**TRIENNIAL STATUS CHECK REQUIRED4**

Has the study received at least one prior HRP regulatory audit?

**TRIENNIAL REGULATORY AUDIT REQUIRED5**

**NO**

**YES**

**YES**

**NO**

**1** RCO audits are audits conducted, supervised, or verified by the facility’s lead RCO.

**2** Human subject research studies approved by the R&DC prior to January 1, 2008, do NOT in most cases require an HRP regulatory audit. The exception to this “Grandfather rule” is those studies initially approved prior to January 1, 2008, that involve interaction or intervention with human subjects and remain open to enrollment.

**3** Studies in long-term follow-up of clinic data or data analysis only means that the research is permanently closed to the enrollment of new subjects; *and* 2) all subjects have completed all research-related interactions or interventions; *and* 3) the research has progressed to the point that it involves only accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care; *OR* the remaining research activities are limited to data analysis, including analysis of identifiable private information or identifiable biospecimens. Chart review/database studies are “permanently closed to the enrollment of new subjects” when the researchers will continue to collect long-term follow up data about the completed IRB-approved cohort but will not add data about other subjects. A chart review/database protocol is in data analysis when the remaining research activities do not include adding additional subjects or adding new data elements.

**4** RCOs must confirm and document that the status of the study has not changed (i.e., still remains in long-term follow-up or data analysis only). This confirmation must occur through a review of IRB records or protocol documents (e.g., review for any submitted amendments) as well as communication with the PI and must occur within 3 years of the last HRP regulatory audit and every 3 years thereafter until the study closes. If the study status has changed from long-term follow-up or data analysis only, an HRP regulatory audit must be conducted in the reporting period in which this was discovered and subsequent HRP regulatory audits must resume.

**5** Except for exempt studies approved under the Pre-2018 Common Rule, all human subjects studies are required to receive a regulatory audit at least every 3 years. An initial HRP regulatory audit must be conducted within 3 years of the R&DC approval date. Subsequent HRP regulatory audits must occur within 3 years of the previous HRP regulatory audit. Exempt studies approved under the 2018 Common Rule are required to have HRP regulatory audits. Exempt studies previously exempted from subsequent HRP regulatory audits (i.e., had one previous HRP regulatory audit) must have their next HRP regulatory audit or status check no later than May 31, 2027.

Is the study in long-term follow-up of clinical data or data analysis only status?**3**

**YES**

**NO**

**YES**

Does the study involve intervention or interaction with human subjects *and* is still open to enrollment? **2**

**NO**

**NO**

Was the study approved prior to January 1, 2008?**2**

Is the study an exempt human subjects study approved under the Pre-2018 Common Rule?

**YES**

**REGULATORY AUDIT NOT REQUIRED.**