

HEI Study Oversight Processes

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September 8, 2020



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Agenda

Introduction

Getting Started: Contracts & Quality Assurance Plans

Q&A

During the Research Project: Progress Reports & Check-ins

Q&A

Science Communication: Final Report, Publications, and Meetings

Q&A

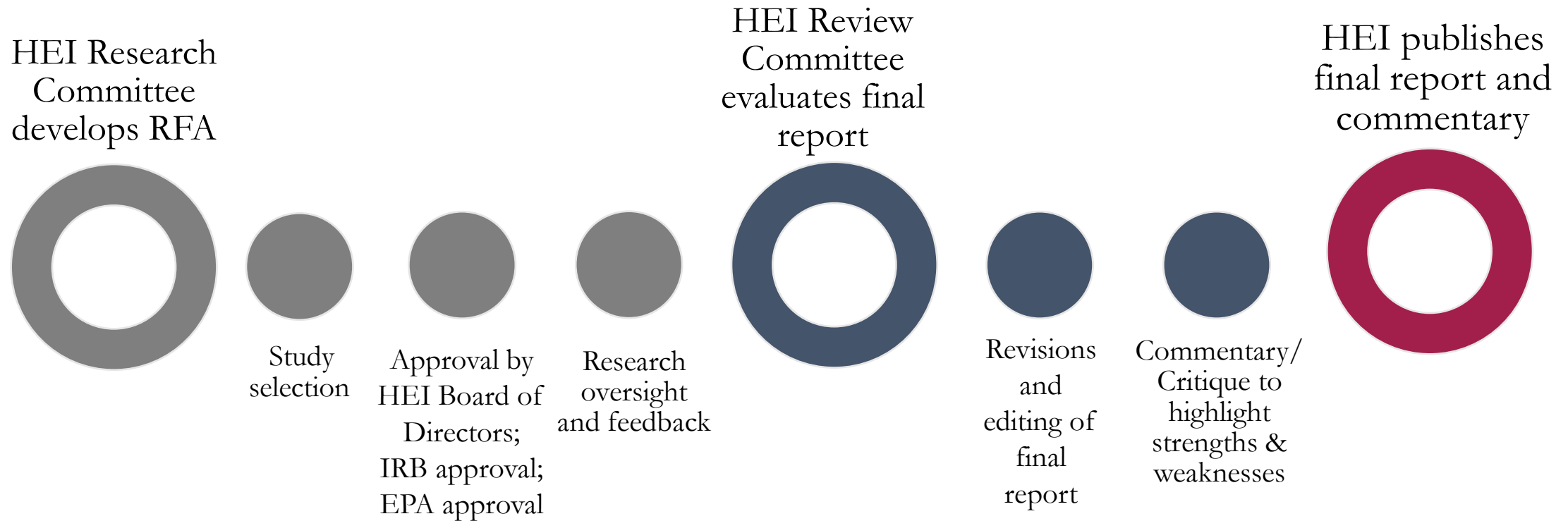
HEI's Goals

To build a **coherent research program** for each set of related studies addressing questions in a more comprehensive way than would be possible with independent studies.

To provide **timely, high-quality information** to its sponsors and regulatory agencies for technological and regulatory decisions

HEI has rigorous oversight and evaluation procedures to ensure the proposed goals are met. The HEI contract is not a grant like with NIH.

HEI Process Timeline



Part 1: Before the Study Starts

Negotiation of Contract

HEI's Research Agreement is a cost-reimbursement contract, not a grant; issued for one year with annual renewal.

The contract contains a **Statement of Work**: an approved, brief description of tasks to be performed during the contract year, the budget for Year 1, and the original application.

The contract may be amended only upon written agreement between the investigator's institution and HEI. Any change in plans needs to be approved by the Research Committee.

No work should be started, nor should any study costs be incurred, prior to signing of the contract -- unless explicit written authorization is provided in advance by HEI's Director of Finance and Administration (Jacqueline Rutledge).

Studies Involving Human Data

Applicant must submit a written assurance for compliance with the guidelines established by the US EPA and Department of Health and Human Services (DHSS) (application form F-11).

Before the contract is signed, investigators need to submit a detailed protocol and documentation certifying an appropriate **IRB or Ethics Board** has reviewed and approved the proposed study in accordance with the DHHS regulations, i.e.

- The entire application that was sent to the IRB (including all supporting documentation, such as the study protocol, questionnaires, etc.);
- Statement of approval or exemption from the IRB;
- Approved informed consent document (if applicable) or a statement from the IRB that the investigator does not need to obtain informed consent.
- If the IRB approval has an end date, renewal applications and approvals should be sent to HEI when they are due.

HEI is required to share all IRB documentation with the US EPA, which provides its own separate approval before the contract with HEI is signed.

Quality Assurance/Quality Control

QA/QC plan is required for all projects and should be submitted to HEI early in the first year, before data collection starts.

Components include:



Conflict of Interest (New!)

HEI requires investigators to disclose any potential conflicts of interest including:

- financial relationships with entities in the exposure science/env. health areas that could influence, or be perceived to influence, the research; and
- interactions with any industry, government, or nonprofit entity that could be considered broadly relevant to the work described.

HEI requests that investigators send a COI disclosure form when the study starts, and again at submission of the draft final report. All information is kept confidential.

Q&A: Getting Started

Part 2: While the Study is Ongoing

Progress Reports

Why: To indicate what progress has been made, which objectives have been completed, and what problems, if any, have been encountered.

When: At 5 and 10 months during each contract year; in the final year, the 10-month report is replaced by a draft *Final Report*

Reviewed by: HEI Research Committee and Science Staff

The **ten-month report** is a combined progress report and renewal application for the next year's funding and includes:

- Summary of results obtained during the funding period
- Work Plan including statement of work
- Budget for the upcoming year
- Any problems encountered and plans to address them

Note: Rosenblith Awardees also include a letter from the mentor.

Budget and Invoices

Invoices should be submitted to Jacqueline Rutledge.

Any proposed budget changes should be sent to HEI for approval.

Any changes larger than \$5,000 require approval by the Research Committee.

At the end of the contract year, the total spending is reviewed.

If the project is behind, the PI can request a no-cost extension.

Unspent funds can be transferred to the next contract year (*with necessary amendments to contracts and revised budget forms*).

Site Visits

HEI may conduct informational site visits of its funded investigators during the study virtually or in person at your institution.

The site visit team consists of members of the HEI Research Committee, HEI scientific staff, and other experts.

The purpose of these visits is to:

evaluate the status of the project,
provide the investigator with expert technical advice,

facilitate exchange of ideas between the investigator and other experts in the field.

The overall goal of any feedback on the study is to arrive at the best possible, high quality outcome of the study, while staying true to the original goals.

Quality Assurance/Quality Control Audits

For all studies involving human data and certain other studies of regulatory significance, HEI works with an external QA audit team that conducts *confidential* audits.

- Depending on the study, one **on-site audit** will be conducted about half-way through the study, as well as an audit of the final report. For some studies only an **audit of the final report** will be conducted, usually **offline** (remote).
- On-site audits usually take 2 or 3 days and include interviews with key personnel, data audits, and checking of statistical code.
- Results are confidential, only shared with HEI's Director of Science. Any issues will be communicated with the PI and resolved with the audit team. The final report includes a QA statement documenting the process (*but not any confidential details*).

Q&A: Doing the Research

Part 3: Science Communication

HEI Conference and Workshops

HEI holds an annual conference that all principal investigators are contractually required to attend*. Each PI is asked to submit an abstract and present a poster. The Annual Conference provides an opportunity for:

- HEI sponsors to learn more about the funded studies,
- HEI to receive feedback on its research program, and
- Informal interactions among investigators, Research and Review Committee members, sponsor representatives, HEI staff, and other attendees.
- May include general workshops on broader issues of current interest and/or small investigator workshops focused on a specific RFA.

** Attendance of the PI will be covered by HEI, separately from the contract. During the first year, we ask that you present the approach & methods and any preliminary or related results.*

Manuscripts and Meeting Abstracts

HEI encourages investigators to publish results of research conducted under HEI funding in peer-reviewed journals and other scientific literature, as well as at meetings of established scientific organizations (Art. 16). A statement acknowledging HEI support and a disclaimer* must appear in all publications resulting from work funded by HEI.

Responsibilities of the PI:

- Share a copy of all manuscripts based on all or part of the HEI-funded work at the time of submission and of final publication;
- Share all meeting abstracts at the time of submission and a final version of the poster or oral presentation.

HEI generally does not comment on manuscripts or abstracts unless we notice that the results may have been misrepresented.

** language provided by HEI in its contract with the investigator's institution*

Looking Ahead to the HEI Research Report

Investigators are contractually required to prepare a *comprehensive final report* that describes the entire study and its findings.

- The HEI Research Report with its Commentary are the principal means by which HEI communicates results of its research, incl. the evaluation and interpretation of those results.
 - Each report is peer-reviewed by scientists with appropriate technical expertise, including a biostatistician. The Review Committee evaluates the report and writes a Commentary that is published with the final report.
- Reports are widely distributed and are registered with the National Technical Information Services and indexed by bibliographic services (incl. PubMed).

More: [Investigators' Guide: Preparing the Final Report](#)

**We will hold a separate meeting to go over the report and review process when your study is close to completion.*

Policy on Data Access

HEI maintains a strong policy on facilitating access to underlying data and methods for the studies it funds that assists with review and validation of the work. HEI supports data access and transparency through:

- Creation of databases
- Reanalysis of studies
- Extended analyses

All studies should include a plan for making data available at the end of the study.

The policy protects the confidentiality of any volunteers who may have participated in the study and respects intellectual interests of the investigators who conducted the study.

Thank You!

Science Administrative Assistant

Lissa McBurney

Director of Finance & Administration

Jacqueline Rutledge

Science Liaisons

Allison Patton, Dan Crouse, Eleanne van Vliet, Hanna Boogaard, Pallavi Pant

(Acting) Director of Science

Annemoon van Erp



HEI Progress Report Form

I. Brief Description of Study Aims and Design

II. Brief Statement of Work (SOW) for Current Performance Period

III. Response to Comments or Suggestions from Research Committee (If any)

IV. Progress Made in Current Performance Period and Preliminary Results

V. Difficulties Encountered

VI. SOW for Next Performance Period (Include a timeline)

VII. Budget (for 10-month Progress Reports) (Attach your proposed budget and justification)

VIII. Other Attachments (Please list and attach meeting abstracts and manuscripts that were submitted or published during the performance period)