

Review Process

Research Involving Prisoners as the Subject Population:

If prisoners are proposed as part of the inclusion criteria in a new project application, at the time of initial review, the project will be reviewed with special consideration given to the 7 additional findings outlined under 45 CFR 46305(a). The investigator must complete the 'Checklist for Studies Involving Prisoners' and attach it with the new project application.

Research Involving Subjects Who Become Prisoners After Enrollment:

If the investigator becomes aware of a subject who becomes a prisoner after enrollment, the investigator should notify the IRB immediately by submitting a memorandum requesting an amendment to the project for inclusion of prisoners, along with a completed 'Checklist for Studies Involving Prisoners'. The IRB will re-review the protocol based on the 7 additional findings as outlined in the checklist.

Upon IRB approval of the research, the Research Compliance Office will send a certified letter to the OHRP, **if applicable**, for final approval. NOTE: The OHRP must approve all DHHS research involving prisoners.