Principal Investigator: Project Title:

Does the proposed activity involve any of the following?

Question		Response	Need more Information?
5.1	Human Research?	■ Yes ☐ No	Additional Help
If Yes to 5.1	*5.1.1: Use of radioactive material or the radiation from radioactive material in or on humans?*	☐ Yes ■ No	See Guidelines for Research Involving Exposure of Human Subjects to Ionizing Radiation
If Yes to 5.1	*5.1.2: Indicate IRB Approval Status* Research is considered exempt under 46.104(d)(2): Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)	☐ Not Yet Submitted **OR** HUM ID: _____	If you don't yet have an IRB Number, click Not yet submitted. If you have an IRB Number, click Add. -- Use the search interface to find your Human Subjects Application in eResearch Regulatory Management (IRB). -- Once Human Subjects Application(s) are associated with your PAF, the Status, Approval Date, and Expiration Date are automatically updated. IRB approval not required to submit proposal.
If Yes to 5.1	*5.1.3 Will the project use an external (i.e., commercial, other academic, or hospital-affiliated) IRB as the single IRB-of-record?*	☐ Yes ■ No	Some sponsors (e.g., NIH) require a single IRB-of-record (sIRB) for multi-site (multi-institutional) human subject studies. If an external (i.e., non-UM) IRB will serve as the single IRB for all participating sites, you must budget the IRB fees as a direct cost to the project if applicable. Formal relationships between U-M and the external IRB are established through written authorization agreements (individual or master agreements) reviewed by the IRB and signed by an institutional official. See the HRPP sIRB webpage for a list of external IRBs with whom U-M has a service agreement. Always consult your U-M IRB to determine if the use of an external IRB as the sIRB will be appropriate for the project.
If Yes to 5.1.3	*5.1.3.1: Please indicate the external IRB:*	☐ Advarra ☐ Chesapeake IRB ☐ National Cancer Institute CIRB ☐ Schulman IRB ☐ Western IRB ☐ Other _____	Identify the specific external IRB you are using. If you do not recognize the named IRBs, you may wish to consult your UM-IRB for further assistance.
If Yes to 5.1	*5.1.4 Has or will the project team coordinate with Clinical Trial Support Unit (CTSU) in regards to this project?*	☐ Yes ■ No	Support Units (currently for Medical School faculty) are available to assist study teams with the administrative and regulatory activities needed for clinical trial study activation. For more details, review the Clinical Trail Support Office website.

If Yes to 5.1.4	*5.1.4.1 Clinical Trial Support Unit:*	☐ Acute, Critical Care, Surgery & Transplant ☐ Ambulatory & Chronic Disease ☐ Behavior, Function & Pain ☐ Children's ☐ Heart, Vessel, Blood ☐ Oncology ☐ Neurosciences & Sensory	Select the appropriate Clinical Trial Support Unit. The selected office will also receive emails during the routing/award process and have read access to the record.
5.2	Use or derivation of human induced pluripotent stem cells (iPSC) or human embryonic stem cells (hESC)?	☐ Yes ■ No	See Human Pluripotent Stem Cell Research Oversight at the University of Michigan
If Yes to 5.2	5.2.1: Indicate HPSCRO Approval Status:	☐ Not Yet Submitted **OR** Date of HPSCRO Approval: _____	HPSCRO hES Cell Research Application is available by emailing the HPSCRO staff at **hpscroquestions@umich.edu** or by calling 734-615-8936.
5.3	Use of vertebrate animals, including custom antibody production?	☐ Yes ■ No	Federal and University policies require approval from Institutional Animal Care and Use Committee (IACUC) when research involves the use of vertebrate animals or when an investigator provides antigen to an outside vendor for the production of custom antibodies. Need more information... See IACUC website.
If Yes to 5.3	5.3.1: Additional IACUC Information (select at least one of the following):	Will any vertebrate animal work be conducted at U-M?* ☐ Yes ☐ No If Yes, ☐ eRAM Protocol not yet started ☐ eRAM Protocol approved and/or started eRAM Protocol ID: _____ Will a protocol for vertebrate animal work be held and approved at another institution?* ☐ Yes ☐ No If Yes, attach a document	An eRAM Protocol is an application created in the eRAM system to seek approval for the use of vertebrate animals in research. If you don't yet have an eRAM Protocol number, click Not Yet Started. If you have an eRAM Protocol number, click eRAM Protocol Started then click Add. - Use the search interface to find your protocol (PRO). - Once the protocol is associated with your PAF, the Status, Approval Date, and Expiration Date are automatically updated. - IACUC approval is not required to submit a proposal. Indicate if a protocol will be held and approved at another institution.
5.4	Does this project involve research in a U-M laboratory with biological materials?	☐ Yes ■ No	Includes research lab space on the U-M Ann Arbor, Dearborn, and Flint campuses.
If Yes to 5.4	*5.4.1: Use of recombinant or synthetic nucleic acid molecules (rDNA or SNA)?*	☐ Yes ☐ No If Yes, 5.4.1.1	Recombinant and synthetic nucleic acids are defined as: (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;

		Indicate the type of viral vector or bacterial construct to be used _____	(ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or (iii) molecules that result from the replication of those described in (i) or (ii) above. Source: NIH Guidelines
If Yes to 5.4	*5.4.2: Use of infectious agents (i.e., bacteria, viruses, parasites, fungi, prions)?*	☐ Yes ☐ No If Yes, 5.4.2.1 Indicate the type of viral vector or bacterial construct to be used _____ **AND** 5.4.2.2 Are any of these infectious agents on the Federal Select Agents and Toxins List? ☐ Yes ☐ No	An infectious agent or pathogen is a biological agent that causes disease or illness to its host (e.g., a human, animal, or plant). Additional Help Only list non-recombinant infectious agents here. Include species/genera, or common name. See the Federal Select Agents and Toxins List. These are highly regulated biological agents and toxins that have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. Additional Help: See the U-M Introductory Guide for Faculty Wishing to Use Select Agents in Their Research
If Yes to 5.4	*5.4.3: Use of biological toxins (i.e., toxic substances produced by bacteria, fungi, protozoa, insects, animals, or plants)?*	☐ Yes ☐ No If Yes, 5.4.3.1 Indicate the biological toxins to be used_____ **AND** 5.4.3.2 Are any of these biological toxins on the Federal Select Agents and Toxins List? ☐ Yes ☐ No	Biological toxins are hazardous substances produced by microorganisms, animals, insects, and plants that can be harmful when inhaled, ingested, injected, or absorbed. See the Federal Select Agents and Toxins List. These are highly regulated biological agents and toxins that have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. Additional Help: See the U-M Introductory Guide for Faculty Wishing to Use Select Agents in Their Research
If Yes to 5.4	*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)?*	☐ Yes ☐ No	This question applies to work occurring in non-hospital U-M research labs where employees may have exposure to human blood, body fluids, or unfixed tissue; human cells or cell lines, or HIV or Hepatitis B Virus. Additional Help: See U-M EHS for additional information.
If Yes to 5.4	*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)?*	☐ Yes ☐ No If Yes, 5.4.5.1 Indicate the animal-derived substances to be used.	This question applies to substances from non-human primates, ruminants, swine, fowl, or any wild vertebrate animal. Include the species of animal from which the substance is derived.

		_____	
If Yes to 5.4	*5.4.6: Use of transgenic animals?*	☐ Yes ☐ No If Yes, 5.4.6.1 Indicate the species of transgenic animals to be used. _____	A transgenic animal is one in which new or altered genes from another organism have been experimentally inserted into their genome by genetic engineering techniques. Note that IACUC approval is required for all research with vertebrate animals.
If Yes to 5.4	*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)?*	☐ Yes ☐ No If Yes, 5.4.7.1 Indicate which of the above biological materials will be administered to vertebrate animals. _____	This question applies to vertebrate animals whether they are transgenic or not. Note that IACUC approval is required for all research with vertebrate animals.
If Yes to 5.4.1, 5.4.2, 5.4.3, 5.4.4, 5.4.5, 5.4.6, or 5.4.7	*5.4.8: Indicate the IBC Application(s) that cover the use of biological materials above in questions 5.4.1 - 5.4.7:*	☐ Not Yet Submitted **OR** IBCA Number: _____	The U-M Institutional Biosafety Committee (IBC) has purview over the types of work identified through the questions above. Contact ibcstaff@umich.edu with questions about the review and approval process, or see the IBC website.
5.5	Restrictions on openness of research?	☐ Yes ■ No	Need more information... See Regents' Policy Concerning Research Grants, Contracts, and Agreements
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?	☐ Yes ■ No ☐ Unsure	See University of Michigan Introductory Guide for Faculty Members Wishing to Use Select Agents in their Research. See the CDC National Select Agent Registry for a list of Select Agents and Toxins and other information.
If Yes or Unsure to 5.6	*5.6.1: Please provide further detail on the possible export controls:*	*Write in brief, 1 sentence description here:* _____	See the UM export control webpage for more information: http://research-compliance.umich.edu/export-controls?print=
5.7	Are there any enhanced security requirements for this project (e.g., CUI, FISMA, or classified research)?	☐ Yes ■ No ☐ Unsure	Enhanced security means proposal submissions or awards that have IT Security requirements such as National Industry Standards and Technology (NIST), or that have enhanced Personnel or Physical Security requirements such as background checks, logical or physical restricted access, mandatory security training, citizenship requirements, distribution restrictions, etc.

			1) Controlled Unclassified Information (CUI) is information that requires safeguarding or dissemination controls pursuant to and consistent with applicable law, regulations, and government-wide policies. CUI security controls are usually invoked by DFARS 252.204-7008, Compliance with Safeguarding Covered Defense Information and DFARS 252.204-7012, Safeguarding Covered Defense Information and Cyber Incident Reporting. CUI security controls are established by NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations (when CUI is held or generated when conducting research and operating a system on behalf of the federal government [Federal Information Security Management Act, FISMA]) and NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations (when CUI is held or generated incidental to a research contract). 2) Classified research will typically involve a "Classified Contract" which is defined by the Federal Acquisition Regulations as "Any contract that requires, or will require, access to classified information (Confidential, Secret, or Top Secret) by the contractor or its employees in the performance of the contract. All "Classified Contracts" must have, at a minimum, the FAR Clause 52.204-2, Security Requirements, incorporated into the contract. This clause binds the contractor to meet the security requirements identified in the National Industrial Security Program Manual (NISPOM). Classified research contracts require a DD Form 254, Contract Security Classification Specifications. This form is used to identify security requirements that the contracting agency will impose on a contractor.
If Yes or Unsure to 5.7	*5.7.1: Please provide further detail on the security requirements.*	*Write in brief, 1 sentence description here:* _____	
5.8	Use of radioactive materials for (non-human) research?	☐ Yes ■ No	See General Radiation Safety Protocols
If Yes to 5.8	*5.8.1: Indicate the IBC Application(s) that cover the use of biological materials above in questions 5.4.1 - 5.4.7:*	☐ Not Yet Submitted/Pending **OR** Radiation Policy Committee (RPC) Approval Number:: _____	Enter your Radiation Policy Committee (RPC) approval Number. For questions, contact EHS Radiation Safety Services at 734-764-6200
5.9	Use of unbound engineered nanoscale particles or nanofabrication technology?	☐ Yes ■ No	Various types of nanoscale materials are either manufactured, modified, or used in research applications on the UM Campus. Need more information... See The Scale of Things
If Yes or 5.9	*5.9.1: Particles/nanofabrication technology description:*	*Write in brief, 1 sentence description here:* _____	EHS has a useful tool to assess the various characteristics of your work with nanomaterials and to submit for the safety review process.
5.10	Use of controlled substances (as defined by the federal Controlled Substances Act) or Propofol in a U-M research laboratory?	☐ Yes ■ No	See the U-M Controlled Substances in Research Monitoring Program for additional information on U-M policy and processes. Also, see the DEA website for schedules of controlled substances.

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?	☐ Yes ▣ No	If yes, you will need to include your ORSP Special Service Proposal (SSP) number, or Unfunded Agreement (UFA) number. Need more information... See, Materials Transfer or Non-Disclosure Agreements
If Yes to 5.11	*5.11.1: Please indicate which UFA(s) relate to this research:*	SSP Number: _____ *Write in brief description here:* _____ _____ **OR** UFA Number: _____	Special Service Provider numbers are provided by Project Representatives for various types of agreements that are ancillary to sponsored activity and that require ORSP processing or authorized signature but do not require a PAF. E.g., Material Transfer Agreements, Data Use Agreements, Software Licenses, and Nondisclosure Agreements. Note that ORSP handles these agreements and assigns SSP numbers when items or information are coming into the University while OTT handles such agreements for items and information being provided by the University to other organizations. Need more information... contact the Project Representative who would handle the provider of the information or material.
5.12	Is an intellectual property disclosure related to this proposal on file in the Office of Technology Transfer?	☐ Yes ▣ No	If yes, you will need to indicate your Office of Technology Transfer (OTT) File number. Need more information... See Office of Technology Transfer
If Yes to 5.12	*5.12.1: Provide the OTT file number:*	OTT File Number: _____	Need more information... See Office of Technology Transfer