**Yale University Human Research Protection Program**

Request for Permission to Serve as a Yale University

Unaffiliated Investigator

Individual

Individual Participating as an Employee of an Agency, Private Practice or Business

910 FR 1

(2021-1)

**Yale University, Federalwide Assurance No. 00002571**

This section is to be completed by the Principal Investigator.

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| --- | --- |
| **1.** | **Name of Unaffiliated Investigator:** |
|  | |
| **2.** | **Yale IRES IRB Protocol #** |
|  | |
| **3.** | **Name of Yale Principal Investigator:** |
|  | |
| **4.** | **Protocol Title:** |
|  | |
| **5.** | **Describe the role and responsibilities of the individual requesting Unaffiliated Investigator status in the research:** |
|  | |
| **6.** | **Describe why this individual is needed for the conduct of this study:** |
|  | |
| **7.** | **Describe the Principal Investigator’s plan for supervision of this individual’s work:** |
|  | |
| **8.** | **Is the individual paid for his/her work?** |
| YES  NO | |
| **9.** | **If yes, is there a Professional Service Agreement with the Unaffiliated Investigator in place?** |
| YES  NO | |

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**Principal Investigator’s Signature Date**

**Unaffiliated Investigator Attestation**

This section is to be completed by the proposed unaffiliated investigator.

Do you or your spouse or child have an incentive or interest, financial or otherwise, that may be related to this research?

Yes  No

Do you or your spouse or child have any patent (sole right to make, use or sell an invention) or copyright (exclusive rights to an original work) interests related to this research protocol?

Yes  No

**If yes to either of the above questions, please, describe:**

**Review and check the boxes next to each requirement to indicate your agreement:**

The Investigator requesting Unaffiliated Investigator status via this request has reviewed and agrees to abide by: (a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent: see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); (b) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46, and all Subparts (c) the U.S. Food and Drug Administration (FDA) regulations for the protection of human subjects at 21 CFR part 50; (d) the Yale University Federalwide Assurance (FWA) and the specific terms of the Yale University FWA; (e) the relevant Yale University policies and procedures for the protection of human research participants, and (f) *HIPAA at Yale, Researcher’s Guide to HIPAA* (if applicable).

The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human research participants involved in research conducted under this Request.

The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for individuals participating in research conducted under this Request, including, but not limited to, HIPAA’s Privacy and Security Rules and the requirements governing the use and disclosure of Protected Health Information in research.

The Investigator will abide by all determinations of the Yale University Institutional Review Board(s) (IRB) designated under the above-referenced FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

The Investigator will complete human subjects protection training and other applicable educational training as required by Yale University and/or its Human Research Protection Program prior to initiating research covered under this Request.

The Investigator will report promptly to the Principal Investigator of this research and the IRB any proposed changes in the research conducted under this Request. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

The Investigator will report immediately to the Principal Investigator of this research and the IRB any unanticipated problems involving risks to subjects or others in research covered under this Request.

If the Investigator is involved in enrolling research participants, the Investigator will obtain, document, and maintain records of informed consent for each person enrolled or each person’s legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA referenced above) and as consistent with the IRB approved protocol.

The Investigator acknowledges and agrees to cooperate in assisting the IRB in carrying out its responsibility for initial and continuing review, record keeping, reporting, auditing, monitoring and certification for the research referenced above.

The Investigator will provide all information requested by the IRB in a timely fashion.

The Investigator will not enroll research participants in research or otherwise initiate research activity under this Request prior to IRB review and approval of the proposed research and approval of this Request by Yale University.

The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research participant and that the participant’s rights and welfare must take precedence over the goals and requirements of the research.

**Unaffiliated Investigator Signature**:

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|  |  |
| --- | --- |
| Name: |  |
| Address: |  |
| Phone: |  |
| Email: |  |

Submit the request in IRES IRB with the following documents:

Documentation of Human Subjects Protection Training

Documentation of HIPAA Training (if applicable)

Current CV or Résumé

Current License (if applicable)

Letter of Support from Agency, Private Practice or Business (if applicable)

This section is to be completed by the HRPP Office.

**HRPP Staff Review:**

**Approval recommended**

**Approval recommended with comments:**

**Approval not recommended with the following rationale:**

**Prepared by:**

|  |  |
| --- | --- |
| **Name:** |  |
| **Role:** |  |

**APPROVAL OF REQUEST:**

**Institutional Signatory Official (or Designee) Signature**:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_

|  |  |
| --- | --- |
| **Name:** |  |
| **Role:** |  |

This Agreement is effective upon approval of Yale Institutional Signatory Official or Designee.