IRB Policies and Procedures – Butler University
Policies and Procedures for the Protection of Human Subjects in Research
Approved December 1994; modified December 2001, May 2009, July 2011, January 2012, December 2015, October 2017, January 2019, June 2019, May 2024.

Overview

At Butler University, responsibility for overseeing the policies and procedures for the protection of human subjects in research resides with the Provost/Vice President for Academic Affairs. Relevant functions and responsibilities include the development of an institutional policy, establishment of procedures to ensure protection for human subjects in research, continuing education of personnel with respect to the policy, modification of the policy to maintain its conformity with laws and regulations, and provisions of appropriate administrative support and legal assistance for the IRB. Management of compliance and maintenance of records also occurs under the aegis of the Office of the Provost, within the Butler Office of Sponsored Programs.

The IRB is the institutional body that governs the procedures to be used in research with humans, including protocol approvals as well as suspensions and terminations. The board ensures compliance with the Code of Federal Regulations and the Federal wide Assurance, a declaration of compliance for the protection of human subjects in research. Butler IRB members are appointed by the Provost/Vice President for Academic Affairs for three-year staggered terms.

Applicability

Any research involving human subjects that is conducted by faculty, staff, or students at Butler University (regardless of funding) must be submitted for review to the IRB. Review and approval by an IRB at another institution does not constitute an exemption from review by the Butler IRB, although the Butler IRB may elect to rely upon the review of another qualified IRB.

Human subjects research is defined as a **systematic investigation** designed to develop or **contribute to generalizable knowledge**. Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Research includes questionnaires, interviews, tests, observations, surveys, and other experiments under the auspices of the University. Under the definition of research, the rule identifies activities that do not meet the definition of research including: "Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research and historical scholarship)…that focus directly on the specific individuals about whom the information is collected."; public health surveillance activities authorized by a public health authority to assess onsets of disease outbreaks or conditions of public health importance.; and certain criminal justice and intelligence activities.

Institutional Review Board (IRB)

The IRB is responsible for the review, approval or disapproval of all research subject to this policy.

1. Membership

a) The IRB shall be composed of at least five individuals, including at least four faculty members and one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person affiliated with the University. The University IRB shall include at least one faculty member whose primary concerns are in a non-scientific area. The Director of the Butler Office of Sponsored Programs and the Research Compliance Officer will be ex-officio non-voting members of the IRB.

b) The Provost and Vice President of Academic Affairs will appoint all members. Membership on the IRB shall be staggered so that the terms of no more than two members will expire in any given year. Members may be reappointed.

c) The IRB shall elect two officers, a Chair and a Vice Chair, to serve three-year terms. Officers may be re-elected. The Director of the Butler Office of Sponsored Programs and/ or the Research Compliance Officer will be the Secretary to the IRB.

d) No member who has a conflicting interest in a particular research project may participate in the IRB's initial or continuing review of that research except to provide information requested by the IRB.

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

2. Responsibilities of the IRB

a) Be responsible for the review of proposed research projects involving human subjects and the approval, required modifications for approval or the disapproval of the proposed research.

b) Determine the most appropriate type of review (i.e. Exempt, expedited or full) for a proposed research project. In cases of an Exempt review, the IRB chairperson and/or one member of the IRB will evaluate the proposal. An Exemption Reviewer has the authority to approve a study, ask for clarification to ensure the procedures meet the Exempt criteria, or disapprove the research for exemption. The chairperson shall provide oversight to the Exemption review process to ensure compliance with the policies and procedures of this Board.

c) A proposed study that is disapproved for exemption is eligible for submission to the IRB as a Full or Expedited application. In cases of an Expedited review, the IRB chairperson and/or one or two members of the IRB designated by the IRB chairperson will evaluate the proposal. In cases of a Full Review, (1) the review must be conducted at a convened meeting (2) a majority of members must be present, (3) at least one member whose primary concerns are in nonscientific areas must be present at the meeting, and (4) the study must receive approval of a majority of the members present at the meeting.

d) Notify the investigator and the Provost and Vice President of Academic Affairs in writing, of its decision. 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) Conduct continuing reviews of approved research in accordance with this policy and report all findings and actions to the Provost and Vice President of Academic Affairs.
f) Require that information given to subjects as part of informed consent is in accordance with this policy and applicable law. Require documentation of informed consent or waive documentation in accordance with this policy.
g) Establish written policies for conducting the initial review, approving of continuing projects for annual review or any changes in procedure.
h) Require prompt reporting to the Provost and Vice President of Academic Affairs and the appropriate government agency of unanticipated problems involving risks to subjects or others.
i) Be responsible for reporting to the Provost and Vice President of Academic Affairs and the appropriate government agency any serious or continuing non-compliance by investigators.

3. Meetings

The IRB will meet at least twice a year. The IRB will have other meetings as needed. These meetings will be called by the Chair or at the request of a majority of the members on the IRB. A quorum is a majority of the voting members. A majority vote of the members present is required to approve research protocols.

4. The Criteria for Approval (45 CFR 46.111).

In order to approve research covered by this policy the IRB shall determine that all of the following requirements listed under45 CFR 46.111 are satisfied.

If the IRB determines that one or more of the criteria are not met, or if the IRB feels that it cannot determine whether a criterion is met, the study cannot be approved.

5. Federalwide Assurance (FWA)

The Federalwide Assurance (FWA) is a declaration of compliance with the federal regulations for the protection of human subjects in research. It is approved by the Office for Human Research Protections (OHRP) for all human subjects research conducted or supported by the Department of Health & Human Services (HHS). Butler University has committed to provide full compliance with the regulations under FWA Number: 00008336. Institution/Organization (IORG) #: 0003837. IRB Registration#: 0004541.

Responsibilities of Researchers

It is the responsibility of the researcher to know and comply with the Butler University Policy and Procedures for the Protection of Human Subjects and the requirements of the IRB. Research investigators shall make a determination as to whether research will involve human subjects, as defined. When it is not clear whether the research involves human subjects, researchers should seek assistance from the chair of the IRB or the research compliance officer.

Researcher Responsibilities

- Comply with the policy and procedures to obtain approval for the project.
- Complete the Application for Approval describing the research to ensure the protection of human subjects and submit the completed form to irb@butler.edu.
- Ensure that required compliance with the policy on informed consent is followed.
- Inform the IRB and the research compliance officer of any problems related to human subjects as part of the research.
- Ensure that the IRB is informed and approval is obtained for any changes in the research involving human subjects, including project continuations beyond the annual anniversary date of approval.
- During continuing review submissions, provide to the IRB and the research compliance officer a brief description of the results of the research, as well as benefits to and problems for the subjects.
- Maintain all appropriate records related to the research and the measures to protect human subjects.
- Require prompt reporting to the IRB, within five business days, of unanticipated problems involving risks to subjects or others and a noncompliance event.
- Demonstrate completion of an education program on the use of human participants in research by using an online education program through the Collaborative Institutional Training Initiative (CITI). Following investigators' initial training, refresher courses must be taken every three years. If the investigator is mainly engaged in biomedical research, he or she must complete the Biomedical Researcher CITI component. If the investigator is mainly engaged in social or behavioral research, he or she must complete the Social/Behavioral/Educational Researcher CITI component.

StudentResponsibilities

Should the researcher be a student, the student's academic or research advisor assumes primary responsibility for the proposed activity. The advisor is to familiarize the student with his or her obligation for the protection of subjects from risks incurred as a result of participating in the research. Student researchers must complete the Student Researcher Course of CITI training and repeat the training every three years.

Application and Protocol Guidelines

Any Butler employee or student planning to conduct research involving human subjects should proceed as follows:

Application Process

- Read the Basic HHS Policy for Protection of Human Research Subjects (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html) and complete the CITI training requirement (https://www.citiprogram.org).

- Complete and submit the application form and any associated research documents (i.e., Informed Consent Statement, flyers, brochures, survey, etc.) to irb@butler.edu.
- Application forms and information available at IRB Forms and Submission.
- The applicant submits an electronic copy with signatures and all necessary appendices as a single document to IRB@butler.edu.

Review Process

A preliminary review (pre-review) will be performed to ensure that all application elements are complete, and to confirm that all listed personnel have completed CITI training. The application will be held in abeyance until all training deficiencies have been addressed. Upon satisfactory preliminary review, the application is forwarded to the IRB.

Depending on the type of research study, IRB review will follow one of three types:

Exempt Review (review by the IRB Chair and/or the chair's designee only)

This applies to any Human Subjects Research that fits in one or more of the following categories:

(1) Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

> (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
>
> (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
>
> (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(3)(i) **Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:**

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch

activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed,or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Expedited Review (review by the IRB Chair and a second reviewer)

This applies to any research activities that (1) present no more than minimal risk to human subjects (45 CFR 46.102(i) defines minimal risk as "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"and (2) involve only procedures listed in one or more of the following categories:

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

i. 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 expeditedreview.)

ii. 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:

i. 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

ii. from other adults and children, 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 subject's 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). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Full Review (review by the full IRB)

This applies to any research studies involving more than minimal risk to human subjects as defined by 45 CFR 46.102(i).Research that is considered minimal risk may also be referred to the full board for review in the following situations:

- The research study does not fit any exemption and expedited category listed above.
- The study is referred to the full board by an expediting reviewer. For example, a reviewer may seek guidance from the full board in determining whether a study meets the regulatory definition of minimal risk or when the scientific question posed by the PI exceeds the expertise of the identified expediting reviewer pool

Exempt Review Process

The research compliance officer forwards an electronic copy of the application to the IRB chair and/or a board member to review the application. The research compliance officer records the rotation of board members conducting exempt reviews and, to the extent possible, equitably distributes the reviews among the board members (Note: the exempt review rotation and the expedited review rotation are separate.)

If the reviewer is a board member and determines that revisions are warranted, the reviewer composes an email specifying the revisions needed to the chair and the research compliance officer. If the revisions are minor administrative corrections, the chair will make the revisions on behalf of the applicant. If the revisions require clarification and justification, it will be sent to the applicant for responses. Once the revisions are made, the IRB chair will inform the Butler Office of Sponsored Programs to issue the approval letter. The director will sign the approval letter, and the Butler Office of Sponsored Programs will send it along with the approved documents to applicants and the IRB chair. The research compliance officer will store the approvals for the Butler Office of Sponsored Programs' files.

If/when the reviewer determines that no revisions are warranted, the reviewer communicates this approval to the chair and the Butler Office of Sponsored Programs director. Upon confirmation by the IRB chair, the director will sign the approval letter, and the Butler Office of Sponsored Programs will send it along with the approved documents to applicants and the IRB chair. The research compliance officer will store the approvals for the Butler Office of Sponsored Programs' files.

If the IRB chair reviews and determines that revisions are warranted, the chair will make the revisions on behalf of the applicant if the revisions are minor administrative corrections. If the revisions require clarification or justification, the chair composes an email specifying the revisions needed and sends the comments in an email to the applicant. The applicant then replies to the chair, who will evaluate the reply. This process is repeated until the reviewer determines that no further revisions are warranted.

If/when the IRB chair determines that no revisions are warranted, the chair communicates this approval to the Butler Office of Sponsored Programs director. The director will sign the approval letter, and the Butler Office of Sponsored Programs will send it along with the approved documents to applicants and the IRB chair. The research compliance officer will store the approvals for the Butler Office of Sponsored Programs' files.

Expedited Review Process

The research compliance officer forwards an electronic copy of the application to the chair and a board member based on rotation/expertise to serve as a "second reviewer." The research compliance officer records the rotation of board members conducting expedited reviews and, to the extent possible, equitably distributes the reviews among the board members (Note: the expedited review rotation and the exempt review rotation are separate.)

The second reviewer emails all concerns and recommendations about the protocol to the chair. Given this input, the chair determines whether and what revisions to the protocol are necessary.

If revisions are warranted, the chair communicates directly with the applicant, copying the research compliance officer on all correspondence. The applicant replies to the chair, who determines (consulting with the second reviewer as necessary) whether the applicant has resolved concerns. This process continues until the chair determines that no further revisions are warranted.

If/when the chair determines that no revisions are necessary, the chair communicates this approval to the Butler Office of Sponsored Programs director to issue the approval letter. The director will sign the approval letter, and the Butler Office of Sponsored Programs will send it along with the approved documents to applicants and the IRB chair. The research compliance officer will store the approvals for the Butler Office of Sponsored Programs' files.

Full Review Process

The research compliance officer will ask the Butler Office of Sponsored Programs director to arrange a meeting of the board, in accordance with established procedures.

If the board determines that revisions are warranted, the chair communicates directly with the applicant, copying the research compliance officer on all correspondence. The applicant replies to the chair, who determines (consulting with the board as necessary) whether the applicant has resolved concerns. This process continues until the chair determines that no further revisions are warranted. If/when the chair determines that no revisions are necessary, the chair communicates this approval to the Butler Office of Sponsored Programs director. The director will sign the approval letter, and the Butler Office of Sponsored Programs will send it along with the approved documents to applicants and the IRB chair. The research compliance officer will store the approvals for the Butler Office of Sponsored Programs' files.

Continuing Review/Closure Process

Continuing review/closure is required for all full-review protocols. Continuing review is not required in the following circumstances:

1. Any expedited Review Protocol, unless the IRB determines that the continuing review is required during the initial review. The IRB is required to justify why the continuing review would enhance protection of research subjects.
2. Any Exemption requiring limited IRB review.

3. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care."

Continuing Review procedures are described below.

- If the protocol is being extended, the investigator will send to the research compliance officer an electronic copy of the CR application, the originally approved application, and the most recent approval letter from the applicants. The renewal submission will be reviewed based on the level of review granted during the last IRB review.
- If the protocol is being closed, the applicants will send an email to the research compliance officer at irb@butler.edu, including the following information: study title; PI name and any applicable student researcher; message indicating that the study is closed. For expedited and full-board studies, a renewal/closure form must also be submitted.

The Butler Office of Sponsored Programs will administratively close a protocol if no continuing review/closure form has been submitted six months after the expiration date.

Procedures for Accepting the Approval of Another Institution's IRB

As permitted and encouraged by applicable federal regulations to eliminate duplicative efforts, the Butler IRB has approved the following Procedure for Accepting Approval of Another Institution's IRB (Cooperative Research Review)

I. Eligibility for Consideration

This Procedure for Accepting Approval of Another Institution's IRB applies only to human subject research meeting the eligibility requirements set forth below. For clarity and consistency, it is noted that human subject research is defined within Definitions 1 and 2 of the Butler University Policies and Procedures for the Protection of Human Subjects in Research (the "Butler IRB Policy"). The Butler IRB will evaluate on a case-by-case basis requests from investigators for the Butler IRB to accept and rely upon another institution's IRB approval in lieu of submitting a protocol (using the Butler University application form) to the Butler IRB for review and approval, consistent with 45 CFR 46.114.

Research is eligible for consideration only if:

1. The researcher has submitted, as an investigator, a protocol to another qualified IRB (i.e., one that has a current Federal Wide Assurance with OHRP) or the researcher has been asked to join an ongoing research project where approval has already been obtained from another qualified IRB;

2. A Butler University faculty member, employee, or student is a participating researcher in the project; and

3. The research will be conducted entirely at another institution, or Butler University is listed as a site on the approved application.

II. Materials to be Submitted

The researcher must submit the following documentation to the Butler IRB prior to beginning any data collection:

1. A completed, signed Application Form for Accepting Approval from Another IRB
2. Documentation establishing that the institution whose IRB approves the protocol has a current Federal Wide Assurance with OHRP;
3. A copy of the protocol and submission approved by the qualified IRB; and
4. A copy of the letter of approval from the other institution's IRB.

Note: The above materials must be submitted before a Butler investigator (faculty, staff, or student) can participate in a research project that has already received approval from another IRB.

III. Review Process, Authority for Review

The research compliance officer will review the Application for Accepting Approval of Another Institution's IRB. The research compliance officer shall have the sole authority to determine whether the research qualifies, based upon eligibility and submitted materials, for accepting another IRB's review and determination.

IV. Outcome

If all required materials have been submitted and the research meets the eligibility requirements for accepting approval of another institution's IRB, the research compliance officer will inform the Butler Office of Sponsored Programs director. The Butler Office of Sponsored Programs will, within five days of receipt of materials, send the investigator a letter accepting the approval from the other institution's IRB.

If, after reviewing the submitted materials, it is determined that the research fails to meet the eligibility requirements for accepting approval from another institution's IRB, the investigator will be required to submit the protocol to the Butler IRB for approval before data collection can begin.

If data collection has already begun, the Butler IRB chair or designee has the authority to require the investigator to cease data collection or take any other action deemed necessary under the circumstances. Likewise, if the investigator fails to submit all of the required materials before beginning data collection, the Butler IRB chair or designee has the authority to require the investigator to immediately cease data collection or take any other action deemed necessary under the circumstances. The investigator will be notified, in writing, within five business days of the IRB determination, and the investigator shall have an opportunity to respond in person or in writing.

The Butler IRB will follow the approval dates for the protocol as determined by the off-site IRB approval. Expiration of off-site IRB approval for a protocol means that the Butler IRB acknowledgment has also expired.

Although applications in this category are not reviewed by the Butler IRB, records are maintained. Procedures are outlined as follows:

- The applicant submits all necessary materials either as hard copy or electronic copy (with all signatures and appendices as a single document) to the research compliance officer at irb@butler.edu .
- If additional information is required, the research compliance officer communicates directly with the applicant.
- If/when no further information is needed, the research compliance officer communicates this information and the outcome to the Butler Office of Sponsored Programs director to issue the approval letter. The director will send the signed acceptance letter to the applicants and the research compliance officer. The research compliance officer will store it for the Butler Office of Sponsored Programs' file.

- If the other institution's IRB determines that the research qualifies as either expedited or full-board study, Butler applicants will be expected to additionally submit the renewal submission to the Butler Office of Sponsored Programs prior to the expiration date.

Guidelines for Faculty Completing Research Protocols

- Describe the purpose of the study, and in non-technical terms, what will happen to your subjects.

- Describe anypotential risks to the subjects.

- Give the ages, sex, and number of subjects, and explain how they will be recruited.

- Describe the procedures for obtaining informed consent as provided for in the Code of Federal Regulation section 46.116.

- Provide copies of questionnaires, letters, stories, or other documents to be used in the investigation.

- If minors are involved, describe the procedures for obtaining individual assent to participate from minors capable of giving assent, as well as the procedures to obtain parental or guardian consent.

- Explain fully the knowledge to be gained and/or the benefits to the subjects from the proposed research. Justify the risks that the subjects may incur.

- Explain what, if any, support services will be provided in the event of harm to a subject.

Informed Consent Procedures

Unless exempted or specifically waived by the IRB in accordance with federal regulations, it is the researcher's obligation to obtain the legally effective informed consent of the subject or the subject's legally authorized representative prior to the start of data collection. In addition, the researcher must solicit the assent of any minor subject capable of assenting. To be legally effective, informed consent should: be in language understandable to the subject or the representative; be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and not

include 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 research investigator, the sponsor, the institution, or its agents from liability for negligence.

Informed consent is more than just a signature on a form; it is a process of information exchange that may include, in addition to reading and signing the informed consent document, subject recruitment materials, verbal instructions, question/answer sessions, and measures of subject understanding.

Basic Elements of Informed Consent

A subject's consent is "informed" if he/she has a reasonable comprehension of that to which he/she is consenting. The investigator must use language appropriate to the subject's ability to comprehend. While the appropriate reading level of the consent document must be adjusted when different populations are recruited (e.g., college students, practicing physicians, homeless adults), investigators should strive to make their consent document comprehensible to the vast majority of their proposed subjects.

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Pursuant to 45 CFR 46.116 and 21 CFR 50.25, certain basic elements must be included in any informed consent document that is presented to potential research subjects. They are:

- Statement that study involves research; explanation of purposes of research and expected duration of subject's participation; description of procedures to be followed and identification of any experimental procedures.
- Description of risks or discomforts to subject.
- Description of benefit to subject or to others.
- Disclosure of alternative procedures, if appropriate.
- Description of the extent to which confidentiality will be maintained.
- For research involving more than minimal risk, explanation as to whether compensation and medical treatments are available if injury occurs.
- Explanation of whom to contact if questions arise about the research, the subject's rights, or research-related injury.
- Statement that participation is voluntary, refusal to participate involves no penalty or loss of benefits, and the subject may discontinue at any time.
- If minors are involved, a specific section for the parent/guardian to indicate refusal to allow participation.

Video/Audio Taping Procedures

Unless exemptible, projects involving the use of videotaping or audiotaping must make specific mention of these practices in the consent documents. The subject must have the choice of whether to participate in the electronic recording procedures. This consent is separate and distinct from consent to participate in the project; therefore a separate signature and date line is required. This consent may be integrated with the main consent. Videotapes must be appropriately secured during a project and destroyed after the project to protect the anonymity of the subject.

Additional Consent Requirements

When called for by the IRB, the research investigator must provide additional elements of information to the subject, including the possibility of currently unforeseeable risks; any additional costs to the subject that may result from participation in the research; the consequences of a subject's decision to withdraw from the research; procedures; informing subjects of significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation; and the approximate number of subjects involved in the study.

Documentation of Informed Consent

The researcher shall be responsible for ensuring that informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the IRB. Each person signing the written consent form is given a copy of that form. A written consent form should include those standard elements listed above, and contain the subject's signature and date lines. This form may be read to the subject or the subject's legally authorized representative. In any event, the research investigator shall give either the subject or the representative adequate opportunity to read the form before signing it.

Short Form

A "short form" may also be used, in which the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When the short form is used, researchers should ensure that a copy is given to the subject or the representative and that a written summary of what is to be said to the subject or the representative receives prior approval by the IRB. Furthermore, a witness should be present at the oral presentation, and the subject (or representative), the witness, and the researcher (or person obtaining consent) must sign the short form. Research investigators are responsible for placing the consent documents signed by human research subjects in a repository approved by the IRB chair.

Informed Consent Waivers

Waiver of Informed Consent. In cases where the research would be jeopardized by full consent procedures, full or partial consent may be waived by the IRB if it is found that:

- the research involves no more than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation. Also, the IRB may waive the requirement for signed consent forms if 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. Requests for a full or partial waiver of informed consent procedures must be accompanied by sufficient justification. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Waiver of Documentation of Informed Consent. When an IRB has not waived the requirement for seeking prospective informed consent of the subjects or the parental permission of children who are subjects, under the HHS regulations at 45 CFR 46.117(c), it may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- 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
- 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 (e.g., drawing a blood sample, or asking shoppers in a mall about the ambient lighting or temperature).

Special (Vulnerable) Populations

The IRB, in compliance with federal regulations, gives special consideration to proposed research involving: prisoners, children, persons with physical or mental handicaps, fetuses, pregnant women, in-vitro fertilized human ova, and other potentially vulnerable groups. Of particular concern is research involving children as subjects. Parental consent (as well as IRB approval) must be obtained prior to any research project that alters a child's routine or behavior. This includes research conducted in classroom settings, such as educational tests, and surveys. Parental consent may be waived only when the child is legally designated an emancipated minor or when it is determined by the IRB that parental permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children). Furthermore, assent of the children must be obtained unless the IRB determines that the capability of the children is so limited that they cannot reasonably give assent. For research conducted in settings in which general blanket participation forms have been signed by guardians, (e.g., schools, classrooms), specific consent of the guardian and assent of the child must still be obtained for each project conducted with these subjects unless there will be no

manipulation of the subject's behavior or disruption of the normal routine of the individuals in these settings.

Minors (Children) as Research Subjects

The Definitions section, below, provides the definition of minors per federal regulations. Of four categories of human research involving children, three categories may be approved by an IRB. The four categories differ from one another according to the level of risk involved, the prospect of direct benefit to the research subjects, and the anticipated research findings. For all four categories, the proposed research activity must satisfy the requirements for parental or guardian permission and child assent. Depending on the category, additional conditions must be met in order for the IRB to approve the research activities. The three categories approvable by an IRB are:

- Regulations allow the IRB to approve research if the IRB finds that the risks of the research are no more than minimal.

- Regulations allow the IRB to approve research if the IRB finds that: 1) more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject or by a monitoring procedure that is likely to contribute to the subject's well-being; 2) the risk is justified by the anticipated benefit to the subjects; and 3) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

- Regulations allow the IRB to approve research if the IRB finds that: 1) more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well-being of the child; 2) the risk represents a minor increase over minimal risk; 3) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; and 4) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

The fourth category of approvable research involving children requires the IRB to make certain findings and refer the proposed research activity to the Secretary of HHS for further review and approval.

Assent Requirement

"Assent" is defined by the regulations as a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. (45 CFR 46.402(b)). This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether children are capable of assent, the IRB is charged with taking into account the ages, maturity, and psychological state of the children involved. The IRB has the discretion to judge children's capacity to assent for all of the children to be involved in a proposed research activity, or on an individual basis.

Suspension or Termination of Approval

The 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, the Provost/Vice President for Academic Affairs, and if the research is externally funded, to the sponsor.

Review by Provost & Vice President of Academic Affairs

IRB approvals, actions, and recommendations are subject to review and to disapproval or further restrictions by the Provost/Vice President for Academic Affairs. Such disapprovals or further restrictions shall then be returned to the IRB and the investigator. However, IRB disapprovals, restrictions, or conditions cannot be rescinded or removed except by further action of the IRB or in the case of federally funded research, by appeal to the Department of Health and Human Services or other federal agency with appropriate jurisdiction.

Maintenance of Records

The IRB, in cooperation with the Butler Office of Sponsored Programs director, shall prepare and maintain documentation of its activities. Records associated with research protocols are retained for three years after the termination of the study. Required records include:

- Copies of all research protocols reviewed, scientific evaluations, if any, that accompany the protocols, approved sample consent documents, progress reports submitted by investigators, and reports of injuries tosubjects.
- Minutes of IRB meetings 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 controversial issues and their resolution.
- Records of continuing review activities.
- Copies of all correspondence between IRB and the investigators
- A list of IRB members as required by the US Department of Health and Human Services.
- Written procedures for the IRB as required by this policy.
- Statements of significant new findings provided to subjects.

Definitions

Butler University has adopted the following definitions from federal regulations to guide researchers and other interested parties in determining the necessity for review:

Assent: A subject's affirmative agreement, oral or written, to participate in research. Failure to object cannot be construed as assent.

Human subject: A living individual about whom an investigator, whether professional or student, conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Identifier: Information that can be used to link a sample or scientific result with a specific person or group of people. The Health Insurance Portability and Accountability Act (HIPAA) recognizes 18 identifiers that may make health information identifiable to an individual, including name; all geographic subdivisions smaller than a state, including street address, city, county, precinct, zipcode, and equivalent geocodes (except for the initial three digits of a zipcode if more than 20,000 people reside in the area); all elements of dates (except year), including birthdays, and ages over 89 (including year); phone numbers; fax numbers; email addresses; Social Security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers (including license plate numbers); device identifiers and serial numbers; web universal resource locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers; full-face photographic images and any comparable images; and any other unique identifier, characteristic, or code.

Informed consent. An ongoing process by which a subject (or his or her legal representative) voluntarily confirms his or her willingness to participate in a particular research project, after having been informed of all aspects of the research that are relevant to the subject's decision to participate. Informed consent is often but not always documented by means of a written, signed, and dated informed consent form with documentation, which is retained in the subject's record.

Institutional Review Board (IRB).Any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of biomedical and/or behavioral (general) research involving human subjects. The primary purpose of such review is to ensure the protection of the rights and welfare of the human subjects. This independent body is constituted of members with varying backgrounds (e.g., medical, scientific, nonscientific, and unaffiliated).

Interaction. Includes communication or interpersonal contact between investigator and subject.

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.

Investigator. Any individual involved in conducting human research studies; specifically, an individual who interacts with human subjects or accesses identifiable information for research purposes.

Legally authorized representative. 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. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research."

Minimal risk. Means that the risks or 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 examination or tests.

Minors (children). Persons who have not attained the legal age for consent to treatments or procedures involved in the research or clinical investigation, under the applicable law of the jurisdiction in which the research or clinical investigation will be conducted. Per Indiana state law, "minors" are defined as "persons less than 18 years of age"; therefore, they are considered "children" for purposes of the regulations. Exception: According to Indiana state law, a minor may consent for himself/herself if any of the following are true: 1) by law the minor is considered emancipated; 2) the minor is at least fourteen 14 years of age, not dependent on a parent for support, is living apart from parents or from a legally responsible individual or organization and managing his/her own affairs; 3) the minor is or has been married; 4) the minor is in the military service of the United States; or 5) the minor is authorized to consent to the health care by any other statute. For studies that involve prospective and/or current subject(s) that reside in states other than Indiana, the applicable law(s) of each applicable state will be reviewed to ensure that the applicable requirements for children to consent are met.

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).

Research. A systematic investigation designed to develop or contribute to generalizable knowledge. Research encompasses work that is conducted on or off campus and includes questionnaires, interviews, tests, observations, surveys, and other experiments, regardless of the content or routine nature of the research. The policy applies to research that is preliminary in nature as well as fully developed study. Research extends, but is not limited, to any systematic collection of data from human subjects that occurs in conjunction with classroom projects, "demonstration," and "service" programs.

Research protocol. The procedures and rules for dealing with the subject and the records derivedfrom the subject.