**OTRS Workflow of Regulatory Support for “Not Research” or “Not Human Subjects” Projects**

**Researcher contacts OTRS requesting regulatory support for the submission of a basic science/translational project that falls under the IRB-exempt category of “Not Research” or “Not Human Subjects.”**

OTRS requests additional information about the project from the researcher.

**OTRS submits a Protocol Number Request Form to PRMC to generate a record in OnCore on behalf of researcher.**

OTRS assists researcher with development of protocol document, if necessary, and IRB application.

**OTRS populates the OnCore record, completes the ePRMS Initial Submission Short Form and the Clinical Trial Billing Checklist, obtains the researcher’s signature, drafts the IRB application in ARROW, and submits the project to PRMC on behalf of researcher.**

OTRS corresponds with PRMC regarding revisions, if necessary.

PRMC approval is received via email.

**OTRS finalizes the IRB application in ARROW and submits project to IRB on behalf of researcher.**

OTRS corresponds with IRB regarding revisions, if necessary.

IRB Determination is received directly from ARROW system via email.

For projects that the IRB determines to be “Not Research” or “Not Human Subjects,” no IRB follow-up is required throughout the project.

*Note – substantial changes to the project may require a new IRB application.*

**OTRS completes the necessary information in OnCore, the PRMC Coordinator updates the project’s status in OnCore to “open,” and the research project can begin.**

**OTRS requests project status updates from researcher every 6 months and makes relevant changes in OnCore. If there are any changes to the data analysis section, OTRS will submit a PRMC amendment on behalf of the researcher.**