Policy/Procedure/Guideline No:	::Based on the most applicable policy manual policy:: E.g. 04-40-001.100
Policy/Procedure/Guideline Name:	ClinicalTrials.gov Registration, Maintenance, and Results Reporting of Investigator-Initiated Trials
Effective Date:	01-Dec-2018
Last Review Date:	14-Nov-2018

PURPOSE:

This policy establishes Oregon Health and Science University (OHSU) standards for registration, record upkeep, and reporting of studies where the OHSU investigator is the "responsible party" via ClinicalTrials.gov in effort to:

- Adhere to the Food and Drug Administration (FDA) requirements for clinical trial registration, maintenance, and results reporting (See References)
- Adhere to the National Institutes of Health (NIH) requirements for clinical trial registration and results reporting (See References)
- Preserve the University's ability to publish results of clinical trials in juxtaposition with the International Committee of Medical Journal Editors (ICMJE) standards (See References)
- Outline Principal Investigator and departmental responsibilities

DEFINITIONS:

Clinical Trial – OHSU recognizes the definition of a clinical trial as established by the ICMJE. Specifically, a clinical trial is any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention and a health outcome.

Health-Related Interventions - Those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes.

Health Outcomes - any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Applicable Clinical Trial (ACT) – Introduced by the Food and Drug Administration Amendments Act (FDAAA), this term characterizes interventional studies that primarily investigate drugs, biologics, or devices which require registration via the Clinical Trial Registry Data Bank. To determine if a study is an ACT, utilize the Checklist and Elaboration for Evaluating *Whether a Clinical Trial or Study is an Applicable Clinical Trial*, located at https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf. (also add this to References section)

Primary Completion Date – Referenced on ClinicalTrials.gov via the Food and Drug Administration Amendments Act (FDAAA), primary completion date is the date at which the final enrolled subject was examined or received an intervention for the purposes of collection of data for the primary outcome measure, whether the clinical trial concluded according per protocol or was terminated, withdrawn, or suspended. Think of this as the "Primary Outcome Measure Completion Date"

Study Completion Date – Referenced on ClinicalTrials.gov via the Food and Drug Administration Amendments Act (FDAAA), study completion date is the date at which data collection ceased for the purpose of the secondary outcome measure(s) and adverse event(s), whether the clinical trial concluded according per protocol or was terminated, withdrawn, or suspended. Think of this as the "Full Completion Date"

Responsible Party – The individual who is responsible for registering a clinical study and submitting the clinical trial information to ClinicalTrials.gov. OHSU recognizes the Principal Investigator as the responsible party of a clinical trial if they:

1. Are responsible for conducting the trial
2. Have access to and control over the data from the trial
3. Have the right to publish the results of the trial

   AND

4. Have the ability to meet all of the FDAAA and NIH (if applicable) requirements for the submission of clinical trial information (See References)

Studies conducted within Knight Cancer Institute (KCI) may not be applicable to this policy. Study teams and Principal Investigators conducting investigator-initiated trials within KCI should contact their regulatory specialist for more information.

RESPONSIBILITIES:

Principal Investigator

The Principal Investigator of an OHSU investigator-initiated trial is required to:

1. Register the trial via ClinicalTrials.gov prior to the enrollment of the first subject (First Subject First Visit (FSFV).

2. Designate him/herself as the Responsible Party of the trial in the Protocol Registration and Results System (PRS).

3. Update the trial record via ClinicalTrials.gov at least once every 6 months or when there are substantial changes.

4. **Human subject research studies:** Submit the most recent IRB-approved informed consent form (ICF) to ClinicalTrials.gov within 60 days of the last subject visit.

5. **ACTs only:** Submit primary outcome measure results to ClinicalTrials.gov within 365 days after reaching the primary completion date. Submit secondary outcome measure results and adverse events to ClinicalTrials.gov within 365 days after reaching the study completion date.

6. **NIH-funded interventional human subject trials:** Submit primary outcome measure results to ClinicalTrials.gov within 365 days after reaching the primary completion date. Submit secondary outcome measure results and adverse events to ClinicalTrials.gov within 365 days after reaching the study completion date.

Before departing OHSU, close out completed trial records, transfer the Responsible Party of ongoing trial records to another Principal Investigator, OR designate him/herself as the Responsible Party at the new organization.

Trial registration, record updating, and results reporting can be performed by visiting https://register.clinicaltrials.gov

Per OHSU Policy No. 04-00-005, current and/or future study funding may be withheld if a Principle Investigator has not registered, has noncompliant record(s), has not made progress in achieving resolution, and/or is nonresponsive in communicating and demonstrating intent to achieve resolution.

COMPLIANCE ASSURANCE PROCESS:

OHSU research central services will conduct ongoing audits of OHSU Investigator-Initiated Clinical Trials to ensure compliance with applicable regulations, as described above.

If noncompliant records are identified, the University will provide notification to seek resolution through this sequence:

- The study team and Principal Investigator will be contacted with initial notification of current noncompliance upon identification of non-compliant record

- If neither Principal Investigator nor study team members provide response and the noncompliant record(s) is/are not updated within a reasonable timeframe, a progressive escalation process may be pursued, as follows:

    1. Notification to Department Chair and Office of Proposal and Award Management (OPAM)

2. Funding subject to suspension AND Notification to associated Dean AND Senior Vice President for Research

RELATED DOCUMENTS/REFERENCES:

FDA requirements for clinical trial registration:
https://clinicaltrials.gov/ct2/manage-recs/faq#42CFRPart11

FDA requirements for Applicable Clinical Trial results reporting:
https://clinicaltrials.gov/ct2/manage-recs/faq#fr_6

NIH requirements for clinical trial registration and results reporting:
https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm

ICMJE standards:
http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

OHSU Policy No. 04-00-005
https://o2.ohsu.edu/policies-and-compliance/ohsu-policy-manual/chapter-4-research-services-intellectual-property/ohsu-policy-04-00-005.cfm