Office of Human Research Ethics Training Tips
NIH Grant Concordance Declaration, April 2017

NIH Required Declaration of Concordance

I. Regulatory Requirement

- NIH sees only grant submission, but NOT the IRB submission;
- The IRB only body that sees both grant and human subject submission,
- Therefore, NIH relies on the IRB to declare that the IRB submission and the grant submitted are identical
- Required to be done only at time of initial review; unless grant renewals are competitive.
- Must be part of full board or expedited review and so documented in the minutes & approval.

II. What to Review

- Do the following match:
  - Title
  - Grant #
  - Awardee
  - Sponsor
  - Investigator & co-Investigators
  - Study Design
  - Staffing Levels appropriate
  - Study Objectives
  - Research Site

- If IRB submission is for only part of the total grant, confirm that the proposed study is included in the larger grant. Please note that the submission is only a part of a larger grant.

- Be sure to check the concordance box on your reviewer checklist and include in your recommendation that the grant is or is not concordant.

III. Examples: Common areas of non-congruence between grants and protocols include:

- Data collection procedures that are proposed in the grant application but are not described in the IRB-approved protocol;
- Descriptions of the study population(s) and number of participants to be recruited;
- Descriptions of collaborating institutions and listed research sites that are proposed in the grant application but are not described in the IRB-approved protocol;
- Co-investigators and/or research personnel (including students) listed in the grant application but not in the IRB protocol (or vice-versa).