**Where to submit documents from the Regions/other EPA sites**

We are working to enhance the capacity of each office and region within EPA to have someone in-house to be the point person for human subjects research. For the most part, that person is the representative to the Human Research Ethics Council (HREC). To identify your representative, please visit the HREC page on the Human Subjects Research intranet page.

Whenever possible, research projects should first go to the HREC member for initial review and consultation. But if that is not possible or practical, you will submit documents directly to the Human Subjects Research Review Official (HSRRO).

Protocols should come to the HSRRO prepared in accordance with the checklist and with the cover memo completed and attached.

In order to ensure you understand what should come to the HSRRO and what does not, we have attached two documents for your review. They are:

- Approval Process Table This table contains a comprehensive list of the steps in the human subjects review process and the individuals responsible for approving, depending on the nature of the submission.

- Approval Process Flow-Chart: This graphic display was developed as a visual representation of the steps in the Approval Process Table. The process begins with the Principal Investigator (PI) proposing a study, and ends with the HSRRO's approval of the study.

Any questions about this process, or about the research you are (thinking about) conducting should be directed to:

Toby Schonfeld, PhD
Human Subjects Research Review Official
schonfeld.toby@epa.gov
202-564-2550

| Who should review/approve human studies in each Region/other EPA location? | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Research Scenario | | | | | | |
| | Interventional Human Study | Observational Human Study | Database study with no interaction | Exempt HSR (a) | Not HSR | Changes to approved study | |
| | | | | | | Minor | Substantive (b)(c) |
| PI | X | X | X | X | X | X | X |
| IRB | X | X | X | X | | X | X |
| HSO or HREC member (d) | X | X | X | X | X | X | X |
| HSRRO | X | X | X | X | | | X |

Footnotes:

a. HSR = Human Subjects Research as defined in 40 CFR 26.101.
b. Substantive changes as defined in on EPA Human Subjects Research Intranet site
c. **Adverse Events** significant enough for a subject to be removed from study, or that results in an **Unanticipated Problem Involving Risks to Subjects or Others** (UPRISO) as defined by the IRB of record should also be submitted through the Substantive Study Change pathway. Otherwise, we expect investigators to follow the definitions and reporting timeframes for adverse events and unanticipated problems of the IRB of record for their project. See the intranet site for more information
d. If there is no Human Subjects Officer (HSO) in your Region and if the HREC member is unavailable, please forward materials to the HSRRO directly.

# Human Subjects Review for Regions/other EPA sites

Final approval for studies involving human subjects, database studies, and substantive changes in approved studies


Conditional Approval of studies involving human subjects


Minor changes to approved studies; studies that do not qualify as human subjects research