|  |
| --- |
| yaleclr**Yale University**  **Human Investigation Committee/Human Subjects Committee**  **Request for Approval of Modification to Change Principal Investigator**  **100 FR12 (2017-1)**  **Instructions:** This form should be only used to request a *change* of the **Principal Investigator (PI)** on a research protocol. In IRES IRB, create Modification/Update that will affect ‘Other parts of the study’. Be sure to upload this completed and signed form in the Supporting Documents page. Change the PI on the Basic Information page and update any relevant study documents (study protocol, site addendum, consent forms, HIPAA RAF, etc.) to reflect the change of the Principal Investigator. An investigator may not act as the PI of a study without IRB approval.  **Note**: All active subjects participating in research activities must be notified promptly that the PI has changed. Notification must be documented in research records. |
| **HIC/HSC Protocol Number: *Type here* Date: *Choose a date***  **Title of Research Project: *Type here***  **Current PI**: ***Type here*** **New PI\***: ***Type here*** |
| * **Disclosure of Interest:** Does the proposed Principal Investigator or any of his/her family members (spouse, child, domestic partner) have an incentive or interest, financial or otherwise, that may be viewed as affecting the protection of the human subjects involved in this project, the scientific objectivity of the research or its integrity? See Disclosures and Management of Personal Interests in Human Research <http://www.yale.edu/hrpp/policies/index.html#COI>   Yes No  *All Yale University and Yale New Haven Hospital individuals listed as co-investigators must have a current financial disclosure form on file with the University’s Conflict of Interest Office.*  If this has not been done, the individual(s) should follow this link to the COI Office Website to complete the form:  <http://www.yale.edu/coi/>  NOTE: The requirement for maintaining a current disclosure form on file with the University’s Conflict of Interest Office extends primarily to Yale University and Yale-New Haven Hospital personnel.  **Whether or not they are required to maintain a disclosure form with the University’s Conflict of Interest Office, all investigators and individuals deemed otherwise responsible by the PI who are listed on the protocol are required to disclose to the PI any interests that are specific to this protocol.**  \**Individuals must meet the criteria set out in the Yale University Faculty Handbook (located at* [*http://www.yale.edu/provost/handbook/yfhtoc.html*](http://www.yale.edu/provost/handbook/yfhtoc.html)*) in order to serve as principal investigators on Yale research studies. Researchers not meeting these criteria who wish to serve as PI require special approval. Approval is protocol-specific, and must be obtained for each protocol submitted to the HIC/HSC. To obtain the form to request special approval, visit* <https://your.yale.edu/research-support/human-research/forms-templates>*.*   |  | | --- | | ***Current Principal Investigator Attestation:***  **I will no longer serve as PI on the study noted above as of *Choose a date*.**  ***Insert name of new PI* has the appropriate knowledge and credentials to serve as PI on this study and I have provided him/her with all of the necessary information and critical documents for the study.**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature of Current Principal Investigator** New Principal Investigator Assurance As the Principal Investigator of this research project, I certify the following:   * I assume full responsibility for the protection of human subjects and the proper conduct of the research. * Subject safety will be of paramount concern, and every effort will be made to protect subjects’ rights and welfare. * The research will be performed according to ethical principles and in compliance with all federal, state and local laws, as well as institutional regulations and policies regarding the protection of human subjects. * All members of the research team will be kept apprised of research goals. * I will obtain approval for any subsequent changes or modifications to this study prior to their initiation, as well as approval for continuing review prior to the date that approval for the study expires. * I will report to the HIC/HSC any serious injuries and/or other unanticipated problems involving risk to participants. * I am in compliance with the requirements set forth in the Yale University Faculty Handbook and qualify to serve as the Principal Investigator of this project or have acquired the appropriate approval from the Dean’s Office or Office of the Provost, or Yale-New Haven Hospital General Counsel. * I will identify a successor if I stop being Principal Investigator and facilitate a smooth transfer of investigator responsibilities. * I have reviewed the study and the documents associated with the study, and accept responsibility to serve as the PI on this study.   **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature of New Principal Investigator** | |