University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #:	**TITLE: Federal Agency "Specific" Requirements IRB/ORI Coordination**		**Page 1 of 3**
Approved By: ORI Director	Signature	Date	Date First Effective: 12-14-12
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date:

OBJECTIVE

To describe policies and procedures at the University of Kentucky (UK) for institutional review and oversight of human subject research supported by the following agencies: Department of Justice (DOJ) [Bureau of Prisons and National Institute of Justice]; Department of Energy (DOE); Environmental Protection Agency (EPA); United States Department of Education (US DoED)

GENERAL DESCRIPTION

Several of the federal agencies that adopted the Common Rule (i.e. Federal Policy for the Protection of Human Subjects) have issued policy and regulation that differ from the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) Department of Health and Human Services (DHHS) requirements. IRB policy dictates that agency "specific" requirements must be met when reviewing and approving a study that is supported or funded by the federal agencies which have additional policy or regulation governing human research. The Principal Investigator (PI) is responsible for assisting the IRB in identifying applicable agency requirements, for implementing the research consistent with agency requirements, and for complying with the specific agency human subject protection regulations.

This SOP outlines general procedures for IRB review of human subject research supported or regulated by the following agencies: Department of Justice (DOJ) [Bureau of Prisons and National Institute of Justice]; Department of Energy (DOE); Environmental Protection Agency (EPA); United States Department of Education (US DoED).

Specific guidance on each of these agency's requirements serves to guide both Principal Investigators (PIs) and the IRB in ensuring compliance. ORI maintains the agency specific guidelines on the ORI website.

RESPONSIBILITY

Execution of SOP: PI/Study Personnel, IRB, IRB Chair, Office of Research Integrity (ORI) Director, ORI Staff

PROCEDURES

Submission and Screening

1. The PI is responsible for reviewing the ORI agency specific guidance and for communicating with the regulatory/funding agency to identify its specific human research protection requirements.

2. The PI identifies the applicable agency in the IRB application and addresses in an attachment to the application any agency specific requirements.

3. ORI staff screen the submission consistent with procedures in the IRB Review SOPs and Protection of Vulnerable Subjects SOP, taking into account any applicable agency specific requirements as outlined in guidance documents and checklists. ORI staff provides IRB reviewers with web links or copies of the applicable guidance or checklists.

IRB Review

1. When reviewing research regulated or supported by the following agencies, the IRB utilizes ORI agency specific guidance and IRB checklists:

    - Environmental Protection Agency (EPA) – (40 CFR 26, Subpart B, C and D);
    - US Department of Education (US DoED) - (34 CFR 97 Subpart A and D, 34 CFR 98, 99, and 34 CFR 350, 356);
    - Department of Justice (DOJ) Bureau of Prisons – (28 CFR 46, 28 CFR 512), National Institute of Justice (28 CFR 22);
    - Department of Energy (DOE) – (10 CFR 745.103 and Directive DOE O 443.1B).

2. The IRB considers specific findings as required by the applicable agency. Specific findings are documented following standard operating procedures outlined in the applicable IRB Review SOP.

3. The PI is responsible for submitting to the applicable agency all reports and documentation required by the agency. Prior to initiation of the research, the PI is responsible for obtaining final agency approval if required by the agency.

Reporting and Recordkeeping

1. The PI is responsible for complying with both the IRB and agency specific recordkeeping and reporting requirements.

2. ORI staff maintain IRB records in accord with provisions of the applicable federal agency.

3. ORI staff make records accessible for inspection by authorized representatives of applicable federal agency.

REFERENCES

40 CFR 26, Subpart B, C, and D
34 CFR 97 Subpart A and D
34 CFR 98, 99
34 CFR 350, 356
10 CFR 745.103
DOE O 443.1B
28 CFR 46
28 CFR 22
28 CFR 512