



1. * Regulatory oversight: (check all that apply)

- DOD (Department of Defense)
- DOE (Department of Energy)
- DOJ (Department of Justice)
- ED (Department of Education)
- EPA (Environmental Protection Agency)
- FDA (Food and Drug Administration)
- HHS (Department of Health and Human Services)
- ICH GCP (International Center for Harmonization of Good Clinical Practice)
- OCR (Office of Civil Rights)
- VA (Department of Veterans Affairs)
- NSF (National Science Foundation)
- Other federal agency
- Tribal law
- None of the above

2. Special determinations and waivers: (check all that apply)

Determination

- Children
- Children who are wards of the state
- Cognitively impaired adults

Neonates of uncertain viability

Nonsignificant risk device

Non-viable neonates

Pregnant women

Prisoners

Students / Employees

Waiver of consent documentation

Waiver of consent for emergency research

Waiver of HIPAA authorization

Waiver/alteration of the consent process

3. * Type of research: (check all that apply)

Biomedical / clinical

Social / behavioral / educational

Other

4. Additional study features: (check all that apply)

Clinical Trial

Certificate of Confidentiality

Deception

5. Missing materials:

6. Notes:

7. Add supporting documents:

Name

There are no items to display

8. Do the General Data Protection Regulations (GDPR) apply?

Yes No [Clear](#)

OK

Cancel