

	Office of Sponsor and Regulatory Oversight	Document #: 402
	Regulatory Compliance and File Management Policy	Revision #: 1
		Effective Date: 27AUG2019

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 (IND) or Investigational Device Exemption (IDE), or supported by a CCR-held Master File, shall follow the policy.
- 2.3. Limitation
 - 2.3.1. Personnel are not bound to this policy when working on non-IND/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. 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 and using the Regulatory Compliance and File Management policy.
- 3.3. 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. Compliance
 - 6.1.1. OSRO Regulatory will ensure that clinical trials under a CCR-held IND/IDE are conducted in compliance with governing regulatory authority regulations.

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6.1.2. OSRO Regulatory will be the regulatory sponsor on clinical trials for which CCR holds the IND or IDE.

6.1.3. 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.

6.1.4. OSRO Regulatory will be responsible for:

6.1.4.1. IND and IDE preparation and submission to the FDA when this service is requested by the Investigator,

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

6.1.4.3. Electronic Trial Master File system (eTMF) management,

6.1.4.4. Annual Report preparation and submission,

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

6.1.4.6. Final Clinical Study Report preparation and submission,

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

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

6.2. Regulatory File Management

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

6.2.2. OSRO Regulatory will maintain electronic copies on a secured, restricted access, validated server.

6.3. This Policy shall be reviewed periodically and updated as necessary.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	27AUG2019	New Document