NEW IRB SUBMISSION CHECKLIST

Submission Date: __________  JeffTrial #: __________  Portal App. ID.: __________

Principal Investigator: _____________________________________________

Required paperwork for submission (attached):

Full Board Review (requires 6 hardcopies in addition to JeffTrial and Portal Submission)
~ Greater than minimal risk – Reviewed by the full board ~
 □ OHR-1 (All training and conflicts have been checked)
 □ OHR-2/2A/2B
 □ OHR-8/8A/8B, etc
 □ OHR-15 (Biological Specimen Use) or OHR-16 (if study involves genetic research)
 □ Additional Documents (See Below)

Exempt Study Review (JeffTrial and the Portal submissions only - no hardcopies)
~ 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 (JeffTrial and Portal only – no hardcopies)
~ Minimal risk – Reviewed by subcommittee ~
 □ OHR-1 (All training and conflicts have been checked)
 □ OHR-4 (Chart Review) or OHR-15/15A (Biological Specimen Use)
 □ OHR-3 or OHR-5
 □ OHR-16/16A (if study involves genetic research)
 □ Additional Documents (See Below)

All Other Expedited Study Review (JeffTrial and Portal only – no hardcopies)
~ Minimal risk – Reviewed by subcommittee ~
 □ OHR-1 (All training and conflicts have been checked)
 □ OHR-2/2B
 □ OHR-15/15A; OHR-16/16A; OHR-3 or OHR-5; OHR-8/8A/8B, etc
 □ Additional Documents (See Below)

Additional Document Requirements (2 copies for Full Reviews, E-copy for all other studies)
 □ Protocol with PI signature (IIT Protocol for Expedited Reviews when applicable)
 □ Investigator’s Drug Brochure / Package Inserts (Must supply for all drugs)
 □ Device Brochure
 □ Form FDA 1572 (submit copy with all FDA-regulated studies)
 □ Grant (if federally funded)
 □ PRC Protocol Cover Sheet (if scope of study involves cancer)
 □ PRC Approval Letter (Cancer Research Only)
 □ OHR-25 (Device Worksheet); OHR-26 (Research involving children); OHR-27 (Research involving Pregnant Women, Fetuses, & Neonates) **6 copies for Full Reviews**
 □ Phone Script Attached **6 copies for Full Reviews**
 □ Survey/Questionnaires **6 copies for Full Reviews**
 □ Advertising (radio, newspaper, websites, recruitment letters) **6 copies for Full Reviews**

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.

Reviewed by:
Principal Investigator: _____________________________________________

Signature ___________________________ Date __________

Note ** Only one copy of this form is needed with the original documentation**

Revised: 5/11/2016 3:27 PM Heather Krupinski