



** It is possible that not all of these questions will be applicable to your particular research project. Please answer as it relates to your research.*

1. General Information

1.1 What is the title of this project?

1.18 Please list 3 descriptive key terms not contained in the project title.

2. People

2.1 Will students work on this project?

2.2 Does this project include Subcontracts, Subawards, Subgrants, Consortium Agreements, or Other subagreements to other institutions or agencies, external to U of M?

If yes, please provide the person's name, institution/affiliation, e-mail address, and their administrative contact name and e-mail address.

2.22 Excluding subcontract personnel, are there other personnel not affiliated with UM?

If yes, please provide the person's name, institution/affiliation, e-mail address, and their administrative contact name and e-mail address.

2.5 Will the project involve any Co-PI's or Co-Investigator's?

If yes, please provide the person's name, institution/affiliation, e-mail address, and their administrative contact name and e-mail address.

2.10 Please select the effort period and specify the amount of proposed effort for the period, or indicate "None."

Months:

- None
- Summer
- Academic Year
- Calendar Year (not applicable to U-Year faculty)

Please list other Personnel (e.g., GSRA, Postdoc, Lab Assistant):

3-4. Other

3.7 What is the period of performance of this project? (i.e. 1/1/18-12/31/20)

4.1 Please provide room number(s) for U-M space:

4.4 Will work be completed off U-M property (owned or leased)? If so, please specify location(s):

5. Research Activity

Does the proposed activity involve any of the following:

5.1 Human research?

**5.1.1* Use of radioactive material or the radiation from radioactive material in or on humans?

**5.1.2 If yes*, please indicate IRB approval status (Option 1: Not yet submitted, or Option 2: provide HUM ID, status, approval date, and expiration date.):

***5.1.3** Is the Sponsor using an external or non-U-M (i.e., commercial, other academic, or hospital affiliated IRB as the single IRB-of -record?

***5.1.3.1** *If yes*, please indicate the commercial/central IRB the Sponsor is using (e.g., Chesapeake IRB, National Cancer Institute CIRB, Schulman IRB, Western IRB, or other).

***5.1.4** Has or will the project team coordinate with a Clinical Trial Support Unit (CTSU) in regards to this project?

***5.1.4.1** *If yes*, please indicate the Clinical Trial Support Unit:

5.2 Use or derivation of human induced pluripotent stem cells (iPSC) or human embryonic stem cells (hESC)?

***5.2.1** Please indicate HPSCRO approval status (Option 1: Not yet submitted or Option 2: Provide date of HPSCRO approval):

5.3 Use of vertebrate animals, including custom antibody production?

***5.3.1** Will any vertebrate animal work be conducted **at U-M**?

***5.3.2** *If yes*, please choose at least one of the following:

***5.3.3** Please enter IACUC protocol information (i.e., number, status, approval date, expiration date and species).

***5.3.4** Will a protocol for vertebrate animal work be held and approved **at another institution**?

***5.3.5** *If yes*, Please enter IACUC information for the other institution (will also need approval document)

5.4 Does this project involve research in a **U-M laboratory** with biological materials?

***5.4.1** *If yes*, Use of recombinant or synthetic nucleic acid molecules (rDNA or SNA)?

***5.4.1.1** *If yes*, Please indicate the type of viral vector or bacterial construct to be used:

***5.4.2.** Use of infectious agents (i.e., bacteria, viruses, parasites, fungi, prions)?

***5.1.2.1** *if yes*, Please indicate the infectious agents to be used:

***5.4.2.2** Are any of these infectious agents on the Federal Select Agents and Toxins List?

***5.4.3** Use of biological toxins (i.e., toxic substances produced by bacteria, fungi, protozoa, insects, animals, or plants)?

***5.4.3.1** *If yes*, Please indicate the biological toxins to be used:

***5.4.3.2** Are any of these biological toxins on the Federal Select Agents and Toxins List?

***5.4.4 Use in a U-M research laboratory** of human-derived substances (including cell/cell lines, blood products, body fluids, tissues, pathology materials, organs, body parts, cadavers)?

***5.4.5** Use of animal-derived substance (i.e., cells, tissues, fluids from non-human primates, ruminants, swine, fowl, or any wild vertebrate animal)?

***5.4.5.1 If yes,** Indicate the animal-derived substances to be used.

***5.4.6 If yes,** Use of transgenic animals?

***5.4.6.1 If yes,** Indicate the species of transgenic animals to be used.

***5.4.7** Will any of the following be administered to vertebrate animals: rDNA, SNA, infectious agents, biological toxins, human-derived substances (including cell/cell-lines, blood products, body fluids, tissues, pathology, materials, organs, body parts, cadavers), animal-derived substances (including cells, tissues, fluids from non-human primates, ruminants, swine, fowl, or any wild vertebrate animal)?

***5.4.7.1** If yes, indicate which of the above biological materials will be administered to vertebrate animals.

***5.4.8** Indicate the IBC Application(s) that cover the use of biological materials above in questions 5.4.1 - 5.4.7 or if it is not yet submitted/pending:

5.5 Restrictions on openness of research?

5.6 Does the research project involve possible export controls or delivery of a physical item, such as a product or material, including models and prototypes?

***5.6.1** Please provide further detail on the possible export control:

5.7 Are there any enhanced security requirements for this project (e.g., CUI, FISMA, or classified research)?

***5.7.1** Please provide further detail on the security requirements.

5.8 Use of radioactive materials for (non-human) research?

***5.8.1 If yes,** please provide RPC approval number or answer "not yet submitted/pending":

5.9 Use of unbound engineered nanoscale particles or nanofabrication technology?

***5.9.1 If yes,** please provide particles/nanofabrication technology description:

5.10 Use of controlled substances (as defined by the federal Controlled Substances Act) or Propofol in a U-M research laboratory?

5.11 Are there any non-financial agreements (e.g., material transfer, data use, software license, non-disclosure, confidentiality, export control, or teaming agreements) in place related to this proposal?

***5.11.1 If yes,** please indicate which UFA(s) relate to this research:

5.12 Is an intellectual property disclosure related to this proposal on file in the Office of Technology Transfer?

***5.12.1 If yes,** please provide the OTT file number:

6. ATTENTION: Complete this page for Grants.gov proposals (NIH, USDA, etc)

6.1 By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances* and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S Code, Title 18, Section 1001). *The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions. Please confirm if you agree.

I agree

6.2 Are Human Subjects Involved? If yes, see questions to the right.

***6.2.1** Is the Project Exempt from Federal regulations?

***6.2.2** If yes, check appropriate exemption number.

***6.2.3** If no, is the IRB review Pending?

***6.2.4** If pending, please provide Human Subject Assurance Number. If not pending, please provide IRB Approval Date.

6.3 Are Vertebrate Animals Used? If yes, see questions to the right.

***6.3.1** Is the IACUC review Pending?

***6.3.2** If yes, please provide Animal Welfare Assurance Number. If no, please provide IACUC Approval Date.

6.4 Is proprietary/privileged information included in the application?

6.5 Does this project have an actual or potential impact - positive or negative - on the environment?

***6.5.1** If yes, please explain:

***6.5.2** If yes, has an exemption been authorized or an EA or EIS been performed?

***6.5.3** If yes, please explain:

6.6 Is the research performance site designated, or eligible to be designated, as a historic place?

***6.6.1** If yes, please explain:

6.7 Does this project involve activities outside the United States or partnerships with international collaborators?

***6.7.1** If yes, identify countries:

6.8 Are vertebrate animals euthanized?

***6.8.1** If yes, is method consistent with American Veterinary Medical Association (AVMA) guidelines?

***6.8.2** If no, to AVMA guidelines, describe method and provide scientific justification.

6.9 Is program income anticipated during the periods for which the grant support is requested?

***6.9.1** If yes, please provide the budget period, anticipated amount, and source of the program income.

6.10 Does the proposed project involve human embryonic stem cells?

***6.10.1** If yes, please provide the registration number of the specific cell line(s) from the following list <http://stemcells.nih.gov/research/registry/>. OR if a specific stem cell line cannot be referenced at this time, indicate that one from the registry will be used.

6.11 Does the proposed research involve human specimens and/or data?

***6.11.1** If yes, please provide an explanation of why the application does not involve human subjects research