Continuing Review (CR)/Annual Status Report (ASR) Submission Tips

### General

- Submit applications promptly to avoid lapse in approval and cessation of research activities.
- Address any administrative notes requiring further action from the previous year’s review prior to submission.
- Add new funding applications via amendment if any changes to the protocol or other study materials are needed.
- Ensure consistency between different application pages (e.g., Research Status page and Research Progress page).
- Make selections on the Research Status page to reflect the overall study status rather than a temporary state (e.g., if there is a planned “pause” for interim analysis but recruitment will be continuing after that, then select “Recruitment is ongoing”).
- Refer to the previous year’s reported accrual number to calculate the total enrollment of participants (i.e., last year’s reported total to date plus number of participants enrolled during the current review period equals the total accrual).
- Ensure all university requirements (e.g., human subject protections training, RCR training, COI disclosure) have been met for all study team members.
  - This includes external collaborators covered by an Individual Investigator Agreement.
  - Use the study team lookup feature to check the status ([http://go.osu.edu/studyteamlookup](http://go.osu.edu/studyteamlookup)).
  - If needed, personnel can be removed through a separate but concurrent personnel change request.
  - Once requirements have been met, external personnel who are removed can be added back to the study by amendment (after the continuing/annual review is approved), typically using the Individual Investigator Agreement.
  - Guest accounts for external collaborators require an annual renewal. Contact ORIS for assistance with guest account renewal ([orhelpdesk@osu.edu](mailto:orhelpdesk@osu.edu)).
Continuing Review (CR)

- **NCH Personnel**: Ensure all external NCH study personnel are identified on the Nationwide Children’s Hospital reliance acceptance letter.

- **Changes**: Only the following changes are permitted at continuing review:
  - ✓ Increase study accrual goal
  - ✓ Add/remove Ohio State study team members
  - ✓ Revise consent form to add new study sponsor when funding is added and no other changes to study materials are required
  - ✓ For NIH-funded research with ongoing recruitment, add Certificate of Confidentiality text to consent form confidentiality section (if not already included)

- **Funding page**: Update the Buck-IRB funding section and when applicable, the informed consent sponsor field and HIPAA section if new funding is added.

- **Research Progress page**: If research status changed from a more terminal status reported the previous year (e.g., from data analysis only to recruitment is ongoing), explain the change in the “Summarize the progress of the Ohio State research” question.

- **Risk Assessment page**:
  - ✓ For studies with multiple DSMB reports available from the last approval period, upload all available DSMB reports since the previous review (initial or continuing review), not just one report.
  - ✓ Describe only determinations that qualify (e.g., clinical hold, sponsor suspension, UPIRSO, serious/continuing non-compliance) since the last review (initial or continuing review).

Annual Status Report (ASR)

- **Number of participants enrolled to date**:
  - ✓ Currently: Include the number of participants enrolled to date in the “Summarize the progress of the Ohio State research” question.
  - ✓ In the future: Buck-IRB will be revised to elicit the number enrolled to date in a separate question.