Research Involving Prisoners

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

- Yes
  - Has a previously enrolled subject become a prisoner?
    - Yes
      - Additional determinations are discretionary.
    - No
      - Does the research target prisoners or will the research use prisoners?
        - Yes
          - Additional determinations are discretionary.
        - No
          - The IRB must make the additional determinations set forth in 45 CFR 46.305.

- No
  - The IRB must find that one of four categories in 45 CFR 46.306 permits the research to go forward.

  Is the research funded by DHHS?

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

- No
  - 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?

- Yes
  - No certification from DHHS is required.

- No