# CTSI-Ed human and animal protection documentation for career development applications

**Protections for Human Subjects**

If your research involves human subjects please indicate whether you (or your mentor) have an IRB-approved or IRB-exempted protocol. For each relevant protocol please provide the following information: Protocol Number; P.I.; Title; and Exemption date (if applicable) or Approval Dates. You must be named as an approved investigator on the protocol(s). Indicate if you have a submitted or pending IRB protocol, (and include the relevant information, as below).

If additional human subjects research is proposed, pending or planned, that is not included in a currently IRB-approved or IRB-exempted protocol, then please state whether you expect the IRB to exempt this research and which exemption applies. State whether the research meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, and please specify: 1) the justification for the exemption, 2) human subjects characteristics and involvement, and 3) sources of biological materials and data used in the research. For research that you do not expect the IRB to exempt under 45 CFR Part 46, please provide justification for involvement of human subjects and describe the proposed protections from research risk relating to their participation according to the following five review criteria: 1) types and magnitude of risk to subjects, 2) nature and adequacy of protection against risks, 3) potential benefits of participation to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. If you believe that your human subjects research may involve vulnerable populations, please state the nature of the potential vulnerability and protections that will be included.

For additional information, please refer to the NIH [Human Subjects Protection and Inclusion Guidelines](http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf) (http://grants.nih.gov/grants/peer/guidelines\_general/Human\_Subjects\_Protection\_and\_Inclusion.pdf)

**Inclusion of Women, Minorities, and Children**

When the proposed project involves human clinical research, please describe the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. NIH Human Subjects Protection and Inclusion Guidelines state in part, “Public Law 103-43 requires that women and minorities be included in all clinical research studies, as appropriate for the scientific goals of the work proposed…. NIH policy also states that children (defined as persons under the age of 21) be included in human subjects research supported by NIH unless an acceptable justification for their exclusion is provided.”

If children are included as research subjects, please address the nature and adequacy of human subjects protections under federal rules. Please see NIH, Grants & Funding, Inclusion of Children Policy Implementation, <http://grants.nih.gov/grants/funding/children/children.htm>, including the link to 45 CFR 46, Additional Protections for Children Involved as Subjects in Research.

**Vertebrate Animals**

If your research involves vertebrate animals, please indicate whether you (or your mentor) have an IACUC-approved protocol. For each relevant protocol please provide the following information: Protocol Number; P.I.; Title; and Approval Dates. You must be named as an approved investigator on the protocol(s).

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

For additional information on review of the Vertebrate Animals section, please refer to the NIH [Worksheet for Review of the Vertebrate Animal Section](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150) (http://grants.nih.gov/grants/olaw/VASchecklist.pdf)

**University of Minnesota Research Policies & Resources**

The University of Minnesota has extensive policies, procedures, and resources on human subjects protection and on animal care and use in research. Demonstrating compliance is an important part of any application for research funding. You are responsible for determining applicable policy and showing compliance. For more information, see Office of Vice President for Research, Research Resources, with links, at <http://www.research.umn.edu/forresearchers/resources.html#.VOze0nzF9u0>.

**Additional Questions**

Applicants should also provide answers to the following questions:

1. How is your research different from your mentors?
2. Have you started or completed the IRB, IACUC and/or IBC approval process for your study as an independent study?
3. Will your TL1 project alter your mentor’s protocol?
4. Are you listed as staff on your mentor’s IRB, IACUC and/or IBC application?