Departmental Clinical Trial Checklist - SCCC

New Projects

Required
The following documents and information are required for ORA to start work. If any of the items below are not provided, ORA will return the submission indicating what is missing to be resubmitted when all items below are included.
Note: This checklist excludes IITs/IISs which follow a separate process. IRB and FP submissions must be linked.

IBIS Agreement

☐Clinical trial agreement (word format preferred)
☐Sponsor/CRO contact information
☐All individuals who should be included on communications about the agreement
☐Letter of indemnification (word format preferred) (if provided initially)

IBIS Funding Proposal (FP) (excluding cooperative group studies)

☐Sponsor's budget (excel preferred). Blank budget forms are not acceptable.
☐Draft informed consent form
☐Protocol
☐SDG PROTOCOL PRIORITY MEETING MINUTES
☐TAGS for SDG groups (to allow proper assignment based off tier and SDG group).
☐All individuals who should be included on communications about the budget/coverage analysis
☐FDA IND Letter or FDA Letter acknowledging IND Submission OR FDA Device Letter (if IDE device)
☐SCCC Lab budget (if applicable)
☐Any other internal budgets (i.e. biospecimen shared resources) that are needed (if applicable)

IBIS Funding Proposal (FP) (cooperative group studies)

☐Funding sheet
☐National coverage analysis (if available)
☐Draft informed consent form
☐Protocol
☐TAGS for SDG groups (to allow proper assignment based off tier and SDG group).
☐All individuals who should be included on communications about the budget/coverage analysis

IBIS M1900364/ FP00008441 (FP-Revision) (Dr. Nimer-ETCTN/Catch2020)

☐Internal SCCC Budget
☐Protocol
☐Draft informed consent form

Optional (will not prevent ORA from starting work)

Providing documents and information below at the time of submission, may contribute to more efficient turnaround time.

IBIS Funding Proposal (FP) (excluding cooperative group studies)

- ☐Lab Manual
- ☐Imaging Manual
- ☐Investigational Brochure
- ☐IRB Number

Amendments

IBIS Amendment[1]

- ☐Clinical Trial Amendment (word format preferred)
- ☐Sponsor/CRO contact information (if different from original Agreement)
- ☐All individuals who should be included on communications about the Amendment (if different from original Agreement)
- ☐Revised Budget in excel format (if applicable)
- ☐Revised Protocol (if applicable); redlined AND clean versions preferred
- ☐Revised clean Informed Consent (if applicable)
- ☐IRB approval Letter of revised Protocol or PI change related to amendment (UM or external IRB) (if applicable)
- ☐JHS CTO Application and Draft JHS Calendar (optional) if amendment adds JHS as study location, changes PI, or affects JHS budget
- ☐CTRS budget if amendment adds CTRS or affects CTRS budget

1 Amendments for cooperative groups studies are submitted as amendments to MCA Agreements