Yale YSM PRE-AWARD TEAM (YPAT) PROPOSAL INFORMATION FORM

FOR YSM PRE-AWARD ONLY
IRES PD#: _____, Notified: _____
☐COI Disclosure ☐PPAA ☐SPA Training ☐Effort Verification
PHS AGENCIES FAQ

Directions: Please complete sections 1-6 for all proposals and complete section 7 if submitting to NIH.

In adherence of OSP's internal proposal review guidelines, YPAT requires email receipt of final proposal documents 7 business days in advance of the sponsor deadline to allow for a full administrative review.

Section 1: Principal Investigator and Project Information

PI Name:		
Primary Project Location (Building Name & Room #):		
Project Title:		
Proposal Type: Select	**Program Type:** Select	**Award #** ***(NIH Resubmissions & Renewals):***
PI Proposed Effort:	VA appointment? ☐ Yes ☐ No	eBRAP Username *(for DOD proposals)*:
Primary Sponsor Name:		
Flow through? ☐ Yes ☐ No If "Yes," list originating sponsor:		
Funding Opportunity #:	NOSI (Notice of Special Interest):	
Project Start & End Date: to		
Sponsor Deadline:	Final Docs Due:	Deadline Time ***(only if before 5PM)***:

Section 2: Major Goals Statement

Provide a brief statement **(1-2 sentences)** of the overall objectives of the project, subproject, consortium arrangement or description of activity.

Section 3: Budget Information

YALE PERSONNEL – LIST NAME, ROLE, EFFORT, AND SELECT APPROPRIATE DESIGNATIONS FOR EACH

Name	Role	Effort	Key Personnel	VA Appointment
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

SUBCONTRACTS AND CONSULTANTS – PROVIDE PI OR CONSULTANT NAME ALONG WITH THEIR UNIVERSITY AND AGENCY NAME.

Name	Administrative Contact	Email

Section 4: Human Subjects & Vertebrate Animals

HUMAN SUBJECTS

Are Human Subjects Involved? ☐ Yes ☐ No If project is exempt, provide exemption number: **N/A**
Note: If you answered "Yes," and are submitting to NIH/AHRQ, then you **must** complete the PHS HS Study Record: **PHS FORM CLICK HERE**

Will this be a clinical trial? ☐ Yes ☐ No
If "Yes," is this trial a Phase III ☐ Yes ☐ No Delayed Onset Study? ☐ Yes ☐ No

Does the proposed project involve human fetal tissue obtained from elective abortions? ☐ Yes ☐ No
If yes, the proposal must include the following two attachments: HFT Compliance Assurance & HFT Sample IRB Consent Form. For NIH policy visit ***NOT-OD-19-137***

VERTEBRATE ANIMALS

Are Vertebrate Animals Used? ☐ Yes ☐ No
Involves the Use of Live Vertebrate Animals (laboratory animals or wildlife)? ☐ Yes ☐ No
Involves the use of live cephalopods (octopuses, squid, cuttlefish, or nautilus)? ☐ Yes ☐ No

Are animals euthanized consistent with AVMA guidelines? ☐ Yes ☐ No
If euthanizing **not** consistent with AVMA guidelines, describe method and provide justification:

Section 5: Regulatory Questions

Will this project involve YNHH services/staff? ☐ Yes ☐ No

Does this proposal involve special research (either COVID-19 or Stem Cell research)? ☐ Yes ☐ No

Is there proprietary/privileged information included in the application? (patentable ideas, trade secrets, etc.) ☐ Yes ☐ No

Does the project have an actual impact on the environment? (threatens the environment or public health) ☐ Yes ☐ No

Is the research performance site designated, or eligible to be designated, as a historic place? ☐ Yes ☐ No

WILL EHS MATERIALS BE USED ON THIS PROJECT ☐ Yes ☐ No **IF "YES," INDICATE WHICH MATERIAL(S) BELOW:**

☐ Recombinant DNA	☐ Hazardous Chemicals	☐ Radioactive Materials/Sources	☐ Select Agents
☐ Human Gene Transfer	☐ Biohazards	☐ Controlled Substances	☐ Radiation Generating Equipment
☐ Class 3b or 4 Lasers	☐ Human Pathogens	☐ Human Embryonic Stem Cells	If Human Embryonic Stem Cells will be used on this project provide ESCRO#:

Section 6: Export Questions

Does the proposed sponsored project involve the use of any Controlled Un-Classified Information? ☐ Yes ☐ No

'Controlled Unclassified Information' (CUI) is information that requires safeguarding or dissemination controls pursuant to and consistent with applicable law, regulations, and government-wide policies but is not classified under Executive Order 13526 or the Atomic Energy Act, as amended. If your proposal seeks funding from a federal agency and you are unsure if CUI will be received or generated in the performance of the proposed research, please consult this link to determine if CUI is Involved.

Does the proposed project refer to or require any of the following:

☐ Export controls in general or receipt of export-controlled materials ☐ Publication Restrictions ☐ Restrictions on foreign nationals

Collaboration with a foreign entity or foreign national? ☐ Yes ☐ No If "Yes," provide name of country(ies):

Will any part of the proposed sponsored project be conducted outside the US? ☐ Yes ☐ No

Any foreign travel, especially foreign travel with a laptop or other electronic device? ☐ Yes ☐ No

Will this project involve the transfer or shipment of equipment, materials, software, or data or provision of services outside the US? ☐ Yes ☐ No	If "Yes," specify country(ies) and detail shipments or services.
Does the project involve any technology or software which involves encryption, possible military applications or the possibility to use such technology in development of weapons? ☐ Yes ☐ No	If "Yes", provide a description of the technology and software involved:

Section 7: NIH APPLICATIONS – Answer the following questions only if your application is being submitted to the NIH.

Will you require a single IRB? (for multi-sites, includes AHRQ) ☐ Yes ☐ No

Single IRB policy applies to domestic sites of NIH/AHRQ-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research. ***NOTE: LETTER OF SUPPORT FROM YALE'S HRPP OFFICE WILL BE REQUIRED.*** *Click* ***HERE*** *for more information.*

Does any of the proposed research involve human specimens and/or data **NOT CONSIDERED HUMAN SUBJECTS RESEARCH?** ☐ Yes ☐ No

Disclaimer: Applications involving the use of human specimens or data may not be considered to be research involving human subjects, depending on the details of the materials to be used. For detailed instructions click ***HERE****. Additionally, De-identified samples do not count as human subjects. For de-identified samples, either exemption 4 should be picked or the "Not Human Subjects Research" attachment needs to be included. To decide whether your research involves human subjects refer to the RESEARCH INVOLVING PRIVATE INFORMATION OR BIOSPECIMENS.*

Will this project involve key biological and/or chemical resources? ☐ Yes ☐ No

Does this project involve the collection of LARGE-SCALE human or non-human genomic data? ☐ Yes ☐ No

If yes, is there a plan for the submission of sharing of such data? ☐ Yes ☐ No

NIH PHS ASSIGNMENT REQUEST FORM (OPTIONAL)

Suggested awarding components			
Suggested study sections			
Identify scientific areas of expertise needed to review your application			

List of individuals who should not review your application and why *(optional)*	

Reset Form