Procedures for Research Involving Human Participants

Approved and administered by Warner Pacific University
Institutional Review Board
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Table of Contents

Preface

These policies and procedures were designed to assist faculty, staff, and students at Warner Pacific University (WPU) who conduct research with human participants. This document describes WPU's Institutional Review Board (IRB), the policies that govern research with human participants, and the procedures WPU researchers must follow.

Novice researchers and those new to WPU should read the entire document, whereas experienced WPU researchers may use this as a reference document when they prepare the *WPU-IRB Application*.

Purpose of the Institutional Review Board

WPU's Institutional Review Board reviews all proposed research that involves human participants and is conducted under the auspices of the institution (e.g., by faculty, students, staff). The board helps to ensure that WPU researchers conform to ethical standards and thus shares responsibility for the protection of human participants, researchers, and the University. Furthermore, the board is committed to carrying out this charge in a manner that will support and assist researchers.

For research and research-related activity involving human participants, WPU is guided by the ethical principles set forth in the *National Commission for the Protection of Human Subjects of Research: The Belmont Report* and is guided by the procedures of Title 45, Part 46 of the Code of Federal Regulations (*45 CFR 46*).

The following principles are primary considerations of the Warner Pacific University IRB:

1. Researchers must provide for the safety, health, and welfare of participants. Rights, including the right to privacy, must not be unduly infringed upon.

2. The direct or potential benefits to the participant and/or the importance of the knowledge gained must outweigh the inherent risks to the participant; risks are always to be minimized.

3. Participation must be voluntary and informed consent must be obtained, unless these requirements are waived by the IRB (waivers are covered in this document).

4. An individual does not give up any rights by consenting to participation and has the right to withdraw from a project at any time or may refuse to participate without loss of benefits to which the participant is otherwise entitled.

5. Information about participants is to be safeguarded (i.e., researchers must maintain confidentiality to the extent allowed by law).

Essentials for WPU Researchers

Research Defined

The Code of Federal Regulations (CFR), which governs much of WPU's policy regarding research with human participants, contains the following definition:

> *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 45 CFR §46.102 (d)

WPU's IRB considers "generalizable knowledge" as research results that are published, bibliographically available (e.g., theses and dissertations), presented outside the University (e.g., professional conference), or developed for others to build upon (e.g., pilot data for an investigator from another institution).

Responsibilities

The responsibility for maintaining ethical standards and protecting human rights rests with the individual researcher (and research advisors of WPU students). The IRB review is required as an added measure of assurance and as a local resource for the interpretation of ethical guidelines. Engaging in research with human participants without IRB approval puts the researcher and institution at risk and constitutes a violation of University policy.

Along with meeting the specific requirements of a particular research study, investigators are responsible for ongoing requirements in the conduct of approved research that include, in summary:

1) obtaining and documenting informed consent of participants or participants' legally authorized representatives prior to participation in research, unless these requirements have been waived by the IRB;
2) obtaining prior approval from the IRB for any modifications of previously approved research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to participants (in cases of emergency adjustments to informed consent, the IRB should be notified as soon as possible thereafter); and
3) ensuring that progress reports and requests for continuing review and approval are submitted to the IRB in accordance with the policies, procedures, and actions of the IRB.

In certain circumstances, investigators also would be responsible for meeting the following additional regulatory requirements:

1) providing to the IRB prompt reports of any unanticipated problems involving risks to participants or others;
2) providing to the IRB prompt reports of serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB; and
3) maintaining certain records as required by the HHS regulations for at least three years after completion of the study.
4) complying with requests for information from the IRB about adherence to approved procedures after the onset of data collection.

(Some of the previous text is taken from the OHRP web site, http://www.dhhs.gov/ohrp/)

Roles and Responsibilities of Investigators and Research Staff

Principal Investigator

The Principal Investigator (PI) is ultimately responsible for assuring compliance with applicable University IRB policies and procedures, DHHS Federal Policy Regulations, and FDA regulations and for the oversight of the research study and the informed consent process. Although the PI may delegate tasks to members of his/her research team, s/he retains the ultimate responsibility for the conduct of the study.

Who May Serve as a Principal Investigator?

Because PI responsibilities involve direct interaction and supervision of the research team, the PI must be a current employee or student of the University who is operating within their University role to oversee the conduct of the study. PIs leaving the institution are responsible for notifying the IRB well in advance of their departure so that they can make arrangements to either close the study or name another appropriately qualified individual currently at the institution to serve as the PI.

The following individuals may serve as PI:

Faculty members: All categories of compensated faculty members may serve as PI if their institution allows them to serve as Principal Investigator on applications for sponsored funding administered through the University. Adjunct faculty of the University, including lecturers and instructors, are not permitted to serve as a PI or Faculty Mentor but may serve as co-investigator.

Staff: University staff may serve in this role if they have appropriate qualifications to conduct the research and if they have obtained approval to conduct the research from their immediate supervisor.

Students: Students may serve as Principal Investigators for their own research projects and are responsible for submitting the IRB application. However, when a student is listed as the PI, **a faculty mentor must be listed on the protocol submission**. If a student from another institution is also a staff member at the University, a faculty mentor is not required. In these circumstances, all requirements listed above under "Staff" must be met.

Note: The IRB reviews and holds student research projects to the same standards as human subject research conducted by faculty or staff. IRB approval or exemption must be obtained prior to initiating any research activity under IRB oversight. **"Retroactive" IRB approval or exemption is not permitted under federal regulations and University policy**. Failure to obtain IRB approval for research with human subjects may preclude the use of the previously collected data and could result in other institutional sanctions.

General Responsibilities of Principal Investigators

As a general condition for the approval of a research study, the IRB holds the Principal Investigator of the study responsible for ensuring that:

- risks to research subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose the subjects to risk; and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
- risks to human research subjects are reasonable in relation to the anticipated benefits (if any) to the individual, and the importance of the knowledge that may be expected to result;
- selection of human subjects and patients for research participation is equitable;
- individuals are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research, and that informed consent will be obtained from each prospective human research subject, or his/her legally authorized representative, in accordance with, and to the extent required, by University policies and federal regulations;
- informed consent of human research subjects will be obtained in advance of research participation and appropriately documented in accordance with, and to the extent required, by University policies and federal regulations;
- where appropriate, there is routine monitoring of the data collected to ensure the safety of human research subjects;
- the privacy of human research subjects is protected and the confidentiality of data is maintained;
- appropriate additional safeguards are included in the study to protect the rights and welfare of human research subjects who are likely to be vulnerable to coercion or undue

influence (e.g., children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons).

Specific Responsibilities of Principal Investigators

The IRB holds the principal investigator of an approved research study responsible for:

- promptly responding to all requests for information or materials solicited by the IRB, including the timely submission of the research study for IRB renewal;
- ensuring that adequate resources and facilities are available to carry out the proposed research study;
- abstaining from enrolling any individual in a research study (i) until such study is approved in writing, by the IRB; (ii) during any period when the IRB or sponsor/principal investigator has suspended study activities; or (iii) following IRB or sponsor/principal investigator-directed termination of the study;
- ensuring that all associates, colleagues, and other personnel assisting in the conduct of the research study are appropriately informed of (i) the study procedures; (ii) informed consent requirements; (iii) the potential adverse events associated with study participation and the steps to be taken to reduce potential risks; (iv) adverse event reporting requirements; and (v) data collection and record-keeping criteria;
- conducting the study in strict accordance with the current IRB-approved research protocol except where a change may be necessary to eliminate an apparent immediate hazard to a given human research subject;
- reporting promptly to the IRB any deviations from the currently approved research protocol;
- requesting IRB approval of any proposed modification to the research protocol or informed consent documents prior to implementing such modifications;
- obtaining prospectively and documenting informed consent in accordance with the current IRB-approved informed consent documents (i.e., unless the IRB has granted a waiver of the consent process) maintaining adequate, current, and accurate records of research data, outcomes, and adverse events to permit an ongoing assessment of the risk/benefit ratio of study participation;
- reporting promptly to the IRB (and, if applicable, the sponsor and FDA) any internal or external adverse event that is considered to be 1) unexpected; 2) serious and 3) possibly or definitely related to the study;
- reporting promptly to the IRB any significant changes in the risk/benefit of study participation;
- ensuring that, in the event a research subject experiences a significant adverse event, every reasonable effort is made to provide the subject with adequate care to correct or alleviate the consequences of the adverse event to the extent possible;

- ensuring that human research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study;
- ensuring that all listed investigators have the appropriate credentials to conduct the portion of the study in which they are involved and have completed the applicable University required Human Subject Research training modules through NIH;
- maintaining adequate and accurate research subject records to reflect adherence to protocol specific requirements.

Sub-Investigators and Research Staff

Appropriately qualified sub-investigators and research staff may perform tasks as delegated by the Principal Investigator but they do not accept primary responsibility for the research study.

General Responsibilities of the Sub-Investigator and Research Staff

- Completing required institutional and protocol specific training
- Adhering to the federal regulations, state and local laws, institutional policies and procedures surrounding the safety and protection of human participants
- Assuring participant privacy and confidentiality according to HIPAA guidelines, institutional regulations, and HRPO policies and procedures.

(Some of the previous text is taken from the OHRP web site, http://www.dhhs.gov/ohrp/)

Research in the Classroom, Pilot Studies, Program Evaluations

In the classroom, research-related activity whereby data from participants who are not class members are collected by students as a class exercise or for course credit and for which the findings are not expected to be disseminated beyond the university context, is the responsibility of the instructor. Instructors supervising such research-related activity must be familiar with IRB policies and issues, as reflected in this manual, in order to ensure that participants in student projects are treated ethically (e.g., risks are low, written informed consent is obtained as necessary, confidentiality is maintained). It is recommended that instructors complete online training prior to supervising such projects through the National Institute of Health: https://phrp.nihtraining.com.

Pilot research may take many forms. Sometimes pilot data are disseminated by presentation or publication or in a report to a granting agency, other times they are not. Sometimes pilot research involves testing a survey instrument with colleagues or students, perhaps as part of an educational exercise. Other times it might involve an experimental manipulation with participants (sometimes from vulnerable populations) from outside the university. Researchers are urged to err on the side of caution and to consult with an IRB member if uncertain how to proceed.

IRB approval is not needed for curriculum projects, workshop evaluations, and administrative review projects (program evaluations) if results are not to be distributed outside of the institutional setting. If, after the fact, it is thought that data collected for a non-research project are worthy of dissemination to a wider audience, than an IRB application is required for what is then considered archival research (i.e., research activity involving already-collected data). **In all cases, the definition of research, provided at the beginning of this section, should help guide researchers on whether or not IRB approval is necessary.**

Considerations for WPU-IRB Approval

Overview

When the IRB reviews a protocol, it determines whether the following requirements are satisfied (45 CFR §46.111 a).

1. Risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, 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 participants 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 participants 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 participant or the participant's legally authorized representative, in accordance with, and to the extent required by 45 CFR § 46.116.

5. Informed consent will be appropriately documented. *(see Informed Consent and The Informed Consent Document section for details)*

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

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

When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, persons with mental disabilities, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

Review Categories

Research involving human participants or data derived from human participants falls into one of three categories:

EXEMPT (requires one reviewer → an IRB co-chair)

- ✓ approval for 4 years
- ✓ reviews typically take 2 to 3 weeks (reviews may take longer if researchers do not respond rapidly to any concerns raised by the co-chair)

EXPEDITED (requires two reviewers → an IRB member + an IRB co-chair)

- ✓ approval for 1 year (continuation request required for longer duration)
- ✓ reviews typically take 3 to 4 weeks (reviews may take longer if researchers do not respond rapidly to any concerns raised by the IRB member or co-chair)

FULL BOARD (requires all IRB members to review and a meeting to be convened)

- ✓ approval for 1 year (continuation request required for longer duration)
- ✓ reviews typically take 4 to 6 weeks during the academic year and are not conducted during the summer

Researchers initially select the category for their proposed research and then complete the *WPU-IRB Application* based on that determination. Final determination of the category rests with WPU's IRB. The IRB co-chair will advise the researcher if elements in the application are deemed to warrant a different category than the one selected by the researcher. Please note that the Warner Pacific IRB is responsible for approving the research processes set forth in the application. However, the Warner Pacific IRB is not responsible for giving permission to collect data from WPU staff, faculty, and/or students.

The following sections describe the three categories in some detail in order to assist researchers in determining which review category fits their proposed research.

EXEMPT

Generally, research that does not propose to disrupt or manipulate participants' normal life experiences, or incorporate any form of intrusive procedures, may be classified as exempt. According to 45 CFR §46.101 (b), research activities in which the only involvement of human participants will be in one or more of the following six categories are considered exempt:

1. Research conducted in establi1shed or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 2 above if: (i) The human participants are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii)

possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

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.

Exempt status does NOT APPLY to research involving pregnant women, fetuses, human in vitro fertilization, and prisoners.

Exempt status described in item one may in special circumstances apply to children, but the educational setting and procedures for data collection will be scrutinized closely by the IRB co-chair.

Furthermore, the exemption in item two does not apply to children, EXCEPT for research involving observations of public behavior when the researchers do not participate in the activities being observed. When observational studies with children are considered exempt, the IRB co-chair will examine the research procedures with utmost caution.

EXPEDITED

Research that is judged to involve **no more than minimal risk** to participants and includes appropriate informed consent procedures can be classified as expedited.

"**Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR §46.102 (i)).

Often, research involves at least minimal levels of risk to human participants (e.g., mild anxiety, embarrassment, physical discomfort, etc.). It is the researcher's responsibility to consider ALL possible risks.

As risks arise, the researcher must implement safeguards. Examples of safeguards against improbable events are: emergency medical procedures in the event of unexpected accident,

seizure, or illness during the data collection and emergency psychotherapeutic procedures in the event of unexpected psychological trauma. The greater the probability of any such risk, the greater the responsibility of the researcher to provide such safeguards for the protection of participants' safety and well-being. Other risks to consider, though not an exhaustive list, would include: possible excessive negative reaction of participants to the introduction of sensitive stimulus information during the research procedures, the potential for extreme effects on participants' relationship status as a result of research participation, any strong reactions to procedures that may violate participants' belief systems, and the possibility of moral violations as perceived by the participants.

In instances where the research might cause an adverse emotional reaction in the participant, researchers should identify a contact organization (including a phone number) that can help participants work through the emotional response evoked by the research.

The following pages detail the federal criteria for expedited research.

Research activities that:

1. present no more than minimal risk to human participants, AND
2. involve only procedures listed in one or more of the categories described.

NOTE: Activities should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants. The categories in this list apply regardless of the age of participants, except as noted. The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' 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.

Categories of Research That May Be Reviewed by the IRB through an Expedited Review Procedure (Source: 63 FR 60364-60367, November 9, 1998)

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that

significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

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

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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 non-disfiguring 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 participant or an invasion of the participant'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 non-research 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 participants. 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. (***See Additional Considerations for exceptions***)

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 participants. 45 §CFR 46.101(b) (2) and (b) (3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB (i.e., full board review) as follows:
    a. where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or
    b. where no participants have been enrolled and no additional risks have been identified; or
    c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

FULL BOARD

Research that is judged to involve **more than minimal risk**, as defined earlier in this document, must be submitted for full-board review. Full-board review is necessary when researchers plan to use procedures that are personally intrusive and/or have the potential to produce stress or trauma beyond what is likely to be encountered by the participants in their everyday lives.

The lead investigator and all co-investigators must submit evidence of ethics training. They are to complete the National Institute of Health at https://phrp.nihtraining.com. Please submit evidence of completion with the IRB application to irb@warnerpacific.edu.

Full-board reviews are conducted only during the fall and spring semesters. When an application for full-board review is submitted via email it is forwarded to one of the IRB Co-Chairs who verifies its status and then calls for a meeting of the entire board. The lead investigator is invited to present the proposal to the board at this meeting. After presenting the proposal and answering any questions, the lead investigator is excused from the meeting while the board deliberates and then votes to approve (as is, or with revisions), not approve, or table

(e.g., if more information needs to be gathered or an expert external to the board consulted). Please note that it may take several weeks to convene a full-board meeting and full-board meetings are not conducted during the summer.

Informed Consent and the Informed Consent Document

The process of obtaining informed consent must comply with the requirements of 45 CFR §46.116. Documentation must conform to 45 CFR §46.117. *Above all, it should be noted that informed consent is a process, not just the presentation of a form or the collection of a signature*. The information provided to prospective participants must enable an individual to make an informed decision about whether to volunteer for participation. As such, the informed consent process is a fundamental mechanism demonstrating respect for the individual. Because the process is intended to inform the potential participant, "lay language" should be used and scientific jargon or "legalese" avoided to the extent that is possible. It is important to think of the informed consent document as an educational tool as well as a legal contract. The written presentation of information provides the basis for consent and, because a copy is retained by the participant, is useful for future reference.

Examples of informed consent documents are included within an appendix. Waivers to standard consent procedures and documentation are addressed in the next section.

Standard Informed Consent Documentation

Most studies require a standard, written consent document. The consent document ***must be prepared on WPU letterhead stationery (or with WPU logo)*** in language that participants can clearly understand, and it must:

1. State the following, ***verbatim***, at the top of the form:
   CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH

2. Include a descriptive title, the name and phone number of the lead investigator and, ***if the lead investigator is a student, also the name and phone number of the research advisor***. Please specify school/program affiliation.

3. Describe the general purpose and nature of the study in easily understood language.

4. Describe clearly and completely what the participant will be asked to do, the type of data to be collected, where and when data collection will occur, and the

expected duration of the participation. If data collection is through questionnaire or interview, please describe the types of questions to be asked or include examples of questions. If some questions will be of a sensitive nature, be explicit in your description or be sure to include as an example one of the more sensitive questions.

5. Describe the procedures for maximizing confidentiality (***do not just state that details of participation will be kept confidential and do not guarantee confidentiality***). Researchers should note that anonymity and confidentiality are not the same. When data are anonymous, researchers and others do not know from whom the information came. Because researchers usually collect data directly from participants or use other mechanisms such as the Internet that can sometimes be traced back to individuals, data are rarely anonymous. When data are kept confidential, the researcher knows the source but strives to protect the privacy of the information.

6. Describe the risks and benefits of participation (include even minor risks/discomforts, any costs or compensation to the participants, as well as benefits to the discipline). **Do not just state that risks are minimal**. Examples of acceptable forms of the risks statement (when applicable) might be "there are no foreseeable risks" or "the risks inherent in this study are no greater than those normally encountered during regular classroom participation." If participants are students, patients or employees of an institution in which research is being conducted, they must be informed that nonparticipation or withdrawal from the study will not affect their grade, treatment, care or employment status, etc. If researchers wish to offer student-participants extra credit for a course, an alternative source of extra credit (of equal value and comparable effort) ***must be made*** available for students not wishing to participate.

7. For research involving more than minimal risk (i.e., full-board review), describe the procedures to be used if the risk is realized and who will pay for treatment/assistance.

8. ***Immediately prior to the signature line, include <u>verbatim</u>*** the following statement in cases of adult participation:

> *Participation is voluntary. You may decide not to participate in this study and if you begin participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please sign below if you*

would like to participate in this research. A copy of this form will be given to you to retain for future reference. If you have any concerns about your selection or treatment as a research participant, please contact the Institutional Review Board, AF Gray 302, Warner Pacific University, 2219 SE 68th Ave. Portland, OR 97215; 503-517-1050; irb@warnerpacific.edu

In cases of parents or guardians, use this verbatim statement:

Participation is voluntary. You may decide not to allow your child to participate in this study and if (s)he begins participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please sign below if you would like to participate in this research. A copy of this form will be given to you to retain for future reference. If you have any concerns about your selection or treatment as a research participant, please contact the Institutional Review Board, AF Gray 302, Warner Pacific University, 2219 SE 68th Ave. Portland, OR 97215; 503-517-1050; irb@warnerpacific.edu

9. Signatures – Be sure to include space and lines for signatures from both the participant and the researcher.

In addition to the elements of a standard informed consent document:

✔ All participants must read, and sign the consent form.

✓ Participants must be given an opportunity to have questions about the research answered prior to their participation.

✓ Participants must retain a complete copy of the consent form (it need not be a signed copy).

✓ All signed consent forms must be retained for three years after the completion of the project. When the lead investigator is a student, it is the research advisor's responsibility to maintain the signed consent forms. These forms must be kept **on the WPU campus**.

<u>Retaining and Storing Signed Informed Consent Documents</u>

Signed informed consent forms are legal documents, and the researcher has legal responsibilities in handling them. They should be stored in a secure location, which is accessible to the

University in the event that an inquiry should require an examination of them. Access to these documents should be limited to those persons who have a need to know their contents, ordinarily the investigator (and co-investigators), a representative of the IRB, the IRB Administrator on behalf of the University, and authorized federal officials. In compliance with federal regulations consent documents must be retained for a period of three years following the completion of the research.

Consent documents become part of the IRB file of a project and, as such, are subject to Federal audit. Therefore, the IRB will review carefully both the content of and the storage provisions for all consent forms.

Waivers to Standard Consent Procedures

Under certain circumstances, elements of a standard consent process may be waived. All waivers must be approved by the IRB, and requests for waiver must be fully justified by the researcher when submitting an application to the IRB.

According to 45 CFR §46.116 (c) and (d), **the IRB may approve a consent procedure that does not include, or that alters, some of the elements of informed consent (i.e., the process), or waive the requirement to obtain informed consent.** This section applies to benefit and service programs and experimental studies that could not practically be carried out with standard consent procedures.

Regarding benefit and service programs, the IRB must conclude that:
see 45 CFR §46.116 (c)

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

AND

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

In addition, in accordance with 45 CFR §46.116 (d), the IRB may waive part or all of the normal consent requirements if:

1. the research involves no more than minimal risk to the participants;
2. the waiver or alteration of normal consent procedures will not affect adversely the rights and welfare of the participants;
3. the research could not be carried out practicably without the waiver or alteration;

AND

4. whenever appropriate, the participants will be provided with additional pertinent information after participation.

This latter category of waiver includes cases in which an investigator desires to withhold from the participant some information about the project that, if known by the participant, would bias the results of the study. Ordinarily, the investigator will plan a debriefing session after completion of a person's participation in order to provide the participant with the missing information; the investigator will also ordinarily give the participant the option of including his/her data in the study or having it destroyed. In no case should an investigator seek to withhold information about the research or the participant's role in it solely to reduce the chances of refusal to participate by potential participants.

According to 45 CFR §46.117, **the IRB may waive the requirement for the investigator to obtain a signed consent document** for some or all participants if it finds either:

a. that the only record linking the participant and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality.

OR

b. that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

This waiver applies especially to interviews (including face-to-face and telephone interviews) where the investigator's sole knowledge of the identity of the interviewee would come from the consent document.

Waiver of written consent procedures does not imply waiver of the researcher's responsibility to obtain voluntary participation. In all cases, the researcher must provide the participant with a statement of the research that includes all relevant elements of informed consent. It is the recommendation of the WPU IRB that, wherever practical, when an Informed Consent Form is

waived, a cover letter be submitted to participants that contains the same elements as the informed consent form, but which is retained by the participant rather than signed and returned. The cover letter must include a statement such as "completion of the survey and/or return of the questionnaire indicates consent to participate in the study."

This procedure is applicable when participant risk is very low and preservation of anonymity is enabled (i.e., participants' identities remain unknown to the researcher). It is recommended that researchers conducting exempt-status projects consider this approach in order to preserve anonymity and to eliminate the need for maintaining and storing consent forms for three years following completion of the project. The participant must also be given a clear and free choice to accept the invitation to participate or to refuse without prejudice or penalty. If participants are students, patients or employees of an institution in which research is being conducted, they must be informed that nonparticipation or withdrawal from the study will not affect their grade, treatment, care or employment status, etc.

Research with Children & Other Vulnerable Populations

Subparts B, C, and D of 45 CFR address research with pregnant women, human fetuses, and neonates (B), prisoners (C), and children (D). If a researcher wishes to conduct research with participants described by subparts B or C, they must contact a co-chair for clarification.

Because of WPU's focus on education-based research, the additional protections regarding children are addressed in this section, which is based on 45 CFR §46.401 – §46.409.

Research with Children

Conducting research involving children – persons under 18 years of age – requires special attention to the child's age, his/her ability to understand what is asked of him/her, and his/her relationship to parents or guardians. In all cases, the investigator must demonstrate respect for the rights of the participant within the proposed consent procedures, which should be developmentally appropriate to the age and circumstances of the participant.

Research involving greater than minimal risk must be thoroughly justified by the anticipated benefits to participants or by the anticipated generalizable knowledge.

Researchers must obtain permission from parents (guardians) **AND** assent from the minor participant. "*Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be considered as assent." (45 CFR §46.402)

Children ages 10-18 are required to sign a **written assent form**. For older adolescents (15-17 years) this may be the same consent form signed by the parents with an additional signature space for the adolescent, provided that the language of the consent form may be easily understood by the adolescents. For 10-15 year-olds, a separate assent form, less detailed than the parents' and written in simplified language, is desirable.

Children younger than 10 are required to provide **verbal assent**. That is, the researcher must explain the project activities and ask if they wish to participate. It is a good idea to have verbal assent witnessed by an independent party such as the teacher or parent. If a child chooses not to participate, the decision must be honored. As with adult participants, the researcher must allow children the opportunity to ask any questions about their participation. Researchers must clearly describe the procedure for obtaining assent in the IRB proposal. Additionally, the investigator must use special care to discontinue the participation of children who appear to experience undue stress from the research procedures. A verbal script must be submitted as part of the protocol.

Research with infant participants is best conducted with a parent present.

If the intended participants are **wards of the state,** additional safeguards may be necessary. For example, the IRB may require for each child appointment of an advocate in addition to any other individual acting on behalf of the child. (45 CFR §46.409)

Research with Children – Parental Permission & Participant Assent

Requirements for permission by parents or guardians and for assent by children are described in detail in 45 CFR §46.408. The main points are summarized below.

Adequate provisions must be made for soliciting the assent of children for participation in research. The IRB will take into account the ages, maturity, and psychological state of children involved in research for the purpose of determining whether a child is capable of assenting to participate.

The IRB may waive the assent requirement under circumstances in which consent (for adults) may be waived (see the Waivers to Standard Consent Procedures section). This must be thoroughly justified in the IRB application.

Researchers may only need permission from one parent or guardian for research not involving greater than minimal risk or for research involving greater than minimal risk but presenting the prospect of direct benefit to individual participants.

Permission from parents or guardians shall be documented in accordance with and to the extent required by 45 CFR §46.117 of Subpart A. (45 CFR §46.408)

Under certain circumstances, the IRB may waive the requirements for obtaining parental or guardian permission if a researcher justifies and documents this need under 45 CFR §46.116(c) or (d).

Additional Considerations

Audio recordings: Exempt or Expedited?

In an effort to clarify the use of audio recordings in a human participants research study, the IRB at WPU offers the following guidance.

For a study that proposes to use audio recordings and would be considered for Exempt Review, the conditions of Exempt Category 2 must be met. If these conditions are not met, then the study falls under Expedited Category 6 and must undergo an Expedited Review.

As a reminder, exempt Category 2 is:

> Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

Expedited Category 6 is:

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

As part of an Exempt IRB application, researchers using audio recordings should address the following in their application:

- Does the study exhibit any characteristics of an expedited study?
- Will the topic of the research cause enough discomfort to participants that the study involves minimal risk?
- How will participants' identities be kept confidential?
- How will the data be handled and stored?
- Who will have access to recordings?
- When will audio recordings be destroyed?

Furthermore, because participants have the right to know where and for how long audio recordings of their interviews will be stored, investigators will include their procedures for storing and disposing of audio recordings in consent forms along with a schedule for disposal (e.g., researchers may state either that they will dispose of audio recordings after transcription or after a three-year period).

Deception: Expedited or Full Board?

When describing the purpose and description of research to prospective participants, researchers should not be misleading or untruthful. However, there are times when full disclosure would jeopardize the research. The nature of the deception dictates whether an **expedited review** or **full-board review** is necessary.

For example, participants might not be informed of the actual purpose of certain procedures in order to obtain unbiased results. No more than such mild deception can be tolerated in a study submitted for **expedited review**. However, researchers should be aware that information that may affect the objectives of the study may not be withheld if it relates to the risks participants may face and hence might affect their willingness to participate.

Any intentional deception involving misleading or untruthful information provided to participants must be considered in a **full-board review**. Further considerations for this type of research follow.

Intentionally misleading or providing untruthful information to participants is not considered a desirable procedure. All other possible alternative research strategies should be explored and eliminated before settling on a deceptive approach. Should a researcher choose to implement a deceptive strategy, it will be necessary to provide a clear justification of the procedure to the IRB as well as additional measures to protect participants.

Justification for the use of "more-than-mild" deception must consider:

1. *Alternatives*: Alternative research methods that would not require the adoption of deceptive practices (e.g., role playing, gaming approaches, simulation strategies, etc.).

2. *Value*: The value of the research being conducted. Though scientific gain is not a total justification, it is necessary to demonstrate increased benefit to offset the increased participant risk where deception is involved.

3. *Safety*: Steps taken to further insure participant safety. Deception is taking advantage of the participant's willingness to participate and thus renders the participant vulnerable to increased psychological or physical harm. Steps must be taken, and clearly explained in the proposal, to protect against harm to the participants.

4. *Debriefing & Apology*: Where deception is used and the consent document intentionally omits information or misleads the participant, it is important to repair this deficiency. A thorough debriefing of the participants is desirable, in which the deceptive strategy is explained and justified and an apology for the deception is issued. Deceptions with potential long-term negative implications for participants should be avoided. It is also desirable, at the time of debriefing, to allow participants to withdraw permission to include their data in the results and to destroy any records of their participation.

Classroom-Based Research Projects

All activities meeting any one of the definitions of human subjects' research and carried out at Warner Pacific University or under its auspices must be reviewed and approved by a WPU IRB prior to the start of the activity. That said the University also recognizes that some student projects conducted to fulfill course requirements involve activities that, in a different context, might meet the definition of human subjects research. It is the policy of the University to not require IRB review of classroom research projects, that are designed to teach students research methods except for the following: Doctoral dissertations; funded research; research conducted through collaborations external to WPU, Master's theses, and honors theses. All of these must be reviewed and approved by the IRB before students may begin their research.

In the circumstance of a classroom assignment that would otherwise constitute human subjects research but which does not require IRB review because it is a classroom assignment, the individual faculty members and departments are responsible for overseeing the activities as defined below under faculty responsibilities. This means faculty and departments are responsible for ensuring that the students are adequately trained and that their planned research activities are designed with appropriate and adequate safeguards in place in order to ensure that the activities are within the scope of ethical conduct.

Guidelines for a Classroom-Based Research Project

In order to determine if classroom assignment based research does not require IRB approval the following conditions must be met:

- The risk level of the project is minimal (no more than would be encountered in routine daily activities).

- Unless a student is qualified to do so, there may be no studies that involve interaction with vulnerable subjects (e.g., pregnant women, children,

prisoners, or cognitively impaired persons). Observational study of protected vulnerable populations can be done with the appropriate protections in place.

- No identifiers are collected.
- The project is limited to surveys/questionnaires/interview procedures, observation of public behavior, or standard educational exercises directly related to the topic(s) being studied.
- Surveys/questionnaires/interviews, if used, may contain sensitive personal questions (e.g., questions about alcohol/drug use, sexual behavior/attitudes, criminal activity, medical history, grades/test scores) or other personal information only if surveys are completely anonymous.
- No Warner Pacific faculty, staff or student is receiving monetary compensation or any type of support from an external company/organization/agency for collecting, analyzing or reporting the results of this project.
- The project is not conducted on VA premises and does not use VA resources, and is not otherwise subject to oversight by a federal regulatory body.
- Subjects are recruited in a voluntary manner.
- The data are not archived or saved in any way to be used in the future. It is also understood that the end result of the research may be presented in the classroom to peers but may not be used for any publication or public presentation outside of the immediate classroom.

Faculty Responsibilities

Faculty who require students to do classroom based research projects assume responsibility for the conduct of those projects and assure that the guidelines outlined here are met and that research that falls outside of these criteria is submitted to the IRB for a regular review.

It is the responsibility of faculty to determine whether an assigned project involving humans can be classified as a course-related student project under the criteria above. Faculty should contact the IRB chair for assistance if needed in making this determination. It is the responsibility of the WPU faculty to discuss general principles of ethical conduct in research with the students prior to the initiation of the project. Faculty are strongly encouraged to participate in online training through the National Institute of Health: https://phrp.nihtraining.com. In addition, the faculty member must ensure that all surveys/questionnaires/interviews are preceded by a disclosure of the following points to the respondent. If an information sheet or any recruitment materials are used, these points must be in that document:

- The student identifies him/herself as a WPU student who is performing the activity to fulfill a course requirement, and the course is specifically identified.

- The name of the supervising faculty member to contact for questions is provided.

- The persons who have access to the individual data and/or summarized results are specified (e.g., instructor only, company/organization/agency).

- Respondents are informed that their participation is completely voluntary and confidential.

- Care should be taken to protect the rights and welfare of the individuals who act as participants. Standard research practices such as obtaining consent, ensuring confidentiality, responsible fieldwork, and giving participants a contact name should be employed.

(Some of the previous text is inspired by the IRB policies at Northwestern University)

Research Involving Students

Researchers conducting studies that involve recruitment of participants who are also students enrolled in courses that they teach or mentor the instructor/graduate student teaching the course, must include a clear statement that addresses this duality and respect for students' voluntary involvement in the research. This statement is necessary for students to be informed, and to understand that when their professor/instructor is also a researcher who is recruiting their participation in a study, it is not coercive in nature and will have no impact on course/program evaluation or grade. This statement should be included in ***all*** communications (e.g., recruitment scripts and invitation letters) as well as informed consent forms.

An example statement to be included in an informed consent is: "Your decision to participate in this study, or not, will have no impact on your evaluation in this class or affect your course grade."

Please see "Research Policy" for more information regarding using WPU students, faculty, and staff in research.

Data Security

An important part of an application to the IRB is the plan that protects data from improper disclosure. In our increasingly computerized world, that plan must address storage and

processing of data on personal computers, WPU servers, and any other systems that allow access, exchange, and storage of personal information about research participants.

In most WPU research, investigators need to be vigilant but can follow such familiar strategies as using a password-protected computer. Examples of these data that need to be protected but do not require extensive security include interviews and surveys about topics yielding data, if disclosed, would generally not put identified individuals at civil liability or material harm.

The Principal Investigator (PI) is responsible for ensuring that research data is secure when it is collected, stored, transmitted, or shared. In addition, the PI is responsible for making it clear to participants that while all efforts to ensure data is secure, it is impossible to ensure 100% data security. All members of the research team should receive appropriate training about securing and safeguarding research data. For example, the research team should understand they need to document their standard practices for protecting research data so that they can provide these details to the IRB if a mobile device is lost or stolen. Data security must be discussed regularly at research team meetings, and data security details must be included in the study data and safety monitoring plan.

Assessing the Data Security Method Needed

Based on the type of data involved in the study, the IRB is required to 1) assess potential risks to participants, and 2) evaluate the researchers' plan to minimize risks. All research activities result in some type of risk and the researcher has the responsibility to mitigate the risk of improper disclosure.

What is the risk?

- Is the data identifiable, de-identified (coded), or anonymous?
- Is sensitive information being collected that could result in harm to participants?
- What is the risk of harm to the participant or others?

What are the protections against anticipated threats or hazards (during collection, transmission, storage)?

- Encryption of data on device to protect against loss/theft of device
- Use of secure data transmission channels to protect against data interception
- Strong passwords to protect against unauthorized access
- Store data behind a secure Pitt or UPMC firewall whenever possible
- Ensure strong data security controls on all storage sites

Other Considerations: The data and safety-monitoring plan should indicate that research team meetings include discussions about, but not limited to:

- Software on computers to protect against malware
- Data security to ensure all software updates and patches are being applied
- Data collection, transmission, and storage methods employed
- Data collected is only that data necessary to answer the research question
- Codes are not stored with the corresponding de-identified data
- Encryption methods are being used on all portable devices (laptops, mobile devices, and removable storage)

Access to Faculty, Students, and Staff for Research Purposes

Historically the use of surveys has provided the basis for a variety of purposes for actuarial, educational research, demographic data, and many other uses, However, with the advent of current technology via e-mail and the internet have greatly expanded the number, type , and usefulness of many of the these instruments, both institution sponsored and unsolicited. The overwhelming nature of this problem has result in survey fatigue, e-mail overload, and a lack of reported data to the Office of Assessment and Institution Research. This policy aims to prevent survey fatigue, protect confidentiality and employee rights, and ensure that access does not conflict with any current or planned research to be conducted by the University or its administrative/academic units.

Internal and External Users

In general, priority is given to research that may be of demonstrated benefit to the institution rather that those that benefit the researcher or sponsoring agency.

Students, faculty or staff, that are perusing research projects that involve access to data held by the University, conduct surveys with faculty, staff or students at Warner Pacific University and/or will use materials that represent the University (i.e. University logo, mascot, grounds) must apply for permission. An application of approval includes the following:

1. Study title
2. Title and names of authors
3. Brief description of the research including objectives and timeline
4. Details of sampling methodology for research involving institutional data.
5. Description of participants and their recruitment and/or description of data requested.
6. Approval by their direct supervisor and area Vice President and in some cases, President of the University.
7. Approved application must be included in IRB application.

Please note, data collection cannot begin until application is approved by WPU Institutional Review Board.

For more information about this policy, including for external users, please see the WPU Research Policy

Initiation, Continuation, Revision, Conclusion of IRB Approval

Approval for WPU IRB applications will be sent to the lead investigator and the faculty advisor (if the lead investigator is a student researcher). Researchers *must in no circumstances collect data* until they have been advised that their applications have been approved.

Full Board and Expedited applications will be granted a 3 year approval. Researchers will have the opportunity to request a continuation of that approval prior to the 3 year anniversary date. Expired projects must be submitted as a new project for an entirely new review. Approval of the continuation is dependent on the researcher's responses to a series of questions about the progress of the study.

Exempt applications are granted a 4-year approval and there are no options for continuation.

Changes to existing protocols may be requested in as an amendment/modification, and include a thorough description of changes to an existing, approved study, and any new or revised documentation. IRB co-chairs review these requests on an as-needed basis.

Lead investigators and research advisors will receive notification when IRB approvals have expired.

IRB Non-Compliance and Reported Irregularities during Research

The following steps will be followed in cases where a researcher (i.e., lead investigator or research advisor) do not adhere to IRB Guidelines.

If the non-compliance is because the researcher was unaware of IRB Guidelines and federal law, an IRB co-chair will communicate via e-mail with the researcher in order to explain the nature of the non-compliance. The co-chair will propose a solution that will remedy the situation. All communication will be maintained by the IRB co-chair.

If the issue of non-compliance persists or the researcher rejects the co-chair's solution, the co-chair will request a meeting between the researcher and both IRB co-chairs. At this meeting, notes will be kept as to the nature of the non-compliance and the researcher's willingness to

remedy the situation. These notes will be maintained by the IRB co-chair who initiated the meeting.

While IRB co-chairs must adhere to this protocol, they may also find it helpful to contact knowledgeable campus members relevant to each case. These individuals could include grant coordinators, university counsel, past IRB co-chairs, and professors with expertise in the research area. Each case is vastly different and may usually be resolved with time and wisdom without permanently jeopardizing researchers, WPU, or most importantly human research participants.

In most cases, the researcher in non-compliance is acting out of ignorance and not willful intent. In addition, most cases are resolved while maintaining compliance with federal law.

It should be noted that violation of federal law associated with these IRB Guidelines may result in drastic consequences, such as the suspension of all federal research funds. Therefore, it is imperative that all WPU researchers comply with WPU IRB Guidelines.

Reports of irregularities during the conduct of an IRB-approved study will be addressed on a case-by-case basis and with due consideration to federal requirements. As with issues of non-compliance, communication will be established between IRB co-chairs, researchers, and participants, if necessary. WPU Counsel will be consulted as necessary. Depending on the severity and nature of the project and infraction, federal authorities may need to be contacted.

Other WPU IRB Procedures That Address Federal Requirements

The IRB has other responsibilities besides the review of new and continuing research applications.

The IRB regularly disseminates its record of approved applications to IRB members and research administrators on campus. These records will be made available to other interested parties from the University community who request them.

The IRB communicates with other offices on campus as is appropriate to the thorough review of applications and the coordination of research policies. For example, issues of biosafety will be addressed as necessary with university personnel with expertise in biosafety.

The IRB has the responsibility to examine an investigator's adherence to planned procedures in the application under two circumstances:

1. the IRB has determined that an investigator has been previously and flagrantly non-compliant with IRB guidelines, or the IRB has encountered other convincing evidence that an investigator is currently being non-compliant, reckless, or inattentive to participants' rights;

2. the IRB will randomly select two projects annually in which investigators will be asked to report on their fulfillment of the research and consent procedures they described in their applications. In the first case, the investigator and his or her supervisor will report on compliance. In the second case, the investigator will report on compliance.

When a serious violation has occurred that mandates reporting to the federal Office for Human Research Protections, the IRB co-chairs will assume responsibility for filing the report at <http://www.hhs.gov/ohrp/policy/incidreport_ohrp.htm>.

Likewise, co-chairs are responsible for reporting serious adverse effects on participants at <http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm>. Depending on the circumstances, co-chairs will attempt to alert the federal authorities as soon as is possible and not after three months after first learning about the potential serious problem.

The Ethical Basis of IRB Policy

The following is an excerpt from **The Belmont Report**: **Ethical Principles and Guidelines for the Protection of Human Subjects of Research**.
See http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

> **1. Respect for Persons.** Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.
>
> An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.
>
> However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. Beneficence. Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their

institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children -- even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. Justice. Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are **(1)** to each person an equal share, **(2)** to each person according to individual need, **(3)** to each person according to individual effort, **(4)** to each person according to societal contribution, and **(5)** to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example,

during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

Frequently Asked Questions

Frequently asked questions of a more general nature can be found at the U.S. Department of Health and Human Services web site: http://www.hhs.gov/ohrp/policy/faq/index.html