GUIDANCE: IRB Review of Vulnerable Populations

1 PURPOSE
1.1 This guidance establishes the process when the Sharp HealthCare (SHC) Institutional Review Board (IRB) reviews research involving subjects likely to be vulnerable to coercion or undue influence.
1.2 The guidance begins when a research study is submitted to the IRB that includes subjects who may be vulnerable to coercion or undue influence.
1.3 The guidance ends when the IRB makes its determination to approve or not approve the research.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None.

3 POLICY STATEMENT
3.1 Certain groups of participants are considered to be particularly vulnerable to coercion or undue influence in a research setting. These vulnerable participants, as outlined in 45 CFR 46.111(b) are children, wards of the state, prisoners (SHC does not conduct research with prisoners), pregnant women and fetuses, persons who are mentally disabled or otherwise cognitively impaired, and economically or educationally disadvantaged persons. In addition, other special populations, including students, employees, illiterate English speaking subjects, non-English speaking subjects, and individuals with increased susceptibility to harm from the procedures of the specific study under review (e.g., individuals who would be answer survey study questions about their sexual assault) are also considered as vulnerable to coercion and undue influence.
3.2 Appropriate additional safeguards must be included in the study to protect the rights and welfare of these vulnerable participants.
3.3 The investigator must provide sufficient justification for inclusion of vulnerable populations and a plan for how the rights of these subjects will be protected from possible coercion.
3.4 The Sharp HealthCare (SHC) Institutional Review Board (IRB) must determine whether the involvement of such populations in research is justified and determine whether the proposed study minimizes or eliminates the risks to vulnerable subjects.
3.5 Additional requirements might apply, depending on the source of support/funding (e.g., Department of Defense, Department of the Navy, and the Environmental Protection Agency) see Appendix C – Additional Requirements section in the MANUAL: Investigator Guidance (HRP-101).

4 RESPONSIBILITIES
4.1 The principal investigator (PI), IRB staff and members carry out this procedure.

5 PROCEDURE
5.1 This procedure provides guidance for research participation of students, employees, illiterate English speaking subjects, non-English speaking subjects, and economically and educationally disadvantaged persons. Because of the complexity of the issues, specific guidance is provided in separate sections for the following vulnerable populations: a) pregnant women and fetuses, b) children, c) research participants with impaired decision making capacity, and those likely to need surrogate consent. GUIDANCE: Informed Consent Process for Research (HRP-090); GUIDANCE: Written Documentation of Consent (HRP-091).
5.1.1 Research involving Employees and Students. Employees, lab personnel, students, and trainees at SHC and other facilities under the purview of the IRB are considered vulnerable participants, in particular because of the risk of coercion and undue influence.
5.1.1.1 The IRB chair and IRB members will review the benefits of participation to ensure there are no coercive elements; ensure that the protocol and consent provide adequate protections for vulnerable populations; and verify that the research is in compliance with federal and institutional directives regarding vulnerable populations.
5.1.2 The IRB specialist will review the application to ascertain if vulnerable populations are likely to be recruited and secure additional consultations to provide additional expertise on special populations.

5.1.3 Illiterate English Speaking Participants. An investigator who has received IRB approval for a study may enroll individuals who can speak and understand English, but cannot read or write. The following must be followed:

5.1.3.1 The participant must be able to (a) place a written mark on the consent form, (b) comprehend the concepts of the study and understand the risks and benefits of the study as it is explained verbally, and (c) indicate approval or disapproval for study enrollment.

5.1.3.2 If the PI uses the above method to obtain consent, there must be documentation on the participants consent form specifying what method was used to communicate the information and the specific means that the participant communicated agreement to be in the study.

5.1.4 Non-English Speaking Participants.

5.1.4.1 If a research participant does not understand English, the informed consent document should be in a language readily understood by the participant.

5.1.4.2 If the PI anticipates that consent interviews will be routinely conducted in a language other than English, a translated consent document must be submitted. It is the IRB’s preference that the translation is completed by a certified translator. It is the PI’s responsibility to ensure that the translation is accurate.

5.1.4.3 A copy of the consent document must be given to the participant. While a translator may be helpful in facilitating conversation with a non-English speaking participant, verbal translation of the consent document must not be substituted for a written translation.

5.1.5 Economically and Educationally Disadvantaged.

5.1.5.1 For research involving economically disadvantaged participants, special care must be taken to assure that any financial incentives offered do not represent the sole grounds for the individual’s participation in the research protocol. Financial incentives should also not be used to encourage participants to assume risks that they would not ordinarily incur.

5.1.5.2 The consent form for research involving educationally disadvantaged participants must be written in language and with terminology appropriate to the participant. The PI must discuss orally every aspect of the study with the participant to insure his/her understanding.

5.1.6 Pregnant Women and Fetuses. 45 CFR 46, Subpart B provides additional protections for research involving pregnant women. Pregnant women should not be excluded from research as participants if the risk to the fetus is minimal. See CHECKLIST: Research Involving Pregnant Women (HRP-412).

5.1.6.1 If pregnant women are included in a research protocol, the informed consent must address the possible impact of the research activity on the fetus.

5.1.6.2 Investigators and designees who conduct studies targeting conditions specific to pregnant women must obtain informed consent from both the pregnant woman and the father of the fetus, however, consent of the father is not necessary if:

5.1.6.3 The purpose of the study is to meet the health needs of the mother.

5.1.6.4 The identity or whereabouts of the father cannot be reasonably ascertained.
5.1.6.5 The father is not reasonably available.
5.1.6.6 The pregnancy is the result of the rape.

5.1.7 Children. Federal regulations (45 CFR 46, Subpart D) require that investigators explicitly address the measures taken to protect the rights and welfare of children participating in research. See GUIDANCE: Child Assent, Parents or Guardians Permission, Waiver and Special Circumstances (HRP-014).

5.1.8 Participants with Diminished Decision-Making Capacity
5.1.8.1 The IRB reviews the risk-benefit analysis including the possibilities of coercion and undue influence, and must determine whether such participants should be recruited and whether support mechanisms, such as surrogate consent, are appropriate. GUIDANCE: Legally Authorized Representative (Surrogate Consent) (HRP-013).

5.1.9 The IRB uses CHECKLIST: Research Involving Cognitively Impaired Adults (HRP-417) to guide the assessment of whether cognitive impairment may prevent a participant or group of participants from giving informed consent. PI's should use the same criteria for making this determination and obtain the appropriate consent.

5.1.10 Re-consenting should be used for participants with fluctuating decision-making capacity or those with decreasing capacity to give consent.

6 MATERIALS
6.1 GUIDANCE: Legally Authorized Representative (Surrogate Consent) (HRP-013)
6.2 GUIDANCE: Child Assent, Parents or Guardians Permission, Waiver and Special Circumstances (HRP-014)
6.3 GUIDANCE: Informed Consent Process for Research (HRP-090)
6.4 GUIDANCE: Written Documentation of Consent (HRP-091)
6.5 MANUAL: Investigator Guidance (HRP-101)
6.6 CHECKLIST: Research Involving Pregnant Women (HRP-412)
6.7 CHECKLIST: Research Involving Cognitively Impaired Adults (HRP-417)

7 REFERENCES
7.1 45 CFR §46.102
7.2 45 CFR 46, Subpart B
7.3 45 CFR 46, Subpart D)
7.4 45 CFR §46.111(b)

This document is available on www.sharp.com/research , IRBANA or by contacting research@sharp.com.