NEW IRB SUBMISSION CHECKLIST

Version Date (FOR OHR USE): 1/20/20

Submission Date: \_\_\_\_\_\_\_\_\_\_ JeffTrial #: \_\_\_\_\_\_\_\_\_\_ Portal App. ID: \_\_\_\_\_\_\_\_\_\_

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

FOR OHR USE: Acceptance Date: \_\_\_\_\_\_\_\_\_\_ Meeting Date: \_\_\_\_\_\_\_\_\_\_ IRB Control #: \_\_\_\_\_\_\_\_\_\_

PLEASE NOTE: For studies with a consenting document, please create a new study record in JeffTrial and submit the required documents electronically using the Portal. For studies without a consenting document, please submit the required documents electronically using the Portal. A new study record in JeffTrial does not need to be created.

In addition, for full reviews, 3 collated packets of hardcopies are also required.

Full Board Review

~ *Greater than minimal risk* – *Reviewed by the full board* ~

□ OHR-1 (All training and conflicts have been checked)

□ OHR-2/2B

□ OHR-8/8B, etc.

□ OHR-15 (Biological Specimen, Tissue and/or Genetic Research)

□ Additional Documents (See Below)

Exempt Study Review

~ *Minimal to no risk* – *Administratively reviewed: does not require board review* ~

□ OHR-1 (All training and conflicts have been checked)

□ OHR-18

□ OHR-3 or OHR-5

□ Additional Documents (See Below)

Expedited Chart/Database Review or Tissue Collection Study Review

~ *Minimal risk* – *Reviewed by subcommittee* ~

□ OHR-1 (All training and conflicts have been checked)

□ OHR-4 (Chart Review) or OHR-15 (Biological Specimen, Tissue and/or Genetic Research)

□ OHR-3 or OHR-5

□ Additional Documents (See Below)

All Other Expedited Study Review

~ *Minimal risk – Reviewed by subcommittee* ~

□ OHR-1 (All training and conflicts have been checked)

□ OHR-2/2B

□ OHR-15; OHR-3 or OHR-5; OHR-8/8B, etc.

□ Additional Documents (See Below)

Additional Document Requirements

□ Protocol with PI signature (IIT Protocol for Expedited Reviews when applicable) – 2 hardcopies

□ Investigator’s Drug Brochure / Package Inserts (Must supply for all drugs) – 2 hardcopies

□ Device Brochure / Instructions for Use – 2 hardcopies

□ Form FDA 1572 (submit copy with all FDA-regulated studies)

□ Grant application

□ PRC Protocol Cover Sheet (if scope of study involves cancer)

□ PRC Approval Letter (Cancer Research Only)

□ Radiology Feasibility Assessment Approval Letter (if study requires imaging)

□ OHR-25 (Device Worksheet)

□ OHR-26 (Research involving Children); OHR-27 (Research involving Pregnant Women, Fetuses, & Neonates)

□ Phone Script

□ Survey/Questionnaires

□ Advertising (radio, newspaper, websites, recruitment letters, etc.)

□ If part of cooperative single IRB submission, approval by the Federal department or agency supporting or conducting the research or lead institution

□ This form

If submitting a study sponsored in any part by the Department of Defense, please refer to OHR Policy G620 and contact the OHR prior to submission.

**FOR OHR USE:**

**□** Full

**□** Expedited: Expedited studies assigned per 45 CFR 46.110, expedited categories list (11/09)

□ Exempt: Exempt per 45 CFR 46.101(b)