

For Investigator Use Only.

INSTRUCTIONS

Request for Re-Approval Of a Protocol for Research Involving Human Subjects (Form 5R)

Use this form when requesting continuing review for renewal of approval, or re-approval, of a currently approved research study. Studies that are in data analysis only still require renewal. The HIC commonly refers to this form as Form 5R. **Do not include this Instruction section** when submitting a Form 5R to the HIC.

Ensure that Requests for Re-approval are Timely:

Federal regulations and Yale University policy require continuous approval of a research study. When re-approval of a research study does not occur prior to the end of the approval period specified by the HIC, the approval for the research study expires. When the study's approval period has expired, all research activity must stop unless the HIC finds that it is in the best interest of individual subjects to continue. A principal investigator, who believes it is in the best interest of the subjects to continue research interventions, must submit a written request to the HIC, with a justification as to why permission to continue the research should be granted. Enrollment of new subjects cannot occur after the expiration of HIC approval.

List All Active Research Study Personnel and Ensure Training:

List the names of all current members of the research team in the chart provided on the Form 5R. (To expand the chart, press "enter" in the grey box in the name column) Indicate in the "Affiliation column" whether the research team member is a part of the Yale Faculty or staff, or a part of the faculty or staff of a collaborating institution. Investigators are reminded that they may designate on the form the names of individuals who serve as consultants on the research project. Consultants should be identified by noting a "Cslt" notation after their name.

Individuals serving as consultants on the research cannot obtain, receive or possess identifiable private information of subjects. Thus, individuals from Yale or other institutions who will interact with subjects or their data must be listed as investigators or study personnel on the protocol. Any individual external to Yale, whether serving as an investigator or consultant, must confer with their institution's IRB to determine whether approval from their institutional IRB is required.

Ensure that all individuals participating in the research are in compliance with the University's human subject protection and HIPAA training requirements. (See <http://info.med.yale.edu/hic/>).

List New Research Investigators or Personnel:

Investigators wishing to add *new* members to the research team, e.g., research personnel not previously listed on the initial protocol application or subsequent submissions, must

submit a request to add the new personnel that is found at:

<http://info.med.yale.edu/hic/forms/forms/RequestAdditionRemovalInvestigatorsOrKeyStudyPersonnel.doc>.

Attestation of Individual Conflicts of Interest:

The certification by all study investigators and personnel relative to any protocol-specific conflict of interest (COI) that is required on the initial protocol application does not need to be repeated on the request for re-approval. However, the principal investigator must certify on the Form 5R the presence or absence of any real or potential protocol-related COIs for him/herself and each member of the research team. Each individual reporting a new, or previously undisclosed, protocol-related COI must do so by submitting one copy of the protocol-specific COI disclosure form.

Individuals, who previously disclosed a protocol-specific COI, are required to provide an update using the protocol-specific COI form. All protocol-specific COI disclosure forms must be submitted to the HIC concurrent with the Form 5R submission. For information on protocol-related COI see: <http://info.med.yale.edu/hic/policy/index.html>

Do Not Identify Study Subjects:

When responding to questions on the form, e.g., reporting adverse events, unanticipated problems or subject withdrawals, do not include subject names, initials or any personally identifiable information on this form or on any documents submitted to the HIC.

Active Protocols Must Contain all Elements Needed to Ensure Subject Protections:

Federal guidance and University IRB policy change over time in response to new initiatives to ensure the protection of subjects participating in research. Thus, the HIC may require that a research protocol be re-written and submitted on the most current version of the HIC application. The re-writing of active protocols ensures the integration of all active amendments and reflects accurately all current research activities. The HIC will identify protocols that must be re-written in the new format during the course of its regular operations and inform the principal investigator in writing of the need to submit a re-written protocol. Investigators, who have been directed by the HIC to re-write the protocol into the new format, must do so and attach it to the Form 5.

Alternatively, investigators may opt to re-write their research protocols at any time to ensure that all protocol elements are updated and represented fairly. Use the HIC Protocol Application Form when re-writing your protocol. Any changes to the protocol must be accompanied by the Request for Approval of Amendment Form. Both forms can be found at <http://info.med.yale.edu/hic/forms/index.html>.

Principal Investigator Qualifications: Investigators are reminded that University policy permits only full-time Yale faculty members holding the ranks of Assistant, Associate, or Full Professor, or the ranks of Research Scientist, or Senior Research Scientist to serve as Principal Investigators on research studies conducted on its premises or funded by grants awarded through the University. (See www.yale.edu/provost/handbook)

Any student, fellow, or post-doctoral trainee who wishes to serve as a principal investigator for a research study must have a faculty sponsor. Associate Research Scientists may either have a faculty sponsor or obtain special permission from the School of Medicine Dean's Office to serve as PI. For more information see <http://info.med.yale.edu/hic/forms/forms/PermissionToServeAsPI.doc>.

Public Registration of Study:

Depending upon the type of study and/or the journal in which the results will be published, it may be necessary to register the research project with a public registration data bank. If the study is registered with a public registry (such as clinicaltrials.gov) which also serves as a recruitment mechanism, it is necessary to amend the recruitment procedures section of HIC application to indicate the public registry as a method of recruitment.

Areas of Research

This section attempts to collect specific attributes about each protocol that are used by the University for research administration reporting and monitoring purposes. Please check all that apply.

Clinical Research: The NIH defines categories of human clinical research using a three-part definition as summarized below. Clinical research is research in which it is necessary to know the identity of the patient from whom the cells, tissue, specimens or data are derived.

Patient-Oriented Research: Research conducted with human subjects (or material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects or their identifiable data. Excluded from this definition are in-vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) research on mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, (d) development of new technologies.

Epidemiologic and Behavioral Research: Clinical research in this area is divided into five categories: (a) research on the identification and understanding of risk and protective factors associated with the onset and course of illness, and with health conditions; (b) research on the effects of illness or physical condition on behavioral and social functioning; (c) treatment outcomes research; (d) research on health promotion and disease prevention (i.e., behavioral interventions); and (e) research on institutional and organizational influences on health.

Outcomes Research and Health Services Research: Clinical research in this area is done to understand the results of health care practices and interventions. It is necessary to know the identity of the patient from whom the cells, tissue, specimens or data are derived, in order to correlate the impact of care or interventions on the health outcomes of patients and populations.

□ **Translational Research #1 (“Bench-to-Bedside”)**: The process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. Included in this category is some research using animal models that represent the final steps immediately prior to the development of human protocols or FDA filings. It also includes the development of technological modifications needed to translate laboratory techniques into use in humans and the validation of these techniques in humans.

□ **Translational Research #2 (“Bedside-to-Practice”)**: Research aimed at enhancing the adoption of best practices in the community. It includes investigation of the effectiveness of interventions in real-world settings and the transfer of evidence from randomized controlled trials into practice.

□ **Interdisciplinary Research**: A mode of research by teams or individuals that integrates information, data, techniques, tools, perspectives, concepts, and/or theories from two or more disciplines or bodies of specialized knowledge to advance fundamental understanding or to solve problems whose solutions are beyond the scope of a single discipline or area of research practice.

□ **Community-Based Research**: Broadly defined, community-based research takes place in community settings and brings together researchers and community partners with the purpose of solving a pressing community problem or effecting change in the community. This may or may not include community-based participatory research (CBPR), a collaborative process that begins with a research topic of importance to the community and involves community members in the design and implementation of the research projects.

Please annotate “N/A” for sections in this form that are not applicable to the study.

Need help completing this form? Contact the HIC at 785-4688.

The Following Documents Are Necessary For Review of a Request for Re-Approval:

- 1 original and 2 copies of the Form 5R
- 2 copies of the HIC application
- 2 copies of any consent documents
- 2 copies of the sponsor protocol (if applicable)
- 2 copies of the Investigator Brochure if it has been revised, and not previously submitted to the HIC
- 1 copy of each protocol-specific Conflict of Interest forms (if applicable)
- 1 copy of DSMB reports (if applicable)

- If you are adding any new (not previously approved by the HIC) surveys, tools, assessments, recruitment and subject educational material (e.g., pamphlets, brochures) planned for future use, three copies of the Request for Approval of Amendment must be submitted along with two copies of all documents. If applicable, include Internet web pages from recruitment sites.
- A copy of the most recent annual IND report submitted to the FDA if this study operates under an IND and the principal investigator serves as the sponsor-investigator.
- Do NOT include on-site monitoring reports, unless they delineate major protocol violations (http://www.info.med.yale.edu/hic/policy/protocol_deviations.pdf)