Proposed Drug Study

Approved Drug for a Labeled indication
- IND not needed

Approved Drug used for an unlabeled indication
- Consult FDA as needed
  - Study meets IND exemptions 21 CFR312.2(b)
    - Yes - IND not needed
    - No - Sponsor-Investigator Prepares and submits IND FDA forms 1571, 1572, & 3674
    - 30-day Window for FDA response

- Respond to FDA Questions
  - IND Approved
    - Yes - Study may begin
    - No - Delay or Clinical Hold
  - IND not needed

Unapproved Drug
- **IND required**