**Spectrum Health Research Process**

1. **Execute a Confidentiality Disclosure Agreement (CDA) if applicable**

2. **Protocol Review by PI/Study Team**

3. **Strategic, Financial and Scientific Department Vetting**

4. **Feasibility (Resources, Patient Population, Ancillary Service Needs etc)**

5. **PI or study support staff provide appropriate information to OSP via the Intake Process**
   (includes but not limited to protocol, sponsor contacts, contract, ICF)

**OSP**

- Review contract with legal and negotiate with sponsor

OSP will keep PI informed of progress, cause approvals, and send final contracts to PI for signature

**Budgeting/CA**

- Finalize CA with CA Liaison and obtain ancillary service approvals

Negotiate and finalize budget with OSP input

**IRB**

- Submit protocol package to IRB including legal reviewed ICF and SH ICF (if available)

IRB Approval/Contingencies Obtained and final ICF is provided to OSP and IRB

STOP!!!! Do not proceed until:
- IRB approves study and ICF
- Clinical Trials Management System (CTMS) build complete
- Reconcile language in contract, budget, CA and ICF
- Contract and Budget fully negotiated

Contract Executed and Kick-off Meeting Scheduled

OSP submits award setup to finance; finance setup CMS approvals and account in Lawson