Sponsor-Investigator/Investigator-Initiated Investigational Device Exemption (IDE) Checklist
Pre-IRB Approval Assessment

PI Name:

IRB #:

IDE #:

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 Teresa Stilley, teresa.stilley@hsc.utah.edu **48hrs prior to the scheduled assessment**. Feel free to contact Teresa Stilley with any questions during this process. If needed, templates (logs and language) may be available upon request.

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.

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/