OMB No. ####-####
Approved for use through ######, ####

Office for Human Research Protections (OHRP)
Research Complaint Form

OHRP reviews and investigates hundreds of complaints each year. Before you begin, it may be helpful for you to know the following about the types of complaints we do and do not address:

1. OHRP evaluates complaints about research that is conducted or supported by the U.S. Department of Health and Human Services (HHS).
2. OHRP evaluates complaints about research to which OHRP's jurisdiction applies through a Federalwide Assurance (FWA).
3. OHRP evaluates complaints about institutions or Institutional Review Boards (IRBs) that review research conducted or supported by HHS.
4. OHRP evaluates complaints that, if proven, would be a violation of the regulations at 45 CFR part 46.
5. OHRP may refer you or your complaint to another government department, agency, or office for assessment.

Please provide as much of the following information as possible. An asterisk (*) indicates fields that are required. Submission of an incomplete complaint or failure to submit requested information may mean that OHRP is unable to address the complaint and may lead to closure of a complaint.

1. *Alleged Complaint Type (please check all that apply):

- ☐ Issues related to an Institution (not related to the IRB)
- ☐ Issues related to an IRB
- ☐ Issues or problems with informed consent (including undue influence or coercion)
- ☐ Issues or problems with a study
- ☐ Risks to subjects
- ☐ Failure to report an issue (e.g., to an IRB, institutional officials, or OHRP)
- ☐ Issues related to a researcher or research team
- ☐ Other

2. Name of institution(s) conducting the research or reviewing IRB (if applicable):

3. Research/Study title (if applicable):

3(a). Brief description of the study (if applicable):

3(b). IRB study number (if applicable):	3(c). Researcher's Name (if applicable):	3(d). Name of HHS Funder (if applicable):

4. *Detailed description of the complaint:

OHRP accepts complaints submitted anonymously. OHRP asks complainants who identify themselves whether OHRP may disclose their identity to the institution where the alleged noncompliance may have occurred.

5. First Name of person submitting this form:	6. Last Name of person submitting this form:
7. Submitter's email:	8. Submitter's phone number *(with area code)*:

9. Please keep my name and contact information confidential: ☐ Yes ☐ No

If applicable, you may upload supporting documentation. Please do not upload any documents with personally identifiable information or private health information.