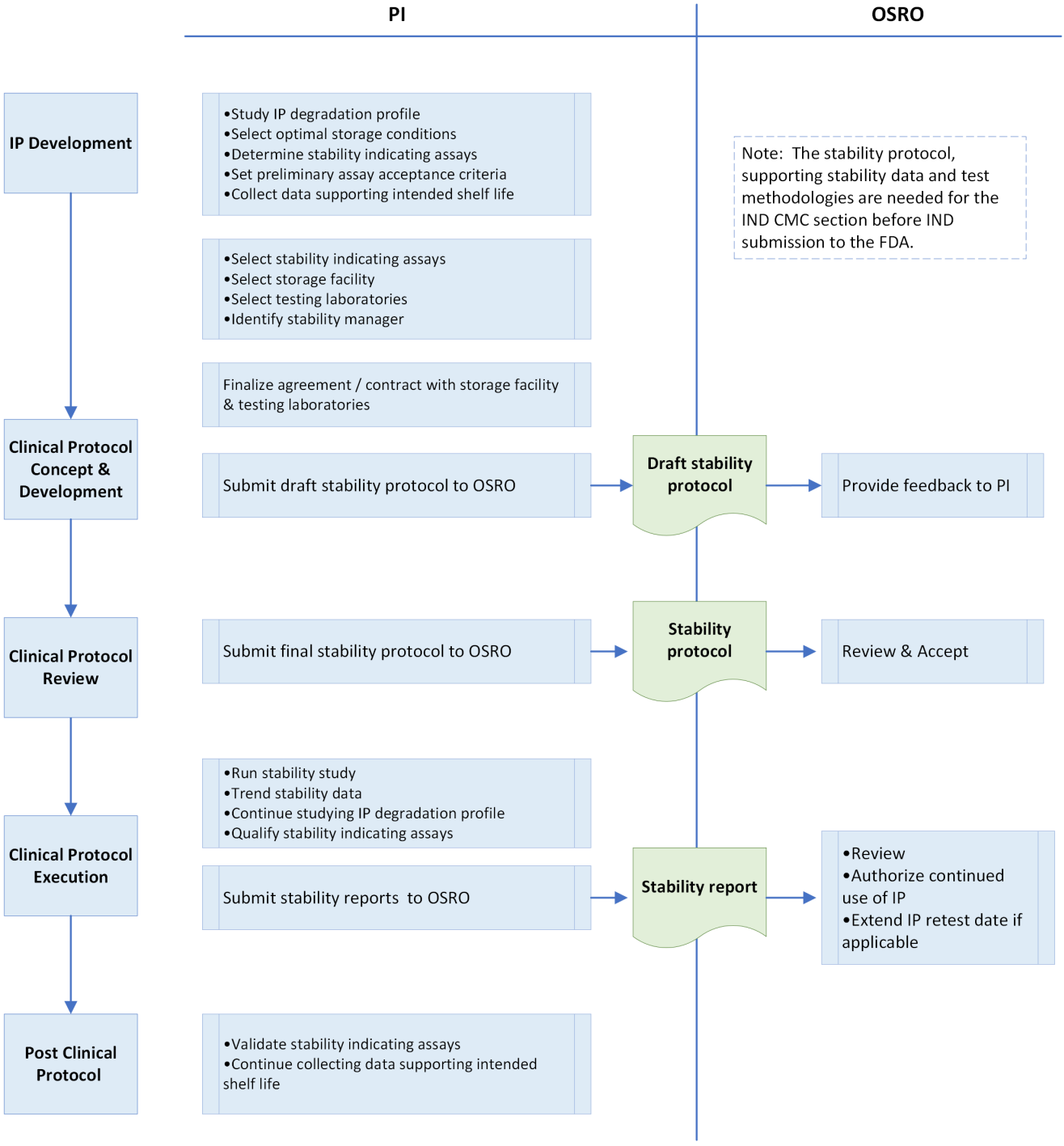
OSRO ensures CCR's regulatory compliance with sponsor obligations for Investigational New Drugs (IND) and Investigational Device Exemptions (IDE), including oversight of investigational product (IP) stability studies when CCR serves as the IP manufacturer.

The required documents, their provision to OSRO, and OSRO's actions are overlaid with key milestones in IP development and clinical testing in the graphic below. Recommended references are listed on the next page. Stability-related questions and documents should be sent to OSROStudyAgent.



References / Recommended Reading

1. OSRO policy: 502 Investigational Product Stability Studies
2. OSRO SOP: 501-S06 Testing and Retesting Procedures for Investigational Products
3. Office of Research Support and Compliance (ORSC) Guidance: Stability Testing of Investigational Drug Substances and Products within the NIH Intramural Research Program, Version 1.0, December 2022. Contact the Stability Guidance Committee at stabilityguidance@nih.gov
4. 21 CFR Part 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General
5. 21 CFR Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals
   - 5.1. 21 CFR 211 Subpart I Current Good Manufacturing Practice for Finished Pharmaceuticals – Laboratory Controls
     - 5.1.1. Questions and Answers on Current Good Manufacturing Practice Requirements | Laboratory Controls | FDA
6. 21 CFR Part 312 Investigational New Drug Application
7. ICH E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry (FDA), March 2018
   - 7.1. ICH E6(R3) Good Clinical Practice (GCP) draft Guidance for Industry (FDA), May 2023
8. ICH Q1A(R2) Stability Testing of New Drug Substances and Products Guidance for Industry (FDA), November 2003
9. ICH Q1E Evaluation of Stability Data Guidance for Industry (FDA), June 2004
10. ICH Q5C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products Guideline for Industry (FDA), July 1996
11. ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Guidance for Industry (FDA), September 2016
12. TRS 1010 - Annex 10: WHO guidelines on stability testing of active pharmaceutical ingredients and finished pharmaceutical products, 2018

Change Summary

Revision Number	Effective Date	Description of Change
1	28MAY2024	New Document