Research Involving Prisoners

Is the research funded by DHHS or subject to a DHHS – approved assurance?

Does the research target prisoners or will the research use prisoners?

Has a previously enrolled subject become a prisoner?

Additional determinations are discretionary.

Is the research funded by DHHS?

The IRB must make the additional determinations set forth in 45 CFR 46.305.

The IRB must find that one of four categories in 45 CFR 46.306 permits the research to go forward.

The IRB must send a letter to OHRP certifying that it has taken all actions required in Subpart C.

The IRB must receive a notice from OHRP permitting the research to go forward.

Is the research not funded by DHHS, but covered by a DHHS-approved assurance?

No certification from DHHS is required.

Yes

No

Yes

No