Appendix 1 – IND Checklist

IND Submissions to FDA

For detailed description of FDA requirements

☐See 21 CFR 312.33 for content and format of IND application

☐1571 (IND cover sheet) is required

Upon initial IND submission:

- In Section 10, the serial number should be '000' (see IND Handout pg 3)
- In Section 11, only the 'Initial Investigational New Drug Application (IND)' box should be checked

Upon subsequent submissions:

- The serial number should increase consecutively in the order of submission (e.g.,001, 002)
- If more than one type of information is included in a submission, all boxes that correspond to the type of submission should be checked

☐ClinicalTrials.gov registration – see HSO website for more information

- Applicable clinical trials include those involving a FDA IND
- At the UI, the responsible party of an investigator-initiated study is the PI
- Federal deadline - no later than 21 days after enrollment of first participant or Publishing deadline - prior to the enrollment of the first subject (International Committee of Medical Journal Editors)
- After submission to CT.gov, review can take 30 days; once accepted record & NCT# available on CT website in 2-5 business days
- Contact the HSO to get a username for CT.gov Protocol Registration and Results System
- If UI is IRB of record, provide the CT.gov registration number (NCT#) in HawkIRB Section VII.B.1

☐Form FDA 3674 (ClinicalTrials.gov Certification of Compliance) or other form of certification

- Must accompany certain human drug and biologic product applications to the FDA (New IND applications and new protocols submitted as an amendment to the IND)

IND Submissions to IRB

IND Application should include:

☐Copy of initial 1571

☐Protocol

☐Investigator Brochure

☐Documentation from FDA (that study may proceed or date application was received)

☐1572 is optional

*Include the 1571 & FDA documentation in the 'Sponsor Documentation' category on Attachment page

If the IRB determines that an IND is required, but the FDA disagrees, attach documentation of the FDA's determination that an IND is not needed (see IND Handout pg 4).

Reporting requirements to FDA

Once the IND is in effect, submit the following to the FDA.

☐Protocol Amendment

- New protocol - any study not contained in the IND application
- Protocol changes – changes/additions to protocol
- New investigator – within 30 days of addition of investigator

☐Information Amendment - for any essential information not included in item 1 above

☐IND safety reports – (see IND Handout pgs 7-9)

☐Annual reports – within 60 days of the anniversary date that he IND went into effect
☐Notice of intent to withdraw IND
☐Financial disclosure information- changes must be during/for 1 year after completion of study
☐Certification of Compliance Form (FDA Form 3674) – for new protocols submitted as an amendment to the IND application
☐Clinical Trials.gov reporting and results

- Update records - within 30 days of a change in recruitment status, or completion date. Protocol amendments/other updates must be made every 12 months
- Submit results - no later than 1 year after the primary completion date

Reporting requirements to IRB

The same information that is submitted to the FDA must be submitted to the IRB, but the format and the timing of the submissions will vary.

Modifications

Should describe:
☐Protocol Amendments, including new protocols, protocol changes and new investigators
☐Information Amendments
☐Notice to withdraw IND

Should include:
☐Corresponding 1571 documenting a change in serial number & describing the type of submission (upload on top' of previous 1571 (see IND Handout pg 3)
☐Documentation of FDA submission and the date

Timing - Submit the IRB modification at the time of the IND submission to the FDA

Addition of New Protocol

If a new protocol is added to an IND application, the IRB expects the IND holder to maintain:

☐One overall IRB application containing

- The entirety of the IND application
- A full history of the initial submission
- All amendments that are submitted to the FDA

☐A separate IRB application for each ancillary study to be conducted at the UI that

- Includes the required IND information relevant to the ancillary study only
- References the IRB ID# of the main IND study in Section I.4

Reportable Event Forms (REFs)

Are used to report IND Safety/adverse event reports that meet the following definitions:

☐A serious adverse drug event that the PI determines to be related to the study drug, whether it is **unexpected or expected** that occurs in a subject enrolled by a UI investigator

☐A serious, unexpected, suspected adverse reaction (SUSAR) occurs in a subject at a non-UI site and the event impacts UI subjects or the conduct of the study at the UI (e.g., results in an amendment to protocol) it meets the reporting requirements of an **unanticipated problem involving risks to subjects (UPIRTSO)**

☐Attach a copy of IND safety report that was sent to FDA to the REF

Timing – Submit within 10 working days of the event or the investigator becoming aware of the event.

Annual Reports

Required at the time of Continuing Review (CR).

☐If the due date of the first annual report does not coincide with the date the IRB Continuing Review is due, describe in the CR that the annual report is not yet due

☐An annual report is expected to be attached to all subsequent CR applications

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Financial Disclosure

Information is reported via eCOI system and not to the IRB.

FDA recordkeeping requirements for sponsors-investigators

The FDA requires that you maintain the following documents:

Record type

☐Drug accountability and disposition
☐Case histories
☐Financial interest records
☐Subject case histories

Duration

☐During and for 2 years after the date a marketing application is approved for the drug for the indication for which it is being investigated

☐If no application is to be filed or if the application is not approved for such an indication, maintain the following records until 2 years after the investigation is discontinued and FDA is notified (IRB or other requirements may differ)

IRB recordkeeping requirements for sponsors-investigators

The IRB expects that you retain the following:

Record type

☐All IRB application forms, approval notices, signed Informed Consent Documents
☐All correspondence related to use of human subjects in research

Duration

☐Research records that do not involve Protected Health Information (PHI) must be kept for 3 years after the close of the study in HawkIRB

☐Research records involving PHI must be kept for 6 years after the close of the project in HawkIRB

☐Research records for VAMC studies must be kept indefinitely

The IRB recommends the sponsor-investigator maintain all correspondence with the FDA.