Investigator Initiated Studies Process

1. Amendment Prepared or Received
2. PRC Review Required?
   - Yes: Submit to PRC
   - No: Amendment Implemented

- Submit to PRC
- PRC Approves
- Submit to IRB of Record
- IRB of Record Approves

Submit:
- Protocol (tracked and clean)
- Summary of Changes to protocol
- Amendment Cover Sheet
- Amendment DART Form (full board review only)