

## Human Subjects Research Studies Regulatory Basics for REDCap Success!



### **Tip 1: Is your project considered human subjects research?**

A research project is considered “human subjects research” if the investigator conducting the research will be gathering identifiable information (including coded data) about individuals. If you have questions about whether an activity is human research, request a determination from the IRB Office via the eIRB.



### **Tip 2: Familiarize yourself with the regulatory requirements needed in order to utilize REDCap for your research study**

OCTRI staff will review your project information provided to us when you submit the OCTRI Resource Request Form. IRB approval is not required at this step, however, it is required before you launch your project into “final production”.

Here are the things that OCTRI staff will look for when we review your project:

- *Please note that REDCap, specifically, needs to be mentioned in your study documents (ex. protocol, DSMP, local context summary) as the location where you will be storing data. **OCTRI WILL LOOK FOR THIS.** If we do not see REDCap included in your protocol (or other study documents), we will ask you to submit a modification in the IRB. See example boilerplate REDCap language below. For more boilerplate language or help, please email the OCTRI navigator ([octri@ohsu.edu](mailto:octri@ohsu.edu)).*
  - Example 1: “Data for this project will be stored in OCTRI's installation of REDCap, a highly secure and robust web-based research data collection and management system.”
- *Are you using REDCap to conduct an online survey? – **All messages** that go out to study participants via REDCap need to have IRB approval. It is the investigator’s responsibility to ensure that survey language has IRB approval.*
- *Is your project an investigator-initiated (non-industry funded) project with an IND/IDE? Please keep in mind that REDCap is **not** CFR Part 11 compliant.*



### **Tip 3: Add your investigator to your REDCap project**

Study staff often changes throughout a project’s lifespan. Do yourself a favor and **add your investigator** to your REDCap project. That way they will be able to add new study staff if there are any changes.



### **Tip 4: When in doubt, know who to ask!**

*The OCTRI Navigator can help guide you through the IRB process, regulatory requirements, and other questions about best practices for conducting your research study. They can be reached by email or by phone at: [octri@ohsu.edu](mailto:octri@ohsu.edu) / (503) 418-9790*

*For all REDCap specific questions including technical questions, data management consultations, and information about REDCap training requirements, contact OCTRI Informatics Research Support at [octrihelp@ohsu.edu](mailto:octrihelp@ohsu.edu)*