

	Office of Sponsor and Regulatory Oversight	Document #: <b>201</b>
	<b>Qualified Medical Expertise Policy</b>	Revision #: <b>1</b>
		Effective Date: <b>05AUG2019</b>

## 1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Qualified Medical Expertise 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. Medical personnel or consultants working on studies conducted under a CCR-held Investigational New Drug (IND) application, Investigational Device Exemption (IDE), or Master Files (MF) under OSRO oversight shall follow the policy.
- 2.3. Limitation
  - 2.3.1. Medical personnel working on non-IND or IDE studies.
  - 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 Qualified Medical Expertise Policy.
- 3.2. OSRO personnel are responsible for understanding and using the Qualified Medical Expertise policy.
- 3.3. The OSRO Director is responsible for establishing and maintaining the Qualified Medical Expertise Policy.

## 4. References

- 4.1. U.S. Department of Health and Human Services' Guidance for Industry: E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1), dated March 2018

## 5. Definitions

Refer to the OSRO Lexicon.

## 6. Policy

- 6.1. Medical personnel will be qualified by education, training and experience before accepting responsibility for assigned clinical trial functions.
  - 6.1.1. Evidence of qualifications will be by current curriculum vitae and/or other relevant documentation.

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- 6.2. The Principal Investigator is responsible for ensuring the care and safety of study participants. The Principal Investigator may delegate this responsibility to other qualified, experienced and trained medical personnel.
- 6.3. The Sponsor will appoint a study medical monitor to advise on trial-related medical questions or problems, serve as the Sponsor’s assessor of safety signal, and reviewer and approver of relevant study related documents.
- 6.4. This Policy shall be reviewed periodically and updated as necessary.

**7. Change Summary**

Revision Number	Effective Date	Description of Change
1	05AUG2019	New Document