

Opportunity Title: HHS Compliance Oversight Fellowship Opportunity Reference Code: HHS-OASH-2023-0204

Organization U.S. Department of Health and Human Services (HHS)

Reference Code HHS-OASH-2023-0204

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<u>Store</u> or <u>Google Play Store</u> to help you stay engaged, connected, and informed during your ORISE experience and beyond!

A complete application consists of:

- An application
- Transcripts Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- One educational or professional recommendation. Your application will be considered incomplete, and will not be reviewed until one recommendation is submitted.

All documents must be in English or include an official English translation.

Application Deadline 10/25/2023 11:59:00 PM Eastern Time Zone

Description *Applications will be reviewed on a rolling-basis.

HHS Office and Location: A fellowship opportunity is available in the Division of Compliance Oversight (DCO) within the Office for Human Research Protections (OHRP) (https://www.hhs.gov/ohrp/index.html), Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services (HHS) located in Rockville, Maryland. Remote or hybrid flexibility will be considered.

OHRP provides leadership in the protection of the rights, welfare and wellbeing of subjects involved in research conducted or supported by HHS.

Research Project: OHRP's DCO has responsibility for oversight of compliance with the U.S. Department of Health and Human Services (HHS) regulations for the protection of human research subjects (see 45 CFR Part 46 at http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html). In carrying out this responsibility, OHRP reviews allegations of noncompliance involving human subject research conducted or supported by HHS or that are otherwise subject to the regulations and determines whether to conduct a for-cause compliance investigation. DCO also conducts a program of not-for-cause evaluations of institutions and reviews and responds to incident reports from assured institutions.

The research participant will assist DCO in carrying out its broad responsibility for oversight of compliance with HHS Protection of Human Subjects Regulations at 45 CFR Part 46. This includes reviewing incident reports and complaints regarding allegations of noncompliance as well as and conducting site assessments and conducting research regarding compliance polices and procedures.

Under the guidance of a mentor, research activities may include:

• Research and analyze HHS divisions approaches to compliance



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oversight procedures and prepare related reports for OHRP leadership.

- Research and assist OHRP's Division of Compliance Oversight in the
 development and implementation of recommendations made by the
 Government Accountability Offices report entitled *Institutional Review*Boards: Actions Needed to Improve Federal Oversight and Examine
 Effectiveness, GAO-23-104721, Published: Jan 17, 2023. Publicly
 Released: Feb 16, 2023.
- Research and collect data about research institutions that conduct HHS-supported human subject research and the IRBs that oversee that research.
- Research and assist in the development of OHRP compliance policies.
- Participate in internal and public presentations related to 2018 regulations (45 CFR 46) for the protection of human research subjects.
- Participate in Departmental or Agency committees and working groups on issues related to human subject protections.
- Collect, analyze, and evaluate information to develop and revise documents related to OHRP's compliance policies.
- Coordinate responses to requests for information, technical assistance and guidance related to human subject research policy.

Learning Objectives: The research participant will learn about procedures DCO implements to carry out its mission to conduct oversight of compliance with HHS Protection of Human Subjects Regulations at 45 CFR Part 46. They will learn how to facilitate and engage cross-division collaboration regarding human subjects research protections within HHS. In addition, the research participant will learn processes and procedures for interacting with the Governmental Accountability Office (GAO). The research participant will learn how to evaluate incident reports and complaints regarding allegations of noncompliance as well as gain experience researching compliance polices and procedures.

<u>Mentor(s)</u>: The mentor(s) for this opportunity are Lisa Buchanan (<u>lisa.buchanan@hhs.gov</u>) and Amanda Sly (<u>Amanda.Sly.@hhs.gov</u>). If you have questions about the nature of the research please contact the mentor.

<u>Anticipated Appointment Start Date:</u> 2023. Start date is flexible and will depend on a variety of factors.

<u>Appointment Length</u>: The appointment will initially be for one year, but may be renewed upon recommendation of HHS and is contingent on the availability of funds.

Level of Participation: The appointment is full-time.

<u>Participant Stipend</u>: The participant will receive a monthly stipend commensurate with educational level and experience.

<u>Citizenship Requirements</u>: This opportunity is available to U.S. citizens only.

ORISE Information: This program, administered by ORAU through its contract with the U.S. Department of Energy (DOE) to manage the Oak Ridge Institute for Science and Education

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> (ORISE), was established through an interagency agreement between DOE and HHS. Participants do not become employees of HHS, DOE or the program administrator, and there are no employment-related benefits. Proof of health insurance is required for participation in this program. Health insurance can be obtained through ORISE.

> The successful applicant(s) will be required to comply with Environmental, Safety and Health (ES&H) requirements of the hosting facility, including but not limited to, COVID-19 requirements (e.g. facial covering, physical distancing, testing, vaccination).

> Questions: Please visit our Program Website. After reading, if you have additional questions about the application process please email HHSrpp@orau.org and include the reference code for this opportunity.

Qualifications The qualified candidate should have received a master's or doctoral degree in one of the relevant fields. Degree must have been received within the past five years.

> Candidates with experience in Human Subject Research are encouraged to apply.

Preferred Experience:

- Experience working with public health programs, health research, and/or program evaluation
- · Experience in writing technical papers that address specific aspects of the protection of human subjects in biomedical and behavioral research

Eligibility Requirements

- Citizenship: U.S. Citizen Only
- Degree: Master's Degree or Doctoral Degree received within the last 60 month(s).
- Discipline(s):
 - Life Health and Medical Sciences (1●)
 - Social and Behavioral Sciences (1●)

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