INVESTIGATOR FORM

Principal Investigator:

Proposal Number:

Sponsor:

Project Number:

Project Title:

Overview: Expectations of external sponsors require varying institutional procedures which necessitate clearly identifying individuals conducting research activities. Completion of this form provides information to OSPA and the COI Office critical for ensuring that the University adheres to relevant regulations and policies.

Instructions: Submit this completed form to your <u>ORA Grants and Contracts Administrator</u> in anticipation of proposal submission where the source of funding will be from any of the following sponsors (directly or as flow through):

Agency for Healthcare Research and Quality (AHRQ)	Indian Health Service (IHS)
Agency for Toxic Substances and Disease Registry (ATSDR)	Juvenile Diabetes Research Foundation (JDRF)
Alliance for Lupus Research (ALR)	Lupus Foundation of America (LFA)
Alpha-1 Foundation	National Institutes of Health (NIH)
American Asthma Foundation (AAF)	National Science Foundation (NSF)
American Cancer Society (ACS)	Office of Global Affairs (OG)
American Heart Association (AHA)	Office of the Assistant Secretary for Health (OASH)
American Lung Association (ALA)	Office of the Assistance Secretary for Planning and Evaluation
Arthritis Foundation (AF)	Office of the Assistant Secretary for Preparedness Response (ASPR)
Centers for Disease Control and Prevention (CDC)	Office of Public Health and Science
CurePSP	Substance Abuse and Mental Health Services Administration (SAMHSA)
Food and Drug Administration (FDA)	Patient-Centered Outcomes Research Institute (PCORI)
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Health Resources and Services Administration (HRSA)	Susan G. Komen for the Cure (Komen)

For all sponsors with the exception of NSF, the table below should list all Investigators currently named for the project, including UMSL and non-UMSL personnel. For NSF projects, list only UMSL Investigators. For guidance on determining Investigators and additional relevant information, refer to page 2 of this form and the University of Missouri System COI policies.

Investigator's Name (first and last)	UM EMPLID (if applicable)	Affiliation and Job Title	Role on the Project	Official Use: OIDF DATE

*List additional Investigators on a separate attached page.

Other Significant Contributors (OSCs): Individuals identified as OSCs may or may not meet the definition of Investigator. OSCs deemed to be Investigators should be listed in the table above. List all other OSCs below.

Non-Investigator OSC's Name (first and last)	UM EMPLID (if applicable)	Affiliation and Job Title

*List additional OSCs on a separate attached page.

By signing below, the Principal Investigator certifies that this form contains all Investigators and OSCs currently named for the project. An updated Investigator Form must be submitted to and approval received from the COI Office before any additional Investigators participate in the project.

Signature:

Principal Investigator (printed name)

Form prepared by: ____

Phone	
Email:	

Version Date 12/2019

PROPOSAL SUBMISSION REQUIREMENTS

All UMSL Investigators must have a current Outside Interest Disclosure Form (OIDF) on file (i.e., OIDF submitted within 12 months of the submission date for this proposal) prior to proposal submission when the source of funds will be from any of the sponsors listed on page 1 of this form.

For **non-UMSL Investigators**, contact your <u>ORA Grants and Contracts Administrator</u> to identify required disclosures or certifications.

PROPOSALS WILL NOT BE SUBMITTED UNTIL IT IS CONFIRMED THAT ALL UMSL INVESTIGATORS HAVE A CURRENT OIDF ON FILE AND THAT REQUIRED CERTIFICATIONS ARE RECEIVED FOR NON-UMSL INVESTIGATORS.

GUIDANCE FOR DETERMINING INVESTIGATORS

Principal Investigators (PIs) are responsible for identifying who on their projects meets the definition of an Investigator

Who is considered an Investigator? UMSL utilizes the term "Investigator" to determine personnel required to comply with certain regulatory requirements, such as the rules governing conflict of interest. UMSL has concluded that the following definition should be used when determining who is an "Investigator" on a research grant proposal or project:

Investigator means the project director/principal investigator (PI/PD) and any other person, regardless of title or position, who is **responsible for the design, conduct, or reporting of research**, which may include, for example, collaborators or consultants.

The term "Investigator" includes, at a minimum, the following:

All Key Personnel¹. For <u>PHS proposals</u>, this is all individuals identified in the "Research & Related Key/ Senior Personnel" section of the proposal application, except those individuals identified as "Other Significant Contributor" (OSC). Individuals identified as OSCs may or may not meet the definition of Investigator.

¹[Please Note: UMSL may utilize the term "key personnel" differently in other settings or situations e.g. The Institutional Review Board (IRB) requires all personnel who interact with

human subjects and/or human subjects data to be added as "key personnel" on an approved IRB

application.]

Some federal agencies have provided additional guidance to assist in making this determination. The Public Health Service (PHS) gives the following interpretation:

"...we note that the definition refers to the **function** of the individual on the PHS-funded project; i.e. his/her responsibility for the design, conduct, or reporting of the PHS-funded research, **and not to his/her title or the amount or source of remuneration**."

The National Institutes of Health (NIH) provided the following FAQ to assist in identifying those personnel within the definition of "Investigator":

Question: Who is considered an "Investigator" for this purpose? Is it only the Principal Investigator? **Answer:** No. "Investigator" means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. Institutions should **consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work**. When the definition of investigator is limited to titles or designations (e.g., to principal investigators, key personnel, faculty) the risk that an unidentified FCOI may compromise the research enterprise increases.

RESPONSIBILITIES OF INVESTIGATORS

Once identified as an Investigator, those individuals will be required to comply with all applicable training and/or reporting procedures as defined by the sponsor's COI policy. The COI Office will contact all Investigators to inform them of the relevant responsibilities. When including Investigators from outside the University of Missouri-St. Louis, the COI Office will work with the PI and the outside Investigators to address any reporting requirements necessary.