1. Purpose

To outline the Office of Sponsor and Regulatory Oversight (OSRO) tasks in the development, review, and acceptance of Center of Cancer Research (CCR) clinical research protocols.

2. Scope

2.1. Protocols developed by CCR investigators, under CCR sponsorship and overseen by the Office of Sponsor and Regulatory Oversight (OSRO) are within scope.

2.2. Limitations

2.2.1. Activities performed by non-OSRO staff are given only to provide context around the OSRO activities. OSRO assumes no control over these personnel and their actions.

2.2.2. The OSRO review process does not include reviewing the science supporting the protocol.

3. Responsibilities

3.1. OSRO reviews and accepts initial protocols and amendments to protocols.

3.2. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assist OSRO as needed.

4. References

4.1. 202 Protocol Development Policy

4.2. 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. 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. For consultations, reviews and acceptances of protocols and amendments, OSRO requires the following documentation provided in Microsoft Word format.

- Research concept, draft protocol, or draft amendment
- A list of specific questions to be answered
- All necessary supporting documents required to research submitted questions
- Informed Consent form
- Investigator's Brochure, Product Label, or Instructions for Use or equivalent
- A summary of manufacturing information for products that CCR manufactures
- Manual of Procedures, if applicable

6.3. Review Process for an Initial (New) Protocol

6.3.1. Refer to Figure 1 for the initial protocol review workflow.

6.3.2. If consulted by the Principal Investigator (PI) or Protocol Support Office (PSO) manager in the concept phase of the protocol, OSRO will provide feedback.

6.3.3. The OSRO review is based on compliance, consistency, clarity to maximize data integrity and subject safety.

6.3.4. Following the scientific review by the Scientific Review Committee (SRC), the protocol may require revising before the final draft is produced.

6.3.5. When the final draft is ready for review, the protocol is uploaded to the OSRO SROS Request for Service System.

6.3.5.1. OSRO will only accept a protocol final draft in Microsoft Word format.

6.3.5.2. The protocol review period should be no more than 15 business days.

6.3.5.3. OSRO comments and suggested edits are provided on F02-202-S01 Protocol Review.

6.3.6. Based on OSRO feedback, the PI finalizes the protocol and resubmits it via the OSRO SROS Request for Service System.

6.3.6.1. OSRO will only accept the finalized protocol in Microsoft Word format with tracked changes.

6.3.6.2. The protocol review period should be no more than 15 business days.

6.3.7. OSRO accepts the protocol after all outstanding comments and/or suggested edits have been addressed.

6.3.7.1. The protocol acceptance period should be no more than 5 business days.

6.3.7.2. A protocol acceptance notification is sent to the PI.

6.4. Review Process for an Amended Protocol

6.4.1. Refer to Figure 2 for the amended protocol review workflow.

6.4.2. When a PI plans to amend a protocol, s/he may consult OSRO with questions regarding the amendment.

6.4.3. When the final draft is ready for review, the protocol is uploaded to the OSRO SROS Request for Service System.

6.4.3.1. Note: OSRO will not accept an amendment which adds a new investigational intervention to the original protocol. The addition of a study intervention requires a new protocol.

6.4.3.2. OSRO will only accept an amendment final draft in Microsoft Word format and includes a track changes from the previous OSRO-accepted version.

6.4.3.3. The amended protocol review period should be no more than 10 business days.

6.4.3.4. OSRO comments and suggested edits are provided on a review form.

6.4.4. Based on OSRO feedback, the PI finalizes the protocol amendment and addresses the comments on the protocol review form. Both documents are resubmitted via the OSRO SROS Request for Service System.

6.4.4.1. OSRO will only accept the finalized protocol in Microsoft Word format with tracked changes.

6.4.4.2. The amended protocol review period should be no more than 10 business days.

6.4.4.3. The amended legacy protocol review period should be no more than 5 business days.

6.4.5. OSRO accepts the protocol after all outstanding comments and/or suggested edits have been addressed.

6.4.5.1. The amended protocol acceptance period should be no more than 5 business days.

6.4.5.2. A protocol amendment acceptance notification is sent to the PI.

6.4.5.3. The acceptance notification includes a statement on whether the amendment must be submitted to the Food and Drug Administration (FDA) either 5 days (IDE), 25 days (IND), or 30 days (change in product manufacturing or study agent) prior to implementation.

6.4.6. OSRO will formally accept protocol changes that are required by the Institutional Review Board (IRB). Prior to submitting the protocol addressing the IRB stipulation to the IRB, the PI submits the protocol, informed consent and the IRB stipulation document via the OSRO SROS Request for Service System.

6.4.6.1. The protocol acceptance period should be no more than 5 business days.

6.4.6.2. A protocol acceptance notification is sent to the PI.

6.4.6.3. No other changes apart from the response to the IRB stipulation should be provided. If additional changes are present in the protocol a full amendment review will be required.

6.5. Following IRB approval of the protocol or protocol amendment, the PI is sent a protocol signature page to affirm the conditions by which the PI agrees to conduct the clinical study.

6.5.1. The form must be signed and returned to SROSERDG@tech-res.com.

7. Associated Documents

7.1. 202-S01-W01 Reviewing Protocols

7.2. F01-202-S01 Protocol Signature Page

7.3. F02-202-S01 Protocol Review

7.4. F06-202-S01 Protocol Amendment Acceptance

7.5. F07-202-S01 Protocol Acceptance

7.6. F08-202-S01 Protocol Review – Legacy Protocol

8. Change Summary

Revision Number	Effective Date	Description of Change
1	03SEP2020	New Document
2	17NOV2021	Step 3.1.1 – added "The OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor assists OSRO as needed." Step 3.2 – added "Non-Significant Risk Device Study (NSR)" Step 6.2.3 – added "or NSR" General updates to procedure and flow
3	03JUN2022	Section 2 – clarified that CCR is sponsor and OSRO oversees studies Step 3.2 moved to Step 6.3.3 Step 2.2.3 – removed Step 6.1 – added Step 6.3.4 – added Step 6.4.6 – added Section 7 – added associated forms Provided document submission email, SROSProtocolReview@tech-res.com Provided target time limits for review and acceptance periods Figure 1 and 2 moved to Section 9. Appendix Updated process to include SROS activities General updates to procedure and flow
4	08FEB2023	Updated the document submission process to the OSRO SROS Request for Service System website (https://ncirfs.powerappsportals.com/add-rfs-information/) • Steps 6.3.6, 6.3.7, 6.4.3, 6.4.4, 6.4.6 Step 6.3.3 – replaced Step 6.3.4 – removed Step 7.6 – added
5	07MAR2023	Step 6.4.5.3 – added "or 30 days (change in product manufacturing or study agent)"
6	27MAR2024	Step 6.4.4.3 – added

9. Appendix

Figure 1. Initial Protocol Review Workflow.

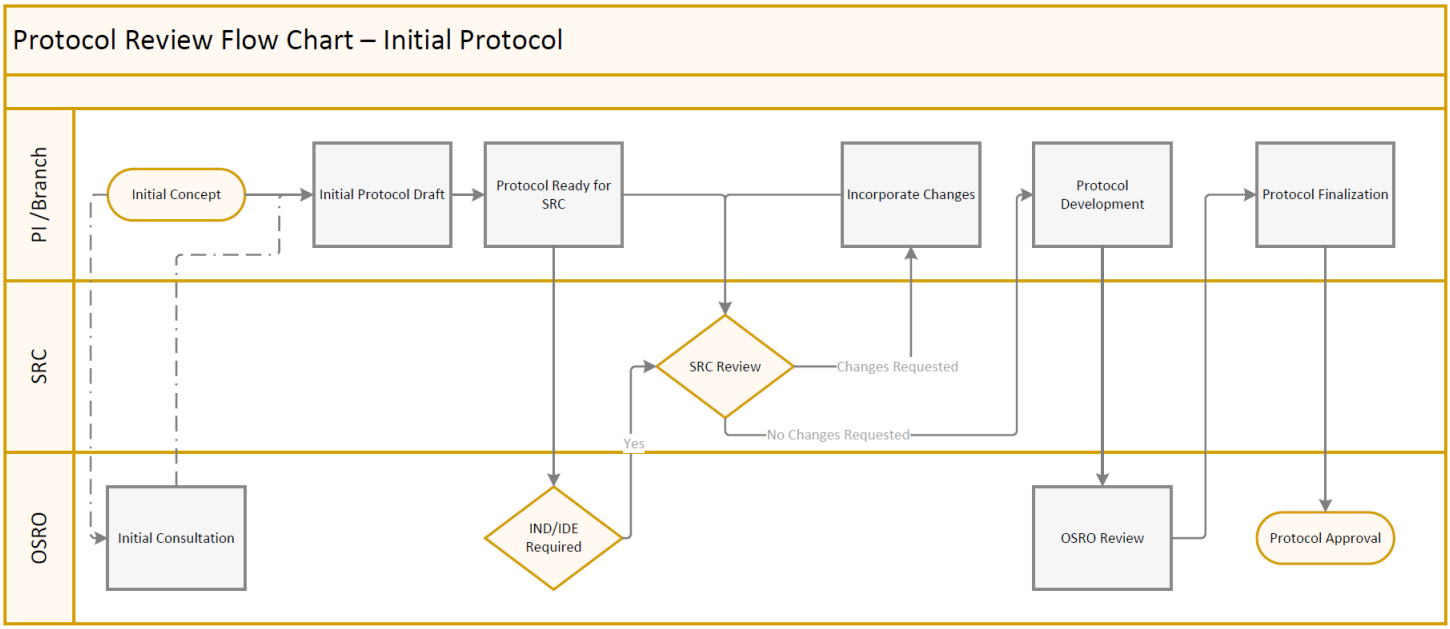

Figure 2. Amended Protocol Review Workflow.