**Sponsor-Investigator/Investigator-Initiated Investigational Device Exemption (IDE) Checklist**

 **Pre-IRB Approval Assessment**

**PI Name:**

**IRB #:**

**IDE #:**

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**Objective:**

This clinical investigation has been deemed to be an IDE Sponsor-Investigator (SI)/Investigator-Initiated (II) trial. According to the FDA regulations the SI/II must adhere to sponsor and investigator responsibilities. Prior to receiving IRB approval the clinical investigation must be assessed. The objective of this routine assessment is to assure the rights and welfare of human research participants as well as adherence to Good Clinical Practices and applicable federal regulations in preparation for conducting the clinical investigation.

**Instructions:**

Below is a checklist for documents or clinical investigation materials that will be reviewed during the assessment. Complete the checklist to the best of your ability. Submit the completed checklist to Kristin Kolsch, kristin.kolsch@hsc.utah.edu **48hrs prior to the scheduled assessment**. Feel free to contact Kristin Kolsch with any questions during this process. If needed, templates (logs and language) may be available upon request. IRB questions should be directed to Lacy Clegg, lacy.clegg@hsc.utah.edu at the IRB.

In addition it is also recommended that you complete a Sponsor-Investigator Policies and Procedures document for this study. Template may be found at <http://irb.utah.edu/forms/health-sciences.php>. The completed document should be attached to the ERICA application under “Other Documents” on the Documents and Attachment page.

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| **IND Assessment Checklist** |
| **Check, if app.** | **Document or Clinical Investigation Materials** | **Location(s) of Documents/Materials** (Regulatory Binder - Section, Patient Folder, ERICA, uTRAC etc…) |
| **FDA Forms:** Should be located in the Regulatory Binder and attached in ERICA. |
|  | Initial FDA Form 1571 or Cover Letter – Application Cover  |  |
|  | Supplemental FDA Form 1571’s or Cover Letters |  |
|  | FDA Form 3674 – Certification of Compliance |  |
|  | FDA Form 3454 – Certification: Financial Interest and Arrangements of Clinical Investigation (if applicable) |  |
|  | FDA Form 3544 – Disclosure: Financial Interest and Arrangement of Clinical Investigation (if applicable) |  |
| **Regulatory Binder:** Correspondence  |
|  | FDA Correspondence Section |  |
|  | IRB Correspondence Section |  |
|  | Misc. Correspondence Section (if applicable) |  |
|  | Note-to-File Section (if applicable) |  |
| **Regulatory Binder:** Clinical Investigation Logs (templates available)  |
|  | Subject Screening Log |  |
|  | Subject Identification Log (if applicable)\*Subject Screening Log may incorporate Subject Identification Log |  |
|  | Monitoring Visit Log (if applicable) |  |
|  | Staff Signature Log |  |
|  | Delegation of Tasks Log\*Staff Signature Log may incorporate Delegation of Task Log |  |
|  | Serious Adverse Event Log\*Location may be participant file |  |
|  | Adverse Event Log\*Location may be participant file |  |
|  | Concomitant Medication Log\*Location may be participant file |  |
|  | FDA Correspondence Tracking Log |  |
|  | Staff Training Log |  |
| **Regulatory Binder:** Curriculum Vitae and Medical License |
|  | Curriculum Vitae’s and Medical License’s\*For all individuals on the 1572\*\* CV’s signed/dated |  |
| **Regulatory Binder:** Laboratory |
|  | Laboratory Normal Values\*For all clinical investigation labs |  |
|  | Laboratory Director Curriculum Vitae and Medical License \*Not required but recommended\*\* CV signed/dated |  |
|  | Lab Certification – CLIA |  |
|  | Lab Certification – CAP\*Not required by recommended |  |
|  | In-house Urine Pregnancy Test Package Insert |  |
|  | In-house Urine Pregnancy Test – Lot #, Exp. Date(s) \*Log |  |
| **Regulatory Binder:** Reports |
|  | FDA Safety Reports Section\*Corresponding 1571 (if applicable) |  |
|  | FDA Annual Reports Section\*Corresponding 1571 (if applicable) |  |
|  | FDA Information Amendment(s) Section\*Corresponding 1571 (if applicable) |  |
|  | Monitoring Reports/DSMB Minutes Section |  |
| **Regulatory Binder:** Misc. Information Sections |
|  | Investigator Brochure Section\*Device Label or Package Insert may be acceptable |  |
|  | Protocol Section\*Match attachment in ERICA |  |
|  | Informed Consent Form Section\*Once approved place copy in Regulatory Binder |  |
|  | Questionnaires, Ads, Surveys Section\*Match attachment(s) in ERICA |  |
| **Regulatory Binder:** Drug Accountability  |
|  | Device Receiving/Shipment (Return) Log |  |
|  | Device Subject Dispensing Log |  |
| **Trial Document:** Protocol or policies/procedures document should contain the following sections, provide pg. # (template language available) |
|  | Annual Reports (if applicable) |  |
|  | Amendments: IRB and FDA |  |
|  | Adverse Event Reporting |  |
|  | Unexpected and Serious Adverse Event Reporting: IRB and FDA |  |
|  | Randomization: Procedure, Blinding, Breaking the Blind (if applicable) |  |
|  | Protocol Violations/Deviations: IRB and FDA |  |
|  | Record Keeping |  |
|  | Data, Safety, and Monitoring Oversight Committee (if applicable) |  |
|  | Multi-Site Study Locations (if applicable) |  |
| **Trial Document:** Informed Consent Form (should contain the following sections) |
|  | Device Charge |  |
|  | ClinicalTrials.gov Language |  |
|  | All Required Template Elements |  |
|  | Procedure/Study Visit List or Descriptions |  |
| **ERICA System:** Completed or uploaded in ERICA |
|  | COI Disclosure Completed |  |
|  | Protocol – Same as Regulatory Binder Version and Attached |  |
|  | Informed Consent Form Attached |  |
| **Source Documents/Participant Folder/Case Report Forms:** |
|  | Informed Consent Process Documentation or Checklist\*template available  |  |
|  | Eligibility Criteria (Enrollment Process)\*template available |  |
|  | Documents that will be used to record all observations and other data pertinent to the investigation on each individual administered the investigational device or employed as a control – Case Report Forms |  |
| **ClinicalTrials.gov:**  |
|  | ClinicalTrials.gov Record Created | Yes or No:  |
|  | ClinicalTrials.gov NCT # (if applicable) | NCT #: |
|  | ClinicalTrials.gov Record Released | Yes or No: |
|  | Responsible Part is the PI | Yes or No: |
| **uTRAC Application:** |
|  | Application Created | Yes or No: |
|  | Application in Active State | Yes or No: |
| **IDE Application:** Available if needed – always keep an exact copy for your records |
|  | Initial IDE Application Available | Yes or No: |
| **MISC:** Required for any NIH Trials |
|  | Good Clinical Practice (GCP) Training Records (every 3 years) | Yes or No: |
| **CMS Approval:** Centralized and/or Local MAC Review and Approval https://pulse.utah.edu/site/comser/clreco/DMC/ |
|  | Approval Letters | Yes or No: |
|  | Device Code Created | Yes or No: |

**Coordinator Comments:**

**Definition:**

**Sponsor-Investigator:** An individual who both initiates and conducts an investigation, under whose immediate direction the investigational drug/device is administered or dispensed (or used). The requirements applicable to a sponsor-investigator are both those applicable to an investigator and a sponsor.

*21 CFR 812.3(o), \*also referred to as investigator-initiated*

**Sponsor and Investigator Responsibilities:**

**Investigational Device Exemption (IDE):** <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812&showFR=1>

**Additional Responsibilities:**

**Protection of Human Subjects:** *21 CFR 50* <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1>

**Financial Disclosure by Clinical Investigators:** *21 CFR 54*

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=54&showFR=1>

**Current Good Manufacturing Practice Regulations and Investigational New Drugs:** *21 CFR 210*

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=210&showFR=1>

**Good Clinical Practice E6(R2):** <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r2-good-clinical-practice-integrated-addendum-ich-e6r1>

**Device Billing (CMS Requirements):**

<https://www.cms.gov/medicare/coverage/IDE/index.html>

<https://pulse.utah.edu/site/comser/clreco/DMC/>