**IRB SUBMISSION CHECKLIST**

* IRB Application
* Protocol
* Investigator Brochure and Investigators Manual (if applicable)
* FDA information (IDE or IND)
* Grant/funding material (if applicable)
* External Site IRB approval letter (if applicable)
* Appendices (if applicable)
* Informed Consent Form (or Documentation for Waiver)
* HIPAA Research Authorization Language
* Waiver of HIPAA Authorization for screening/recruitment purposes
* Other Consents, Assent, or Parental Permission Form (if applicable)
* Other Institutional Approvals (if applicable) (e.g., Maternal-Fetal Welfare Committee)
* Data Collection Forms
* Recruitment Materials (e.g., advertisements, flyers, posters, social media, ResearchMatch)
* Instruments (e.g., surveys or questionnaires to be completed by subjects)
* Subject materials (e.g., letters, pill diaries, instructional manuals)
* Verify all investigators and key personnel have completed CITI training
* Verify all investigators and key personnel have completed COI disclosures
* All forms signed by PI, Sub-Investigators, and Department Chair as necessary
* ClinicalTrials.gov registration (if applicable)