1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Interim Analysis Reporting 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. Investigators, research team members, other departmental personnel, and external NIH collaborators and contractors when they are working on studies conducted under a CCR-held Investigational New Drug (IND) application, Investigational Device Exemption (IDE), or supported by a CCR-held Master File under OSRO oversight shall comply with the policy.

2.3. Limitations

2.3.1. Personnel are not bound to this policy when working on non-IND or IDE studies and/or no interdepartmental collaboration with OSRO as Sponsor is required.

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

3. Responsibilities

3.1. The Center for Cancer Research Management is committed to providing resources to meet the requirements for implementing an Interim Analysis Reporting Policy within OSRO and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding and using the Interim Analysis Reporting Policy.

3.3. The OSRO Director is responsible for establishing and maintaining the Interim Analysis Reporting Policy.

4. References

4.1. ICH E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry (FDA), March 2018

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. All interim analysis, both formal planned analysis and any instance when an informal analysis is called for, along with the operational aspects surrounding the enrollment halt and decision making in relationship to the interim analysis must be described in the protocol.

6.2. The Principal Investigator (PI) and/or the study Statistician as appropriate will prepare the interim analysis report summarizing the data supporting the interim analysis.

6.3. The report shall contain the appropriate data elements to support the conclusion of the interim analysis.

6.4. The report shall be approved by the trial Sponsor (OSRO) prior to enrolling the next group of participants and provided to the Safety Oversight Committee.

6.5. Approved reports will be filed in the site study file.

6.6. For the purpose of this policy an interim analysis includes:

6.6.1. Formal interim analysis for futility;

6.6.2. Dose escalation/de-escalation decision;

6.6.3. Dose Limiting Toxicity (DLT) determination; and

6.6.4. Any informal interim analysis that includes analysis of grouped participant data to determine action on the study.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	26AUG2021	New Document
2	18SEP2023	Biennial review Step 4.1 – added hyperlink Step 6.7 – removed