

| FOR YSM PRE-AWARD TEAM USE ONLY                             |                  |  |  |  |  |
|---|------------------|--|--|--|--|
| IRES PD#:   | PHS AGENCIES FAQ |  |  |  |  |
| Compliances: ☐ COI   ☐ PPAA   ☐ SPA   ☐ Effort Verification |                  |  |  |  |  |
| Notified: Final Docs I                                      | Due:             |  |  |  |  |

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.

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|--|------------|-------------------------|------------------------|------------|--------------------------------------|-----------------------|-------------------|--|
| Section 1: Principal Investigator and Project Information  |            |                         |                        |            |                                      |                       |                   |  |
| PI Name:   |            |                         |                        |            |                                      |                       |                   |  |
| Primary Project Location (Building Nam   | e & Roo    | m #):                   |                        |            |                                      |                       |                   |  |
| Project Title:   |            |                         |                        |            |                                      |                       |                   |  |
| Proposal Type:   | Progra     | Program Type: Award     |                        |            | rd # (NIH Resubmissions & Renewals): |                       |                   |  |
| PI Proposed Effort:  | VA app     | oointment?  Yes         | ☐ No                   | eBR        | RAP Username (for DOD proposals):    |                       |                   |  |
| Primary Sponsor Name:  |            |                         |                        |            |                                      |                       |                   |  |
| Will Yale be a subaward?   Yes   N   | 0          | If "Yes", list originat | ting sponsor:          |            |                                      |                       |                   |  |
| Funding Opportunity #:   |            |                         | NOS                    | SI (Notice | e of Special Interest):              |                       |                   |  |
| Project Start & End Date:  | to         |                         |                        |            |                                      |                       |                   |  |
| Sponsor Deadline:  |            | Deadline 1              | Γime <i>(only if b</i> | efore 5PI  | <b>M</b> ):                          |                       |                   |  |
| Section 2: Major Goals Stateme   | ent        |                         |                        |            |                                      |                       |                   |  |
| Provide a brief statement (1-2 sentences)  |            | erall objectives of the | e project, sub         | project, c | consortium arrangement or de         | scription of activity | /.                |  |
|  |            |                         |                        |            |                                      |                       |                   |  |
|  |            |                         |                        |            |                                      |                       |                   |  |
| Section 3: Budget Information  |            |                         |                        |            |                                      |                       |                   |  |
| YALE PERSONNEL - LIST NAME, ROLE   | , EFFOR    | T, AND SELECT APF       | PROPRIATE              | DESIGN     | NATIONS FOR EACH                     |                       |                   |  |
| Name   |            | Role                    |                        |            | Effort                               | Key<br>Personnel      | VA<br>Appointment |  |
| Name   |            | Role                    |                        |            | Elloit                               | reisonnei             | Appointment       |  |
|  |            |                         |                        |            |                                      |                       |                   |  |
|  |            |                         |                        |            |                                      |                       |                   |  |
|  |            |                         |                        |            |                                      |                       |                   |  |
|  |            |                         |                        |            |                                      |                       |                   |  |
| SUBCONTRACTS AND CONSULTANTS   | - PROVI    | DE PI OR CONSULT        | TANT NAME              | ALONG      | WITH THEIR UNIVERSITY A              | ND AGENCY NAM         | ЛЕ.               |  |
| Name   | Admin      | istrative Contact       |                        |            | Email                                |                       |                   |  |
|  |            |                         |                        |            |                                      |                       |                   |  |
|  |            |                         |                        |            |                                      |                       |                   |  |
|  |            |                         |                        |            |                                      |                       |                   |  |
|  |            |                         |                        |            |                                      |                       |                   |  |
| Section 4: Human Subjects & Ve   | ertebra    | te Animals              |                        |            |                                      |                       |                   |  |
| HUMAN SUBJECTS  Are Human Subjects Involved?  Veg 1  |            | If project is evemp     | t provide eve          | mation     | numbor                               |                       |                   |  |
| Are Human Subjects Involved? Yes No If project is exempt, provide exemption number:  *Note: If you answered "Yes," and are submitting to NIH/AHRQ, then you must complete the PHS HS Study Record:   |            |                         |                        |            |                                      |                       |                   |  |
| Will this be a clinical trial? Yes No  |            | Mill/Alling, then you   | i iliust compi         | ete the r  | -113 113 Study Necolu.               |                       |                   |  |
| If "Yes," is this trial a Phase III Yes  | _          | Delayed Onset Stud      | y? 🗌 Yes               | ☐ No       |                                      |                       |                   |  |
| Does the proposed project involve human fetal tissue obtained from elective abortions?   |            |                         |                        |            |                                      |                       |                   |  |
| If yes, the proposal must include the following two  | o attachme | ents: HFT Compliance A  | Assurance & HF         | T Sample   | e IRB Consent Form. For NIH poli     | cy visit NOT-OD-19-1  | 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   |            |                         |                        |            |                                      |                       |                   |  |
| Are animals euthanized consistent with AVMA guith anizing <b>not</b> consistent with anizing <b>not</b> consistent | _          |                         |                        | ification: |                                      |                       |                   |  |

| Section 5: Regulatory Questions   |                              |                  |                          |   |                                   |  |  |  |
|---|------------------------------|------------------|--------------------------|---|-----------------------------------|--|--|--|
| Will this project require new space, renovations to existing space, or additional equipment?  Yes No  |                              |                  | If "Yes" please explain: |   |                                   |  |  |  |
| Will this project involve YNHH service  | es/staff?  Yes  No           |                  |                          |   |                                   |  |  |  |
| Does this proposal involve special res  |                              | or Stem Cell res | earch)?                  | ☐ Yes ☐ No  |                                   |  |  |  |
| Is there proprietary/privileged informa   | tion included in the applic  | ation? (patental | ble ideas                | , trade secrets, etc.)  | Yes 🗌 No                          |  |  |  |
| Does the project have an actual impa  | ct on the environment? (th   | hreatens the en  | vironmen                 | nt or public health)  | ☐ No                              |  |  |  |
| Is the research performance site designated, or eligible to be designated, as a historic place? Yes No  |                              |                  |                          |   |                                   |  |  |  |
| WILL EHS MATERIALS BE USED O  | N THIS PROJECT Y             | es No IF         | "YES," I                 | NDICATE WHICH MATERIA   | L(S) BELOW:                       |  |  |  |
| Recombinant DNA   | Hazardous Chemic             | als              | Radi                     | ioactive Materials/Sources  | Select Agents                     |  |  |  |
| Human Gene Transfer   | Biohazards                   |                  | Conf                     | trolled Substances  | Radiation Generating Equipment    |  |  |  |
| Class 3b or 4 Lasers  | Human Pathogens              |                  | Hum                      | uman 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 fol    | llowing:         |                          |   |                                   |  |  |  |
| ☐ Export controls in general or recei   | pt of export-controlled ma   | terials          | Publica                  | tion Restrictions [   | Restrictions on foreign nationals |  |  |  |
| Collaboration with a foreign entity or f  | oreign national?             | s ☐ No If "Y     | es," prov                | vide name of country(ies):  |                                   |  |  |  |
| Will any part of the proposed sponsor   | ed project be conducted o    | outside the US?  | ☐ Ye                     | s 🗌 No  |                                   |  |  |  |
| Any foreign travel, especially foreign  | travel with a laptop or othe |                  |                          | 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   |                              |                  |                          |   |                                   |  |  |  |
| Section 7: NIH APPLICATION  | S - Answer the follo         | wing question    | ons onl                  | y 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?   |                              |                  |                          |   |                                   |  |  |  |
| 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 no review your application   | eeded to                     |                  |                          |   |                                   |  |  |  |
| List of individuals who should not review your application and why (optional)   |                              |                  |                          |   |                                   |  |  |  |