NIH Proposal: Statement of Intent for Collaborating Institutions

This document can be used by institutions collaborating with MGB institutions on NIH proposals that do not have their own established statement of intent document.

SPONSOR
FUNDING ANNOUNCEMENT

PASS THROUGH ENTITY (PTE) – Prime Institution	
Prime PI	
Prime Institution	
Project Title	

SUBRECIPIENT					
Cooperating Inst.					
PI Name		ERA Commons ID			
PI Phone		PI E-Mail			
Project Period		Direct Costs		Total Costs	
Performance Site		F&A Costs			
BUSINESS CONTACT INFORMATION					
Name					
Address					
Bus. Phone		Bus. E-Mail			
UEI		Other Mailbox			

PROJECT INFORMATION	YES/NO	ASSURANCE #	APPROVAL DATE OR PENDING
Human Subjects	Choose one:		
Vertebrate Animals	Choose one:		
Human Embryonic Stem Cells	Choose one:		
Inventions And Patents *(For Renewal Applications)*	Choose one:		
Program Income	Choose one:		

CERTIFICATIONS

The appropriate programmatic and administrative personnel of the Subrecipient involved in submitting proposal documentation with PTE in response to the Funding Announcement are aware of Sponsor policy requirements detailed in the NIH Grants Policy Statement available at https://grants.nih.gov/policy/nihgps/index.htm.

In the event the Project is awarded, PTE and Subrecipient shall establish the necessary inter-institutional agreements consistent with those policy requirements.

In signing below, Subrecipient's Business Official certifies it has been made aware of Sponsor policy requirements and is willing to abide by all requirements should a notice of award and resulting subaward be issued by PTE. Sponsor requirements are outlined in more detail on the following page.

Name and Title _____ **Signature** _____

Date _____

SPONSOR REQUIREMENTS

We recommend that the department check off the items below that will apply to the subrecipient's scope of work before sending this document to the subrecipient. Items marked with an "*" apply to all NIH awards. Items marked with a "+" apply to most NIH awards.

☐ * United States Public Health Service (PHS) regulations governing financial conflicts of interest (COI) are codified at 42 CFR Part 50, Subpart F. If Subrecipient does not have a PHS compliant COI policy, they must follow MGB COI policy.

☐ *If Subrecipient will be conducting research or related activities using live vertebrate animals*, Animal Welfare Requirements apply: the *PHS Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) requires that an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare (OLAW). If the Subrecipient does not have an Animal Welfare Assurance with OLAW, the Subrecipient will apply for an Assurance or Foreign Assurance (if outside the U.S.) prior to the issuance of a Subaward. Subrecipient shall prepare the Assurance as instructed by OLAW and in accordance with the PHS Policy, and the authorized IACUC, or equivalent animal welfare oversight body, shall review those components of the application related to the care and use of animals. Subrecipient shall also comply with additional requirements that may be needed to satisfy Sponsor requirements, including executing project-specific Memorandums of Understanding between the institutional IACUCs or equivalents, the provision of animal research protocols or protocol equivalents in English, and descriptions of the regulatory environment for the site. No costs for activities with live vertebrate animals may be charged to Sponsor grants in the absence of a valid Assurance on file with OLAW and until all Sponsor requirements are met.

☐ *If Subrecipient will be engaged in Human Subject research*, Human Subjects Protections apply: Institutions that are engaged in nonexempt human subjects research and institutional boards (IRBs) reviewing research that is subject to the Health and Human Services (HHS) regulations must comply with the regulations at 45 CFR 46 (Revised Common Rule 46.101(a) and Pre-2018 Common Rule §46.101(a)). Subrecipient must provide written assurance that it will comply with 45 CFR 46, obtain a Federalwide Assurance (FWA) with the HHS Office for Human Research Protections (OHRP) and establish appropriate policies and procedures for the protection of human subjects (Revised Common Rule 45 CFR §46.108(a)(3) & (4) and Pre-2018 Common Rule 45 CFR 46.103(b) (4) & (5)).

☐ + Policy for Data Management and Sharing (DMS Policy): Subrecipient must comply with the Data Management and Sharing Plan approved by Sponsor, outlining how scientific data and any accompanying metadata produced in the research will be managed and shared.

☐ * Record Retention and Access Policy: Sponsor, Inspectors General, the Comptroller General of the United States, and the PTE, or any of their authorized representatives, has the right of access to any documents, papers, or other records of the Subrecipient which are pertinent to the Sponsor's award, to make audits, examinations, excerpts, and transcripts. Subrecipient may be asked by PTE at least once a year to provide access to lab notebooks, data, and documentation that supports the research outcomes as described in progress reports.

☐ * Patents and Inventions Policy: Subrecipient must report Subject Inventions to PTE in sufficient time for PTE to report such inventions to Sponsor.

☐ * Program Income Policy: Subrecipient must report to PTE gross income-earned by that is directly generated by the grant-supported activity or earned as a result of the subaward.

☐ * Public Policy Requirements, Objectives, and Other Appropriation Mandates: Subrecipient must comply with requirements that apply to its entity type.

☐ * Subrecipient must have a Unique Entity Identifier (UEI) prior to a Subaward being issued. Please see this guide to obtaining a UEI.

STATEMENT OF WORK