## Assuring Your Team Remains in Compliance after Your Project Has Been Determined Not Human Subjects Research

This informational page is to assist people whose projects are reported to not meet the definition of research involving human subjects.

Although your project does not need further oversight in its current form, any changes made to your project may need to be submitted to the IRB in order to make sure all participants involved in your project are legally and ethically protected. Changes should be submitted through a Request for Determination (RFD).

It is normal for the scope and/or direction of a grant funded project to change.We encourage all grantees to adapt project activities as needed and to collect the data necessary to successfully meet their objectives. Our intent is to support organizations by ensuring the appropriate level of protection and oversight from OHSU’s IRB throughout the duration of the project.

**Examples that may require a new RFD include but are not limited to:**

* Changes to the design of your project
* Collecting information from project participants using new and/or additional data collection methods (survey, focus group, etc.)
* Asking participants questions that are different than those discussed in the original RFD
* Collecting and retaining participants’ names, addresses, or other identifying information
* Connecting personal identifiers to collected data
* Changing the overall intent of the project (e.g. from quality improvement to research)
* Changing plans around how results will be used and/or shared (e.g. publication in an academic journal, as a model for other organizations to implement, etc.)

**If you’re proposing a change to your project’s design, scope, and/or data collection methods, follow the steps below:**

1. Contact the CPP team at [KnightCancerCRO@OHSU.edu](mailto:KnightCancerCRO@OHSU.edu) to discuss the change. They can help determine whether you’ll need to submit a new RFD.
2. If a RFD is required, the CPP team will support you in updating and submitting the RFD form for a new determination.
3. **Project activities involving human subjects (including participant recruitment, data collection, etc.) must wait until the new determination is received.**