Judson University, Elgin, Illinois

Institutional Review Board

Procedures and Policies

With acknowledgements to:
Trinity Christian College
North Park University
Wheaton College
Wartburg College
Walden University
Office of Human Subjects Research
(National Institutes of Health)

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INSTITUTIONAL REVIEW BOARD

Purpose:
Judson University Institutional Review Board policy requires that researchers respect and protect the rights and welfare of human subjects recruited for, or participating in, research sponsored through Judson University. The Judson University Institutional Review Board (IRB) maintains primary responsibility for oversight in the protection of human subjects recruited and/ or participating in research projects. Judson University IRB is guided by the principles set forth by the Belmont Report in accordance with Title 45 Code of Federal Regulations, Part 46 (45 CFR 46). Furthermore, the Judson University IRB will conform to all applicable federal, State and local laws and regulations.

The major roles of IRBs in the oversight of research are:

1. Initial review and approval or disapproval of the proposed research activity
2. Ensuring that the proposed *informed consent* process meets all of the requirements of 45 CFR 46.116
3. Providing continuing oversight for progress reports and protocols for ongoing research studies

Introduction:

History:

Protecting Human Subjects: The Adequacy and Uniformity of Federal Rules and their Implementation (1981)

The Commission stated that it "is clear that researchers and IRB members desire help both in understanding the policies and principles that underlie the regulations governing research with human subjects, and in identifying the issues to which one should be sensitive in designing or reviewing research proposals".

"*The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research."*

On September 30, 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research submitted its report entitled "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The Report, named after the Belmont Conference Center at the Smithsonian Institution where the discussions which resulted in its formulation were begun, sets forth the basic ethical principles underlying the acceptable conduct of research involving human subjects. Those principles, **respect for persons, beneficence**, and **justice**, are now accepted as the three quintessential requirements for the ethical conduct of research involving human subjects.

i. *Respect for persons* involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.
ii. *Beneficence* entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.
iii. *Justice* requires that the benefits and burdens of research be distributed fairly.

The Report also describes how these principles apply to the conduct of research. Specifically, the principle of *respect for persons* underlies the need to obtain informed consent; the principle of *beneficence* underlies the need to engage in a risk/benefit analysis and to minimize risks; and the principle of *justice* requires that subjects be fairly selected. As was mandated by the congressional charge to the Commission, the Report also provides a distinction between "practice" and "research." The text of the *Belmont Report* is thus divided into two sections: (1) boundaries between practice and research; and (2) basic ethical principles. The full text of the *Belmont Report*, which describes each of the three principles and its application, is provided in the Guidebook in Appendix 6; a summary follows.

The scope of IRB is broad. Generally, any research involving living humans, human tissues or specimens, or humans' records or data that is conducted by faculty, staff, student, employee, requires IRB review, irrespective of the risks, scope, funding, or location of the research. It is the responsibility of the IRB to protect human subjects, tissues, specimens, and human records.

The Higher Learning Commission requires that an IRB be implemented at Judson University.

Institutional Responsibilities

Each institution engaged in research must establish one or more IRB, or designate one from another institution, to review and approve research involving human subjects performed at its facilities. Before any human subjects research can be conducted, the institution must provide the department or agency a written **Assurance** that it will comply with the requirements of the Policy; the Assurance must be approved by the department or agency; and the institution must certify to the department or agency head that the research has been reviewed and approved by an IRB established in accordance with the requirements of the Policy [Federal Policy §46.103(a)].

Specification of quality standards in the conduct of research is an important function of the institutional leadership. Insistence upon well-conceived and -conducted research should be evident both in written policies and in actions of institutional officials. Research that is conducted so poorly as to be invalid exposes subjects and the institution to unnecessary risk. Approval procedures should be devised such that the institution supports only well-designed and properly executed research.

The Assurance

This set of principles should be in the form of a document that is readily available to all staff or faculty personnel who have need of it and can be a part of the staff or faculty manual. It should be written in clear, concise, unambiguous language, understandable to its intended audience.

Each IRB that is designated by an institution under an assurance of compliance approved for federal wide use by the Office for Human Research Protections (OHRP) under §46.103(a) and that reviews research involving human subjects conducted or supported by the Department of Health and Human Services (HHS) must be registered with HHS. An individual authorized to act on behalf of the institution or organization operating the IRB must submit the registration information.

IRB registration becomes effective when reviewed and accepted by OHRP.

(a) Each IRB must renew its registration every 3 years.

(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson

(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

(d) An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

The following information must be provided to HHS when registering an IRB:

(a) The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e)(1) The approximate numbers of:

(i) All active protocols; and

(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an "active protocol" is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

Each IRB must be registered electronically through http://ohrp.cit.nih.gov/efile unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

Assuring compliance with this policy -- research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for federal wide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself.

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with §46.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.

(4) **Written procedures** which the IRB will follow

> (i) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;
>
> (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and
>
> (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) **Written procedures** for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved,

the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under §46.101(b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §46.103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by §46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

IRB review of research

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(f) If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, the IRB must consider the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects. Department of Education (ED) regulations require, in addition, that when an IRB reviews research for one of its programs that purposefully requires inclusion of handicapped children or mentally disabled persons as research subjects, the IRB must include at

least one person primarily concerned with the welfare of these subjects [34 CFR 350.3(d)2); 34 CFR 356.3(c)(2)].

Procedures
Submission of Proposals. Before any activity involving human subjects can be undertaken at Judson University, the investigator shall submit it for approval to the irbchair@judsonu.edu. No research or recruiting of participants shall commence without prior approval from the IRB committee.

The plan of investigation shall include each of the following as applicable:

1. A completed Application for Review of Research Involving Human Subjects (see appendix).
2. Copies of any materials to be used, including research and interview protocols and survey instruments that comply with all applicable laws and policies.
3. A copy of the informed consent
4. Data Use Agreement from any organization providing records to the researcher
5. Signed Letter of Cooperation from any community partner who will be involved in identifying potential participants or collecting data.
6. Copyright, demonstrate public domain, and/or permission to use instruments.
7. If data includes participant identifiers, submit confidentiality agreements for everyone who will have access to data.
8. Plan for dissemination of results to stakeholders and participants.

Notifications
The IRB chair shall notify all investigators of the IRB's decision regarding their application. Approval of applications shall remain effective for twelve months. Investigators will be given an expiration date when they receive their approval. In the event that the IRB committee denies an application, the chair shall explain in writing why approval was not granted and shall specify changes that would be necessary for the application to be approved. The chair shall also notify investigators of their right to appeal the IRB committee's decision to the Provost office.

Continuing Review
The IRB committee shall conduct continuing review of research that it approves at intervals appropriate to the degree of risk, but not less than once per year.

Proposal Reviews:
All research involving human subjects completed at Judson University with students, faculty, staff, administrators, and/ or outside participants, shall be reviewed and approved, prior to data collection or enrollment of human subjects, at the appropriate level stated below. The level of review necessary for a specific investigation shall be based on the content and methodology of the study.

Level 1: Exempt Review
Research activities that qualify for Exempt review include:

1. Research in established or commonly-accepted educational settings, involving normal

educational practices, where students are not identified;

2. Research using educational tests (cognitive, diagnostic, aptitude, achievement) unless information obtained is recorded in a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and any disclosure of the human subjects' response outside the research could reasonably place the subjects at risk of

criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;

3. Research involving survey procedures, interview procedures, or observation of public behavior, that is not exempt under 2 above, if the human subjects are elected or appointed officials or candidates for public office; or federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter;
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publically 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 subjects;
5. Research and demonstration projects that are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Identifiers are: Social Security number, place of employment, code numbers, medical record numbers, position title, etc, that can be linked to individual people and perhaps associated with medical, financial, or employment information. Code numbers substituted for names, kept by the investigator are considered identifiers.

Level 2: Expedited Review

Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. Such research proposals shall be reviewed by two members of the IRB committee who will communicate their decision to the IRB chair. The members conducting the Expedited Review may exercise all the authority of the IRB committee, but may not disapprove the research. In the event that either of the members feel the proposal should receive full review, the investigator shall be informed and the proposal shall be put on the agenda for a "full" IRB review.

The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(a) The categories in this list apply regardless of the age of subjects, except as noted.

(b) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing,

unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(c) The expedited review procedure may not be used for classified research involving human subjects.

(d) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(e) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for

extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) 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.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) 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).

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) 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.

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight 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.

Level 3: Full Review
The Full Review shall be required for research that does not fall into the previous two categories.

Examples that require Full Review include research involving:

1. Vulnerable populations including children less than 18 years of age, pregnant women, handicapped or mentally disabled persons, prisoners, or economically or educationally disadvantaged persons.
2. Possible sources of physical, psychological or social risk including but not limited to aversive stimuli, sensory deprivation, sleep deprivation, or food deprivation.
3. Potential violations of rights to privacy and free choice (any situation involving possible deception in which full informed consent cannot be obtained before the study begins).

The chair shall distribute copies of the plan of investigation to a minimum of three to five committee members for review. The IRB committee has a right to request a meeting if further clarification is needed. Meeting attendance shall include the researcher (s), faculty supervisor, and no fewer than two IRB committee members present. The meeting can take place face to face or synchronously via a secure video link.

Educators Conducting Research

What data can be analyzed from my own current students?
Content that can be deemed a byproduct of typical educational practices for the current students with no student identifiers may include assignments (projects, journals, etc.) standardized test scores, discussions related to curriculum, school records, and additional data developed as part of typical educational practices that is not developed for the sole purpose of a doctoral or master's degree research project.
What types of data may not be collected or analyzed from my own current students?
Interviews
Focus groups
Surveys or tests developed for the purpose of a doctoral research project.

Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

IRB records.

(a) An institution, or when appropriate an IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described above.

(6) Written procedures which the IRB will follow

(i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

(ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and

(iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(7) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

(8) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(9) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(a) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(b) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration 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; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(d) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(e) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(b) A short form written consent document stating that the elements of informed consent required have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

> (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
>
> (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Definitions:

Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Certification means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Human Subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information or records.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

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.

Parent means a child's biological or adoptive parent.

Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Research subject to regulation, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

POINTS TO CONSIDER

1. Do institutional policies comply with applicable regulations and promote appropriate review and approval?

2. Are the relevant institutional channels of communication sufficiently open?

3. Do adequate procedures for monitoring research and conducting audits of the research process exist?

4. Does the institution adequately provide for the training of personnel in policies and procedures related to research with human subjects?

5. Does the institution support educational activities related to the design, conduct, and approval of research?

TRAINING FOR IRB COMMITTEE MEMBERS AND PARTICIPANTS

All members of the IRB must complete the training for "Protecting Human Research Participants" and have a copy of the certificate on file. Each investigator and research assistant must complete the training and have on file in the IRB office.

http://phrp.nihtraining.com/users/login.php

Other important web-based information and guidelines:

Regulations and Ethical Guidelines
http://ohsr.od.nih.gov/guidelines/index.html

IRB Protocol Review Standards
http://ohsr.od.nih.gov/irb/protocol.html

Decision Tree for How to Proceed with Review and Approval of Research Involving Human Subjects
http://ohsr.od.nih.gov/irb/tree.html

Office of Human Research Protections (OHRP)
http://www.hhs.gov/ohrp/

IRB REVIEW OF RESEARCH ACTIVITIES INVOLVING HUMAN SUBJECTS

Federal regulations allow an IRB to approve research only after it has determined that **all** of the following requirements are satisfied:

(a) Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk. Whenever appropriate, researchers should employ procedures that are being performed on subjects for diagnostic or treatment purposes.

(b) Risks to subjects are reasonable relative to **(1)** anticipated benefits, if any, to subjects, and **(2)** the importance of the knowledge that may reasonably be expected to result.

(c) The selection of subjects is equitable. In making this assessment the IRB must take into account the purposes of the research and the setting in which it will be conducted. The IRB must be particularly attentive to the special problems that may arise when research involves vulnerable populations, such as children, pregnant women, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons. If any of the subjects is likely to be susceptible to undue influence or coercion, the IRB may require additional safeguards in the study to protect such subjects.

(d) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, generally by means of a written consent document. The IRB will carefully review these documents to assure that they contain the required elements of informed consent (see 45 CFR 46.116) and that they are understandable to a lay person.

(e) The research plan makes adequate provisions for ensuring the safety of subjects.

(f) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(g) These requirements are incorporated in the NIH IRB review standards (see Attachment) and http://ohsr.od.nih.gov/irb/protocol.html). For all initial protocol reviews, these standards must be addressed and recorded in the minutes.

Protecting the subjects of research is a shared responsibility involving institutional officials, research investigators, IRBs and research subjects. If you want to know more about IRBs or the NIH's system of human subjects research review and regulation, please contact the OHSR, Building 10, room 2C146 (301-402-3444).

IRB Research Protocol

Include the following items when preparing materials for IRB submission.

1. APA format
    a. Cover page
    b. Numbered pages
    c. Abstract and Table of Contents
    d. Double-space (other than attachments)
2. Overview of project
    a. Purpose
    b. Rationale/ significance
    c. Description of general research strategy and design
3. Participants
    a. Who (sample/ population information, not by name)
    b. Criteria for selection
    c. How selected (volunteer or recruitment strategies)
    d. Relationship, if any, to researcher
    e. Risk factors for participants (be specific)
    f. If data collection is being conducted within specific organizations, describe participating organizations in general terms but not by name
4. Data collection methods
    a. Specific steps to gather data
        i. Provide supporting materials for research designs
    b. Instrumentation
    c. How data will be recorded
    d. Secure data storage
    e. Destruction of raw data
    f. If using mixed-methods design, describe each phase
5. Data analysis procedures
    a. Consistent with procedures for particular form of research design and strategy
        i. Provide supporting materials to clarify processes
    b. Statistical or other quantitative processes to be used
    c. Steps for qualitative analysis
6. Confidentiality and consent
    a. Secure storage of information
        i. Hard copy or electronic storage
        ii. Location of stored data
        iii. Security measures
    b. Retention of data
        i. Length of time hard copy, electronic, or other forms of data will be stored until destroyed, following analysis or project completion
    c. Reporting
        i. Specify no identifying characteristics will be included
        ii. Aggregate reporting

iii. Illustrative reporting for qualitative methods
iv. Distinctions as appropriate

d. Steps to gain participant consent
    i. Informed consent (See IRB guidelines)
        1. Identify as a project
        2. Outline data collection procedures
        3. Confidentiality
        4. Rights of participant, (to withdraw at any time with no penalty, what will happen with data if they choose to withdraw, etc…)
        5. Risk to participant
        6. Provide IRB with contact information and researcher's contact information
        7. Date
        8. Signature

7. Attachments
    a. Informed consent form
    b. Data collection tools, protocols, questions
    c. Appropriate IRB application form
    d. If conducting research within a particular organization, include permissions.

References

Decision Tree for How to Proceed with Review and Approval of Research Involving Human Subjects
http://ohsr.od.nih.gov/irb/tree.html

IRB Protocol Review Standards
http://ohsr.od.nih.gov/irb/protocol.html

Office of Human Research Protections (OHRP)
http://www.hhs.gov/ohrp/

Protecting Human Research Participants
http://phrp.nihtraining.com/users/login.php

Regulations and Ethical Guidelines
http://ohsr.od.nih.gov/guidelines/index.html

APPENDIX A

IRB MINUTES TEMPLATE

FORMAT FOR ALL IRB MINUTES

(The order in which agenda items are reviewed is at the discretion of IRB Chairs)

Minutes of the (Institute) IRB Meeting Held on (date)

Members Present: _____(Chair) _____
(indicate who is _____ _____
a non-scientist, _____ _____
non-NIH affiliated, _____ _____
etc.) _____ _____
_____ _____
_____ _____
_____ _____

Members Absent: _____ _____
_____ _____
_____ _____
_____ _____
_____ _____

Guests: _____ _____
(include _____ _____
affiliation) _____ _____

The meeting convened at ------(a.m. /p.m.) with a quorum present.

1. MINUTES OF THE MEETING HELD ON (DATE). (The minutes must be voted on and any changes documented.)

2. ANNOUNCEMENTS

3. INITIAL REVIEWS.

A. Principal Investigator:
Protocol Title:

Protocol precis or summary:

(a) Discussion:

General discussion:

Specific discussions: (include the following headings)

Scientific design (discuss and note that Institute pre-scientific review has been done)

Risks/benefits (assign a level of risk here or at the time of the IRB decision and vote, [(d) below] consistent with page 2, OHSR IRB Protocol Review Standards form. If children are to be enrolled, cite the regulatory reference)

Subject selection (discuss populations to be studied & recruitment plan)

Additional safeguards for vulnerable subjects

Minimization of risks to subjects

Privacy & confidentiality.

Consent document (document that all required elements are present)

Additional considerations (e.g., ionizing radiation; collaborative research; IND, other. State if these considerations do not apply)

(b) Stipulations (number the stipulations)

(c) Recommendations (number the recommendations)

(d) IRB Decision and Vote

State whether the vote is unanimous; if not, state how many members voted for, against or abstained. Document in or attach to the minutes the reason(s) for the minority opinion(s). Members who are affiliated with the protocol must recuse themselves from the IRB discussion and vote, and leave the room during the discussion and when the vote is taken. The minutes should state which member(s) left the room. If a quorum is lost because members recuse themselves, no action may be taken on the protocol.

If the protocol is approved with stipulations and/or recommendations, the minutes must state whether the IRB votes that the stipulations and/or recommendations are to be reviewed by the Chair, by a subcommittee of the IRB, or by the full IRB.

B., C., etc. (Follow same format as above for additional new protocols)

4. EXPEDITED INITIAL REVIEWS, EXPEDITED CONTINUING REVIEWS OR EXPEDITED AMENDMENTS

A. Principal Investigator:
Title and type of expedited action:
Date approved by IRB Chair or designee:

Description of expedited action: (Expedited actions must be listed separately in the minutes. The Chair should provide a brief explanation of any expedited actions. A vote is not required but the IRB has the prerogative to discuss, rescind or amend expedited actions.)

B., C. etc. (List additional expedited actions following the above format

5. CONTINUING REVIEWS (it is useful for the primary or secondary reviewer or the IRB Administrator to have the entire protocol file available for reference at the meeting)

A. Principal Investigator:
Protocol Title:
Protocol Number:
Expiration Date:

Protocol Precis or Summary (if not provided in discussion at (a) below):

(a) Discussion:

(b) Stipulations (number the stipulations)

(c) Recommendations (number the recommendations)

(d) IRB Decision and Vote (Include IRB's reaffirmation of the level of risk or establishment of a new risk level consistent with the OHSR Protocol Review Standards form, page 2)

B., C. etc. (Follow the same format as above for additional continuing reviews)

6. AMENDMENTS

A. Principal Investigator:
Protocol Title:
Protocol Number:
Expiration Date:

Description of the amendment:

(a) Discussion:

(b) Stipulations (number the stipulations)

(c) Recommendations (number the recommendations)

(d) IRB Decision and Vote (include a statement indicating whether or not the protocol's level of risk is altered by the amendment)

B., C. etc. (Follow the same format as above for additional amendments)

7. REPORT OF ADVERSE EVENT(S)

Principal Investigator:
Protocol Title:
Protocol Number:
Date of Adverse Event(s):

Description of the adverse event(s):

Document IRB's acknowledgement of receipt of the adverse event report(s) and discussion. Discussion of serious adverse events occurring on an NIH protocol should include immediate actions taken as a result of the event by the PI; recommendations for further actions, if any, by the IRB (e.g., suspension of subject accrual, etc.), and any necessary recommendations for further reporting (FDA or NIH officials, OHSR, Director CC, etc.).

If the adverse events are reported from non-NIH sites for the IRB's information only, and no action is required on the IRB's part, acknowledgement of the report(s) should be documented.

8. INFORMATION ITEMS

(a) Single Patient Exemption(s)

(b) Other

9. ADJOURNMENT The meeting adjourned at ----- (a.m. /p.m.).

APPENDIX B

APPLICATION FOR APPROVAL OF RESEARCH

APPLICATION FOR APPROVAL OF RESEARCH
Judson University
Institutional Review Board

Principle Investigator

1. Principle Investigator:
    a. Full name
    b. University department and position
    c. Email address
    d. Phone number
2. Person completing this application (if not PI)
    a. University department and position
    b. Email address
    c. Phone number
3. IF the PI is a student, the supervising professor or academic advisor
    a. University department and position
    b. Email address
    c. Phone number

Research Study Identification and Overview

1. Title of study
2. Plain language abstract of the study description and clear statement of its purpose
3. Dates for conducting study
4. Site(s) of study
5. Brief description of the population/ subjects participating in the research study and the criteria of inclusion and exclusion.
6. Identification of special subjects/ populations, if any, such as children and minors, pregnant women, cognitively-impaired persons, prisoners, traumatized and comatose patients, terminally ill persons, elderly, minorities.
7. Brief description of what subjects will be asked to do.
8. Brief description of risks and benefits of subject participation.
9. Brief description of confidentiality provisions and measures to protect the identity and privacy of subjects.
10. Is this research intended for teaching purposes only within courses at Judson University? Will you report or publication of this research be made outside of Judson University classes?

SUBMISSION REQUIREMENTS AND CHECKLIST

This IRB Application Form completed.
A detailed proposal prepared and attached, including but not limited to:

1. Title of research, date and name of principal investigator.
2. Full description of the research, its objectives, subjects, methods, venues, etc.
3. Full description of the population/ subjects participating in the research study and criteria of inclusion and exclusion.

4. Full description of confidentiality provisions and measures to protect the identity of subjects.
5. Full description of what subjects will be asked to do.
6. Full description of provisions to minimize risk to subjects.
7. Full description of provisions to care for subjects where there is risk of research-related accident or injury.
8. Full description of provisions to obtain informed consent from all individuals involved in the research (subjects, parents, participating institutions, etc.).
9. Supporting documents and instruments (blank copies of actual materials to be used, including surveys, questionnaires, subject recruitment materials, announcements, etc.).
10. Executed data agreements and authorizations, and final copies of consent forms of human subjects; should be approved by Judson University IRB committee as soon as possible if they are not submitted with the application.
11. Certification of approval by other committees/ IRB's and relevant agencies, if any.
12. Numbered pages with an identifying header or footer.

As principal investigator, I assure that the information provided is correct, that I will seek Judson University IRB approval for any substantive modifications in the research study, and that I will report promptly any incidents or anticipated problems that may occur during the course of the study that may affect subjects adversely or change the risks and benefits described.

Signature of principal investigator _____

Date of signature _____

If the PI is a student:

Signature of supervising professor or academic advisor _____

Date of signature _____

RISK/BENEFIT ASSESSMENT
APPENDIX C

Risk/Benefit Assessment

RISK

Regulatory definition of minimal risk: 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 (45 CFR 46.102(h) (i)).

Check appropriate risk category:

1._____The research involves no more than minimal risk to subjects.

2._____The research involves more than minimal risk to subjects.

____The risk(s) represents a minor increase over minimal risk, **or**

____The risk(s) represents more than a minor increase over minimal risk.

BENEFIT

Definition: A research benefit is considered to be something of health-related, psychosocial or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

Check appropriate benefit category (ies):

1._____no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition;

2.____no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge to further society understanding of the disorder or condition under study); or

3.____the research involves the prospect of direct benefit to individual subjects.