



## Clinical Trials Research Unit Protocol Submission Checklist

### IRB ELEMENTS:

- Protocol Statement Form
  - investigator's signatures;
  - sub-I's signatures;
  - department chair signatures;
  - hospital admin. signatures;
  - POC admin. signatures;
  - list PI first (include address);
  - complete all sections.
- Informed Consent/Parental Consent/Assent
- Abstract
  - layman's terms;
  - 250 words or less.
- Discussion
- Cover letter(s)
- Attachments
  - questionnaire;
  - ancillary approvals, (i.e., radiation safety, etc.);
  - amendments;
  - investigator brochure.
- Protocol

### OSP ELEMENTS:

- Research Corp. Approval Sheet (Blue Sheet)
- Contract received/forwarded to OSP
- UBIT completed
- Budget (Sponsor's or Investigator's)

### REGULATORY DOCUMENTS:

- Confidential Disclosure Agreements
- Financial Disclosure Statement
- Form 1572 (FDA)
- Investigator Agreement
- Investigator CVs/licenses
- IRB roster
- Lab normals
- Lab certification