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Information from Powerpoint presentation: *NIH Proposals: Write to Win! The Human Subjects Protection Section*, Boston Medical Center, 02.16.11

Human Subjects Protection

***Human Subjects Protection-Categories***

***All research proposals must address the protection of Human Subjects.***

***The NIH provides specific instructions on what you need to write for this subject, categorized by research scenario.***

***It has identified six different scenarios under which all research studies fall. They are:***

***1. No human subjects research (HSR)***

***2. Non-exempt HSR***

***3. Exempt HSR***

***4. Delayed-onset HSR***

***5. HSR involving a clinical trial***

***6. HSR involving an NIH-defined Phase III Clinical Trial***

**Writing the HSP Section of an NIH Research Proposal**

**No matter which scenario your proposal falls under, you should include the following *headings* in your Human Subjects Protection Section of your NIH proposal:**

**Risk to Human Subjects**

**A. Human Subjects Involvement, Characteristics, and Design-You should write this paragraph in your own words, as it pertains to your research.**

**However, using the bullets as a guide, be sure to include the following main points:**

*–Describe the proposed involvement of human subjects, specimens or data in the work outlined in the research strategy section.*

*–Describe and justify the characteristics of the subject population, number, age range and health status, if relevant.*

*–Explain the rationale for involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others.*

*–If relevant, describe procedures for assignment to a study group and/or describe and justify selection of an intervention’s dose, frequency, and administration.*

*–List all collaborating sites where human subjects will be performed for this study and describe their role in the proposed research. Explain how sites will be obtained, managed, and protected.*

**B. Sources of Materials-In your own words, in narrative format, cover the following topics in this section as they relate to your research topic:**

*•Describe the research material obtained from living individuals in the form of specimens, records, or data.*

*•If data will be collected from human subjects, describe how and when it will be collected, and how it will be managed and protected.*

*•Indicate who will have access to individually identifiable private information about subjects.*

***C.* Potential Risks*-*In this section, in narrative form and in your own words, describe the potential risks facing the Human Subjects, their specimens, or data being used for this project. Include:**

*–Potential risks to subjects (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects.*

*–Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research.*

**Adequacy of Protection Against Risks**

**A. Recruitment and Informed Consent-Use this section to describe:**

* *plans for the recruitment of subjects (where appropriate)*
* *process for obtaining informed consent, including description of circumstances under which consent will be sought and obtained*
* *If children are involved (anyone under 21 years old), describe process for meeting parental permission and child assent*
* *Describe who will seek consent and how they are qualified*
* *If waiver is included, provide justification.*
* *Informed consent documents are not necessary unless requested in the RFP guidance.*

***B. Protections Against Risk-*In your own words, include the following points in this category:**

•*Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data; assess their likely effectiveness.*

•*For research that involves vulnerable populations, include information on how you will protect these populations, as outlined in the DHHS and OHRP guidelines, subparts A-D.*

•*Links to additional protections guidelines:*

–*http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartb*

–*http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartc*

–*http://www.hhs.gov/ohrp/policy/index.htm#prisoners*

–*http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd*

–*http://www.hhs.gov/ohrp/children*

•Where appropriate, write out your plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.

•Clinical trials proposals must include a general description of the plan for data and safety monitoring of clinical trials and adverse event reporting to the IRB, NIH, and others.

**Potential Benefits of the Proposed Research to Human Subjects and Others**

•Discuss the potential benefits of the research to the research participants and others.

•Explain why the risks to subjects are reasonable in relation to the anticipated benefits to participants and others.

**Importance of the Knowledge to be Gained**

•Describe the importance of the knowledge to be gained overall or as a result of the proposed research.

•Explain why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.