

Review of Human Research Involving Vulnerable Populations

1.0 Purpose

The purpose of this policy is to define the review process and regulatory requirements for both the investigators and the Wright State University IRB for human subject research involving certain vulnerable populations.

2.0 Scope

This policy applies to all human subject research that is conducted by Wright State University (Wright State) faculty, staff and students and human subject research for which the Wright State Institutional Review Board (hereafter referred to as IRB) acts as the IRB of record for an external entity (e.g., Premier Hospitals, Dayton VAMC).

3.0 Definitions

- 3.1 **Pregnancy** means the period of time from implantation until delivery.
- 3.2 **Fetus** means the product of conception from implantation until delivery.
- 3.3 **Neonate** means a newborn infant under 28 days of age.
- 3.4 **Nonviable Neonate** means a neonate after delivery that is not able after delivery, to survive (given the benefits of medical therapy) to the point of independently maintaining a heartbeat and respiration.
- 3.5 **Cognitively Impaired** refers to an adult with significant limitation in capacity for judgement and reasoning. The impairment may be function of a temporary acute condition (e.g., seizure, encephalopathy) or a more long-term or permanent condition (e.g., Alzheimer's, developmental delay).
- 3.6 **Decisional Impairment** refers to a limitation or lack of capacity to understand information and/or to reason.
- 3.7 **Competence** is a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.
- 3.8 **Decision-making Capacity** refers to a potential subject's ability to make a meaningful decision about whether or not to participate. It is generally thought to include at least the following four elements:
 - 3.8.1 **Understanding** is the ability to comprehend the disclosed information about the nature and purpose of the study, the procedures involved, as well as the risks and benefits of participating versus not participating.

- 3.8.2 **Appreciation** is the ability to appreciate the significance of the disclosed information and the potential risks and benefits for one's own situation and condition.
- 3.8.3 **Reasoning** is the ability to engage in a reasoning process about the risks and benefits of participating versus alternatives.
- 3.8.4 **Choice** is the ability to understand the difference between participating and not participating in research.
- 3.9 **Investigator** means the Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposing of research, including persons who are subcontractors, collaborators, or consultants. At Wright State this definition includes, but is not limited to, the following roles: Principal investigator, co-investigators, research coordinators, research associates, collaborators, and consultants, and may include research assistants and students as identified by the PI depending on their specific roles and responsibilities.
- 3.10 **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research:
- Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or
 - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable specimens.
- 3.11 **Intervention** means both the physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- 3.12 **Interaction** means communication or interpersonal contact between investigator and subject.
- 3.13 **Private information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- 3.14 **Identifiable private information** means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- 3.15 **Identifiable biospecimen** means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
- 3.16 **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.

- 3.17 **Written, or in writing** means writing on a tangible medium (e.g., paper) or in an electronic format.
- 3.18 **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are **deemed not to be research**:
- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
 - Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
 - Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
 - Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
- 3.19 **Institutional Official (IO)** means a high-level official who is the signatory on the Federalwide Assurance (FWA) filed with OHRP and has the authority to represent the institution. The Vice Provost for Research and Innovation (VPR) serves as the IO for Wright State University.
- 3.20 **Federally Funded or supported** means any of the following:
- Funded by a direct federal grant
 - Funded through a sub-award or pilot grant associated with federal dollars
 - Includes personnel on a federally funded training grant
 - Research conducted under a no-cost extension

- Data will be used to support an application for FDA approval or a grant application (e.g., data collection in response to a scored grant submission with plans to re-submit)
- Involves an FDA-regulated product or dietary supplement
- Involves data collection about FDA-regulated products
- Conducted under a contract that requires the investigator to adhere to federal human subjects' regulations (e.g., 45 CFR 46, 34 CFR 97 or other references to the HHS Common Rule)
- Involves any services that could be billed to a federal program

4.0 Policy

The IRB will approve human subjects research that involves the inclusion of vulnerable populations (e.g., pregnant women or human fetuses, nonviable neonates or neonates of uncertain viability, or viable neonates, children, or prisoners) only if the investigator provides sufficient evidence such that the IRB can determine that the research satisfies all applicable institutional, federal, state, and local requirements. For example, for FDA regulated research involving children the IRB will ensure compliance with 21 CFR 50, Subpart D and 21 CFR 56.

For federally funded or supported research, the IRB will comply with all requirements of 45 CFR 46 to the extent that the sponsoring agency has adopted the standards reflected in Subparts B-D (see Sections 5.1-5.3). However, for human subject research that is not subject to 45 CFR 46, Wright State has developed standards that are intended to provide protections equivalent to those described in federal regulations. In some cases, the Wright State Institutional Official (IO) may provide the judgement normally assigned to the HHS Secretary in certain circumstances (see Sections 5.2.4.2 and 5.32).

Wright State has developed standards to protect vulnerable populations not covered by federal regulations. This policy defines these requirements and provides guidance in Sections 5.4-5.6).

5.0 Procedures

When investigators identify the potential to enroll vulnerable subjects in proposed research, they must provide the IRB with a justification for their inclusion in the study. The IRB will evaluate the justification and proposed safeguards, including the consent/assent process and determine whether there is the need for additional protections before approving such research. The IRB recognizes that additional safeguards may need to be included for subjects who are likely to be considered

vulnerable to coercion or undue influence and may decide to require additional protections for other vulnerable populations not described in this policy (e.g., economically disadvantaged).

The following regulatory requirements and guidance are included to ensure compliance and to assist investigators in developing appropriate justifications and safeguards in their IRB applications.

5.1 Pregnant Women, Human Fetuses, and Neonates

A research study is considered to include pregnant women, human fetuses, and/or neonates when any of the above are the target population that will be recruited; or when pregnancy occurs during the course of a research study and information about the pregnancy, fetus and/or neonate will be obtained as part of the research study.

Investigators involving this population must complete and submit any required supplemental information together with their original study application in the electronic submission system or before collecting data in the case where pregnancy occurs during the course of the study.

5.1.1 Pregnant Women and Fetuses

To approve research involving pregnant women or fetuses the IRB must make all of the following findings as defined in 45 CFR 46.204, Subpart B:

- 5.1.1.1 Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
- 5.1.1.2 The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or if there is no such prospect of direct benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
- 5.1.1.3 Any risk is the least possible for achieving the objectives of the research;

- 5.1.1.4 The research must either
- Hold out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus; or
 - Hold no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of Subpart A of 45 CFR 46;
- 5.1.1.5 If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of Subpart A, except that the father's consent need not be obtained if it is appropriately documented that he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- 5.1.1.6 Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- 5.1.1.7 For children as defined in 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of Subpart D;
- 5.1.1.8 No inducements, monetary or otherwise, will be offered to terminate a pregnancy; and
- 5.1.1.9 Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
- 5.1.1.10 Individuals engaged in the research will have no part in determining the viability of a neonate.

5.1.2 Neonates

To approve research involving viable neonates, neonates of uncertain viability, non-viable neonates the IRB must make all of the following findings (when applicable) as defined in 45 CFR 46.205, Subpart B:

- 5.1.2.1 Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;
- 5.1.2.2 Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate; and
- 5.1.2.3 Individuals engaged in the research will have no part in determining the viability of a neonate.

In addition to 5.1.2.1, 5.1.2.2 and 5.1.2.3, neonates of uncertain viability may not be involved in research unless the IRB also finds that:

- 5.1.2.3.1 The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
- 5.1.2.3.2 The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
- 5.1.2.3.3 he legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained except if that consent of the father or his legally authorized representative need not be obtained if there is appropriate documentation that pregnancy resulted from rape or incest.

In addition to 5.1.2.1, 5.1.2.2 and 5.1.2.3, nonviable neonates may not be involved in research unless the IRB also finds that:

- 5.1.2.3.4 Vital functions of the neonates will not be artificially maintained;
- 5.1.2.3.5 The research will not terminate the heartbeat or respiration of the neonate;

- 5.1.2.3.6 There will be no added risk to the neonate resulting from the research;
- 5.1.2.3.7 The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
- 5.1.2.3.8 The legally effective informed consent of both parents of the neonate must be obtained. If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice except that the consent of the father need not be obtained if there is sufficient documentation that the pregnancy resulted from rape or incest. Consent of parents cannot be obtained from a legally authorized representative.

5.1.3 Research Involving Placental or Fetal Material

Ohio Revised Code (ORC 2919.19) prohibits research on all products of conception resulting from purposeful termination of a pregnancy. Therefore, such research is prohibited at Wright State University. Investigators who plan to conduct research involving placental or fetal material should contact the IRB for more guidance prior to submitting a study application.

5.2 Children

Research that involves children, or the use of protected health information of children must meet the criteria for approval set forth in 45 CFR 46 Subparts A and D, unless the research has been determined to be exempt from IRB review.

When children are involved in research, federal regulations require the permission of the parent(s) or guardian before a child can be enrolled in research. While children may be legally incapable of giving informed consent, they nevertheless may possess the ability to assent, or refuse participation in a research study. Assent is a child's affirmative agreement to participate in research after an explanation of the study in language the child can understand.

Investigators should review the IRB's [Informed Consent Policy](#) for more information about parental permission and child assent.

In accordance with Ohio Revised Code (ORC 3109.01), a child in Ohio is defined as any person under the age of 18 who cannot legally consent to treatment and procedures for research. Investigators who plan to conduct research involving children must provide the IRB with sufficient information to determine the risk level of the research study. The IRB will document its findings in the meeting minutes (full board review) or in the approval letter (expedited review). To approve research involving children, the IRB must find that the proposed research falls under one of the following four regulatory categories:

- 5.2.1 **45 CFR 46.404/21 CFR 50.51** - Research not involving greater than minimal risk where adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 46.408
- 5.2.2 **45 CFR 46.405/21 CFR 50.52** - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects where the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:
 - 5.2.2.1 The risk is justified by the anticipated benefit to the subjects;
 - 5.2.2.2 The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
 - 5.2.2.3 Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 46.408.; or
- 5.2.3 **45 CFR 46.406/21 CFR 50.53** - 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 where the IRB finds that more than minimal risk to children is presented

by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

- 5.2.3.1 The risk represents a minor increase over minimal risk;
- 5.2.3.2 The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- 5.2.3.3 The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
- 5.2.3.4 Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in 46.408.

5.2.4 **45 CFR 46.407/21 CFR 50.54** - Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children where the IRB finds:

- 5.2.4.1 The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
- 5.2.4.2 The DHHS Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

- 5.2.4.2.1 That the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or (2) the following:
 - The research presents a reasonable opportunity to further the understanding, prevention, or

alleviation of a serious problem affecting the health or welfare of children;

- The research will be conducted in accordance with sound ethical principles;
- Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

5.2.5 Wards

Research involving children who are wards of the state, or any other agency, institution, or entity (including children in foster placement) must have consent for research given by the agency that has custody of the child. This usually requires the agency to appoint a child advocate with the appropriate background and experience to act in the child's best interests. The inclusion of children who are wards of the state usually requires that the research is:

5.2.6 Related to their status as wards; or

5.2.7 Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

5.2.8 A treatment protocol in which the majority of participants are not wards.

The IRB meeting minutes must document that the research is in accordance with 45 CFR 46.409 and 21 CFR 50.56 and is appropriate for the inclusion of participants who are wards.

5.3 Research Involving Prisoners

For the purposes of human subject research, a prisoner is defined in 45 CFR 46.303(c) as "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing."

Investigators are "engaged" in research involving prisoners when both of the following apply:

- The investigator obtains data through intervention and interaction with a prisoner, or identifiable private information about a prisoner; AND
- The investigator knows that one or more of the proposed subjects includes a person whose circumstances meet the regulatory definition of “prisoner” as defined above.

The IRB does not require investigators to determine prospectively whether each potential subject is or may become a prisoner. For example, if an investigator proposes to perform a chart review of patients who have been treated for a particular disease, it is unlikely that the investigator will know or discover as a result of reviewing charts that one or more of the patients in the cohort is a prisoner. The investigator is not required to seek information about subjects' prisoner status if such information is not necessary to answer the research question.

If, however, the investigator should happen to learn that one or more subjects is actually a prisoner, the protections and requirements described in this section will then apply to the research if that individual is to be enrolled in the study.

The responsibilities for IRB review of prisoner research under Subpart C must be fulfilled for all research subject to the 2018 Common Rule (45 CFR 46) and/or FDA-regulated research. Research not subject to federal requirements may be reviewed without the review of a prisoner representative (see below for more information).

5.3.1 IRB Review of Research Involving Prisoners

Initial review of more than minimal risk research involving prisoners must be conducted at a convened meeting. For research involving prisoners that is subject to Subpart C, an IRB member who qualifies as a prisoner representative must be present at the full board meeting and during the presentation, discussion, and vote of any study which involves prisoners. A majority of the IRB members (exclusive of the prisoner representative(s)) must have no association with the prison involved, apart from their membership on the IRB. This is also true for non-federally regulated research; however, presence of the prisoner representative is preferred, but not required.

The prisoner representative:

- Must be a voting IRB member or voting alternate IRB member.

- Must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections. The prisoner representative must receive all review materials pertaining to the research (same as primary reviewer).
- Must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved. Attendance may be by phone, videoconference, or webinar, as long as the representative is able to participate in the meeting as if they were present in person at the meeting.
- Must present his/her review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.

5.3.2 Required Determinations

For research involving prisoners that is subject to 45 CFR 46 Subpart C, the IRB must make and document the determinations (in the minutes or checklist for expedited research) noted below along with specific findings justifying those determinations:

- Whether the research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2);
- Whether the advantages of participating in this research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such magnitude to impair the participant's ability to weigh the risks of the research against the value of such advantages in the limited choice environment;
- Whether the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- Whether the procedures for the selection of participants within the prison (or other institution) are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners;
- Whether the information is presented in language that is understandable to the participant population;
- Whether the IRB has adequate assurance that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

- If the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Required external reporting for research involving prisoner that is subject to Subpart C can be found in the *Mandatory Reporting Policy*. HHS conducted or supported research involving prisoners as subjects must not proceed until OHRP issues its approval in writing to Wright State on behalf of the Secretary under 45 CFR 46.306(a)(2).

5.3.3 Other Reviews

Under this policy and federal regulations, research involving prisoners cannot receive an exemption determination or be conducted if regulated by the Department of Defense.

Continuing review of a full board study involving prisoners (more than minimal risk involving interventions/interactions) must occur using the same procedures for initial review, including the responsibility of the prisoner representative to review the continuing review materials and participate in the convened meeting as described above. However, such research may receive expedited continuing review under Category 8, if appropriate.

Amendments involving more than a minor change reviewed by the convened IRB must use the same procedures for initial review including the responsibility of the prisoner representative to review the modification and participate in the meeting (as described above).

Minor modifications to research involving prisoners may be reviewed using the expedited procedures described below, based on the type of modification.

5.3.4. Expedited Review of Research Involving Prisoners

Research only involving interactions (not interventions) may receive expedited review if the research involves no greater than minimal risk for the prison population being studied.

For research involving prisoners that is subject to Subpart C, the prisoner representative must concur with the determination that the research involves no greater than minimal risk. The prisoner representative and another voting IRB member must review and approve the study. Review of amendments and administrative updates must use the same procedures as initial review using the expedited procedure.

For research involving prisoners that is not subject to Subpart C, prisoner representative review using the expedited procedure is preferred but not required.

For research that does not involve interventions or interactions with prisoners (e.g., chart reviews, existing data reviews), review by a prisoner representative is not required if the research involves no greater than minimal risk.

5.3.5 Procedures When Subject Becomes a Prisoner While Enrolled in Non-Prisoner Study

For studies originally reviewed and approved by the IRB without prisoners as subjects, if the PI learns that a subject has become a prisoner during the study, the PI must submit a Reportable Event form via the electronic system to inform the IRB of the individual's change in status. In this report, the PI must indicate whether the individual's incarceration is expected to be temporary and, if not, whether the PI intends for the subjects to continue as a participant while incarcerated. If so, the PI must include the following:

- If it is in the subject's best interests to continue in the study as a prisoner, and whether the subject's status as prisoner affects the risks of participation in the study or the potential benefits that might accrue from continued participation.
- If the subject wishes to continue as a study participant, and what the re-consent process will be.
- If there are practical complications of subject continuation in the study,
- If there is any other factor that is important for the IRB to consider when determining whether the subject should continue as a participant in the study.

The IRB must make the final determination whether the subject may continue as a study subject. For studies subject to Subpart C the IRB must:

- Confirm that the incarcerated subject meets the definition of a prisoner.
- Terminate enrollment of the incarcerated subject or review the research study under Subpart C if it is feasible for the incarcerated subject to remain in the study.
- Before terminating the enrollment of the incarcerated subject, the IRB should consider the risks associated with terminating participation in the study. If the incarcerated subject cannot be terminated for health or safety reasons, keep the subject enrolled in the study and review the research under Subpart C.
- If some of the requirements of Subpart C cannot be met, but it is in the best interests of the subject to remain in the study, keep the subject enrolled and inform OHRP of the decision along with the justification for doing so, or
- Remove the subject from the study and keep the subject on the study intervention under an alternate mechanism such as compassionate use, off-label use, etc.

When Subpart C doesn't apply, the IRB will provide equivalent protections by:

- Confirming that the subject meets the definition of a prisoner.
- Deciding whether it is in the best interests of the incarcerated subject to remain in the study or to terminate enrollment.
- Also deciding whether it is feasible for the subject to remain in the study.
- If it is in the best interests of the subject to remain in the study, keep the subject in the study and review the research at next meeting of the convened IRB.

If a subject is incarcerated temporarily while enrolled in a study, the IRB will do the following:

- If the temporary incarceration has no effect on the study, make a determination that the subject can remain enrolled.
- If the temporary incarceration has an effect on the study, the IRB will review the involvement of the prisoner under the above

criteria for an individual who becomes a prisoner while enrolled in a research study.

5.4 Decisionally Impaired Research Subjects

Investigators conducting research involving decisionally impaired subjects must balance the societal commitment to advance important scientific knowledge with the ethical obligation to protect the rights and welfare of human subjects. For this reason, special protections must be considered by both investigators and the IRB when developing and reviewing research involving this vulnerable population.

For studies proposing to include adult decisionally-impaired subject, the following principles always apply:

- 5.4.1 Decisionally impaired subjects must comprise the only appropriate population and research question must focus on an issue relevant to this subject population. If the research question can be answered using non-impaired subjects, then decisionally impaired subjects should not be involved.
- 5.4.2 If the research involves greater than minimal risk, the risk must be commensurate with the degree of potential benefit.

Investigators should also review the Informed Consent Policy for more information on assent, as well as appropriate use of Legally Authorized Representatives (LARs) for this vulnerable population.

5.5 Non-English Speaking

An investigator who intends to include non-English speaking subjects must provide sufficient detail in the research protocol regarding the plan for inclusion, including the plan for obtaining informed consent and HIPAA Authorization and any other additional provisions during the study (see Informed Consent Policy for additional guidance).

If an investigator intends to enroll subjects who speak a language other than English, a translated version of the informed consent form and HIPAA

authorization must be submitted to the IRB for approval prior to use. The investigator must provide the qualifications of the individual or the service that was used to translate the informed consent documents. He/she may wish to delay translating the consent documents until the IRB has granted approval for the English version to avoid extra translation costs.

A translator/translation service fluent in both English and the language of the subject must be present/available during the informed consent process. If research is to be conducted in an affiliated hospital, investigators must consult with hospital administration prior to IRB application to ensure he/she understands and includes any related hospital requirements in the IRB application.

Many research studies include the provision to include individuals who do not speak English even though they are not the targeted subject population for that study. This is likely to occur when there is equitable selection of subjects from Wright State University's general population. In such cases, investigators may consider use of a "short form" in accordance with 45 CFR 46.117(b)(2). The "short form" must be in the subject's native language and approved by the IRB prior to use. However, it is important to understand that the "short form" can only be used once per language per study.

5.6 Students and Employees

Students and employees recruited as research subjects are more vulnerable to coercion because of the possibility that they may perceive grades, employment or other benefits as dependent upon their participation in research. Challenges related to maintaining confidentiality are also greater when subjects are affiliated with Wright State or known to researchers.

Therefore, additional safeguards may be required to protect the rights and welfare of these individuals. One such safeguard is that, absent sufficient justification, investigators should not enroll themselves, employees who report to them directly, or students who are currently enrolled in a class taught by the investigator, in studies determined by the IRB to involve greater than minimal risk. Additional safeguards for research involving students or employees may be required at the IRB's discretion. For more information about research with students, see the [Faculty Research with Students in their Classes Guidance](#).

5.6.1 Recruitment of Students

Investigators who plan to recruit student must be able to provide a rationale, other than convenience, for involving students and must demonstrate in the IRB application how the recruitment method will not lead to potential subjects thinking they will be compromised by not participating. For example, including a rational that describes how participation will be a valuable educational experience demonstrated by a substantive plan for debriefing or a rational that includes a formal student subject pool and related departmental policy.

Class instructors using student's education records (e.g., assignments, grades, journals, etc.) will need to comply with the Family Educational Rights and Privacy Act (FERPA). For more information about FERPA requirements see [Research with FERPA Protected Educational Records Guidance](#).

5.6.2 Recruitment of Employees

Investigators who plan to recruit employees must be able to provide a rationale, other than convenience, for involving employees and must demonstrate in the IRB application how the recruitment method will not lead to potential subjects thinking they will be compromised by not participating.

An employee may not be required to participate in research as a condition of employment. Template consent form language attesting this is required in cases where informed consent will be obtained. Investigators should not use employee data for research purposes without IRB approval and permission from Human Resources.

6.0 Records:

All records related to this process will be stored and maintained in accordance with any Wright State policy, federal regulations and sponsor requirements associated with the human subject research protocol under review.

7.0 References:

- 45 CFR 46, Subpart B "Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research"
- 45 CFR 46, Subpart C "Additional Protections for Prisoners"
- 45 CFR 46, Subpart D "Additional Protections for Children Involved as Subjects in Research"



Vulnerable Populations
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- 45 CFR 46.115(b)
- 45 CFR 46.117(b)(2)
- 21 CFR 56.115(a)(1) - (4)
- 21 CFR 56.115(b)
- 21 CFR 50.51-56
- Wright State *Informed Consent Policy*