

# **Project Review by the Human Subjects Research Review Official (HSRRO)**

## **Primary Tasks**

### **What Projects and Other Activities Require Review by the HSRRO?**

- All support agreements in which support for projects meeting the regulatory definition of research with human subjects is anticipated at any time during the period of support
- All projects conducted or supported by EPA that meet the regulatory definition of research with human subjects
- If requested, the HSRRO may also review any project that plans to collect data from or about humans in order to assist with the determination of whether or not the project meets the regulatory definition of research with human subjects

### **When is HSRRO Review Required?**

- For Support Agreements: Before the agreement is entered into
- For Projects: After the institutional review board (IRB) with jurisdiction over the research has approved the project but before the project begins

### **Documents Required for HSRRO Review of Funding Awards and Other Support Agreements:**

- Copy of the application, work plan, or other pre-award document
- The primary awardee's Federalwide Assurance (FWA) number

### **Documents Required for HSRRO Review of a Project (i.e., HSRRO Confirmation of an Approval or Exemption Determination by an IRB with Jurisdiction over the Research):**

- Copy of the study protocol(s) as actually submitted to the IRB(s) (the pre-award document is not sufficient)
- Copy of the IRB approval (or exemption) letters
- Copy of the IRB-approved consent forms and subject recruitment materials, if applicable
- Copy of all supplementary IRB correspondence

## **Office of the Science Advisor (OSA)**

### **Contact Information for the HSRRO:**

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