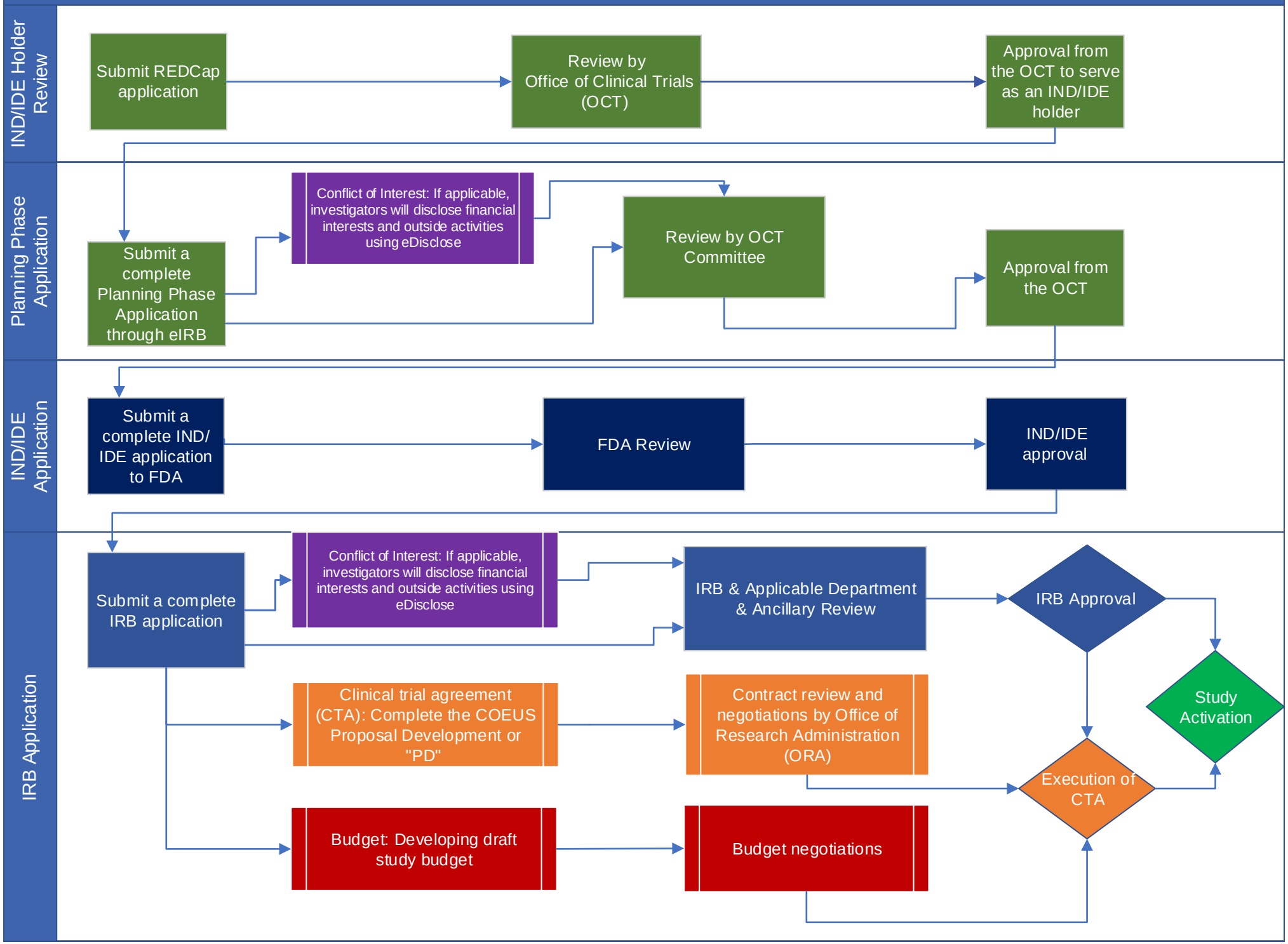
Johns Hopkins University "JHU" Investigator-held INDs/IDEs Review Procedures



Important Notes:
All investigators from all JHU schools who seek to serve in the role of IND/IDE holder must follow the process for pre-approval through the OCT and JHM IRB prior to FDA submission. Once an IND/IDE has been issued, Johns Hopkins Bloomberg School of Public Health (JHSPH) investigators may continue to submit any human subject research applications to the JHSPH IRB for review. Homewood and JHM investigators should continue to submit these applications to the JHM IRB for review.

Planning Phase Application Conflict of interest (COI) Review: If the application involves a COI, it is the responsibility of an investigator to make required disclosures of potential conflicts through eDisclose/web-based disclosure system. The application will be reviewed by the Office of Outside Interests (OOI). For Planning Phase Application IND/IDE Application Submission approval, the OOI's review will be limited to determining whether the individual submitting the application may serve as the IND or IDE holder under JHU's COI policy.

IRB Application Conflict of interest (COI) Review: If the application involves a conflict of interest (COI), all investigators must disclose outside activities using eDisclose. Once the University official has created a management plan, that management plan shall be conveyed to the Covered Individual in writing. All arrangements may be reviewed again if circumstances change or there is new information. The JHM IRBs may not take final action on new applications until COI review is complete, management recommendations are finalized, and any required conflict of interest language has been included in the consent form.

Clinical Trial Agreements: These agreements must be submitted via the COEUS system. The resulting record in the system is called a Proposal Development or "PD" record. Once the complete PD is received and accepted by ORA, the Sponsored Projects Specialist will create a contract file in MyRap and a contract reviewer can be assigned. An IRB approval is needed before the contract can be executed (signatures obtained), unless the contract work scope includes developing the protocol and then submitting it to the IRB. To avoid unnecessary delays, the Prospective Reimbursement Analysis (PRA), budget development, Institution Review Board (IRB), and contract submission should be worked on simultaneously. ORA does not need an IRB approval or a final budget for you to submit a contract with a commercial sponsor for review.

Budget Development: A draft budget is needed to initiate contract review, but a final Sponsor budget and internal budget will be needed to complete the contract negotiation; contract negotiations should proceed in parallel with budget negotiations.

ClinicalTrials.gov Protocol Registration: ClinicalTrials.gov Registration is required for studies that meet the definition of an "applicable clinical trial" (ACT). The responsible party (that is, the IND/IDE holder or designated PI) for an ACT must submit the required clinical trial information no later than 21 calendar days after enrollment of the first participant.

Legend:
- Office of Clinical Trials Review
- JHM IRB Review
- FDA Review
- Conflict of Interest Review
- Budget Development
- Contract Review