Yale **YSM PRE-AWARD TEAM**

FOR YSM PRE-AWARD TEAM USE ONLY

IRES PD#:_____

Notified: _____ Internal Deadline: _____

Compliance: ☐ COI | ☐ PPAA | ☐ SPA | ☐ Effort Verification

***PHS AGENCIES:** https://your.yale.edu/research-support/conflict-interest/frequently-asked-questions-coi

Proposal Information Form (PIF)

Reminder: NIH allows only one resubmission for each new, unfunded application. You may submit an unfunded new application as new again, without resubmission.

PRINCIPAL INVESTIGATOR, SPONSOR, & PROJECT INFORMATION

PI Name: Primary Project Location (Building Name & Room #):

Project Title:

Proposal Type: Award # (*NIH Resubmissions & Renewals*): Program Type:

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 #:

Project Start & End Date: to

Sponsor Deadline Date: Deadline Time (only if ***before 5PM)***:

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

MULTIPLE PI, CO-INVESTIGATOR, & OTHER YALE PERSONNEL

List Name, Role, and Effort **Include following notations: "R" for responsible personnel; "VA" for individuals with VA appointments**

SUBCONTRACTS, OTHER SIGNIFICANT CONTRIBUTORS, & CONSULTANTS

Provide PI and University/Agency Name

ANIMAL & HUMAN SUBJECTS

Human Subjects ☐ Yes ☐ No If project is exempt, provide exemption number:

- For NIH proposals: If yes, the PHS Study Record Form ***must*** be completed. Click **HERE** to download the PHS Study Record Form.

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

Single IRB? (for NIH/AHRQ multi-site studies) ☐ 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 the proposed project involve human fetal tissue obtained from elective abortions? ☐ Yes ☐ No

- If "Yes", proposal must include the following attachments per **NOT-OD-19-137**: 1) HFT Compliance Assurance & 2) HFT Sample IRB Consent Form

Animal Research ☐ Yes ☐ No If "Yes" are animals euthanized? ☐ Yes ☐ No

If "No" to AVMA guidelines, describe method and provide justification

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

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Will **EHS Materials** be used on this Project? ☐ Yes ☐ No **If "Yes", indicate which materials 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 #

THE FOLLOWING QUESTIONS SHOULD BE ANSWERED FOR ALL PROPOSALS

☐ Yes ☐ No	Does the proposed sponsored project involve the use of any Controlled Un-Classified Information? '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: https://www.archives.gov/cui/registry/category-list
☐ Yes ☐ No	Collaboration (for example, via subaward, consultant/vendor contract, or research/service interaction, etc.) with a foreign entity or foreign national? If "Yes", provide country(ies)
☐ Yes ☐ No	Will any part of the proposed sponsored project be conducted outside the US? If "Yes", provide country(ies)
☐ Yes ☐ No	Any foreign travel, especially foreign travel with a laptop or other electronic device? If "Yes", provide country(ies)
☐ Yes ☐ No	Will this project involve the transfer or shipment of equipment, materials, software, or data or provision of services outside the US? If "Yes", provide country(ies) and description of what you are shipping or transferring, or what services you are providing
☐ Yes ☐ No	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? If yes, provide a description of the technology and software involved

FOR NIH PROPOSALS ONLY

1. Does any of the proposed research involve human specimens and/or data? ☐ Yes ☐ No
   - 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**.
   - *Disclaimer:* 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.**
2. Will this project involve key biological and/or chemical resources? ☐ Yes ☐ No
3. 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 and sharing of such data? ☐ Yes ☐ No

   Note: If large-scale data, this must be mentioned in the cover letter and included in the resource sharing plan, per NIH policies. For more information please refer to:
   - **NIH Genomic Data Sharing Grants Policy Statement (GDS Policy)**
   - **GDS Policy/Policy for for Genome-Wide Association Studies (GWAS)**

NIH PHS Assignment Request Form – up to three assignments allowed for awarding components and study sections.

a) Suggested awarding components

b) Suggested study sections

c) Identify scientific areas of expertise needed to review your application

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

Reset Form