Where to submit documents for NHEERL/NERL/NRML/HSC in RTP

The EPA is fortunate to have a Human Research Protocol Office in Chapel Hill, NC. The director of that office, Dan Nelson, has extensive experience in human research ethics and with the regulatory process. As a result, he is available for consultation at any stage of the research process for investigators who are based in RTP.

There are many different kinds of studies performed by investigators in RTP. To ensure that we have captured all of the ways human subjects research happens in RTP, we have developed a grid and a flow chart to demonstrate the approval process for studies. They are as follows:

- Approval Process Table This table contains a comprehensive list of the multiple steps in the review process and the individuals responsible for approving, depending on the nature of the submission. This form was developed to serve as an internal guide for developing operational support for this workflow (e.g., new WebForms and online submission routing), and to ensure that investigators would understand the approval requirements for their particular research scenarios.

- Approval Process Flow-Chart: This graphic display was developed as a visual representation of the steps in the Approval Process Table. Some reviews may happen simultaneously, while other reviews must occur in sequence. 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:

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Who should review/approve human studies in NHEERL/RTP?									
	Research Scenario								
	Controlled Human Exposure Study	Observational Human Study	Database study with no interaction	Exempt HSR (c)	Not HSR (c)	Changes to approved study		CEMALB Studies	
						Minor	Substantive (d)	With EPA Collaboration or Support (e)	No EPA Collaboration or Support (e)
PI	X	X	X	X	X	X	X	X	X
Physician	X	(a)							
Statistics	(a)	(a)							
Dosing	(a)								
Branch Chief	X	X	X	X	X		X	X	
External Peer Reviewers (b)	X	X					(a)	(a)	
HRPO (advisory)	X	X	X				X	X	
IRB	X	X	X			X	X	X	X
QA Review of IRP/QAAP	X	X	X	X	X			X	
HRPO (approval)	X	X	X	X	X	X	X	X	X
Division Director	X	X	X	X	X		X	X	X
ADH	X	X	X					X	
HSRRO	X	X	X	X			X	X	X

Footnotes:

(a) Branch Chief (PI's immediate supervisor) has the discretion to solicit additional reviews by physicians, dosing experts, statisticians or external peer reviewers, depending on nature of study

(b) Number, location and expertise of External Peer Reviewers is at the discretion of Branch Chief. This requirement may be satisfied by study section or similar mechanism for peer-reviewed grants.

(c) Human Subjects Research (HSR) is defined in EPA regulations under 40 CFR 26. Projects not meeting that definition may be classified as "Not HSR." Some HSR may still be exempt under 40 CFR 26.101(b).

(d) Substantive changes as defined in guidance on EPA Human Subjects Research Intranet site

(e) "EPA Support" includes EPA staff, specialized facilities, contractor assistance

Human Subjects Review for NHEERL/RTP Studies

Controlled Exposure Study, Observational study, Database only study*

Other research scenarios