TIP SHEET: ANNUAL REVIEW DECISION TREE

Use this chart to determine if an IRB-approved study qualifies for an abbreviated annual status report (ASR) or requires continuing review (CR)

START HERE

- My study is FDA-regulated
  - Yes
  - No
  - Ohio State is the IRB of record for one or more external sites involved in my study
    - Yes
    - No
    - My study has been approved by the convened IRB (initial and/or previous CR)
      - Yes
      - No
      - My study qualifies for expedited review under categories 2-7
        - Yes
        - No
        - My study remains open ONLY for long-term follow up (including re-contact) and/or data analysis
          - Yes
          - No
          - My study remains open ONLY for accessing follow-up clinical care data and/or data analysis
            - Yes
            - No
            - CR
  - No
  - My study was initially approved prior to 1/21/19 (under Pre-2018 Rule)
    - Yes
    - No
    - My study is minimal risk
      - Yes
      - No
      - CR
    - No
    - CR

Notes: Researchers should use the decision tree each year, as amendments approved since the last IRB review or ASR may affect annual status report eligibility. The IRB may, at its discretion, require continuing review of studies that would otherwise qualify for an annual status report.