1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Regulatory Compliance and File Management 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 and other departmental personnel when they are working on studies conducted under a CCR-held Investigational New Drug application (IND), Investigational Device Exemption (IDE), or Non-Significant Risk Device (NSR) or supported by a CCR-held Master File, shall follow the policy.

2.3. Limitations

2.3.1. This policy does not apply to personnel working on studies that are not under a CCR-held IND, IDE, or is an NSR device study and/or when no OSRO oversight or interdepartmental collaboration 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. CCR Management is committed to providing resources to meet the requirements for implementing the Regulatory Compliance and File Management policy and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding the Regulatory Compliance and File Management policy.

3.3. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO Functional Groups are responsible for understanding the Regulatory Compliance and File Management policy.

3.4. The OSRO Director is responsible for establishing and maintaining Regulatory Compliance and File Management policy.

4. References

Not Applicable.

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. The Office designation of OSRO shall refer both to the Office of Sponsor and Regulatory Oversight staff and the OSRO Sponsor and Regulatory Oversight Support contractor staff.

6.2. Compliance

6.2.1. OSRO Regulatory will ensure that clinical trials under a CCR-held IND, IDE or NSR are conducted in compliance with governing regulatory authority regulations.

6.2.2. OSRO Director will be the regulatory sponsor on clinical trials for which CCR holds the IND, IDE or NSR.

6.2.3. OSRO Regulatory oversight will be provided regardless of study phase, type of intervention, or whether the investigational study agent is manufactured by NIH or an external manufacturer or supplier.

6.2.4. OSRO Regulatory will be responsible for:

6.2.4.1. IND and IDE preparation and submission to the FDA ,

6.2.4.2. Master File preparation and submission to the FDA when agreed by OSRO management,

6.2.4.3. Annual Report submission,

6.2.4.4. Updating IND, IDE and Master File submissions as necessary,

6.2.4.5. Final Clinical Study Report submission,

6.2.4.6. Providing regulatory guidance to study sites, as necessary.

6.2.5. These responsibilities will continue throughout the duration of the trial.

6.3. Regulatory File Management

6.3.1. OSRO Regulatory will maintain paper copies in a secured, restricted access location.

6.3.2. OSRO Regulatory will maintain electronic copies on a secured, restricted access, validated electronic environment.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	27AUG2019	New Document
2	14JAN2022	Biennial review Step 2.2 – added Non-Significant Risk Device Step 3.3 – added SROS contractor Step 6.1 – added Updated document language as required
3	30JAN2024	Biennial review Step 2.3.1 – replaced sentence to clarify language Step 3.3 – removed “and using” Step 6.2.4.1 – removed “when this service is requested by the Investigator