6 Vulnerable Subjects in Research

6.1 Policy

When some or all of the Participants in a Research Under the Auspices of the Institution’s IRB are likely to be vulnerable to coercion or undue influence or have diminished decision-making capacity, the Research must include additional safeguards to protect the rights and welfare of these Participants. The IRB must ensure that all of the regulatory requirements for the protection of Vulnerable Subjects are met and that appropriate additional protections for Vulnerable Subjects are in place.

The following procedures describe the requirements for involving vulnerable Participants in Research Under the Auspices of the Institution’s IRB.

6.2 Involvement of Vulnerable Populations

When some or all of the Participants in a Protocol are likely to be vulnerable to coercion or undue influence, the IRB should include additional safeguards to protect the rights and welfare of these Participants. Some of the Vulnerable Populations that might be involved in Research include individuals who are educationally or financially disadvantaged, Children, Pregnant Women, Fetuses, Neonates, Prisoners, or economically or educationally disadvantaged, or adults who lack the ability to consent, students, employees, or homeless persons.

If the IRB reviews Research that involves categories of Participants vulnerable to coercion or undue influence, the review process will include one or more individuals who are knowledgeable about or experienced in working with these Participants. For example, the IRB will include one or more individuals who are knowledgeable about or experienced in working with Children, Prisoners, or adults with limited decision-making capacity, when reviewing Research that involves individuals from these populations.

Additional requirements for IRB oversight of Research involving Vulnerable Populations can be found at 45 CFR § part 46, which includes the following:

- Subpart B - Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research;
- Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects; and
- Subpart D - Additional Protections for Children Involved as Subjects in Research.

DHHS-funded research that involves any of these populations must comply with the requirements of the relevant subparts. Research funded by other federal agencies may or may not be covered by the subparts.

Under Tulane’s FWA the subparts only apply to DHHS-funded research and research funded by another federal agency that requires compliance with the subparts (FDA regulations include Subpart D, which applies to all FDA-regulated research). The following policies and procedures, which are based on the subparts, apply to all research regardless of funding. The individual sections describe how the subparts apply to DHHS-funded research.
6.3 Definitions

*Vulnerable Population (or “Vulnerable Subjects”)*: This includes the following classes of potential or actual Research subjects: Children, Prisoners, Pregnant Women, mentally-disabled persons, or economically- or educationally-disadvantaged persons.

6.4 Responsibilities

1. The PI is responsible for identifying the potential for enrolling Vulnerable Subjects in the Research Proposal. The PI is responsible for identifying patients who are at risk for impaired decisional capacity as a consequence of psychiatric illness, and who are being asked to participate in a Research study with greater than Minimal Risk.

2. The IRB shall include representation, either as members or ad hoc consultants, individual(s) interested in or who have experience with the Vulnerable Populations involved in a Research Proposal.

3. The IRB reviews the PI’s justifications for including Vulnerable Populations in the Research to assess appropriateness of the Research Proposal.

4. The IRB must ensure that additional safeguards have been included in each study to protect the rights and welfare of Vulnerable Subjects as needed at the time of Initial Review of the Research Proposal.

5. The IRB shall continue to review Research at intervals appropriate to the degree of risk and determine whether the proposed Research continues to fulfill criteria for approval. Information reviewed should include the number of Participants considered as members of specific Vulnerable Populations.

6. For studies that do not have or are not required to have a DSMB or a Data Monitoring Committee and have entered Vulnerable Subjects, the IRB needs to carefully review the DSM plan.

7. The IRB should be knowledgeable about and experienced in working with populations who are vulnerable to coercion and undue influence. If the IRB requires additional qualification or expertise to review a Protocol, it should obtain consultation.

6.5 Procedures

6.5.1 Initial Review of Research Proposal:

The following steps are relevant with respect to initial review of a Research Proposal:

1. The PI should identify the potential to enroll Vulnerable Subjects in the proposed Research at Initial Review and provide the justification for their inclusion in the study.

2. The IRB evaluates the proposed plan for consent of the specific Vulnerable Populations involved. If the Research involves adults unable to consent, the IRB evaluates the proposed plan for permission of Legally Authorized Representatives.

3. The IRB evaluates and approves the proposed plan for the Assent of Participants.

4. The IRB evaluates the Research to determine the need for additional protections and consider the use of a DSMB or data safety monitoring committee, as appropriate.
5. The PI should provide appropriate safeguards to protect the subject’s rights and welfare, which may include the addition of an independent monitor. The independent monitor is a qualified individual not involved in the Research study who will determine the subject’s capacity to provide voluntary informed consent. Populations requiring independent monitoring might include individuals with schizophrenia, other psychotic disorders or conditions characterized by lack of reality testing (i.e., psychosis). Populations not usually requiring independent monitoring would include those with substance use disorders.

6. The IRB assess the adequacy of additional protections for Vulnerable Populations provided by the PI.

6.5.2 **Continuing Review and Monitoring.**

At Continuing Review, the PI should identify the number of Vulnerable Subjects enrolled and any that needed an independent monitor in the progress report.