



## VULNERABLE POPULATIONS: STUDENTS, EMPLOYEES, AND ADULTS WITH IMPAIRED DECISION-MAKING CAPACITY

### 1. Overview

The purpose of this policy is to outline additional protections that investigators and IRBs should consider when proposed research activities involve potentially vulnerable populations, including students, employees, and adults with impaired decision-making capacity.

### 2. Definitions

**Impaired decision-making capacity:** As it applies to informed consent, lacking the ability to provide valid informed consent to participate in research (e.g., as a result of trauma, intellectual disability, certain mental illnesses, cognitive impairment, or dementia). *Note: Impaired decision-making capacity may be temporary, permanent, progressive, or fluctuating.*

**Legally Authorized Representative:** An individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. For purposes of HRPP policy, the following are recognized in Ohio as legally authorized representatives:

- Persons appointed as health care agents under an Ohio Durable Power of Attorney for Health Care
- Court-appointed guardians
- Next of kin in the following order: spouse, adult child, parent, and adult sibling.

### 3. General Information

- A.** Federal regulations require additional protections for subjects 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.
- B.** 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. Investigators and IRBs should give particular consideration to subject selection, recruitment, and informed consent processes.
- C.** Observation of the consent process (e.g., by IRB members or ORRP staff) or other similar protections should be considered when concerns exist about whether potential



participants can exercise free choice regarding research participation. Examples include studies 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

- A. Students, including Ohio State students (e.g., undergraduates, graduate students, medical students, residents, fellows, doctoral students, etc.) may be recruited for research participation; however, a student must not be required to participate in research (without a comparable non-research alternative offered) as a course requirement. Students (individuals or groups) should not be selected solely on the basis of convenience when they would not otherwise be appropriate for inclusion. For more information on equitable selection of subjects, see HRPP policy [\[Recruiting Methods, Recruitment Materials, and Participant Compensation\]](#).
- B. 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 base” of individuals meeting the conditions for study, rather than by personal solicitation of specific students. Strategies to minimize the potential influence of an investigator when recruiting his/her own 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 investigator(s).
- C. Investigators and IRBs must consider strategies to ensure voluntary participation when the subjects of research include students who receive instruction directly from the investigator(s). Young students, in particular, may volunteer to participate in research in an effort to please a teacher (e.g., as when credit is given for participation in class) or because they fear that failure to participate will negatively affect their relationship with the teacher-investigator or faculty in general (i.e., by seeming uncooperative or unaware of scholarly research). Students’ cultural or religious backgrounds (e.g., requiring deference to authority figures) 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-investigators.
- D. Except in unusual circumstances, investigators should not enroll students from their own classes when the research involves greater than minimal risk without the prospect of direct benefit. Such studies should proceed only when the IRB determines that adequate provisions have been made to minimize the possibility of coercion, and that the research is of significant importance and cannot be conducted without the enrollment of these students.
- E. 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 investigators 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 study 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.

- F. 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.
- G. In cases where regular classroom activities are also the topic of research, investigators must clarify for potential research participants (and/or their parents, as applicable) those activities that are optional and distinct from required classroom activities that would take place even without the research. When access to students, educational records, or school facilities is needed for recruitment and/or research activities, a letter of support from an individual authorized to speak on behalf of the school/district (e.g., principal or superintendent) is generally required.
- H. 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"

- A. Ohio State students are offered the opportunity to participate in research (as subjects) in various ways. Examples include participation for credit as part of a course requirement (e.g., Psychology Research Education Program), 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.
- B. To minimize the potential for coercion, alternatives to participating in research for course credit that are offered 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 performance of research studies.
- C. All research participants, including students, must be free to withdraw from participation at any point in a study without penalty. Students who withdraw from a research study for course credit must receive full course credit for participation. When payment is offered, credit for payment should accrue as the study progresses (as appropriate to the research) and should not be contingent upon the student completing the entire study. For more information, see HRPP policy [[Recruiting Methods, Recruitment Materials, and Participant Compensation](#)].
- D. Study-specific informed consent is required as described by federal regulations and HRPP policies [[Informed Consent Process and the Elements of Informed Consent](#)] and [[Documentation of the Informed Consent Process](#)]. Parental permission and assent are required for Ohio State students (including high school students taking Ohio State



courses) who meet the regulatory definition of children. Refer to HRPP policy [[Research Involving Children](#)] for additional guidance on this population.

## 6. Employees as Research Participants

- A. Employees, including university employees (e.g., full-time, part-time, temporary, visiting, student employee appointments) may be recruited for research participation; however, an employee must not be required to participate in research as a condition of employment. Employees (individuals or groups) should not be selected solely on the basis of convenience when they would not otherwise be appropriate for inclusion. For more information on equitable selection of subjects, see HRPP policy [[Recruiting Methods, Recruitment Materials, and Participant Compensation](#)].
- B. 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 base” of individuals meeting the conditions for study, rather than from individuals who report directly to the investigator(s). Strategies to minimize the potential influence of an investigator when recruiting his/her own 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 investigator(s).
- C. Investigators and IRBs must consider strategies to ensure voluntary participation when the subjects of research include employees who are directly supervised by the investigator(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.
- D. Except in unusual circumstances, investigators should not enroll employees under their direct supervision when the research involves greater than minimal risk without the prospect of direct benefit. Such studies should proceed only when the IRB determines that adequate provisions have been made to minimize the possibility of coercion, and that the research is of significant importance and cannot be conducted without the enrollment of these employees.
- E. Additional safeguards may be needed to protect the privacy interests of employees who are also research participants. Workplace conditions may make it difficult for investigators 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 study 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.
- F. 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.



- G.** In cases where regular workplace activities are also the topic of research, investigators must clarify for potential research participants those activities that are optional and distinct from any mandatory workplace activities that would take place even without the research. When access to individuals or the facilities of the site 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**

- A.** 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.
- B.** Investigators 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.
- C.** Federal regulations require additional safeguards to protect the rights and welfare of research subjects 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 of subjects. As when children are the subjects of research, for adults with impaired decision-making capacity to provide informed consent, obtaining assent may be one 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.
- D.** The following are the categories of research that may involve adults with impaired decision-making capacity and any additional conditions that must be met for approval:
- 1.** Research involving not greater than minimal risk that presents the prospect of direct benefit to such adults
  - 2.** Research involving greater than minimal risk but presenting the prospect of direct benefit when comparison of the risk to the anticipated benefit to such adults is at least as favorable as that presented by alternative approaches



3. Research involving greater than minimal risk *without* the prospect of direct benefit but likely to yield generalizable knowledge about the individual's disorder or condition, provided that
  - The risk to such adults presents no more than a minor increase over minimal risk, and
  - The investigators cannot obtain the desired information by enrolling adults cognitively capable of providing consent.
  
- E. Investigators 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 study population and therefore may also serve to justify their inclusion in research
  - The inclusion of individuals who lack capacity may be appropriate in research that offers therapeutic or other benefits to the individual participant when standard approaches are less effective, unproven, or unsatisfactory.
  
- F. Investigators 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
  - Identification of a legally authorized representative who has the authority to consent to the adult's participation in research
  - Obtaining assent 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 study to serve as a legally authorized representative (only) if the participant's decision-making capacity becomes compromised during the study
  - Use of informational/educational techniques to enhance communication and understanding during the consent/assent processes
  - Including "waiting periods" in the consent/assent processes
  - Involvement of a research subject 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
  - Observation of the informed consent/assent processes by a third party as designated by the IRB.



- G.** Regulations require that IRBs regularly reviewing research involving vulnerable subjects consider including one or more individuals who are knowledgeable about and experienced in working with these subjects. When reviewing research involving adults with impaired decision-making capacity, the university IRBs will include an individual(s) with appropriate background, knowledge, and experience, and/or a representative(s) of relevant advocacy groups as a member(s) or consultant(s) to the IRB. For more information, see HRPP policy [[IRB Composition and IRB Member Roles and Responsibilities](#)].
- H.** For information about the requirements for involving adults with impaired decision-making capacity in research in life-threatening situations, see HRPP policies [[Planned Emergency Research](#)] and [[Emergency Use of Investigational Drugs, Biologics, or Devices](#)].

## 8. Assent of Adults

- A.** 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 his/her informed consent must be obtained for any further research, as the consent of the legally authorized representative is no longer valid.
- B.** An adult with impaired decision-making capacity research 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.
- C.** 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.
- D.** Assent processes are to include the key elements of informed consent described in HRPP policy [[Informed Consent Process and the Elements of Informed Consent](#)] and are to be provided in language appropriate for an adult with impaired decision-making capacity, based on the nature of the study and the expected ability of the prospective participant(s) to understand the purpose and the procedures involved in the research.
- E.** 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 consulted



- Assent can be waived using the criteria for waiver (or alteration) of informed consent, as described in HRPP policy [[Informed Consent Process and the Elements of Informed Consent](#)].
- F. The IRBs may determine that the 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.
- G. When the assent of an adult with impaired decision-making capacity is required, the IRBs must determine the appropriate method, if any, of documenting assent. 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.
- H. Generally, when documentation of assent is required an assent form similar to the consent document signed by the legally authorized representative is used. Assent form templates containing the basic elements of informed consent are available on the ORRP website. Alternatively, based on the condition of the adults and nature of the research, for some studies investigators may add a signature line for assent to the consent document that legally authorized representatives will sign. The IRBs can also approve assent forms on a case-by-case basis in other formats that satisfy requirements for obtaining and documenting assent.
- I. When assent is not documented by use of a form as described above, documentation of assent may be limited to verifying that assent took place using a witness or other method. Alternatively, the IRB may 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., a script) that will be provided to participants during the assent process.
- J. In some research, such as longitudinal studies 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 study. In these situations, investigators should consider the need to discuss with prospective participants whether the participant should designate someone at the beginning of the study to serve as a legally authorized representative in the case that the participant's ability to assess his or her own needs/interests becomes compromised during the study.
- K. For cases in which the authority of a legally authorized representative to grant permission for an adult subject's participation in research is unclear, investigators and the IRBs should consult with the Office of Legal Affairs for assistance.

## 9. Applicable Regulations/Guidance

21 CFR 56.111, pre-2018 and Final Rule (45 CFR 46.111), National Bioethics Advisory Commission "Research Involving Persons with Mental Disorders That May Affect Decision-making Capacity" (Volume 1, Report and Recommendations, 12/98), NIH Guidance "Research Involving Individuals with Questionable Capacity to Consent: Points to Consider" (11/09), OHRP "Informed Consent Frequently Asked Questions" (revised 07/14/08),





AAHRPP “Reviewing Research Involving Adult Participants with Diminished Functional Abilities Related to Capacity to Consent” (04/18/13)

**10. History**

Issued: 05/11/2009

Revised: 05/31/2012, 01/13/2020

Edited: 09/19/2016