

## **Industry Sponsored Clinical Drug/Device Investigation (“Clinical Trial”) Project Start and End Date Procedure**

The project duration (start and end date) to be set in Oracle Grants Accounting (OGA) will be:

### **START DATES:**

The latest of:

- The start date specified in the contract, or
- The date of the last signature on the contract.

Studies are not permitted to begin before IRB approval is obtained, or before the contract is fully executed, unless a Pre-award Request Form has been submitted and approved.

### **END DATES:**

- The end date, as defined in the agreement document (amendments, schedules or attachments); or
  - If there is not an end date discussed in the agreement (amendments, schedules or attachments), then the end date as defined in the protocol will be used. (Clinical Trials Contracts Coordinator to provide SPA a copy of the page of the protocol showing the duration of the protocol in the account setup packet); or
  - If neither of these exists, then the last day of the month three (3) years from the established start date of the agreement.
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### **END DATE EXTENSION PROCEDURE:**

Reports will be run on monthly basis by SPA to determine projects that will be ending within 60 days.

#### ***If project was reviewed by the OHSU IRB:***

- SPA Clinical Trial Analyst will access IRB database and review IRB approval status and dates for IRB study associated with OGA project.
- If IRB approval is effective for a period past the current end date, the OGA project end date will be extended to 90 days past the valid IRB approval period and will notify the Study team via email that the OGA project end date has been extended.
- If IRB approval is not effective past the current project end date, the Analyst will ask Study team if the project has ended. If the project has ended the Project Fiscal Manager submits a completed Project Status Form to SPA. If the study is not ended, the OGA project end date will not be extended and the Study team will be notified that they will need to provide a completed and approved Project Status Form as well as obtain continued IRB approval before the project end date will be extended.

#### ***If OHSU IRB has waived oversight to the Portland Veteran’s Affairs Medical Center (PVAMC) IRB:***

- The Analyst will ask Study team if the project has ended. If the project has ended the Project Fiscal Manager submits a completed Project Status Form to SPA. If the study is not ended, the OGA project end date will not be extended and the Study team will be notified that they will need to provide a completed and approved Project Status Form and evidence of IRB approval.

#### ***Notes:***

1. If Study team knows the study end date will need to be extended, a Project Status Form can be submitted at any time along with supporting documentation and/or explanation justifying the extension request.
2. IRB terminations will be provided monthly to SPA to review against the OGA project status.

**Study Team** = PI, Clinical Research Coordinator and Project Fiscal Manager