Changes to Continuing Review

- For studies which are not FDA regulated, continuing review is no longer required if the research is determined to be minimal risk
- IRB can require continuing review on a case-by-case basis (e.g. compliance concerns)
- All other IRB submission/review requirements (amendments & reportable events) unchanged
- Full Board studies with ongoing interventions and FDA regulated research still require annual continuing review

How will the institution track ongoing research activities without continuing review?

- CHOP's human subjects protection program still needs to know what research is ongoing
- Brief activity in eIRB required every 2 years to confirm the study is ongoing
  - Required for expedited & exempt studies •
  - Use the activity to notify IRB of study closure

Do currently approved studies still need to submit for Continuing Review?

- After January 19, 2018:
  - All existing studies will need to submit their next scheduled continuing review
  - If the new regulations are applied then a new expiration date will not be issued
- Consent updates via an amendment may be required
  - To meet new consent requirements

Progress Update Activity