1 PURPOSE

This SOP outlines additional protections that researchers and IRBs should consider when proposed research activities involve potentially vulnerable populations, including students, employees, and adults with impaired decision-making capacity.

2 OVERVIEW

The inclusion of certain groups of participants who may be vulnerable to undue influence or coercion may require additional protections. When reviewing research involving vulnerable populations, the IRB applies any additional federal regulations, state and local laws, and institutional policies as applicable. The IRB evaluates whether additional safeguards have been included project to protect the rights and welfare of participants who may be vulnerable to undue influence. The IRB requires at least one or more knowledgeable individuals or have experience in working with these populations to be part of the review process.

3 GENERAL INFORMATION

3.1 Federal regulations require additional protections for participants vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. These, and other individuals not specifically named in the regulations, may be vulnerable to coercion or undue influence because their autonomy is limited in some way, thereby affecting their ability to provide voluntary, informed consent. (See SOP 014: Research Involving Children and SOP 047: Research Involving Prisoners.)

3.2 Pressures to participate may be subtle, as when research is conducted in settings or institutions providing employment or services (e.g., medical care or education). Individuals may believe that choosing or refusing to participate will influence access to or the quality of employment opportunities or desired services. Research should be designed to address any such potential pressures to maintain an individual's right to decline participation. Researchers and IRB should consider participant selection, recruitment, and informed consent processes.

3.3 Observation of these consent processes (e.g., by IRB members or other WVU OHRP staff) or other similar protections should be considered when concerns exist about whether potential participants can exercise free choice regarding research participation. Examples include research involving individuals whose willingness to participate may be unduly influenced by the expectation of potential benefits for their disease or condition, or those who may be in a position to fear negative consequences (real or perceived) from a supervisor or other authority figure for refusing to participate.

4 STUDENTS AS RESEARCH PARTICIPANTS

4.1 Students, including WVU students (e.g., undergrads, graduate students, medical students, residents, fellows, doctoral students, etc.), can be recruited for research participation. A student must not be required to participate in research (without a comparable non-research alternative offered) as a course requirement. Individual students, nor groups of students, should not be selected solely based on convenience when they would not otherwise be appropriate for inclusion.

4.2 Recruitment of students as research participants must be designed to minimize the possibility of coercion or undue influence. In general, potential participants should be solicited from a broad pool of individuals meeting the conditions for the research rather than by personal solicitation of specific individuals. Strategies to minimize the potential influence of an investigator when recruiting their students include recruitment by general announcements, postings or sign-up sheets, or other methods that require a student interested in participation to initiate contact with the researcher(s).

4.3 Researchers and IRBs must consider strategies to ensure voluntary participation when the participants of research include students who receive instruction directly from the researcher(s). Young students may volunteer to participate in research to please a teacher or because they fear that failure to participate will negatively affect their relationship with the teacher-researcher or faculty in general. Students' cultural or religious backgrounds may also influence their choices. A student's decision about research participation must not affect (favorably or unfavorably) grades, potential letters of recommendation, or other opportunities or decisions made by teacher-researchers.

4.4 Except in unusual circumstances, researchers should not enroll students from their classes when the research involves greater than minimal risk without the prospect of direct benefit to individual participants. Such research should occur only when the IRB determines that adequate provisions have been made to minimize the possibility of coercion, and it is determined that the research is of significant importance and cannot be conducted without the enrollment of these students.

4.5 Additional safeguards may be needed to protect the privacy interests of research participants when the participants are students. Classroom conditions may make it difficult for researchers to keep an individual's participation confidential, which could pose risks to participants (e.g., when stigma is associated with the condition or question in the project or when peer pressure is a component of the research). In such situations, consideration should be given to whether conducting the research off-site and/or outside of regular school hours may minimize potential risks.

4.6 Protecting the confidentiality of research participants' personal information when the participants are students may also present additional challenges. The extent to which personal information and/or research data may be accessible to parents, teachers, or others not directly involved in the research must be considered and disclosed to potential participants and their parents/guardians (as applicable) in the informed consent and assent processes (See SOP 012: Informed Consent Requirements, and SOP 015: Assent and Parental Permission.)

4.7 Certain additional protections for students and parents are provided by federal regulations. The proposed use of student education records for research must comply

with the requirements of the Family Educational and Rights Privacy Act (FERPA). Research involving surveys with students must comply with the Protection of Pupil Rights Amendment (PPRA).

5 STUDENT RESEARCH "POOLS" AND EXTRA CREDIT

5.1 WVU students are offered the opportunity to participate in research (as participants) in various ways. Examples include participation for credit as part of a course requirement, for extra credit in a course, or in exchange for payment. A student must not be required to participate in research for course credit unless a comparable non-research alternative is also offered.

5.2 To minimize the potential for coercion, alternatives to participating in research for course credit must be comparable in terms of time, effort, and fulfillment of course requirements. Examples include reading and/or writing research papers, attending research presentations offered by faculty, or observing the performance of research projects.

5.3 All research participants, including students, must be free to withdraw from participation at any point in a project without penalty. Students who withdraw from a research project for course credit must receive full course credit for participation. When payment is offered, credit for payment should accrue as the project progresses (as appropriate to the research) and should not be contingent upon the student completing the entire project.

5.4 Project-specific informed consent is required as described in SOP 012: Informed Consent Requirements and SOP 016: Documentation of Informed Consent Process. Parental permission and assent are required for any student who meets the legal definition of a child/minor (See SOP 014: Research Involving Children).

5.5 The policy and procedures for offering extra credit as an incentive to WVU students for voluntary participation in research are outlined below:

5.5.1 The department wishing to offer extra credit as an incentive to student research participation develops and submits an Extra Credit Policy Plan to WVU OHRP.

5.5.2 The WVU IRB Chair Committee reviews and approves the Extra Credit Policy Plan.

5.5.3 Upon approval, the department will receive an Extra Credit Policy Approval Letter.

5.5.4 After receiving the approval letter, researchers can submit research protocols providing extra credit opportunities to potential student participants.

5.5.5 When a protocol is submitted for review, the reviewer(s) and/or WVU OHRP staff should verify that an Extra Credit Policy Plan is on file for that department before approval of the protocol.

5.5.6 If an Extra Credit Policy Plan is not on file, the reviewer(s) and WVU OHRP staff should inform the PI so that an Extra Credit Policy Plan can be submitted for review, or the extra credit language should be removed from the protocol.

6 EMPLOYEES AS RESEARCH PARTICIPANTS

6.1 Employees, including university employees (e.g., full-time, part-time, temporary, visiting, student employee appointments, etc.) may be recruited for research participation. However, an employee must not be required to participate in research as a condition of employment. Individual students, nor groups of students, should not be selected solely based on convenience when they would not otherwise be appropriate for inclusion.

6.2 Recruitment of potential participants who are employees must be designed to minimize the possibility of coercion or undue influence. In general, potential participants should be solicited from a broad pool of individuals meeting the conditions for project, rather than from individuals who report directly to the researcher(s). Strategies to minimize the potential influence of a researcher when recruiting their employees include recruitment through a third party unassociated in a supervisory relationship with the employee, postings or sign-up sheets, or other methods that require an employee interested in participation to initiate contact with the researcher(s).

6.3 Researchers and IRBs must consider strategies to ensure voluntary participation when the participants of research include employees who are directly supervised by the researcher(s). An employee's decision about research participation must not affect (favorably or unfavorably) performance evaluations, career advancement, or other employment-related decisions made by peers or supervisors.

6.4 Except in unusual circumstances, researchers should not enroll employees under their direct supervision when the research involves greater than minimal risk without the prospect of direct benefit to individual participants. Such research should proceed only when the IRB determines that adequate provisions have been made to minimize the possibility of coercion, and it is determined that the research is of significant importance and cannot be conducted without the enrollment of these employees.

6.5 Additional safeguards may be needed to protect the privacy interests of employees who are also research participants. Workplace conditions may make it difficult for researchers to keep an individual's participation confidential, which could pose risks to participants (e.g., when stigma is associated with the condition or question under project or when peer pressure is a component of the research). In such situations, research should be conducted off-site and/or outside of regular work hours, when possible, to minimize potential risks.

6.6 Protecting the confidentiality of research participants' personal information when the participants are employees may also present additional challenges. The extent to which medical information and/or research data may be accessible to supervisors or others not directly involved in the research must be considered and disclosed to potential participants in the informed consent process (See SOP 012: Informed Consent Requirements).

6.7 In cases where regular workplace activities are also the research topic, researchers must clarify for potential research participants those activities that are optional and distinct from any mandatory workplace activities that would occur even without the research. When access to individuals or the site's facility is needed for recruitment and/or research activities, a letter of support from someone authorized to speak on behalf of the employees/site may be required.

7 ADULTS WITH IMPAIRED DECISION-MAKING CAPACITY

7.1 Impaired decision-making capacity comprises a broad range of conditions. Examples include healthy individuals in shock (temporary decisional impairment), those born with severe intellectual disabilities (permanent decisional impairment), individuals with age-related dementia (progressive decisional impairment,) individuals with mental illnesses such as schizophrenia (fluctuating capacity), and individuals under the influence of certain drugs (temporary and/or fluctuating capacity). Generally, all adults should be presumed capable of providing informed consent unless there is either specific evidence that an individual's condition/disability would impair reasoning or judgment or another indication that the individual is unable to understand and choose whether or not to participate in research.

7.2 Researchers and IRBs should consider the capacity of potential research participants to provide informed consent. Methods to assess capacity appropriate to the research should be included when necessary. Key factors in individuals' consideration of research participation include an appreciation of how the risks, benefits, and alternatives to participation apply to them personally. When the research involves greater than minimal risk, an independent assessment of the potential participant's capacity to consent should be performed (or confirmed), except in unusual circumstances where the IRB determines that the research is of critical importance and could not be conducted if the independent assessment were to be required. Methods to provide independent assessments include subjective assessments made by a qualified professional independent of the research team or use of a valid objective instrument(s) designed to evaluate capacity.

7.3 Federal regulations require additional safeguards to protect the rights and welfare of research participants who are likely to be vulnerable to coercion or undue influence. Among others, the regulations include children and individuals with impaired decision-making capacity in this category. When children are the and adults with impaired decision-making capacity are included in the research and the ability to provide informed consent is in question, obtaining assent may be an appropriate safeguard (see "Assent of Adults" below). Additional protections for adults with impaired decision-making capacity should be proportional to the severity of the decisional impairment and level of risk.

7.4 Researchers and IRBs should consider the following in their decision to enroll adults with impaired decision-making capacity:

- The extent to which the research aims to improve the understanding, diagnosis, prevention, or treatment of the disorders or conditions that are the cause of the incapacity
- The study of related conditions, phenomena, or circumstances that uniquely affect the research participants may contribute in important ways to the current or future welfare of the population and therefore may also serve to justify their inclusion in research
- The inclusion of individuals who lack the capacity may be appropriate in research that offers therapeutic or other benefits to the individual participant when standard approaches are less effective, unproven, or satisfactory.

7.5 Researchers and IRBs should consider additional safeguards, balancing the need for protection with the individuals' right to autonomy. Examples of additional safeguards include (but are not limited to) the following:

- Securing an independent assessment of the participant's capacity to consent (or valid objective instrument(s) designed to evaluate capacity);
- Identification of a legally authorized representative who has the authority to consent to the adult's participation in research;
- Obtaining assent (if applicable) from the participant, in addition to surrogate consent;
- Regular assessment of the participant's capacity and provisions for reconfirming the consent of a participant who regains capacity during the course of the research;
- Involvement of family members familiar with the participant's personal values;
- Designation of an individual at the beginning of the project to serve as a legally authorized representative (only) if the participant's decision-making capacity becomes compromised during the project;
- Use of informational/educational techniques to enhance communication and understanding during the consent process (such as teach-back method);
- Including waiting periods in the consent process;
- Involvement of a research participant advocate;
- Limiting the risks to which an adult with impaired decision-making capacity is exposed when direct benefits are not anticipated;
- Use of an independent monitor, or data monitoring committee; or
- Observation of the informed consent process by a third party as designated by the IRB.

7.6 Regulations require that IRBs regularly review research involving vulnerable participants consider including one or more individuals who are knowledgeable about and experienced in working with these participants. When reviewing research involving adults with impaired decision-making capacity, WVU OHRP and WVU IRBs will include an individual with appropriate background, knowledge, and experience, and/or a representative of the relevant advocacy group as a member or consultant to the IRB.

7.7 For more information about the requirements for involving adults with impaired decision-making capacity in research in life-threatening situations, see SOP 053: Emergency Use of Investigational Drugs, Biologics, or Devices and SOP 054: Planned Emergency Research.

8 ASSENT OF ADULTS

8.1 An adult with impaired decision-making capacity or other adult cognitively unable to provide informed consent may participate in research only if a legally authorized representative for that adult can give consent for participation in the research, unless the requirement to obtain informed consent is waived by the IRB. If the participant regains (or develops) the capacity to consent, then their informed consent must be obtained for any further research, as the consent of the legally authorized representative is no longer valid.

8.2 An adult with impaired decision-making capacity may be able to assent to participation. The IRB is responsible for determining when the assent of some or all such adults is required in proposed research and the appropriate method for documenting the adult's assent (if any), as described below.

8.3 Assent to participate in research by an adult with impaired decision-making capacity (for whom a legally authorized representative will provide informed consent) is to be obtained when, in the judgment of the IRB, the adult is cognitively capable of providing assent. In determining whether proposed participants are capable of providing assent, the IRBs will take into account the condition and psychological/emotional states of the adults involved. The IRB's determination of the participant's capacity to assent may apply to all or only some of the adults to be involved in a proposed research activity.

8.4 Assent processes are to include the key elements of informed consent described in SOP 014: Informed Consent Requirements and are to be provided in language appropriate for an adult with impaired decision-making capacity, based on the nature of the research and the expected ability of the prospective participant(s) to understand the purpose and the procedures involved in the research.

8.5 The assent of adults with impaired decision-making capacity to participate in research is to be obtained, except in any of the following circumstances:

- The adults are not capable of providing assent based on condition or psychological/emotional state;
- The capability of some or all of the adults is so limited that they cannot reasonably be consented; or

- Assent can be waived using the criteria for waiver (or alteration) of informed consent, as described in SOP 014: Informed Consent Requirements.

8.6 The IRB may determine that assent of some or all of the adults is not required. If assent is not a requirement of some adults, the IRB will indicate which adults (e.g., individuals with severe dementia) are not required to assent.

8.7 When the assent of an adult with impaired decision-making capacity is required, the IRBs must determine the appropriate method of documenting assent (if any). This decision should be based on considerations such as the length and complexity of the research and the adult's condition and psychological/emotional state.

8.8 When documentation of assent is required, either of the two options below are considered adequate:

- An assent form, similar to the consent document signed by the legally authorized representative, is used for the adult assent and signature; or
- A signature line for assent is added to the consent document that the legally authorized representative and adult both sign.

Please note: The IRB can also approve assent forms or revised consent documents on a case-by-case basis in other formats to satisfy requirements for obtaining and documenting assent of adults with impaired decision-making capacity.

8.9 When assent is not documented by use of a form or method as described above, documentation of assent may be limited to verifying that assent took place using a witness or other method. The IRB may also decide that documentation of assent is not warranted. If verbal assent will be obtained, the IRB must review a written description of the information (i.e., script) that will be provided to participants during the assent process.

8.10 In some research, such as longitudinal projects involving progressive disorders or aging populations, participants may be able to provide informed consent at the beginning of their participation but may experience progressive or intermittent symptoms that lead to decisional impairment during participation in the project. In these situations, researchers should consider the need to discuss with prospective participants whether the participant should designate someone at the beginning of the project to serve as a legally authorized representative in the case that the participant's ability to assess their own needs/interests becomes compromised during the project.

8.11 For cases in which the authority of a legally authorized representative for an adult participant's participation in research is unclear, researchers and IRBs should consult with WVU's General Counsel for Research for guidance.

9 REFERENCES

WVU Policies:
SOP 012: Informed Consent Requirements
SOP 014: Research Involving Children
SOP 015: Assent and Parental Permission
SOP 016: Documentation of Informed Consent Process
SOP 047: Research Involving Prisoners
SOP 053: Emergency Use of Investigational Drugs, Biologics, or Devices
SOP 054: Planned Emergency Research

Federal Regulations:
21 CFR 56.111
45 CFR 46.111

AAHRPP:
Standard II.4