1. Purpose

To provide guidelines for the content of protocols which are potentially exempt from requiring an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE).

2. Scope

2.1. This SOP covers studies for which an IND/IDE exemption will be requested from the Food and Drug Administration (FDA).

2.2. Limitations

2.2.1. Clinical study personnel are not bound to this procedure when working on non-IND or non-IDE studies and/or no interdepartmental collaboration with OSRO as Sponsor is required.

3. Responsibilities

3.1. OSRO reviews and approves initial protocols.

3.2. OSRO Regulatory determines if an IND/IDE exemption is appropriate for a study.

4. References

4.1. 202 Protocol Development Policy

4.2. 202-S01 Protocol Development and Review

4.3. 406 Selection of IND or IDE Regulatory Filing Policy

4.4. 21 CFR Part 312.2(b)(1) Investigational New Drug Application – Applicability – Exemptions

4.5. 21 CFR Part 50 Protection of Human Subjects

4.6. 21 CFR Part 56 Institutional Review Boards

4.7. 21 CFR Part 812 Investigational Device Exemptions

4.8. 21 CFR Part 809 In Vitro Diagnostic Products for Human Use

4.9. IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer, Guidance for Industry (FDA), January 2004

4.10. 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. Procedure

6.1. Certain cancer treatment studies of drugs, biological products, or devices are exempt from requiring an IND/IDE if specific criteria are met. Refer to Reference 4.3.

6.1.1. The OSRO Director may determine that a study requires a formal FDA determination for an IND/IDE exemption.

6.2. Protocol requirements

6.2.1. The initial protocol should include all information required for an IND/IDE study.

6.2.2. If the FDA determines that the study is IND/IDE exempt, the following sections will need to be updated as described below, prior to IRB submission:

6.2.2.1. The title page identifies the study as IND/IDE exempt.

6.2.2.2. No FDA reporting requirements are included.

6.2.2.3. No references to an IND/IDE sponsor or OSRO as the sponsor are present.

6.2.2.4. Pharmaceutical Section should include the following language or equivalent:

This study meets the criteria for exemption for an IND as this investigation is not intended to support a new indication for use or any other significant change to the labeling; the drug(s) are already approved and marketed in the United States and the investigation is not intended to support a significant change in advertising or promote or commercialize the drug product(s); and the investigation does not involve a route of administration or dosage level or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product(s).

and/or,

This study meets the criteria for exemption from IDE requirements as this investigation uses a legally marketed device in accordance with its labeling.

and/or,

This study meets the criteria for exemption from IDE requirements as this investigation uses a diagnostic device and: complies with the labeling requirements in 21 CFR Part 809.10(c); the testing is noninvasive; does not require an invasive sampling procedure that presents significant risk; does not by design or intention introduce energy into a subject; and is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure.

6.3. Following the IRB approval of the protocol:

6.3.1. A protocol that is IND and IDE exempt, and is not a Non-Significant Risk device study, will not have OSRO as the Sponsor and will not need to be reviewed further, unless the proposed amendments might affect the determination. Principal Investigators are strongly encouraged to discuss changes that might affect the determination with OSRO prior to amending the protocol.

7. Associated Documents

7.1. N/A

8. Change Summary

Revision Number	Effective Date	Description of Change
1	17SEP2021	New Document
2	29SEP2023	Biennial review Section 4 – updated hyperlinks Step 6.2.2.5 – promoted to Level 2 (new Step 6.3) Step 6.2.2.5.1 – removed Step 6.2.2.5.2 – promoted to Level 3 (new Step 6.3.1) Step 6.3 – removed