Departmental Clinical Trial Checklist (new and amended)

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 and ask for it to be resubmitted when all items below are included.

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.
- ☐Informed consent form (draft is acceptable)
- ☐Final Protocol matching the one submitted (or to be submitted) to IRB
- ☐Feasibility Committee Approval Letter or proof of exemption
- ☐FDA IND Letter or FDA Letter acknowledging IND Submission OR FDA Device Letter (if IDE device)
- ☐CTRS budget (if applicable)
- ☐All individuals who should be included on communications about the budget/coverage analysis.
    - Include specific JHS CTO personnel* **with read-only rights** if study will be using any of JHS resources
- ☐JHS CTO Application (if applicable)
- ☐JHS Calendar (in excel format, if applicable; optional)

IBIS Funding Proposal (FP) (cooperative group studies)

- ☐Funding sheet
- ☐National coverage analysis
- ☐Draft informed consent form
- ☐Protocol
- ☐All individuals who should be included on communications about the budget/coverage analysis
    - Include specific JHS CTO personnel* **with read-only rights** if study will be using any of JHS resources
- ☐JHS CTO Application (if applicable)
- ☐JHS Calendar (in excel format, if applicable; optional)

IBIS JHS Work Order (Created from related FP for new JHS Work Orders and from Agreements for amended JHS Work Orders.)

- ☐JHS Work Order Request Form (fully completed)
- ☐Final Protocol matching the one submitted to IRB
- ☐Draft/Final Informed consent form
- ☐JHS CTO Application
- ☐Draft JHS Calendar (in excel format, optional)
- ☐All individuals who should be included on communications about the JHS Work Order

Optional
The following documents and information should be provided if available at time of submission to ORA. While not providing these documents will not prevent ORA from starting work, providing them may allow ORA to provide a more efficient turnaround time.

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

- ☐Lab manual
- ☐Imaging manual
- ☐Investigational brochure
- ☐IRB Number

* Katuska Barbery, Veronica Del Prete Perez, Ericka Paule Cheriska