

Departmental Clinical Trial Checklist - MSOM

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: Study must be submitted to IRB and linked to funding proposal (FP). Refer to **Implementation of Deadlines for Projects Submitted to Both ORA and IRB** published by OVPRS on 07/26/2024.

IBIS Agreement

- Clinical Trial Agreement (word format preferred)
- Sponsor's budget (excel preferred). Blank budget forms are not acceptable
- Sponsor/CRO contact information
- All individuals who should be included on communications about the agreement and budget/coverage analysis
- Letter of indemnification (word format preferred) (if provided initially)
- FDA IND Letter or FDA Letter acknowledging IND Submission OR FDA Device Letter (if IDE device)

Optional:

- Study Budget Template (internal personnel budget and study-specific costs)

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

- CTRS budget (if applicable)
- All individuals who should be included on communications about the budget/coverage analysis
- JHS CTO Application (if applicable)
- JHS Calendar (in excel format, if applicable; optional)

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.

- Lab Manual
- Imaging Manual
- Investigational Brochure

IBIS Funding Proposal (FP) (cooperative group studies)

- Funding sheet
- National coverage analysis (if available)
- All individuals who should be included on communications about the budget/coverage analysis
- JHS CTO Application (if applicable)
- JHS Calendar (in excel format, if applicable; optional)

Amendments

IBIS Amendment¹

- 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