored Programs - IRB, Haskell Indian Nations University, 155 Indian Ave., Lawrence KS 66046. Proposals may be delivered directly to the Office of Institutional Research and Sponsored Programs at 120 Navarre Hall. Telephone number is (785) 749.8407.

ON WHAT BASES ARE HINU IRB PROPOSALS EVALUATED?

GENERAL ISSUES OF SUBJECT PROTECTION

Given the fundamental charge of the committee, there are particular aspects of the proposal to which HINU IRB will be attending. By law, HINU IRB can only grant approval to projects that satisfy certain requirements. PIs who anticipate evaluation on these requirements and attend to them in their proposals will encounter markedly fewer problems during the HINU IRB approval process. The requirements for approval (as paraphrased from the Code of Federal Regulations), include the following:

Risks to subjects are minimized. This is the first and foremost concern in the review of application by HINU IRB. What potential risks, stresses, or discomforts (if any) will be incurred by participation in this project? Has the PI taken steps in the design or procedures of the study to reduce the possibility of these risks or discomforts?

Risks to subjects are reasonable in relation to anticipated benefits. Do the benefits, if any, to be derived from this research outweigh the risks posed by this research to the subjects?

Informed consent will be sought from each subject (or the subject's legal representative) and documented. Are subjects fully informed of the risks and benefits of participation in the research? Are subjects informed of their basic rights in participating (e.g., withdrawal without penalty)? Are all of the appropriate aspects of informed consent included? If not, have the omissions been adequately justified? If the subjects themselves are unable to give informed consent, has consent been acquired from the appropriate responsible person(s), and has an assent procedure been provided? Is there adequate provision for the documentation of informed consent by the PI? Please note that the most common form of difficulty encountered by HINU IRB in granting approval of projects involves technical problems with informed consent forms (e.g., all the necessary aspects listed in Consent Form Requirements are not included).

Adequate provisions for monitoring data to insure the safety of subjects. Is the research monitored so that previously unforeseen risks come to the attention of the PI? This section also includes the monitoring of data in the case that individual subjects are identified as being at risk for medical or psychological problems. For example, in the course of research on exercise physiology, a PI might discover the presence of a heart murmur; in the course of psychological research on depression, a PI might discover a subject who is at some risk for suicide. What provisions, if any, are made for subjects who are identified as being at risk during the conduct of this research?

Adequate provisions to protect the privacy of subjects and maintain confidentiality. To what degree are subjects' responses protected with respect to confidentiality and anonymity? Will subjects' names be associated with their data? Who will have access to materials (e.g., data sheets, audio recordings or videotapes) through which subjects might be identified? Will response sheets be kept in a safe place? What are the plans for disposition of materials through which subjects might be identified when the study is finished? Appropriate additional safeguards for subjects who are especially vulnerable. Have adequate additional provisions been made to protect the rights of those subjects who might be especially vulnerable to coercion or undue influence? Federal law specifically mentions children, those with physical illness or psychological disorders, or those who are economically or educationally disadvantaged, as being members of this class. Are there any circumstances in the proposed research under which subjects might feel coerced to participate?

HINU IRB POLICY ON EXPERIMENTS INVOLVING DECEPTION OF SUBJECTS

HINU IRB acknowledges that it is occasionally necessary to use deception in a research design in order to protect or strengthen the scientific integrity of an investigation. However, because participants are deliberately misinformed concerning the actual purposes or procedures of the research in such cases, HINU IRB considers such research to not meet the general requirement for informed consent as stated in the Code of Federal Regulations (45 CFR 46.116.a.1). This part of the law delineates the basic elements of informed consent, and states that in seeking informed consent, the following information shall be provided to each subject:

> ...an explanation of the purposes of the research and...a description of the procedures to be followed...

Please note that federal law does not necessarily restrict the concept of "informed consent" to the consent form that subjects sign at the start of a study.

The Code of Federal Regulations, however, does provide for instances in which informed consent can be altered or waived. Under this federal law (45 CFR 46.116.d.1-4), this can occur only if all of the following conditions are met:

(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration [of consent] will not adversely affect the rights and welfare of the subjects;
(3) The research could not practicably be carried out without the waiver or alteration [of consent]; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Therefore, investigators proposing research to HINU IRB in which participants are misinformed concerning the study's procedures or purposes during the course of data collection must address how their proposals meet these conditions. This requirement may be met in a number of ways. However, in order to address these issues and facilitate review of such proposals, HINU IRB recommends that proposals for research involving deception include the following elements:

a. Justification for the Deception. The justification should address condition 3 listed above. Investigators should provide specific and cogent reasons why fully informed consent is not appropriate for this study, and/or the manner in which fully informed consent threatens the integrity of the research.

b. Explicit Statement of No Risk/Minimal Risk. This statement should address conditions 1 and 2 listed on the previous page. Investigators should provide a statement affirming that the proposed research presents no more than minimal risk to the participants. Federal law (45 CFR 46.102.g) defines "minimal risk" as follows:

> *"Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

c. Description of Debriefing. Procedures for debriefing should address condition 4, listed above. Subjects should be informed that deception took place, and should be appropriately informed as to the actual purpose of the research, and the role of the deception in protecting the integrity of the research. Finally, subjects should also be reminded of their right to withdraw from the study at this time; this can be accomplished through a range of various procedures,

extending from the inclusion of a simple statement to that effect in the debriefing, to having the participant sign a second informed consent form at the end of the study.

It is noted that the text of the Code of Federal Regulations allows for the possibility that circumstances may arise in which debriefing may not be judged to be "appropriate." HINU IRB allows for this possibility, but PIs should note that requests to omit such debriefing in research involving deception should be strongly justified.

Although proposals involving deception must meet the conditions for alteration of informed consent, signed informed consent is still required to meet the requirements described in 45 CFR 46.116.a.2-8. Note that the informed consent form may not contain misinformation, may not be used as part of the deception, and may not be used as a means for manipulating subjects' behavior.

The committee has directed the Chair to refrain from sending applications to them that are not complete. Therefore, applicants submitting deception research applications without adequate debriefing procedures will be asked to provide them before the applications are sent on to the committee for review.

THE REVIEW PROCEDURE

When HINU IRB proposals are received, they go through a review process that is detailed in the Assurance Statement filed by the University with the U.S. Department of Health and Human Services.

SCREENING FOR EXEMPT AND EXPEDITED PROJECTS

The HINU IRB coordinator and/or the HINU IRB chair first screens the proposals to determine whether they fit the description of projects that are exempt from IRB (committee) review, or whether they might be afforded an expedited review.

Exempt Review

A proposal may be considered exempt from full committee review if the research being conducted falls into one or more of the following categories, as specified by the federal regulations:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. 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 linked to the subjects.
3. Research involving survey or interview procedures, except where all of the following exist:
    (a). responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, and
    (b). the subject's responses, if they became known outside the research, could reasonably place the subject at risk for 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.

Note that "Exempt" means that the project may be reviewed by the coordinator and/or the committee chair, not that the project may be carried out with no review or approval by HINU IRB.

Expedited Review

Expedited approval may be granted for certain specific classes of projects defined by the Code of Federal Regulations. Most often, PIs can receive expedited approvals for three classes of projects:

(1) projects that have been previously approved by HINU IRB, in which minor protocol changes have been made, or
(2) projects that have been previously approved by HINU IRB, and whose approval date exceeds one year. In this latter case, the expedited approval takes the form of an "update."
(3) some projects not exempt but which involve no more than minimal risk, as described in 45 CFR 46.110 (f) (1-7).

If a proposal fits one of these categories (which are strictly defined by the Federal Code of Regulations: 45 CFR 46), and the application meets criteria for approval, approval notification is sent out immediately to the PI. Upon receipt of this notification, the PI may begin the research.

COMMITTEE REVIEW

Proposals that do not fit either the exempt or expedited-review categories are assigned to three committee members for review. The committee members receive the full application plus appendices, and return their recommendations and comments concerning the proposal to the coordinator. These recommendations and comments are compiled and integrated by the central HINU IRB office, and then presented to the full committee at the monthly meeting. At that meeting, all projects sent out for review are open for discussion and voted on. Results of that committee vote and the commentary from the reviewers are forwarded to the PI.

Forms Of Committee Action

The outcome of the HINU IRB review can take several forms. Each of these particular actions is discussed below.

Disapproval

Projects are disapproved when the committee judges the risk to human subjects participating in such experiments to be unacceptable. The acceptability of the risk is determined by the judgment of the cost/benefit ratio of the research. Thus, higher levels of risk will be tolerated for research in which the potential benefit is judged to be higher; the opposite is true for research that presents no obvious benefit. PIs should note that only a very small percentage of projects reviewed by HINU IRB are disapproved.

Failure on the part of the PI to adequately describe the project in the abstract portion of the application is often the cause for disapproval, since it is here that the PI must describe screening, safety precautions, and contingency plans to meet adverse reactions from subjects to project procedures, as well as to describe the procedures in layperson's terms without technical jargon.

Not Approved

In some cases, not enough information is provided to allow the committee to determine the degree of risk to which subjects will be exposed. This occurs when critical information is omitted from the application. Thus, the application does not describe the project in detail adequate to allow a judgment of either approval, contingency, or disapproval. Occasionally, the cause for a failure to approve lies in the use of technical jargon which neither reviewers nor prospective subjects may understand. In such a case, the PI must submit the needed information so the proposal may be considered at the monthly meeting.

Approval Upon Meeting Contingencies

HINU IRB may withhold approval of the application, contingent upon a request from the committee for clarification of some point concerning the project, or for changes to the consent form or materials involved in the research. The PI then must respond to the request. Depending on the number of contingencies involved in the project, the determination of whether the response is adequate will be made by either the chair and/or coordinator, or the opinion of other HINU IRB members may be sought. If the response adequately meets the contingencies set by the committee, an approval is generated for the project.

Approval

Finally, HINU IRB may approve the application. The approval is usually accompanied by an evaluation of risk for the subjects involved: (a) the subjects will not be at risk, (b) the subjects will be at minimal risk, or (c) the subjects will be at some risk, but the potential benefit from the research outweighs the risk to the subjects. Upon notification of such approval, the PI may begin the research. The department chair and Faculty sponsor (if any) is also notified in the case of such an approval.

Updates And Continuing Review Of Approved Projects

Please note that Federal Regulations limit the tenure of HINU IRB approvals to one year. Therefore, even approved projects are subject to what NIH calls "continuing review." Before the anniversary of each project's approval, the PI will receive a notice from the HINU IRB office that the approval is about to expire, and is prompted for information concerning the proposal with respect to "updating" or extending HINU IRB approval of the project for another year.

If the project is continuing, but the PI envisions that major changes will be made to the approved protocol, the project must be reviewed by the full committee. If the project is continuing as proposed, or is continuing with only minor changes to the protocol, then an expedited approval can usually be granted to update the approval for another year. PIs should note, however, that NIH has recently emphasized the need for thorough continuing review and monitoring of approved projects. Thus, projects that have been previously subject to full IRB review may be reviewed again by the full IRB prior to updating the approval.

At the very least, HINU IRB will require a copy of the consent form currently in use before issuing an expedited (updated) approval. Finally, if the PI reports that an approved project has been completed, that project will be designated Inactive and the HINU IRB documentation of that project will be archived.

CONSENT FORM REQUIREMENTS

These are reprinted here for your convenience in use with the provided consent form examples, which have superscripts referring to the required items. The consent form must include the following items when appropriate and applicable: Remove the superscript numbers from your working document.

1. A statement of the purpose of the research and a brief description of procedures to be followed. Identify any procedures that can be classified as experimental in nature; that is, not well proven or established.
2. A description of any reasonably foreseeable discomforts or risks to the subjects (psychological, sociological, or physical).
3. Inclusion of the Kansas Tort Claims Act statement when more than minimal risk is involved. The statement to be included if the risk is more than minimal is as follows: "In the event of injury, the Kansas Tort Claims Act provides for compensation if it can be demonstrated that the injury was caused by the negligent or wrongful act or omission of a state employee acting within the scope of his/her employment."
4. A description of benefits for the subjects or others which may be reasonably expected from the research.
5. A disclosure of alternative procedures that would be advantageous to the subject. (Usually applicable only to research involving medical treatments.)
6. An offer to answer any inquiries concerning the project and whom to contact, including phone number and address. (questions concerning the procedures, purpose or subject's rights).
7. A statement that participation is voluntary, that participation may be discontinued at any time and that refusal to participate or the decision to discontinue participation will be without penalty or loss of benefits to which the subject is otherwise entitled.
8. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
9. Name of principal investigator(s) and their departments and telephone number(s).
10. Name of subject if other than the one giving consent. (i.e. if subjects are not capable of giving informed consent.)
11. Signature of subject (if appropriate).

12. If subjects are under 18 years of age, or have limited capacity to give informed consent, consent from the parent/guardian is required.
13. Reference to any written explanations given to subjects of procedures to be followed if this explanation does not appear on the consent form.
14. An indication of the time commitment for participation in the study.
15. If the subject pool is likely to have individuals under the age of 18 and they are not to be included, the following shall appear below the signature: "With my signature I affirm that I am at least 18 years of age."
16. The Committee requires that the following should be included: "With my signature I acknowledge that I have received a copy of this consent form to keep." This could be placed under the signature line.
17. When the length of a consent form exceeds one page, a page number format indicating the total number of pages of the consent form (e.g., "1 of 3," "2 of 3," "3 of 3") should be used.

The consent form must include the faculty supervisor's name, department, and department phone number.

EXAMPLES OF INFORMED CONSENT STATEMENTS

Note: Preceding these two illustrative examples is a list of the requirements for informed consent forms. The superscripts that appear throughout these examples correspond to the superscripted requirements or elements of informed consent that appear on that list.

Example #1: A Project involving minimal risk
EXAMPLE OF INFORMED CONSENT STATEMENT

_____
(Name of the Study)

INTRODUCTION

The Department of _____ at the Haskell Indian Nations University supports the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish to participate in the present study. You may refuse to sign this form and not participate in this study. You should be aware that even if you agree to participate, you are free to withdraw at any time. If you do withdraw from this study, it will not affect your relationship with this unit, the services it may provide to you, or the Haskell Indian Nations University.

PURPOSE OF THE STUDY

The Purpose of this Study is:

Insert description of the purpose of the study.

PROCEDURE

The Procedures which will be followed in this study include the following:

Insert description of the procedures that will be followed in the study, such as interviews, surveys, etc.

RISKS

Insert a description of all burdens, inconveniences, pain, discomforts and risks associated with participation in the study. If no risks are anticipated, this should be stated explicitly.

BENEFITS

Insert a description of the potential benefits, if any, to the research subject. Clarify if these are direct benefits (e.g., to the subject), or indirect benefits, (e.g., to society). If there are no anticipated benefits, this should be stated explicitly.

PAYMENT TO SUBJECTS

Insert a statement regarding whether or not subjects will be paid and if so, how much and on what schedule.

INFORMATION TO BE COLLECTED (This section must include a description of the information to be used and disclosed, which identifies the information in a specific and meaningful fashion).

To perform this Study, researchers will collect information about you. This information will be obtained from: [insert description, e.g., your medical record at Clinic X, a health history taken by the researcher, a physical exam

conducted by the researcher, a health questionnaire]. In addition, information will be collected from the study activities that are listed in the Procedures section of this consent form.

The information collected about you will be used by: [list the PI and the class of other persons or groups authorized to use and/or disclose the information internal to the University, Haskell Campus, e.g., Dr. X, members of the research team, the Haskell healthcare facility collaborating in the study, officials at Haskell Indian Nations University that oversee research, including committees and offices that review and monitor research studies.]

In addition, Dr. X and [his/her] team will share information about you with: [list the persons or groups external to the University, Haskell Campus, with whom the researchers may share or disclose the information, e.g. collaborating researchers, colleagues, representatives of XXX Sponsor Name (the sponsor of the study). Include a statement about the purpose of these disclosures).

[If protected health information subject to HIPAA's Privacy Rule will be disclosed: Some persons or groups that receive your information may not be required to comply with the Health Insurance Portability and Accountability Act's privacy regulations, and your information may lose this federal protection if those persons or groups disclose it.]

The researchers will not share information about you with anyone not specified above unless required by law or unless you give written permission.

Indicate how long the researcher plans to use or disclose the information and include an expiration date. If there is no expiration date, state that, e.g., Permission granted on this date to use and disclose your information remains in effect indefinitely. By signing this form you give permission for the use and disclosure of your information for purposes of this Study at any time in the future.

INSTITUTIONAL DISCLAIMER STATEMENT

Kansas Tort Claims Statement Required only if Study involves discernable risks to subjects: "In the event of injury, the Kansas Tort Claims Act provides for compensation if it can be demonstrated that the injury was caused by the negligent or wrongful act or omission of a state employee acting within the scope of his/her employment."

REFUSAL TO SIGN CONSENT AND AUTHORIZATION

You are not required to sign this Consent and Authorization form and you may refuse to do so without affecting your right to any services you are receiving or may receive from the Haskell Indian Nations University or to participate in any programs or events of the Haskell Indian Nations University. However, if you refuse to sign, you cannot participate in the study.

CANCELING THIS CONSENT AND AUTHORIZATION

You may withdraw your consent to participate in this Study at any time. You also have the right to cancel your permission to use and disclose information collected about you, in writing, at any time, by sending your written request to: [Insert name and address of Researcher]. If you cancel permission to use your information, the researchers will stop collecting additional information about you. However, the research team may use and disclose information that was gathered before they received your cancellation, as described above.

SUBJECT CERTIFICATION:

I have read this Consent and Authorization form. I have had the opportunity to ask, and I have received answers to, any questions I had regarding the Study and the use and disclosure of information about me for the Study. I understand that if I have any additional questions about my rights as a research subject, I may call (785) _____ or write the HINU IRB, Haskell Indian Nations University, _____ , Lawrence, Kansas _____.

I agree to take part in this Study as a research subject. I further agree to the uses and disclosures of my information as described above. By my signature I affirm that I have received a copy of this Consent and Authorization form.

_____ _____

Type/Print Subject's Name Date

_____

Subject's Signature

[If signed by a personal representative, a description of such representative's authority to act for the individual must also be provided.]

Sincerely,

John Doe9,
Principal Investigator
Human Studies Dept.
200 Fisher Hall
Haskell Indian Nations University
Lawrence, KS 66045
785 _____

J.D. Smythe, Ph.D.18
Faculty Supervisor
Human Studies Dept.
200 Fisher Hall
Haskell Indian Nations University
Lawrence, Kansas
785 _____

_____

Signature of subject agreeing to participate

With my signature I affirm that I am at least 18 years of age and have received a copy of the consent, form to keep.

ANOTHER TYPE OF CERTIFICATION:

(This statement will be placed on the beginning of the instrument, survey, or questionnaire.)

I have had the opportunity to ask, and I have received answers to, any questions I had regarding the Study and the use and disclosure of information about me for the Study. Upon completion of this survey or questionnaire, I am consenting to the study and I affirm that I am at least 18 years of age.