

PITTSBURG STATE UNIVERSITY

POLICY ASSURANCE HANDBOOK

for

THE PROTECTION OF HUMAN RESEARCH SUBJECTS

Month _June___, 2009

INTRODUCTION

When an institution engages in research that involves human subjects, that institution has an obligation to protect the rights and welfare of the subjects involved. The federal government has provided guidance to institutions through the Code of Federal Regulations, Title 45, Subtitles A through D, Part 46. These regulations mandate that any institution that participates in human subjects research, regardless of funding source, must have an institutional review board (IRB) to insure compliance and protection of the subjects involved.

At Pittsburg State University, the mandated board is the Committee for the Protection of Human Research Subjects (CPHRS). This committee is responsible to the President through the Dean of the Office of Continuing and Graduate Studies.

The CPHRS's responsibility is not to evaluate the quality of research being conducted, but rather to evaluate the adequacy of the protection of the rights and welfare of the human subjects potentially involved in the proposed research.

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I. Institutional Authority

Pittsburg State University (PSU) has established the Committee for the Protection of Human Research Subjects (CPHRS) as its Institutional Review Board (IRB). The authorized institutional official for this IRB is the President of PSU, Pittsburg, Kansas.

II. Jurisdiction and Purpose of the CPHRS

This committee is established to review proposed and ongoing research programs in order to comply with policies established by the Department of Health and Human Services (Title 45, CFR, Part 46) and Pittsburg State University for the protection and safety of human subjects used in biomedical and behavioral research. CPHRS has the authority to approve, modify, and disapprove all research activities in accordance with (IAW) 45 CFR 46 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

This document serves as Pittsburg State University's assurance which contains the written policies and procedures to be followed by the Committee for the Protection of Human Research Subjects, University Departments, faculty, staff, and students when conducting research involving human subjects.

The CPHRS grants authority to individual Pittsburg State University College Department Heads to determine (1) whether the proposed activity constitutes review by the CPHRS according to the definitions of “[research](#)” and “[human subjects](#)” as defined by 45 CFR 46.102(d)(f), and (2) whether research involving human subjects is exempt from IRB review as defined by 45 CFR 46.101(b) as outlined in [Form EX – 1](#), during the initial application process. The CPHRS is the final institutional authority in determining approval and disapproval of all applicable research involving human subjects, regardless of funding source or support. All research involving human subjects covered by this assurance will not be conducted until the CPHRS has reviewed and approved the research protocol and informed consent requirements IAW 46.111, 46.116, and 46.117.

All human subjects research involving pregnant women, human fetuses and neonates (covered in subpart B of 45 CFR 46), prisoners (subpart C), and children (subpart D) will only be approved by the CPHRS. Departments are not authorized to exempt these types of research from review.

III. Governing Principles of the CPHRS

The CPHRS operates in accordance with both 45 CFR 46 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>) and *The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects and Research*, April 18, 1979, (<http://ohsr.od.nih.gov/guidelines/belmont.html>) regardless of whether the research being conducted is subject to Federal Regulations or with whom the source of support originated.

Pittsburg State University and its faculty, staff and student body recognize the importance of their responsibility for protection of the rights and welfare of human subjects in research. No human subject involved in a research activity will be exposed to unreasonable risk to health or well-being.

Research involving minors (persons less than 18 years of age) and others who may have limited ability to provide informed consent and which involves greater than minimal risk must be approved by CPHRS.

Minimal risk is defined 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 or routine physical or psychological examinations or tests.” (45 CFR 46.102(i))

Research involving children, prisoners, pregnant women, human fetuses and neonates as defined in 45 CFR 46, Subparts B, C, and D, must be approved by CPHRS.

Except for research exempted (see Form CR1: Criteria Review for exemption criteria) or waived IAW 46.101(b) or 46.101(i), informed consent will be:

- (a) sought from each prospective subject or the subject's legally authorized representative, IAW, and to the extent required by 46.116;
- (b) appropriately documented, IAW, and to the extent required by 46.117.

Confidentiality of information received from human research subjects will be fully protected, both during and after the conduct of a research activity IAW the limits of the law.

Requests by any human research subject for withdrawal from a research activity will be honored promptly without penalty or loss of benefits to which the subject is otherwise entitled.

IV. Procedures / Guidelines

Is Research Subject to Review?

The first issue that must be determined is whether the proposed research is subject to the CPHRS review. This decision can be determined by the following two questions:

1. Does this activity involve research?
2. Does this research involve human subjects?

According to Federal Policy 45 CFR 46.102(d)(f), **research** is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” The purpose of gathering the data is one way to determine whether the project is generalizable. If the principal investigator intends to publish the results or present the information obtained from the research project outside of the group it was obtained (i.e. outside the classroom) the project/research is designed to contribute to a larger audience. Therefore, the research in this case is generalizable. Most internal program evaluations to determine student satisfaction or knowledge gained through routine program/classroom activity do not meet the federal definitions of research. However, if the principal investigator's intention is to publish the results of the evaluation, this now becomes generalizable knowledge and subject to review. **Human subjects** are defined as “living individual(s) 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.” **Identifiable private information** includes “information about behavior that occurs in a context in which an individual can reasonably expect that no observation 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).”

If the responses to both of the above questions are “Yes,” the proposed research is subject to the CPHRS review.

Application for Research Proposal Review Process

The forms used in the application for review process incorporate the requirements and criteria set forth in [Federal Policy 45 CFR 46](#). The intent of this format is to educate, train, and provide documentation for those involved in the application and review process each time this procedure is followed.

Please refer to the following steps and associated flow diagrams for submitting the research proposal for CPHRS review:

Exempt Review Criteria

1. Determine if exemption criteria apply to the human subjects research by referring to Form CR-1: Criteria Review or the list below.
(You can also refer to the flow diagram [Exempt Review Process.](#))

Exemption categories DO NOT APPLY when the research activities include any of the following:

- Prisoners, fetuses, pregnant women or human in vitro fertilization
- Survey or interview techniques which include minors (under 18 years of age) as subjects
- Research involving the observation of the public behavior of minors (under 18 years of age)
- The deception of subjects
- Techniques which expose the subject to discomfort or harassment beyond levels encountered in daily life (the research activity presents more than minimal risk to human subjects)

Exemption criteria are met if ONE or MORE of the following applies:

- Is this research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - Research on regular and special education instructional strategies
 - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods (often referred to as “action research”)
- Does this research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, WITHOUT:
 - Information being obtained and recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and
 - Any disclosure of the human subjects’ responses 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.
- Does this research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, EXCLUDING:
 - Human subjects who are elected or appointed public officials or candidates for public office, or
 - Federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research thereafter.
- Does this research involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens where the subjects cannot be identified, directly or through identifiers linked to the subjects?
- Is this research or demonstration project(s) subject to the approval of department or agency heads designated to study, evaluate, or examine:
 - Public benefit or service programs?
 - Procedures for obtaining benefits or services under programs?
 - Possible changes in or alternatives to those programs or procedures?
 - Possible changes in methods or levels of payment for benefits or services under those programs?
- Do these taste and food quality evaluations and/or consumer acceptance studies INCLUDE:
 - Wholesome foods without additives being consumed?
 - A food that is consumed containing 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 (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture?

- a. If exemption criteria apply, complete Form CR-1: Criteria Review and [Form AP – 1](#).
 - i. **Submit research proposal for exempt review to Department and the CPHRS**
 - ii. **If Exempt Criteria does not apply, go to step 2.**
- b. Note: If the proposed research activity is exempt from CPHRS review, informed consent is not required.

Expedited Review Criteria

2. Determine if expedited criteria apply to the human subjects research by referring to [Form CR – 1](#) or the list below.
(You can also refer to the flow diagram [Expedited Review Process](#).)

Expedited criteria DO NOT APPLY when the research activities include any of the following:

- Prisoners, fetuses, pregnant women or human in vitro fertilization
- Survey or interview techniques which include minors (under 18 years of age) as subjects
- Research involving the observation of the public behavior of minors (under 18 years of age)
- The deception of subjects
- Techniques which expose the subject to discomfort or harassment beyond levels encountered in daily life (the research activity presents more than minimal risk to human subjects)
- Identification of subjects/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.
- Classified research involving human subjects.

Expedited criteria are met if ONE or MORE of the following applies:

- Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - Research on drugs for which an investigational new drug application is not required.
 - Research on medical devices for which (i) an investigational device exemption application 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.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - from healthy, non-pregnant adults who weigh at least 110 pounds. (Amounts drawn may not exceed 550ml in an 8 week period and collection cannot exceed more than 2 times per week.
 - 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. (Amounts drawn may not exceed the lesser of 50ml or 3ml per kg in an 8 week period and collection may not occur more than 2 times per week.
- Prospective collection of biological specimens for research purposes by noninvasive means.
 - hair and nail clippings in a non-disfiguring manner
 - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
 - permanent teeth if routine patient care indicates a need for extraction
 - excreta and external secretions (including sweat)
 - 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
 - placenta removed at delivery
 - amniotic fluid obtained at the time of rupture of the membrane prior to or during labor

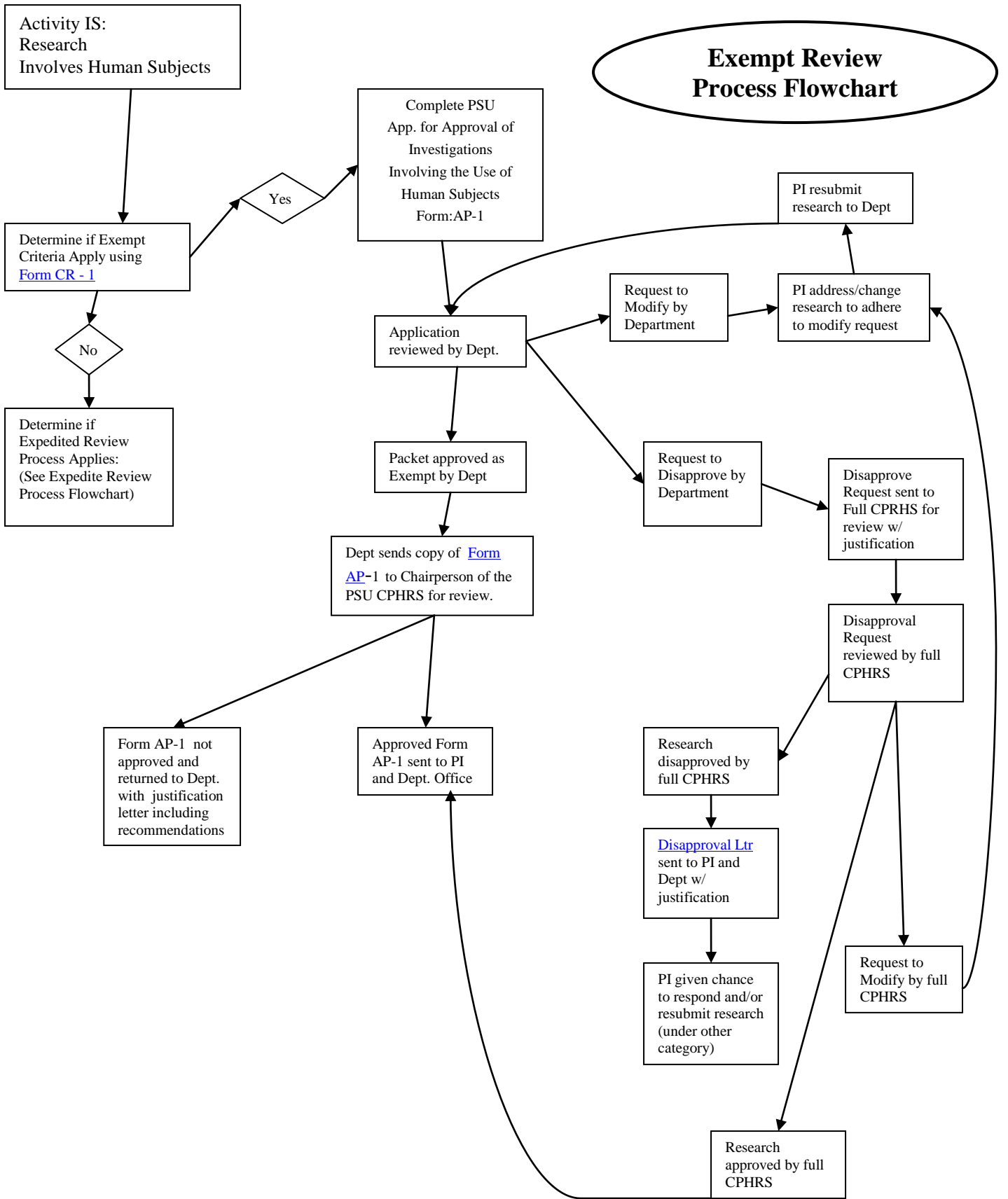
- supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
- mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
- sputum collected after saline mist nebulization
- 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.
 - 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
 - weighing or testing sensory acuity
 - magnetic resonance imaging
 - electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
 - moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- 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)
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- 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.
- Continuing review of research previously approved by the convened IRB (the CPHRS) as follows:
 - 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
 - where no subjects have been enrolled and no additional risks have been identified; or
 - where the remaining research activities are limited to data analysis
- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories ED2 through ED8 do not apply but the CPHRS has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
- Minor changes in previously approved research during the period (of one year or less) for which approval is authorized
 - a. If the above listed expedited criteria apply, complete [Form CR – 1](#), Form AP-1 and Informed Consent Form(s).
(Full Informed Consent forms) [Form IC -1](#), [Form IC – 2](#)
(Request for Waiver forms) [Form IC – 3](#), [Form IC - 4](#)
 - i. Submit research proposal for expedited review to Department and the CPHRS.
 - b. If Expedited criteria do not apply, go to step 3.

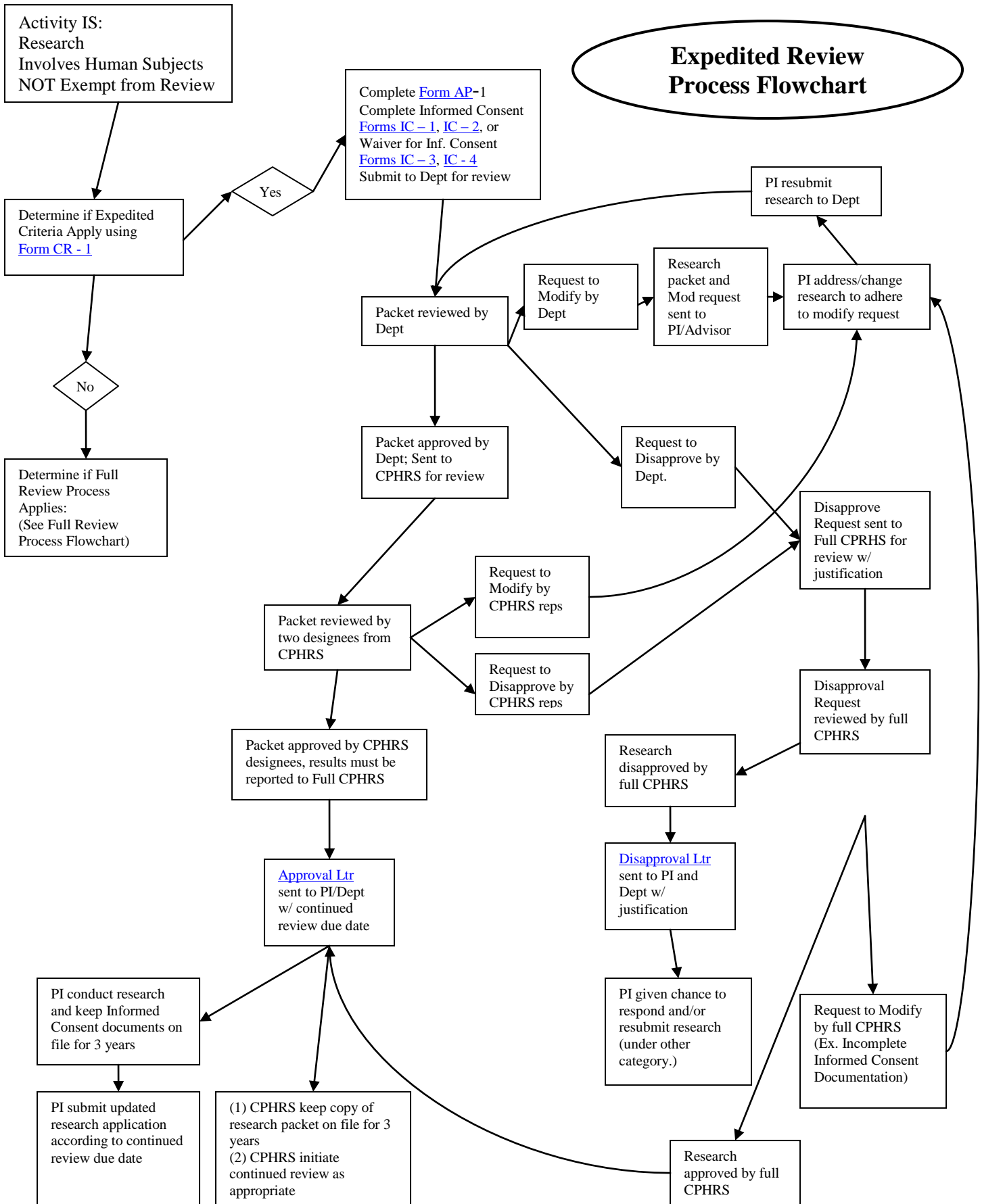
Full Review Criteria

3. Determine if full review criteria apply to the human subjects research by referring to [Form CR – 1](#) or the below listed criteria.
(You can also refer to the flow diagram [Full Review Process](#).)

Full review criteria are met if ONE or MORE of the following applies:

- Research in which more than minimal risks are involved (techniques which expose the subject to discomfort or harassment beyond levels encountered in daily life)
- Research in which identification of subjects/responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's 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 not greater than minimal.
- Research involving prisoners, fetuses, pregnant women, or human in vitro fertilization
- Research involving survey or interview techniques which include minors (individuals under 18 years of age) as subjects
- Research involving the observation of the public behavior of minors (individuals under 18 years of age)
- Research involving the deception of the subjects
- Research which compromises informed consent
- Research which involves the use of information that is not publicly available such as student records or medical charts. Even if the researcher has routine access to such records, if individual identifiers are included in these records, they must be reviewed by full committee.
- Research involving vulnerable populations such as mentally disabled persons or economically or educationally disadvantaged persons
 - a. If the above listed expedited criteria apply, complete [Form CR – 1](#), [Form AP-1](#), and Informed Consent Form(s).
(Full Informed Consent forms) [Form IC -1](#), [Form IC – 2](#)
(Request for Waiver forms) [Form IC – 3](#), [Form IC - 4](#)
 - b. Submit research proposal for full review to Department.





Full Review Process Flowchart

Activity IS:
 Research
 Involves Human Subjects
 NOT Exempt from Review
 NOT Eligible for Expedited Review

Complete [Form CR-1](#)
 Complete [Form AP-1](#)
 Complete Informed Consent
[Forms IC-1, IC-2](#), or Waiver
 for Inf. Consent Forms [IC-3, IC-4](#)
 Submit to Dept for review

Packet reviewed by Dept
 Packet approved by Dept; Sent to CPHRS for review

Packet reviewed by Full CPHRS

Packet approved by full CPHRS

Research disapproved by full CPHRS

Request to Modify by full CPHRS
 (Ex. Incomplete Informed Consent Documentation)

[Approval Ltr](#) sent to PI/Dept w/ continued review due date

[Disapproval Ltr](#) sent to PI and Dept w/ justification

PI conduct research and keep Informed Consent documents on file for 3 years

PI given chance to respond and/or resubmit revised research.

PI submit updated research application according to continued review due date.

(1) CPHRS keep copy of research packet on file for 3 years
 (2) CPHRS initiate continued review as appropriate

PI resubmit research to Dept

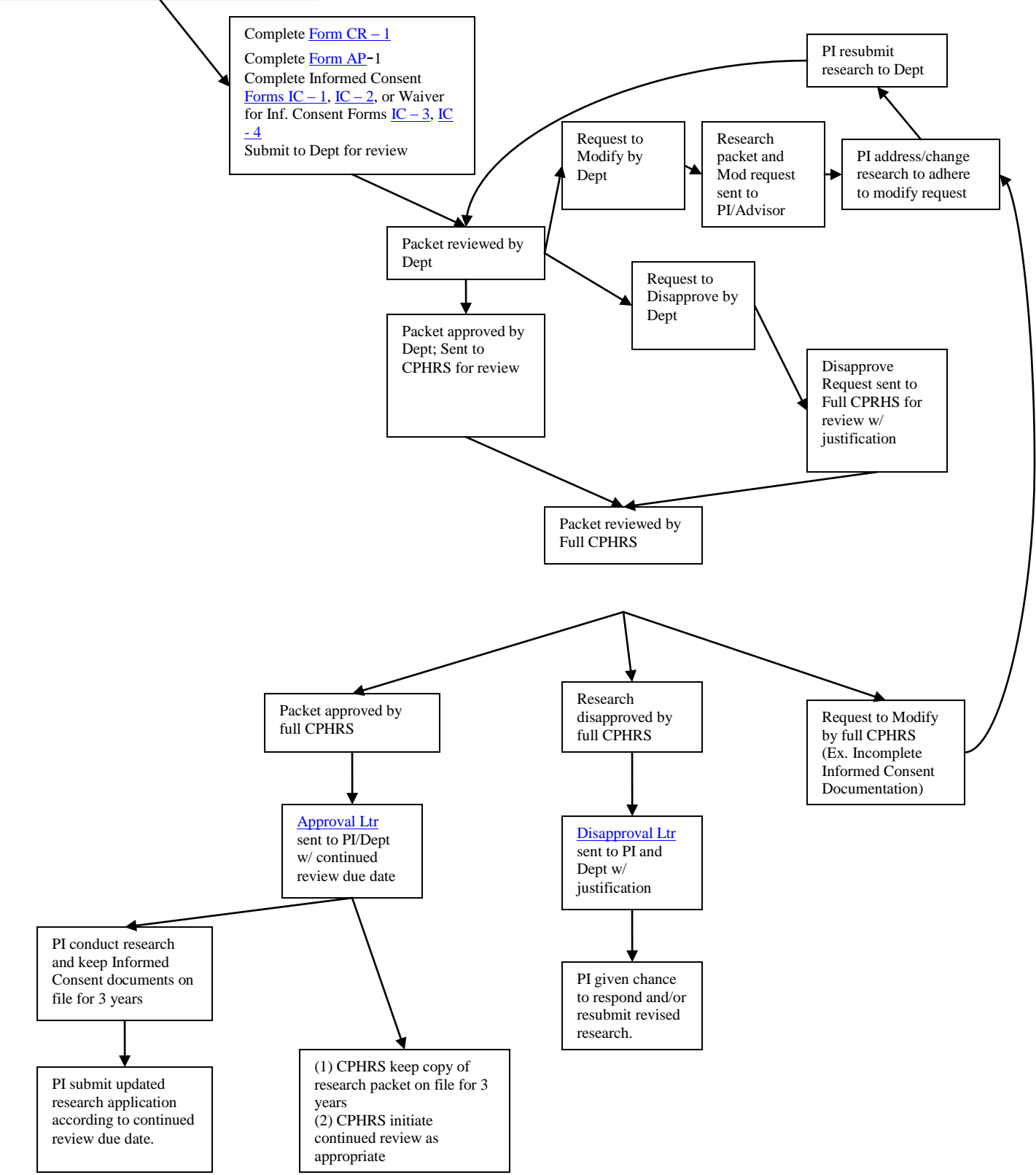
Request to Modify by Dept

Research packet and Mod request sent to PI/Advisor

PI address/change research to adhere to modify request

Request to Disapprove by Dept

Disapprove Request sent to Full CPHRS for review w/ justification



V. CPHRS Review Meetings

The CPHRS is responsible for setting agendas and calling convened meetings as often as required to accomplish the business of the IRB. The meetings are open to the public except for those discussions which the Chair determines deal with private or confidential information. Full Board actions require the presence of a quorum of the voting members, defined as a majority of the membership (excluding the Chair who only votes in the even of a tie) including at least one member whose primary concerns are in nonscientific areas.

Principal Investigators (PIs) are expected to present new research proposals at the CPHRS meetings and to respond to questions from committee members. PIs are excused from the meeting prior to the vote of the CPHRS. PIs are not necessarily expected to be present for the continuing review of research activities, although their presence may be required by the Chair.

Committee meetings are conducted in accordance with Roberts Rules of Order. At a minimum, the Chair conducts the meeting, there is a predetermined agenda, the minutes of the prior meeting are voted upon, and all actions and resolutions require the voice or show-of-hands vote of the members present following discussion and the making and seconding of a motion.

The CPHRS may vote to approve, disapprove, or modify a research proposal. These actions require the vote of a majority of the members present at the meeting. The Chair does not vote, except to break a tie. If the vote is not unanimous, the minority opinion must be recorded in or attached to the minutes. A committee member may abstain from voting for any reason, without explanation. A member may change his/her vote until the time the vote is finally announced by the Chair. After that, a member's vote may be changed only by permission of the Committee which may be given by general consent.

The Expedited Research Review process requires only two CPHRS members to review a research proposal. This Expedited review process may also be used to review and approve minor changes in previously reviewed research during the period for which original approval is authorized. In both cases, the CPHRS Chair, or designated representatives conducting the Expedited review must inform the full CPHRS of research which has been approved by this procedure, and this information should be documented in the minutes.

The CPHRS is authorized to modify, suspend, or terminate approval of research that has been associated with unexpected serious harm to subjects, or is not being conducted in accordance with 45 CFR 46 or the Committee's decisions, conditions, or requirements.

By Federal Regulation, institutional officials may not approve research that has previously been disapproved by the CPHRS.

This section information was largely adapted from the National Institutes of Health (n.d.). website.

A. CPHRS Membership

Committee criteria include (but is not limited to):

- a. Membership is greater than five individuals
- b. Member backgrounds vary to promote complete and adequate review of research
- c. Member knowledge and compliance to PSU commitments and regulations
- d. Member knowledge and compliance to applicable law and federal regulations
- e. Member knowledge and compliance to standards of professional conduct and practice
- f. At least one member has a differing profession
- g. At least one member has primary concerns in scientific areas

- h. At least one member has primary concerns in nonscientific areas
- i. At least one member is not affiliated with PSU
- j. Member selection is not made on the basis of gender, but nondiscriminatory efforts are made to include both men and women

Membership includes (but is not limited to):

- a. Chair, Dean of Continuing and Graduate Studies
- b. Two representatives from the College of Arts and Sciences
- c. Two representatives from the Kelce College of Business
- d. Two representatives from the College of Education
- e. Two representatives from the College of Technology
- f. One community representative
- g. One classified representative

The CPHRS may, in its discretion, invite individuals (*ad hoc members*) with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the committee. *Ad hoc members* may not vote with the CPHRS to determine approval or disapproval of research.

Full CPHRS actions require the presence of a quorum of the voting members, defined as a majority of the membership.

Current Membership

The current members of the CPHRS may be found at the following PSU web site:
<http://www.pittstate.edu/cgs/FacultyNotes/cphrs.html>.

CPHRS and Department Training

The CPHRS Chair insures members and Department Heads receive a copy of the *Pittsburg State University Assurance Handbook*, a copy of [The Belmont Report](#), *Ethical Principles and Guidelines for the Protection of Human Subjects and Research*, April 18, 1979, and a copy of [45 CFR 46, Protection of Human Subjects](#).

The University Handbook is designed, in conjunction with the forms utilized, to educate both the principal investigator, as well as the approving authority each time a research proposal is evaluated. Evaluation criteria are adapted directly from the appropriate sections of 45 CFR 46. Since the CPHRS disseminates partial discrimination to each department in determining the categorization and approval of research, it is critical that each Department Head and designated representative(s) is intimately familiar with the Federal Regulations and requirements.

On-line tutorial training regarding protection of human research subjects is highly encouraged and available through the U.S. Department of Health and Human Service, National Institutes of Health web site at titled [Human Participant Protections Education for Research Teams](#). This training takes approximately two hours to complete and allows you to print a certificate of completion after each section.

CPHRS Decision Actions

The Committee for the Protection of Human Research Subjects (CPHRS) will decide on research proposals after appropriate discussion and voting by a majority of the quorum members present. The investigator will receive documentation of the decision in one of three formats:

1. Approval of Research as indicated with an Approval Letter signed by CPHRS Chair or designee
2. Disapproval of Research as indicated with a Disapproval Letter signed by CPHRS Chair or designee
3. Request for Modification of Research as indicated with a Modification Letter by the CPHRS Chair or designee

Disapproval of research by the CPHRS indicates that there are ethical or procedural conflicts in the project proposal which probably cannot be remedied without major revision. Research cannot be conducted by the principal investigator.

Requests for modification of research by the CPHRS indicate that the details and procedures involved with the research project are not fully complete, but the project is given conditional approval of the proposal. The CPHRS will indicate on the form (and in the minutes) the specific areas that need to be addressed, changed, or clarified by the principal investigator if she/he wishes to implement the proposal. These modifications must be re-submitted to the CPHRS for Full Review at a later date. Research cannot be conducted by the principal investigator until final approval by the CPHRS.

CPHRS Criteria for Approving Research

When reviewing research proposals that include human subjects, the CPHRS must determine that all of the following requirements are satisfied prior to approval.

- (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.

(8) 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.

CPHRS Documentation of Activities

Pittsburg State University's CPHRS (IRB) utilizes this handbook and the forms and application materials referenced within as formats to document 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 controversial issues and their resolution.
 - (3) Records of continuing review activities. ([Forms CRF – 1](#), [CREA – 1](#), [CRES – 1](#))
 - (4) Copies of all correspondence between the IRB and the investigators.
 - (5) A list of IRB members in the same detail as described in [§46.103\(b\)\(3\)](#).
 - (6) Written procedures for the IRB in the same detail as described in [§46.103\(b\)\(4\)](#) and [§46.103\(b\)\(5\)](#).
 - (7) Statements of significant new findings provided to subjects, as required by [§46.116\(b\)\(5\)](#).
- (b) The records required by this policy shall be retained for at least 3 years by the CPHRS, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research by either the responsible Department or the Principal Investigator. All records shall be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner.

VI. Continuing Review

In conducting continuing review (at intervals appropriate to the degree of risk, but not less often than once a year), the CPHRS must ensure the same criteria used for approval during the initial review are satisfied for subsequent reviews. These criteria include risk to subjects, potential benefits to subjects and society, informed consent, and safeguards for human subjects. Continuing review constitutes review of the entire research protocol, not just changes in a protocol.

Federal regulations require that all research projects approved by CPHRS are monitored annually as a minimum (continuing review.) It is the principal investigator's responsibility to ensure continuing review is conducted by the project anniversary date. Projects not reviewed by CPHRS annually will be designated as inactive and approval will be suspended.

Research projects which have been completed prior to the annual anniversary date do not need to go through the continuing review process. However, CPHRS must be notified that the research project has been completed.

In general, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review. However, the expedited review process (assigning two CPHRS members for review versus the full committee) may be used for continuing review of research that was previously approved by the full CPHRS as follows:

(a) Where:

- the research is permanently closed to the enrollment of new subjects;
 - the subjects have completed all research-related interventions; and
 - 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.

When the principal investigator submits research for continuing review under expedited conditions, he/she must include a letter stating which of the above criteria apply to the research being conducted. **Template [Form CREA – 1](#) may be used for this documentation.**

VII. Research Involving Children

Subpart D, of 45 CFR 46 provides additional protection for children involved as subjects in research. Due to the sensitive nature of involving minors (under 18 years of age in the state of Kansas) in human subjects research, this guidance is included to provide further clarification to the Federal Regulations when including children in research. (Specifically, requirements are established for obtaining permission (not consent) by parent(s)/guardian(s) **AND** the assent of the child subject.)

Definitions

1. Children – persons who have not attained the legal age for consent to treatments or procedures involved in the research (under 18 years of age in the state of Kansas.)
2. Assent – a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
3. Permission – the agreement of parent(s) or guardian to the participation of their child or ward in research.

Categories of Research

1. Research not involving greater than minimal risk. There are no additional requirements of investigators or the CPHRS for activities involving this degree of risk other than those dealing with permission and assent.
2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. Research which falls in this risk category may be conducted if the following provisions apply:
 - a. The increased risk is felt to be justifiable by the anticipated benefit to the individual child subject;
 - b. The relationship between the anticipated benefit and the risk involved in the research is at least as favorable as that involved in available alternative approaches to diagnosis and/or treatment of the child.
 - c. Adequate provisions are made for obtaining assent of the child and permission of parent(s)/guardian.

3. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects but likely to yield generalizable knowledge about the subject's disorder or condition. Research in this category may be conducted if the following provisions apply:
 - a. The risk to the child subject is felt to represent a minor increase over minimal risk.
 - b. The experience of the child undergoing the experimental intervention or procedure will be reasonably commensurate to that which he/she would experience in the course of his/her actual or expected medical, dental, psychological, social or educational situations.
 - c. The research is expected to yield generalizable knowledge about the child subject's disorder or condition; and
 - d. Adequate provisions are made for obtaining assent of the child and permission of parent(s)/guardian.
4. Research that does not fall into the above categories yet presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children. All activities involving children as subjects that do not fall into one of the above three categories (i.e., because they involve greater degrees of risk) require review by the Secretary of DHHS in consultation with a panel of experts in addition to review by the Committee. Request for review of such activities should be directed to the chairperson of the HSC.

Requirements for Permission of Parent(s)/Guardian and for Assent of the Child Subject.

1. Investigators must obtain the informed permission of parent(s) or guardian (except as noted below) to involve a child in a research activity. The elements of an “informed consent” are basically the same as the elements of informed consent outlined in [Form IC – 1](#), Informed Consent Instructions. The permission form should be worded in such a manner that it is clear to the person signing the form that these “elements” apply to the child subject. Particular attention should be paid in such documents to the questions of risk to the child, benefit (if any) to the individual child, the question of whether these benefits are only available to the child through his/her participation in the activity, the child's right (if applicable) to refuse to participate, and procedures to be followed if either parent or child wishes to withdraw. The requirement for parental/guardian permission may be waived if the activity is one in which such permission is not a reasonable requirement (e.g., studies on abused/neglected children). If the investigator feels that such a requirement should be waived for a particular research activity, the Committee will work with the investigator to establish an alternative mechanism for protecting the interests and rights of the child.
2. Children who are wards of the state can only be involved in research under special circumstances. Any investigator seeking to involve wards should contact the Committee for assistance in establishing mechanisms to deal with the stringent conditions under which such involvement can take place.
3. Investigators must also make adequate provision for soliciting the assent of the child subject.
 - a. Assent is a concept that includes two basic elements:
 - i. The child's awareness of his/her condition, the nature of his/her illness (if applicable) and of the activities involved in participating in the research project; and
 - ii. the child's expression of willingness to participate in the proposed activity.
 - b. As a general rule children who are seven (7) years of age or older are capable of providing assent. The child's assent can be documented by having him/her sign a short, appropriately worded addendum to the parental permission form. This short paragraph should include a brief description of the nature of the proposed research activity and a statement that the child is willing to participate.

- c. The child subject should also be informed of his freedom to refuse to participate or to withdraw at any time when this is appropriate.
- d. If the child is less than seven (7) years old; or is felt to be incapable of providing assent; or if the anticipated direct benefits to the child are only available through participation in the proposed research activity, the assent requirement may be waived by the Committee.

This section regarding children in research is largely adapted from the Kansas University Medial Center (KUMC) – *Human Subjects Committee Policies and Procedures of Advice and Counsel to Investigators, Addendum – Research Involving Children*, p. 12-13.

VIII. Health Data for Research (HIPAA)

The Health Insurance Portability and Accountability Act of 1996 (otherwise known as “HIPAA” or the “Privacy Rule”) outlines specific standards and obligations regarding the privacy of certain protected health information (PHI). Since the primary function of Pittsburg State University as a state educational institution of Kansas is not to provide health care, the University recognizes itself as a “hybrid entity.” Pittsburg State University voluntarily complies with PHI standards.

PHI consists of information created or received by a health care provider, health plan or health care clearing house that relates to past, present, or future physical or mental health of an individual. It may also include information about health care services or payment for health care services. The Privacy Rule governs PHI in any form: oral, written, or electronic.

If a researcher obtains PHI information from a covered entity (either within or outside of Pittsburg State University,) the subject of the information must have granted permission via a written authorization form, OR one of the following criteria is met:

- a.) the information is “[De-Identified](#)”
- b.) the information is compiled into a [limited data set](#) and a [data use agreement](#) is executed
- c.) the activity qualifies as [preparatory to research](#)
- d.) a [waiver of the individual authorization](#) requirement is obtained from the CPHRS
- e.) the researcher is accessing information solely on [decedents](#).

De-Identification

Health information which has been de-identified (in accordance with 45 CFR 164.502(d) and 164.514(a)(b)(c) of the Privacy Rule) may be disclosed and used for research purposes. To qualify as being de-identified under HIPAA, the following data elements about the individual and the individual’s relatives, employers, or household members must be removed:

- Names;
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geographic codes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
 - The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
 - The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;
- All elements of dates (except year) for dates directly related to an individual including:
 - birth date

- admission date
- discharge date
- date of death; and
- all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- Telephone numbers;
- Fax numbers;
- Electronic mail 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, including finger and voice prints;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code, except a covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:
 - The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and
 - The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

A de-identified data set might include age, gender, ethnicity, marital status and relevant medical information, provided there are no identifying links to the source data. De-identified data is not subject to HIPAA's Privacy Rule. Thus, if a researcher receives only de-identified data or samples from an entity covered by HIPAA, the Privacy Rule's additional requirements do not apply.

If a researcher him/herself views records containing identifiable health information and from those records extracts a de-identified data set, one of the other exceptions to the individual authorization requirement must be met. Alternatively, in some cases, the covered entity may be able to enter into a business associate agreement with the researcher to create a de-identified data set. HIPAA's requirements for business associate agreements must be met.

Limited Data Set and Data Use Agreement

HIPAA permits research using a Limited Data Set, i.e. a data set in which direct identifiers have been removed but certain potential identifiers remain. To qualify as a Limited Data Set, the following direct identifiers of the individual or of relatives, employers, or household members of the individual must be removed:

- Names;
- Street address/Postal address information, other than town or city, State, and zip code;
- Telephone and fax numbers;
- Electronic mail addresses;
- Social security numbers;

- Medical record numbers, health plan beneficiary numbers or other account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers;
- Web universal resource locators (URLs) or Internet protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints; and
- Full face photographic images and any comparable images.

A Limited Data Set is still considered to be PHI under the HIPAA. Prior to disclosing the Limited Data Set, the entity releasing the Limited Data Set and the researcher must execute a Data Use Agreement. The agreement must contain the following elements:

- a) The permitted uses and disclosures by the recipient
- b) The approved users and recipients of the data
- c) Agreement by the recipient not to re-identify the data or contact the individuals
- d) Assurances that the recipient will use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as permitted by the Data Use Agreement
- e) Agreement that the researcher will report to the covered entity any uses or disclosures of the Limited Data Set which were not specifically allowed
- f) Agreement to require that any agents and subcontractors adhere to the same safeguards

Activity Preparatory to Research

HIPAA also permits a researcher to access PHI from a covered entity if he/she attests in writing that:

- The information is being sought solely to prepare a research protocol or for similar purposes preparatory to research;
- No PHI is to be removed from the covered entity by the researcher; and
- The information being sought is necessary for research purposes.

Waiver of Individual Authorization

Researchers may apply for a waiver of the privacy authorization requirements under HIPAA if the research meets the following criteria.

- The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements;
 - An adequate plan to protect the identifiers from improper use and disclosure;
 - An adequate plan to destroy the identifier at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by the HIPAA;
- The research could not practicably be conducted without the alteration or waiver; and
- The research could not practicably be conducted without access to and use of the PHI.

Research on Decedents

In order to access medical records on decedents, HIPAA requires a researcher to provide a covered entity with written assurances that the information is being sought solely for research on decedents, and is necessary for research purposes. The covered entity has a right to require documentation of the death of the individuals.

Much of the information in this section regarding requirements for researchers to be covered if obtaining PHI from a covered entity was taken directly from the University of Kansas, Handbook for The Human Subjects Committee – Lawrence Campus (HSCL), (2003), Appendix II – Research Guidelines for Privacy of Health Information under the Health Insurance Portability and Accountability Act.

D. References

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