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| SOP: SC 501 Version No: Effective Date: 01/01/07 | VULNERABLE POPULATIONS | Supersedes Document Dated: 11/05 |
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1. POLICY

Not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Some persons are in need of extensive protection, even to the point of excluding them from activities that may harm them. Other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. Indeed, some types of research may, in and of themselves, create a vulnerable group – that is, the subjects lose their autonomy or are exposed to unknown risks. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

Potentially vulnerable groups may include:

- Prisoners (These studies are not conducted at Sparrow Health System facilities.)
- Children
- Pregnant women and fetuses
- Cognitively impaired subjects
- Other vulnerable groups

Specific Policies

1.1 Prisoners

The IRB does not currently have the appropriate representation for the protection of prisoners in research on its committee and, therefore, does not allow the inclusion of prisoners in any research conducted at Sparrow Health System facilities. The following guidelines would apply if a subject becomes incarcerated after the research has commenced:

1.1.1 When Subjects Become Prisoners During a Research Protocol

This policy applies whenever any human subject in a research protocol becomes a prisoner at any time during the protocol, *e.g.*, after the research has commenced. This is necessary because it is unlikely that review of the research and the consent document contemplated the constraints imposed by the possible future incarceration of the subject. [The IRB would have to appoint an appropriate prisoner representative to the Committee or invite a consultant with appropriate expertise in prisoner rights to assist in the decision making process if this scenario occurred.]

- If a subject becomes a prisoner after enrollment in research, all research interactions and interventions with, and obtaining identifiable private information about the subject must cease. The Principal Investigator is responsible for reporting this situation in writing to the IRB immediately.*
- At the earliest opportunity after receiving the Investigator's notice or otherwise becoming aware of the prisoner status of a subject, the IRB should review the protocol again with a prisoner representative as a

member of the IRB. The IRB should take special consideration of the conditions of being a prisoner.

- Upon this review, the IRB can either (a) approve the involvement of the prisoner-subject in the research in accordance with this policy or (b) determine that this subject must be withdrawn from the research.
 - Additionally, the IRB should confirm that, when appropriate, the informed consent process includes information regarding when subsequent incarceration may result in termination of the subject's participation by the Investigator without regard to the subject's consent.
- * In special circumstances in which the principal investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the IRB Chairperson may determine that the subject may continue to participate in the research until the requirements of subpart C are satisfied.

1.2 Children

1.2.1 The special vulnerability of children makes consideration of involving them as research subjects particularly important in the deliberations of the IRB. In order to safeguard their interests and to protect them from harm, ethical and regulatory considerations are in place for reviewing research involving children. At the same time, the IRB recognizes the importance of conducting scientifically sound and ethically designed studies in this population.

Two factors make a case for clinical research in children.

- Children differ markedly from both animals and adults, and therefore, these models cannot substitute as alternatives to testing in children.
- Lack of appropriate research in children will increase their risk of harm from exposure to practices and treatments untested in this population. In addition, new therapies could not be developed for diseases that specifically affect children.

However, research in children requires that the IRB carefully consider consent (autonomy), beneficence, and justice.

The determination of risk (possible harm) and possible benefit to the child is at the core of the concept of beneficence when considering research in a pediatric population.

Therefore, the IRB must consider the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the child before it can determine whether or not the IRB has the authority to approve the study.

1.2.2 Research in children requires that the IRB consider the following when reviewing research in a pediatric population.

- Probable risks
- Associated discomforts
- Possible benefits

Determination of probable risks and associated discomforts: Procedures that usually present no more than minimal risk to a healthy child include:

urinalyses, obtaining small blood samples, EEGs, allergy scratch tests, minor changes in diet or daily routine, and/or the use of standard psychological or educational tests. The assessment of the probability and magnitude of the risk, however, may be different in sick children and may vary depending on the diseases or conditions the subjects may have. For example, obtaining blood samples from a hemophiliac child may present more than minimal risk to the child. On the other hand, IRBs may consider that children suffering from chronic illnesses who are accustomed to invasive procedures are placed at minimal risk by involvement in similar research procedures, in contrast to children who have not had such experiences. The IRB must also consider the extent to which research procedures would be a burden to any child, regardless of whether the child is accustomed to the proposed procedures.

Procedures that exceed the limits of minimal risk may be difficult to define in the abstract, but should not be too difficult to identify on a case-by-case basis. Riskier procedures might include biopsy of internal organs, spinal taps, or the use of drugs whose risks to children have not yet been established. Behavioral interventions likely to cause psychological stress may also exceed minimal risk.

Determination of possible benefits: In assessing the possible benefits of research intervention, the IRB should consider the variability in health statuses among potential subjects. For example, a potential subject might be a normal, healthy child, or a child who has been exposed to a disease or a toxin (e.g., meningococcus or lead) where it is known that a percentage of the children exposed will actually experience untoward consequences. A child may also be in an early state of disease, e.g., an HIV-infected child, or may actually suffer from disease or other significant medical condition. Thus, the IRB must take into account the current health status of a child and the likelihood of progression to a worsened state without research intervention.

- 1.2.3. Determination of Risk: Federal regulations require IRBs to classify research involving children into one of four categories and to document their discussions of the risks and benefits of the research study. The Minutes will document how the research protocol meets the required criterion.

The four categories of research involving children based on degree of risk and benefit to individual subjects are as follows:

- 1. Research not involving greater than minimal risk.**
- 2. Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual subject.**

Research in this category is approvable provided: (a) the risk is justified by the anticipated benefit to the subject; and (b) the relationship of risk to benefit is at least as favorable as any available alternative approach.

- 3. Research involving greater than minimal risk with no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.**

Research in this category is approvable provided: (a) the risk represents a minor increase over minimal risk; (b) 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 settings; and (c) the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition.

4. The SHS IRB does not currently allow research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. [The IRB may consider such proposed research on an individual, case-by-case basis.]

Research that is not approvable under 45 CFR 46.404, 46.405, or 46.406 may be conducted or funded by DHHS provided that IRB, and the Secretary, after consultation with a panel of experts, finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a significant problem affecting the health and welfare of children. The panel of experts must also find that the research will be conducted in accordance with sound ethical principles.

If IRB does not believe that a clinical investigation within the scope described in Sections 50.1 and 56.101 and involving children as subjects meets the requirements of Sec. 50.51, Sec. 50.52, or Sec. 50.53, the clinical investigation may proceed only if:

- (a) The IRB finds and documents that the clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
- (b) The Commissioner of Food and Drugs, 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, determines either:
 - (1) That the clinical investigation in fact satisfies the conditions of Sec. 50.51, Sec. 50.52, or Sec. 50.53, as applicable, or
 - (2) That the following conditions are met:
 - (i) The clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
 - (ii) The clinical investigation will be conducted in accordance with sound ethical principles; and
 - (iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in Sec. 50.55.

1.2.4 Parental Consent: Children may be subjects of research only if informed consent is obtained from the parents or legal guardian. The IRB will determine whether the permission of both parents is necessary, and the

conditions under which one parent may be considered not reasonably available.

The regulations provide that the IRB may find that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 (minimal risk research) or 45 CFR 46.405 (research involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects) [45 CFR 46.408(b)]. Where research is covered by 45 CFR 46.406 and 45 CFR 46.407, and permission is to be obtained from parents, both parents must give their permission, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child [45 CFR 46.408(b)].

Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient, if consistent with State law, for clinical investigations to be conducted under 21 CFR 50.51 or 50.52. Where clinical investigations are covered by 21 CFR 50.53 or 50.54 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child if consistent with State law.

Permission by parents or guardians must be documented in accordance with and to the extent required by 21 CFR 50.27. Participation of children in clinical investigations who are wards of state is governed by 21 CFR 50.53, 50.54 and 50.56.

- 1.2.5 Assent of Children: The IRB must determine that adequate provisions are made for soliciting the assent of the children when in the judgment of the IRB the children are capable of providing assent (21 CFR 50.55). In determining whether children are capable of providing assent, the IRB must take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in clinical investigations under a particular protocol, or for each child, as the IRB deems appropriate. When the IRB determines that assent is required, it must also determine whether and how assent must be documented.

Children over the age of 7 must agree to participate in the research and provide written assent and assent forms should be provided based on reasonable age ranges for comprehension i.e., 7-10, 11-15, 16-21 years of age. The actual maturity (rather than specific age ranges) shall dictate the degree of assent and participation in the consent process. When the research offers the child the possibility of a direct benefit that is important to the health or well being of the child and is available only in the context of the research, the IRB may determine that the assent of the child is not necessary. Additionally, in such circumstances a child's dissent, which should normally be respected, may be overruled by the child's parents, at the IRB's discretion.

- 1.2.6 Waiver of Assent: The assent of the child is not a necessary condition for proceeding with the clinical investigation if the IRB determines:

- (1) That the capability of some or all of the children is so limited that they cannot reasonably be consulted, or
- (2) That the intervention or procedure involved in the clinical investigation holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the clinical investigation.

Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement if it finds and documents that:

- (1) The clinical investigation involves no more than minimal risk to the subjects;
- (2) The waiver will not adversely affect the rights and welfare of the subjects;
- (3) The clinical investigation could not practicably be carried out without the waiver; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

1.2.7 The FDA has adopted 45 CFR 46 Subpart D and also addresses the subject of children in its Information Sheets that address assent of minors. The HHS regulations, therefore, serve as the standard for all research activities involving children at Sparrow Health System facilities, regardless of funding source.

1.3 Pregnant Women and Fetuses

1.3.1 Pregnant women or fetuses prior to delivery may be involved in research if all of the following conditions are met:

- A. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
- B. The risk to the fetus is not greater than minimal, or any risk to the fetus, which is greater than minimal, is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;
- C. Any risk is the least possible for achieving the objectives of the research;
- D. The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions of subpart A of 45 CFR 46, unless altered or waived in accord with Sec. 46.101(i) or Sec. 46.116(c) or (d);
- E. The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;
- F. For children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of 45 CFR 46 subpart D;
- G. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

- H. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- I. Individuals engaged in the research will have no part in determining the viability of a fetus.

1.3.2 Research involving fetuses after delivery:

- A. After delivery, fetuses may be involved in research if all of the following conditions are met:
 - 1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses;
 - 2. The individual(s) providing consent under the applicable regulations is/are fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;
 - 3. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
 - 4. 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. Individuals engaged in the research will have no part in determining the viability of a fetus; and
 - 6. The regulatory requirements have been met as applicable.
- B. Fetuses of uncertain viability: After delivery, and until it has been ascertained whether or not a fetus is viable, a fetus may not be involved in research covered by federal regulations unless the following additional conditions are met:
 - 1. The IRB determines that:
 - (i) The research holds out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the research; or
 - (ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the research; and
 - (iii) The legally effective informed consent of either parent of the fetus 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 in accord with 45 CFR 46 subpart A, unless altered or waived in accord with Sec. 46.101(i) or Sec. 46.116(c) or (d).
- C. Nonviable fetuses: After delivery, a nonviable fetus may not be involved in research covered by federal regulations unless all of the following additional conditions are met:

1. Vital functions of the fetus will not be artificially maintained;
 2. The research will not terminate the heartbeat or respiration of the fetus;
 3. There will be no risk to the fetus resulting from the research;
 4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
 5. The legally effective informed consent of both parents of the fetus is obtained in accord with 45 CFR 46 subpart A, except that the waiver and alteration provisions of Sec. 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of the regulations.
- D. Viable fetuses. A fetus, after delivery, that has been determined to be viable is a child as defined by 45 CFR 46.402(a) and may be included in research only to the extent permitted by and in accord with the requirements of 45 CFR 46 subparts A and D.
- 1.3.3 Research involving, after delivery, the placenta, the dead fetus, or fetal material.
- Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.
 - If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent regulations apply.

1.4 Cognitively Impaired Subjects

Although there are no federal regulations specifically written to address the needs of this vulnerable group, the IRB will generally follow the recommendations governing the conduct of research in children and of specific recommendations made by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978).

1.4.1 Selection of Subjects. Research involving individuals with diminished capacity to consent should have a direct relationship to their illness or condition. Particular attention should be paid to institutionalized individuals, as issues of dependence and coercion may be factors that may compromise the voluntary nature of their participation in research. For this reason, subjects should be recruited from among noninstitutionalized populations whenever possible.

1.4.2 Risk Determination: Generally the IRB will follow the recommendations of the National Commission when determining the degree of risk and its impact on the approvability of a research protocol in cognitively impaired subjects as follows:

- a minor increase over minimal risk may be permitted in research involving those institutionalized as mentally disabled, but only where the research is designed to evaluate an intervention of foreseeable benefit to their care.
- for research that does not involve beneficial interventions and that presents more than minimal risk, the anticipated knowledge sought should be of vital importance for understanding or eventually alleviating the subject's disorder or condition.

1.4.3 Limiting Risks. The following measures should be addressed in the protocol to limit a subject's exposure to risk:

- Description of appropriate psychological or medical screening criteria to prevent or reduce the chances of adverse reactions to the therapeutic and research procedures
- Specific diagnostic, symptomatic, and demographic criteria for subject recruitment
- Description of methods for assuring adequate protections for the privacy of the subjects and the confidentiality of the information gathered
- Justification of plans to hospitalize subjects or extend hospitalization for research purposes
- Measures to protect Individually identifiable information
- Measures to ensure that proposed research procedures will not be detrimental to ongoing therapeutic regimens.

1.4.4 Informed Consent: Generally, mentally impaired adults should be presumed competent to understand the issues of being a research subject and either refuse or consent to participate in a research study. Mental disability alone should not disqualify a person from consenting to participate in research; rather, there needs to be specific evidence of incapacity to understand and to make an informed voluntary choice before they are deemed unable to consent for themselves.

The IRB feels that if a cognitively impaired adult subject objects to participate in a research study, that decision should be binding, except when the individual's participation is specifically authorized by a court of law, the intervention is expected to provide a direct health benefit to the subject, and the intervention is available only in the context of the research. This is in keeping with the National Commission's recommendation that "despite the fact that consent may be obtained from a legally authorized representative or guardian, the feelings and expressed wishes of an incompetent person should still be respected".

The IRB will seek legal counsel to assess state laws that might affect the participation of legally incompetent persons and/or the role of guardians in the consenting process.

Studies involving subjects who are decisionally impaired may take place over extended periods. The IRB should consider whether periodic re-consenting of individuals should be required to ensure that a subject's continued involvement is voluntary. The IRB may require that Investigators re-consent subjects after taking into account the study's anticipated length and the condition of the individuals to be included (e.g., subjects with progressive neurological disorders). Additionally, the IRB should consider whether, and when, it should require a reassessment of decision-making capacity.

1.5 Other Vulnerable Groups

Although federal regulations list vulnerable groups, other vulnerable groups may include mentally impaired persons, employees of the Sponsor or Investigator, terminally ill patients, and the very elderly. The IRB will determine special protections for these groups on a case-by-case basis, taking into account the risks and benefits and other protections afforded by institutional policies and state and federal law.

Subjects in "Treatment IND" studies:

Informed consent is especially important in treatment use situations because the subjects are desperately ill and particularly vulnerable. They will be receiving medications that have not been proven either safe or effective, in a clinical setting. (See 56 CFR 312.34) Both the setting and their desperation may work against their ability to make an informed assessment of the risk involved. IRBs must ensure that potential subjects are fully aware of the risks involved in participation.

IRBs should also pay particular attention to Treatment INDs in which the subjects will be charged for the cost of the drugs. The question here is one of equitable selection and the involvement in research of vulnerable populations, particularly economically disadvantaged persons [see 21 CFR 56.111(a)(3)]. If subjects will be charged for use of the test article, economically disadvantaged persons will likely be excluded from participation. The stated purpose of the Treatment IND exemption is to facilitate the availability of promising new drugs to desperately ill patients while obtaining additional data on the drug's safety and effectiveness. Charging for participation may preclude economically disadvantaged persons as a class from receiving access to test articles. The IRB will need to balance this interest against the possibility that unless the Sponsor can charge for the drug, it will not be available for treatment use until it receives full FDA approval [See also IRB Guidebook Chapter 3].

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. RESPONSIBILITY

IRB Administrator (or equivalent) is responsible for maintaining up-to-date review tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.

IRB Chairperson (or designee) is responsible for ensuring the IRB members are well versed in new and evolving regulations and guidelines pertaining to vulnerable

populations, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

IRB Reviewer is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources.

4. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report

45 CFR 46: Subparts A, B, C, D

45 CFR 46.101, 46.115(B), 46.116, 46.122

21 CFR 50: Subpart D 50.51, 50.52, 50.53, 50.54, 50.55,50.56

21 CFR 56.111

56 CFR 312.34

OHRP IRB Guidebook

OHRP Guidance on the Involvement of Prisoners in Research, Dated May 23, 2003

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978.

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

- SC 501-A Checklist – Requirements for Research Involving Children
- SC 501-B Checklist – Requirements for Research Involving Pregnant Women & Fetuses
- SC 501-C Checklist – Requirements for Research Involving Cognitively Impaired Adults

7. PROCESS OVERVIEW

Protocols requesting use of any vulnerable population must be so indicated in the research application. The rationale for the use of the vulnerable population must be documented and supported. Such protocols will be reviewed very closely so that human subjects will be protected. An outside reviewer may be requested by the OROC staff.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

A. Research Involving Children

| Who | Task | Tool |
|---|---|---|
| <i>IRB Coordinator/ IRB Administrator</i> | Maintain and update checklist to conform to applicable regulations and guidelines. Confirm that proposal has informed consent and assent documents as appropriate. | SC 501-A Checklist – Requirements for Research Involving Children |

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| <i>IRB Chairperson or IRB Administrator</i> | Select appropriate primary reviewer(s). | |
| <i>IRB Member (Reviewer) or an Outside Reviewer, if applicable</i> | Complete checklist during review of research and present recommendations at convened meeting. | |

B. Research Involving Pregnant Women and Fetuses

| Who | Task | Tool |
|---|---|--|
| <i>IRB Coordinator/ IRB Administrator</i> | Maintain and update checklist to conform to applicable regulations and guidelines. Confirm that proposal has informed consent and assent documents as appropriate. | SC 501-B Checklist – Research Involving Pregnant Women & Fetuses |
| <i>IRB Chairperson or IRB Administrator</i> | Select appropriate primary reviewer(s). | |
| <i>IRB Member (Reviewer)</i> | Complete checklist during review of research and present recommendations at convened meeting. | |

C. Research Involving Cognitively Impaired Adults

| Who | Task | Tool |
|---|---|--|
| <i>IRB Coordinator/ IRB Administrator</i> | Maintain and update checklist to conform to applicable regulations and guidelines. Confirm that proposal has informed consent and assent documents as appropriate. | SC 501-C Checklist – Requirements for Research Involving Cognitively Impaired Adults |
| <i>IRB Chairperson or IRB Administrator</i> | Select appropriate primary reviewer(s). | |
| <i>IRB Member (Reviewer)</i> | Complete checklist during review of research and present recommendations at convened meeting. | |
| <i>IRB Members</i> | Determine additional necessary protective stipulations to be applied to the research at a convened meeting. | |

D. Research Involving Other Vulnerable Groups

| Who | Task | Tool |
|--|--|-------------|
| <i>IRB Administrator and Chairperson</i> | Confer to determine whether any other special considerations apply or other vulnerable populations are to be the subjects of submitted research. | |
| <i>IRB Members</i> | Determine additional necessary protective stipulations to be applied to the research at a convened meeting. | |