PROTECTION OF HUMAN SUBJECTS PLAN

OVERVIEW & PLAN TEMPLATE for NCATS PRIOR APPROVAL

**OVERVIEW OF REGULATION**

As required by federal regulations (45 C.F.R. 46) and NIH policy, applications that propose to involve human subjects must address:

1. the risk to subjects
2. the adequacy of protections against risk
3. potential benefits of the research to subjects and others
4. the importance of the knowledge to be gained

The following may be used as a guide for the Human Subjects Plan. For full description please refer to [“Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan”](http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf) of the NIH competing application instructions.

Please see following page for PROTECTION OF HUMAN SUBJECTS PLAN TEMPLATE

PROTECTION OF HUMAN SUBJECTS PLAN

**RISKS TO HUMAN SUBJECTS**

*Describe Human Subjects Involvement, Characteristics, and Design, Sources of*

*Materials, and Potential Risk, which must include the following:*

1. *description and justification for the proposed involvement of human subjects*
2. *characteristics of subject population (number, age range, and health status)*
3. *inclusion/exclusion criteria*
4. *rationale for involvement of vulnerable populations (e.g. fetuses, pregnant women, children, prisoners, institutionalized individuals, or others)*
5. *role of collaborating sites where research will be performed*
6. *description and justification of research procedures (including dosage, frequency, etc of intervention)*
7. *description of what research material, data, and information will be collected*
8. *access to personally identifiable information collected and retained*
9. *management and protection of materials and information*
10. *all potential risks to subjects (physical, psychological, financial, legal, or other) including likelihood and seriousness*
11. *any alternative treatments or procedures*

**ADEQUACY OF PROTECTION AGAINST RISKS**

*Describe Recruitment and Informed Consent and Protections Against Risk, which must include the following:*

1. *how subjects will be recruited*
2. *description of informed consent, parental permission and assent*
3. *waiver for any elements of consent*
4. *how risks described previously, including privacy and confidentiality, will be minimized*
5. *additional protections for vulnerable populations*
6. *ensuring necessary medical/professional intervention for adverse events*

**POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO HUMAN SUBJECTS AND OTHERS**

*Describe how potential risks to subjects appear reasonable in relation to anticipated benefits*

**IMPORTANCE OF THE KNOWLEDGE TO BE GAINED**

*Describe how potential risks to subjects appear reasonable in relation to the importance of the knowledge that may result from the study*