1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Posting to ClinicalTrials.gov Policy.

2. Scope

2.1. OSRO in the Center for Cancer Research (CCR), National Cancer Institute (NCI) shall establish and control the policy.

2.2. Limitations

2.2.1. Nothing in this policy will supersede NCI, National Institutes of Health (NIH) or Health and Human Services (HHS) requirements.

3. Responsibilities

3.1. CCR Management is committed to providing resources to meet the requirements for implementing the Posting to ClinicalTrials.gov Policy within OSRO and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding and using the ClinicalTrials.gov Policy.

3.3. The OSRO Director is responsible for establishing and maintaining the ClinicalTrials.gov Policy.

4. References

4.1. FDAAA 801: Section 801, "Expanded Clinical Trial Registry Data Bank," of the Food and Drug Administration Amendments Act of 2007

4.2. 42 CFR Part 11: Clinical Trials Registration and Results Information Submission

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. All clinical trials supported by the NIH will be registered and trial results will be posted in the ClinicalTrials.gov database regardless of the "applicable clinical trial" status in accordance with 42 CFR 11.

6.2. Registration must occur no later than 21 days after enrollment of the first subject.

6.3. For studies which are subject to the results information submission requirements, results information must be submitted no later than 12 months after the primary completion date.

6.4. OSRO delegates the registration and the posting of results of clinical trials sponsored under CCR, NCI held Investigational New Drug applications (INDs) or Investigational Device Exemptions (IDEs), to the Principal Investigator. The NIH Clinical Center Office of Protocol Services (OPS) is the body who registers all applicable clinical trials.

6.5. OPS will provide bi-monthly reports to OSRO with a listing of protocols registered, results posted and out of compliance protocols.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	17SEP2019	New Document
2	22JUL2021	Updated document template. Step 4.2. Added hyperlink. Step 6.4. Responsibility for posting results changed from OPS to PI.
3	01AUG2023	Biennial review Step 6.6 - removed