CENTRAL IRB – SUBMISSION CHECKLIST

Date **Study Coordinator:**

Principal Investigator: **Contact Person:**

Protocol # **Sponsor:**

Study Title:

CENTRAL IRB REQUIREMENTS:

- ☐ Initial Review Submission Form
- ☐ Protocol (date:)
- ☐ Grant application, if applicable
- ☐ Amendments (dates for those included:)
- ☐ Investigator's Brochure (IB), if applicable (Date of IB :)
- ☐ If a DEVICE study, copy of the signed Investigator Agreement for protocols with an IDE, and ONE of the following:

☐ FDA IDE approval letter OR ☐ 510(k) clearance OR ☐ Sponsor letter stating SR device or NSR device

- ☐ Informed Consent /Assent or HIPAA Authorization
- ☐ Advertisements/Recruitment Materials (How many?)
- ☐ Medical License for PI/Sub-Investigators, if applicable
- ☐ Curriculum Vitae for Principal Investigator (PI) & Sub-Investigators
- ☐ Other documents/materials ( )

FLORIDA ATLANTIC UNIVERSITY REQUIREMENTS:

- ☐ Scientific Merit Review (for CT review should be done **before** contract/CTA is negotiated)
- ☐ For industry sponsored: draft CTA/Grant & Budget submitted to Sponsored Programs [with consent(s)]
- ☐ Certification from General Counsel: CTA and Consent are in Agreement [General Counsel's initials _____]
- ☐ FAU Financial Disclosures
- ☐ CITI Human Subjects Research training. In addition CITI Good Clinical Practice (GCP) training for those conducting FDA regulated clinical trials, and CITI Health Information Privacy and Security (HIPS) course for those working with medical records / accessing protected health information (PHI). www.citiprogram.org
- ☐ Pre-Award Routing Sheet submitted to Sponsored Programs
- ☐ Institutional Biosafety or Radiation Safety Committee approval is attached or in progress (if applicable)
- ☐ Supplemental Materials for Investigator Initiated Projects (1571, site agreements) (if applicable)
- ☐ HIPAA Privacy Documents (annual security survey, Data Use or Business Associate Agreements, (if PHI obtained or disclosed)
- ☐ Other:

_____ _____

Signature of Division of Research Authorized Staff **Date**