Review Process for Initial Applications for Human Subjects Research

1. PI submits Application for research with Human subjects to IRBIS
2. Does the application meet the criteria for IRB approval without any additional changes or information?
   - Yes: IRB Approves research, modifications required for any changes to the study
   - No: Proceed to next step
3. Does the research meet the criteria for IRB approval?
   - Yes: Approval with minor stipulations
   - No: Proceed to next step
4. Could substantive changes or additional information be provided that would allow the IRB to determine in the criteria for approval have been met?
   - Yes: Make specific changes to the IRB application
   - No: Deferral: Substantive changes and additional information are necessary in order to determine if the project meets the IRB criteria for approval
5. Did the PI make the requested changes?
   - Yes: IRB approves research, modification required for any changes to study, annual review required if more than minimal risk
   - No: Disapproval: Project cannot meet the criteria for IRB approval even with substantive changes

Key:
- Determinations by the IRB
- Decisions by the IRB chair or an IRB member appointed by the chair of the full IRB
- Decisions by the full IRB
- Actions by PI

Timeline:
- Administrative/technical review: 2-4 weeks depending on volume
- Sub-committee Review: 1-2 weeks
- Full IRB Review: 4-6 weeks depending on volume, schedule, and number of reviews required