

US EPA ARCHIVE DOCUMENT

Approval Process

Step 1: HSR or No: The first step in the process is determining whether or not the project involves human subjects research.

To help determine if your project qualifies as human subjects research, please click here:

<http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1>.

In addition, there are resources to help you. If you work at **NHEERL** in RTP or in Chapel Hill, **NERL** or **NRML** in RPT, or in **Homeland Security** at RTP, you may contact the **Director of the Human Research Protocol Office (HRPO) in NHEERL**.

For all other projects at EPA, please contact the HSRRO for assistance with determining if the project involves human subjects research.

Step 2: When should my project be reviewed?

For interagency or cooperative agreements: Agreements must be reviewed by the HSRRO before the agreement is authorized

For projects conducted by EPA scientists: Approval must be obtained before any human subjects work can begin. Generally, this happens after the project has been approved by the **Institutional Review Board**. But earlier review and consultation by experts in human subjects research is always encouraged; please contact the HSRRO or the Human Subjects Officer (or member of the **Human Research Ethics Council**) in your office for this purpose.

For projects funded by EPA but conducted externally: Grant applications that involve human subjects research must be reviewed by the HSRRO prior to the funding decision. At that point, a conditional approval will be issued for the researchers to proceed with the development of a full proposal.

Once the study has been developed and approved by an appropriate Institutional Review Board, it should be resubmitted to the HSRRO for final approval. Final approval must be administered before any work with human subjects may begin.