The following includes sample language of an IRB Application for an FDA regulated clinical trial. The sample is provided solely for education purposes. It is not template language reviewed or endorsed by the IRB. There is no guarantee that use of the language or descriptions in this example will result in IRB approval. Each research proposal is unique with varying regulatory and ethical issues. Include only the descriptions that apply to your research and specify where italicized options are provided as examples. Do not include any described processes or procedures unless they apply and you are able with qualified staff, systems, or infrastructure to implement in the conduct of your research protocol.

TITLE: Sample Randomized, Placebo-Controlled Trial to assess the (safety/effectiveness/proof of concept) of a FDA-Regulated Product (drug*, device, biologic) Unapproved Use of an FDA-Approved Drug to (diagnose, cure, mitigate, treat, prevent) Condition/Disease**

A DRUG may be an:

- FDA approved drug,
- unapproved use of approved drug,
- investigational drug or biologic,
- other compound or product intended to affect structure or function of the body, or
- alternative medicine product such as dietary supplements, substances generally recognized as safe (GRAS) if in support of a health claim or when used to diagnose, cure, mitigate, treat or prevent disease, or e-cigarette if examining a potential therapeutic purpose.

A DEVICE may be a(an):

- component, part, accessory;
- assay, reagent;
- software or computer/phone application;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

RESEARCH DESCRIPTION

Background: Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study. For research involving investigational drugs, describe the previously conducted animal and human studies. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section. For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol. Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference in the applicable E-IRB "Study Drug" or "Study Device" section.

The condition of study is….

These are the *problems or limitations of knowledge or available therapies* to treat/diagnose/prevent the clinical condition.

This is what is known about the study intervention based on (prior lab, animal, human studies/clinical experience/existing literature). Include findings of laboratory and animal research if applicable.

Rational for study

Medical IRB Research Description

Note: *for FDA regulated studies, information must be attached that provides manufacturing, indications, prior investigations, contraindications, warnings, precautions, instructions, and safety information. This may be an investigator's brochure for investigational drugs; drug monograph, package insert or label; manufacturer's device manual, label for dietary supplements or other products.*

Objectives: List your research objectives. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section.

The purpose is to (*assess, determine, compare, evaluate*) the (*proof of concept, efficacy, effectiveness, safety*) and/or specific purpose (d*ose-response, superiority to placebo, effect of an intervention on disease incidence, disease severity, or health behavior*).

Study Design: Describe the study design (e.g., single/double blind, parallel, crossover, etc.). Indicate whether or not the subjects will receive placebo medication at some point in the research procedures. Also, indicate whether or not the subjects will be randomized in this study. You may reference sponsor's protocol pages and attach as an appendix in the E-IRB "Additional Information" section. (Including the study design table from a sponsor's protocol is helpful to IRB members.)

Community-Based Participatory Research: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.

Research Repositories: If the purpose of this submission is to establish a research repository describe the repository design and operating procedures. For relevant information to include, see question 22 of the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [PDF].

This trial is a (*randomized, placebo-controlled, double-blinded, double-dummy, parallel design, comparative-effectiveness, open-label, dose escalation, dose-ranging, adaptive, cluster randomized, group sequential, multi-regional, superiority or non-inferiority design).*

Study Population: Describe the characteristics of the subject population, such as anticipated number, age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized, adults with impaired consent capacity, prisoners or others who are likely to be vulnerable. If women or minorities are included, please address how the inclusion of women and members of minority groups and their subpopulations will help you meet your scientific objectives. Exclusion of these groups requires clear and compelling rationale that shows inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research.

Inclusion/Exclusion Criteria: *Identify specific characteristics, laboratory tests or clinical indicators that will be used as criteria for enrollment or exclusion. If reproductive status (e.g., pregnancy, lactation, reproductive potential) is an eligibility criterion, provide specific contraception requirements (e.g., licensed hormonal or barrier methods; negative urine pregnancy test).*

Medical IRB Research Description

Subject Recruitment Methods & Privacy: Describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects' identity and the subjects' information. Describe the setting in which an individual will be interacting with an investigator. If applicable, describe proposed outreach programs for recruiting women and minorities as participants in clinical research.

Please note: Based upon both legal and ethical concerns, the UK Medical Institutional Review Board (IRB) will not approve finder's fees for research studies.

Initial Internal Recruitment: Potential subjects will be identified at the investigator's (___) clinic visits and through prospective review of (___) clinic records for primary criteria. Patients who have a treatment relationship with the study investigators will be sent a recruitment letter inviting them to complete a pre-screening questionnaire online or by phone with the assistance of study personnel. The pre-screening questionnaire will be built and maintained in the secure REDCap web application (attach REDCap pre-screening questionnaire with introductory script/paragraph that may also be used as phone script).

Contingency Advertising: If recruitment goals are not met with internal efforts, the CCTS Recruitment/Marketing services will be used to develop advertising flyers and materials as described below.

Individuals who appear to qualify based on the pre-screening will be invited for a screening/enrollment visit at the (____). Individuals who do not meet pre-screening criteria will be asked if they want the investigator to retain their information in order to contact them with future study opportunities. Information for those that answer "yes" will be maintained in the REDCap application (not on the investigator's computer hard drive). Information for those that answer "no" will be deleted from the REDCap database.

Advertising: Specify if any advertising will be performed. If yes, please see "Advertisements - Application Instructions" for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. For additional details, see topic "Recruitment" or "Advertising" on ORI's IRB Survival Handbook web page for the PI Guide to Identification and Recruitment of Human Subjects for Research [D7.0000] document [PDF]. If you will be recruiting subjects via advertising at non-UK owned or operated sites, you should include a copy of written permission from that site to place the advertisement in their facilities.

Medical IRB Research Description

The advertising flyer (CCTS Study Flyer Template) will state that ad is for research; show affiliation with the University of Kentucky; list the purpose or the study; include primary criteria for eligibility; and instructions for interested patients to complete a pre-screening, REDCap questionnaire online or by phone as described above.

Hard copy and electronic versions of the flyer will be placed in public areas throughout the UK Medical Center including wall mounts, monitor screens, publication displays, and UK's recruitment websites (UKclinicalresearch.com, ResearchMatch.org, CenterWatch, CISCRP, Craig's List, Lexington.MD, UK, CCTS). The study may be promoted at CCTS outreach events or via email, listserves, newsletters, social media, including Facebook boost ads, UK_CCTS Facebook, UK_CCTS Twitter, UK and UKHC social media, and departmental/lab pages.

Informed Consent Process: Describe the consent/assent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent (Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application), steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, and if applicable who is authorized to provide permission or consent on behalf of the subject. Describe, if applicable, use of specific instruments or techniques to assess and confirm potential subjects' understanding of the nature of the elements of informed consent (i.e., research involving adult subjects with impaired consent capacity) and/or a description of other written materials that will be provided to participants or legally authorized representatives. If you have a script, please prepare it using the informed consent template as a guide, and submit it on a separate page. For additional information, see the "Informed Consent Standard Operating Procedures (SOPs)" [PDF].

Informed Consent for Research Involving Emancipated Individuals
If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **when preparing the IRB application and prior to submitting the application to the IRB**. Include legal counsel's recommendations (legal counsel's recommendations may be attached in the E-IRB "Additional Information" section as a separate document, if necessary). For a complete definition of emancipated minors, see the section on *Emancipated Individuals* in the Informed Consent SOP [PDF].

Informed Consent for Research Involving Non-English Speaking Subjects
If you are recruiting non-English speaking subjects, the method by which consent is obtained should be in language in which the subject is proficient. Describe the process for obtaining informed consent from prospective subjects in their respective language (or the legally authorized representative's respective language). In order to ensure that individuals are appropriately informed about the study when English is their second-language, describe a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or explain why an evaluation would not be necessary. For additional information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.

Research Repositories
If the purpose of this submission is to establish a research repository describe this in the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the "University of Kentucky Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future Use" [PDF].

Medical IRB Research Description

A copy of the informed consent document will be sent to potential subjects with the screening/enrollment appointment letter to allow ample time for review with family members. Designated study personnel will consent subjects at the beginning of the initial study/screening appointment. These staff members have been trained in all study procedures and are familiar with consenting for the procedures in the proposed study. Staff will begin the process with a brief description of research consent and how it is different from clinical care. A broad overview of the study will be presented and pending continued interest the staff member will conduct a detailed review with the potential subject and family (if available). One of the physician investigators will be available to answer any questions during the consent process. Interested subjects will be presented with a series of open-ended questions designed to assess understanding of study participation, as well as appreciation for voluntariness and right to withdraw. Staff will re-educate the subject to correct misperceptions, incomplete, or incorrect answers. The subject or his/her legally authorized representative will be asked to sign the informed consent/HIPAA Authorization Form. The authorized study personnel obtaining consent also signs the form. Subjects who consent to participate are provided with a signed copy of the consent document as well as contact cards for the investigators, study staff, and the Office of Research Integrity. A summary of the consent process will be documented in the medical record and will include a statement that written informed consent was obtained before the participant was enrolled. To continue the consent process throughout participation, all study visit source documents will include a reminder for staff to request and answer questions; provide new information that would influence ongoing participation; and reiterate that participation is voluntary.

Research Procedures: Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project.

Study procedures and their timing are summarized in the attached study schematic. Consent will be obtained at the initial screening visit. Consenting subjects will undergo screening procedures including medical and family history, vitals, full physical exam, chest x-ray (if not done for standard care in the past year) and laboratory tests. All screening evaluations will be completed and reviewed to confirm that potential subjects meet all eligibility criteria. The investigator will maintain a screening log to record details of all participants screened and to confirm eligibility or record reasons for screening failure, as applicable. Subjects who meet all study criteria will be randomized to the study interventions using (*random number table, computer program, voice-response*). Vital sign assessments will be measured in a semi-supine position after 5 minutes' rest include pulse rate, respiratory rate, and blood pressure. The 12-lead ECGs will be obtained using an ECG machine that automatically calculates the heart rate and wave intervals. Safety labs include hematology, clinical chemistry, routine urinalysis. The PI will review the safety lab reports, document this review, and record any clinically relevant changes occurring during the study. All laboratory tests with values considered clinically significant during participation in the study or within 30 days after the last dose of study intervention will be repeated until the values return to normal or baseline or are no longer considered clinically significant. If clinically significant abnormality is assessed to be related to the study intervention, the intervention will be discontinued either permanently or until values return to normal and the subject will be

medically managed. Specimens for study-specific lab tests, including (_____), will be shipped to (___) central lab for analysis. The study staff will be blinded to results of study-specific labs.

Data Collection: List the data on the application or attach a list of the data to be collected about or from each subject (e.g. interview script, survey tool, data collection form for existing data).

If the research includes survey or interview procedures, the questionnaire, interview questions or assessment scales should be included in the application (use attachment button below).

The data collection instrument(s) can be submitted with your application in draft form with the understanding that the final copy will be submitted to the IRB for approval prior to use (submit final version to the IRB for review as a modification request if initial IRB approval was issued while the data collection instrument was in draft form)

Data relating to the study will be recorded on each subject's (*electronic/printed*) case record stored (*in an encrypted database/spreadsheet/sponsor's electronic case report forms).* Data collection is the responsibility of the study personnel under the supervision of the PI. The PI is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.
The study coordinator in conjunction with the PI will be responsible for checking quality and adherence to the protocol. Any protocol violations will be reported to the PI and to the IRB. Study records will be made available for review by authorized institutional or regulatory agencies. Cumulative data will be analyzed and reported in a confidential manner; names or identifiers will not be associated with any published results.
Records and documents, including signed consent documents, pertaining to the conduct of this study will be retained by the investigator for a minimum of six years after study completion or longer depending on sponsor requirements.

Resources: Describe what resources/facilities are available to perform the research (i.e., staff, space, equipment). Such resources may include a) staffing and personnel, in terms of availability, number, expertise, and experience; b) psychological, social, or medical services, including counseling or social support services that may be required because of research participation; c) psychological, social, or medical monitoring, ancillary care, equipment needed to protect subjects; d) resources for subject communication, such as language translation services, and e) computer or other technological resources, mobile or otherwise, required or created during the conduct of the research. Please note: Some mobile apps may be considered mobile medical devices under FDA regulations (see FDA Guidance). Proximity or availability of other resources should also be taken into consideration, for example, the proximity of an emergency facility for care of subject injury, or availability of psychological support after participation.

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see ORI's Off-Site Research web page); supportive documentation can be attached in the E-IRB "Additional Information" section. Provide a written description of the role of the non-UK site(s) or non-UK personnel who will be participating in your research. The other site may need to complete its own IRB review, or a cooperative review arrangement may need to be established. Contact the Office of Research Integrity at (859) 257-9428 if you have questions about the participation of non-UK sites/personnel.

Medical IRB Research Description

If the University of Kentucky is the lead site in a multi-site study, or the UK investigator is the lead investigator, describe the plan for managing the reporting of unanticipated problems, noncompliance and submission of protocol modifications and interim results from the non-UK sites.

The proposed study procedures will be carried out by trained (….) personnel at the (*facility*). These facilities are all within (*specify distance*) proximity of the UK medical center allowing accessibility to emergency services. Institutional services that will be used for research include (*specify -Investigational Drug Service (IDS), Center for Clinical and Translational Science (CCTS) Bioinformatics/Clinic/Recruitment/Regulatory/Data Trust; Statistical Service; Counseling or Social Support Services*).
The study personnel will follow standard operating procedures for the receipt, labeling, control, storage, traceability, and accountability for the investigational medical device to prevent unauthorized access.

Research Materials, Records and Privacy: Identify the sources of research material obtained from individually identifiable living human subjects. Indicate what information (specimens, records, data, genetic information, etc.) will be recorded and whether use will be made of existing specimens, records or data. Explain why this information is needed to conduct the study.

Return of Research Results or Incidental Findings (if applicable):
If research has the potential to identify individual results or discover incidental findings that could affect the health of a subject, describe plans to assess, manage, and if applicable disclose findings with individual subjects or provide justification for not disclosing. For IRB expectations, refer to the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [PDF].

Existing clinic and hospital records will be accessed for recruitment and/or safety purposes by study personnel with treatment privileges and/or employed by the covered entity. The subject's medical record will be flagged upon enrollment so that internal providers are aware of subject's participation.

Investigational records from this study will be maintained in a confidential manner. Subjects will be assigned a unique identifier that will be used to label and identify subject-specific records. Consistent with IRB procedures, the study records will be maintained for six years after completion of study. Thereafter, paper and electronic records on the investigator's system that contain subject identifiers will be destroyed or erased using data overwriting software per University policy and sponsor directives. De-identified primary data will be archived and preserved for reproducibility. Subsequent analyzed aggregate data will be maintained to enable retrieval if requested during consideration for publication or per data sharing guidelines or per funding agency guidelines.

Medical IRB Research Description

Potential Risks: Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures subjects may encounter while in the study. Please describe any physical, psychological, social, legal or other risks and assess their likelihood and seriousness.

> The risks of procedures
> Risks from study intervention (*including incidence and severity*) include….
> Other social, legal, financial risks include…

Safety Precautions: Describe the procedures for protecting against or minimizing any potential risks, *including risks of breach of confidentiality or invasion of privacy*. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. If vulnerable populations other than adults with impaired consent capacity are to be recruited, describe additional safeguards for protecting the subjects' rights and welfare.

> The enrollment criteria are designed to exclude "at risk" subjects. To the extent possible, the protocol will allow use of existing standard-of-care procedures rather than repeating procedures for research. Results from (clinical assessments/safety labs, etc.) will be reviewed weekly by a physician investigator. Medical assessments and subject-reported events will be captured, recorded, and assessed by the PI or MD investigator. Events determined to be unanticipated problems will be promptly reported to the IRB according to UK IRB Policy timelines. Any clinically significant findings will be investigated (including repeat testing, discontinuation tests, withdraw) and treatment or referral will be provided as indicated. Subjects will be provided with a pager number to reach the study physician on call at any time, as well as a study information/contact card to present to emergency services or other healthcare providers.

Benefit vs. Risk: Describe potential benefits to the subject(s); include potential benefits to society and/or general knowledge to be gained. Describe why the risks to subjects are reasonable in relation to the anticipated benefit(s) to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If you are using vulnerable subjects (e.g., impaired consent capacity, pregnant women, etc…), justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them. For information about inclusion of certain vulnerable populations, see the IRB/ORI Standard Operating Procedure for Protection of Vulnerable Subjects [C3.0100] [PDF].

> Benefits of the current study include…. The potential outcomes of the present study may provide new approaches that will be the focus of future studies.

Available Alternative Treatment(s): Describe, if applicable, alternative treatments and procedures that might be advantageous to the subjects, should they choose not to participate in the study. This should include a discussion of the current standard of care treatment(s).

> Available alternative treatments include (*standard FDA-approved medications; other clinical trials; health behaviors such as diet, exercise, etc*.)

Medical IRB Research Description

Confidentiality: Specify where the data will be stored and how the researcher will protect the data with respect to privacy and confidentiality. Provide a time table for destroying the data and identify how they will be destroyed, or provide rationale for perpetual maintenance [Note: The investigator is responsible for retaining the signed consent and assent documents and IRB research records for at least six years after study closure as outlined in the Study Closure SOP [PDF]. If the research falls under the authority of FDA or other regulatory agency, the investigator is responsible for retaining the signed documents and IRB records for the period specified if longer than six years after completion of the study]. For multi-site studies, the PI consults the study sponsor regarding retention requirements, but must maintain records for a minimum of six years after study closure. If the retention requirements specified in other statutes or external agency's regulations are longer, the agency requirements will apply.].

Also, specify who will access the identified data, and why they need access. If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator. If applicable, describe procedures for sharing data with entities not affiliated with UK.

***Please note**:* The IRB expects researchers to access the minimal amount of identifiers to conduct the study and comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements. If data are going to be collected, transmitted, and/or stored electronically, for appropriate procedures please refer to the guidance document "Confidentiality and Data Security Guidelines for Electronic Data" [PDF].

Also please note that storage of data on cloud services may not be appropriate and is subject to applicable university policies regarding the use of cloud services. If deemed too sensitive or inappropriate to be stored or collected using cloud services, the IRB may require an alternate method of data storage in accordance with applicable university policies and the electronic data security guidance document referenced above.

If a research protocol involves the creation and/or use of a computer program or application, mobile or otherwise, please specify whether the program/application is being developed by a commercial software developer or the research team and provide any relevant information regarding the security and encryption standards used, how data is stored and/or transmitted to the research team, what information about the subjects the program/application will collect, etc. The IRB may require software programs created or used for research purposes be examined by a consultant with appropriate Internet technology expertise to ensure subject privacy and data are appropriate protected.

> **Confidentiality:** Records containing identifiable information will be securely maintained (locked files in a locked research office for paper and encrypted files on the investigator's medical center computer with firewall). A code key linking personal health information with subject study number will be secured in a locked cabinet in the office of the principle investigator. Study personnel authorized agents of the (*University/FDA/Regulatory or Funding Agency/Sponsor*) will have access to the identified data for the purpose of study conduct and oversight. The code key linking study number with personal health information will be destroyed following the required record retention period. All remaining data will be void of identifying patient information. Data will be analyzed and reported in a de-identified, aggregate form.

Does your research involve Non-English Speaking Subjects or Subjects from a Foreign Culture? Yes or No

Medical IRB Research Description

Payment: Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms and schedule of payment. (It is IRB policy that provision should be made for providing partial payment to subjects who withdraw before the completion of the research. Monetary payments should be prorated or paid in full.)

> Subjects will receive $25 per visit for taking part in this study to cover travel and time spent. If they do not finish the study, they will be paid for the part of the study that they completed.

Costs to Subjects: Describe any costs for care associated with research (including a breakdown of standard of care procedures versus research procedures), costs of test drugs or devices, and research procedure costs that are the subject's responsibility as a consequence of participating in the research. Describe any offer for reimbursement of costs by the sponsor for research related injury care.

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> There will be no costs to subjects for any research related activities. All research-related costs will be paid by (*grant; sponsor*). Standard of care procedures will be billed to the patient/insurer per regular procedures.

Data and Safety Monitoring: The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, clinical research, or NIH-funded/FDA-regulated clinical investigations.

If you are conducting greater than minimal risk research, clinical research, or your clinical investigation is NIH-funded/FDA-regulated, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.

If this is a *non-sponsored investigator-initiated* protocol considered greater than minimal risk research, clinical research, or your clinical investigation is FDA-regulated, *and* if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

> The (*Principal Investigator/University Data Monitoring Committee/Independent Data and Safety Monitoring Board)*) will be responsible for this study to review safety, progress, compliance, quality, and data-integrity on an ongoing basis. Reports of data monitoring activities will be reported to the IRB as they occur and in summary form at continuing review.

Subject Complaints: Describe procedures (other than information provided in consent document) for handling subject complaints or requests for information about the research. The procedures should offer a safe, confidential, and reliable channel for current, prospective, or past research subjects (or their designated representative) permitting them to discuss problems, concerns and questions, or obtain information.

> Subjects will be encouraged to address any complaint to any member of the study team including the PI. Subject complaints that are not resolved by research staff will be communicated to and addressed by the PI. If at any point the subject has concerns, complaints or experiences distress that compromises their care or willingness to participate in the study, they will be withdrawn and referred to standard care providers for follow-up. Subjects will be provided with the toll-free number to reach the Office of Research Integrity (ORI) for questions or concerns about the research or their rights as a subject.

: Medical IRB Research Description

Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture:

N/A

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?

N/A

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study
that:

1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

N/A

Medical IRB Research Description

Procedure	Screening (up to X days before Day 1)	Intervention Period [Days or Weeks, etc.]						Follow-up (X days after last dose)
		–1	1	3	7	8	12	
Informed consent	X							
Inclusion and exclusion criteria	X							[Recheck clinical status before randomization and/or 1st dose of study medication or device dispensation.]
Demography	X							
Full physical examination including height and weight	X							
Medical history (includes substance usage [and Family history]	X							Substances: [drugs, alcohol, tobacco, and caffeine]
Past and current medical conditions	X							
[Serum OR urine] pregnancy test (WOCBP only)	X							
[Hepatitis B and C screening]	X							
Laboratory assessments (safety labs)	X	X	X	X	X	X		
Study-specific lab draw		X		X		X		
12-lead ECG	X		X		X	X		
Chest x-ray (if none within past 12 months)								
Vital signs	X	X	X	X	X	X		
[Randomization] if applicable		X						
Study treatment		X	X	X	X	X		
Adverse Event (AE)review		X	←==========					
Serious AE/Unanticipated Problem (UP) review		X	←==========					X
Concomitant medication review		X	←==========					X

Principal Investigator:	**Date:**
Study Title: Sample Clinical intervention of a New Indication for an FDA Cleared Medical Device compared to a Standard Control in Humans	

Study Device Form

For studies:

- designed to determine the **safety or effectiveness of a medical device;** or
- **protocols using a Humanitarian Use Device (HUD);** or
- conducted under a **Treatment Investigational Device Exemption (IDE),**

please complete and attach this form under the Study Device Information section of your E-IRB application.
If your study involves multiple devices, complete applicable sections (and attach additional forms if needed) for each device being investigated.

Where instructions in this form indicate to attach additional materials, please use the "Protocol/Products Attachments" button under the *Additional Information/Materials* section of your E-IRB application to attach them.

SECTION A: Complete for EACH medical device tested in this study.

Include HUDs if applicable. Do not include devices used solely for medical care or to illicit a physiologic response where NO safety or effectiveness data will be collected on or about the device.

NAME OF DEVICE (*include generic and trade name if applicable*):	*** MANUFACTURER(S)** *(Indicate If device was developed by the investigator or other non-commercial entity):*	**ROUTE OF ADMINISTRATION:**	**DEVICE (S) APPROVAL STATUS:**	**Sponsor's Risk Determination**
SAMPLE Device	XYZ Manufacturer (labeling and instruction manual attached)	External use; Off-Label indication on ☐ Check if combination drug/device product	☐ FDA Approved/Cleared for Marketing ☐ FDA Approved Humanitarian Use Device (HUD)** ☑ FDA Approved but testing unapproved use ☐ Not FDA Approved/Cleared ☐ Unsure	☐ Significant Risk (SR) ☑ Nonsignificant Risk (NSR) ☐ Unsure

***Attach two copies of sponsor/manufacturer information (e.g., labeling, indications for use, prior investigations, contraindications, warnings, precautions, instructions, patient information packets, etc).**

**For Humanitarian Use Devices (HUD) attach manufacturer labeling or patient information packet (available from FDA HUD Listing). Unless data is being collected on an indication outside of the HUD labeling, *skip to Section C*.

Principal Investigator:	Date:
Study Title: Sample Clinical intervention of a New Indication for an FDA Cleared Medical Device compared to a Standard Control in Humans	

SECTION B: Applicability of Investigational Device Exemption (IDE) Regulatory Requirements.

Complete this section for research involving devices. Do not complete for HUDs used solely for clinical purposes.

Research testing the safety or effectiveness of a medical device must fit in ONE of the following three categories:

CATEGORY 1: STUDIES EXEMPT FROM IDE REQUIREMENTS - To be exempt from IDE requirements the study would need to meet one of the exemptions in the device regulations [21 CFR 812.2].
CATEGORY 2: NONSIGNIFICANT RISK (NSR) DEVICE STUDY - Conducted only under the purview of the IRB as an Abbreviated IDE. A formal IDE submission to FDA is NOT required [21 CFR 812].
CATEGORY 3: SIGNIFICANT RISK (SR) DEVICE STUDY - Conducted under a formal IDE submitted to and approved by FDA [21 CFR 812].

NOTE: If the device study does not meet one of the Category 1 exemptions, the convened IRB must review the sponsor or sponsor-investigator's SR or NSR determination and modify the determination if the IRB disagrees with the sponsor. Consultation with the FDA may be required at the discretion of the IRB. If FDA has already made an Exempt, SR, or NSR determination for the study, the agency's determination is final.

Definitions are included at the end of this form for reference. FDA contact information is available below.

Section B - CATEGORY 1: Study is Exempt from IDE Requirements

If you consider the study to be exempt from IDE requirements, indicate the applicable IDE exemption, (I, II, or III), and attach any supporting documentation from the FDA or the Sponsor.
Before checking an exemption, ensure the device meets all required criteria or conditions of the exemption.
If unsure, consult FDA regulations (21 CFR 812.2), links to additional guidance, or consult the FDA.

I. Study is EXEMPT because it meets all of the following criteria as an Approved Devices used in accord with Approved Labeling. In order to meet this exemption category, ALL of the following questions must be "true". If ANY of the following statements are "false", the study does not meet this exemption.

1. Device is FDA approved for marketing in the United States.

   ◉ True ○ False

2. The results of the investigation are NOT intended to be reported to FDA as a well-controlled study in support of a new indication for use or intended to be used to support any other significant change device labeling.

   ◉ True ○ False

3. The investigation is being used in accordance with the indications in the approved labeling and does NOT involve a new device indication such as a new population, condition, area of the body, or significant design change.

   ○ True ◉ False

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Section B - CATEGORY 1 (*continued*): Study is Exempt from IDE Requirements

II. Study is EXEMPT because it meets all applicable criteria for ONE of the following IDE Exemption Categories:

Each of the following exemption categories has specific conditions or criteria that must be met in order to qualify for exemption from IDE requirements. If the study meets ANY of the following categories, you are responsible for consulting FDA guidance and/or checking with FDA to confirm the study/device meets all specific criteria in order to be exempt from IDE requirements.

- ☐ Testing of an In Vitro Diagnostic device that is NON-invasive; does NOT require invasive procedure that presents risk; does NOT introduce energy into a subject; will NOT be used as a diagnostic without confirmation by another medically established procedure or product; and results from study device will NOT be used to make clinical decisions;
- ☐ Consumer preference testing of a device if the testing is NOT for the purpose of determining safety or effectiveness and does not put subjects at risk.
- ☐ Testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is NOT for the purpose of determining safety or effectiveness and does not put subjects at risk.
- ☐ Custom device intended for use by an individual patient and NOT for the purpose of determining safety or effectiveness (specific criteria must be met to qualify for exemption).
- ☐ Testing of off-the-shelf (OTS) software as part of an EXEMPT In Vitro Diagnostic device (see section 3.3 & 3.4 of FDA software guidance for specific criteria must be met to qualify for exemption).

III. Study is EXEMPT because the FDA or commercial sponsor has provided documentation indicating that IDE is not required. Attach applicable documentation.

If study met one of the IDE exemption categories above (I, II, or III), skip to Section C of this form (pg 4).

If the study does NOT meet one of the exemptions under Category 1, indicate if device(s) as used in this study meets:

Section B - **CATEGORY 2: Nonsignificant Risk (NSR) Device Study** (conducted under the purview of the IRB only; abbreviated IDE requirements apply)

OR

Section B - **CATEGORY 3: Significant Risk (SR) Device Study** (conducted under a formal IDE submitted to and approved by FDA; full IDE requirements apply)

Click links to view definitions at end of this document and/or consult FDA SR/NSR guidance for examples. Unless documentation of an SR/NSR determination by FDA is provided, the convened IRB will review and make their own SR/NSR determination. Consultation with the FDA may be required at the discretion of the IRB. FDA is the final arbitrator and their determination is final.

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Study Title: Sample Clinical intervention of a New Indication for an FDA Cleared Medical Device compared to a Standard Control in Humans	

☑ Section B - CATEGORY 2: Nonsignificant Risk (NSR) Device Study

While NSR device studies do NOT require an IDE submission to FDA, they are subject to "*abbreviated*" FDA regulatory requirements and sponsor responsibilities★★. Describe or attach documentation to justify NSR designation.

The attached manufacturing brochure describes the indications approved in the FDA clearance for marketing. The device is not invasive, implanted, present a potential for serious risk to health, safety, or welfare; nor is it used to sustain or support human life.
The medical device as used in this study does involve a new indication (new population, condition, area of the body, or significant design change); however, based on (clinical experience/attached literature), the indication would not result in serious risk to health, safety, or welfare.
The device is similar in function to the (___) device which is listed as an example of an NSR device in FDA's Significant Risk and Nonsignificant Risk Medical Device Studies Guidance (https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf)

☐ Section B - CATEGORY 3: Significant Risk Device (SR) Device Study

☐ Check if IDE has been submitted and is pending FDA review or 30-day clearance period

☐ Check if IDE is part of FDA's Expanded Access Program as a Compassionate or Treatment IDE

Attach one of the following to validate the IDE Number*:*

- Written communication from commercial sponsor printed with number
- Commercial sponsor protocol printed with number
- Written communication from FDA (required for investigator holding the IDE★★)

☐ Section B - Unsure

If unsure category that best fits the device(s) you propose to use in your research, consult the guidance links at the end of this form or contact the FDA for an Exempt, SR, or NSR determination.

★★**Sponsor-Investigator Training**: IRB policy requires completion of Sponsor-Investigator Good Clinical Practice Training for investigators who initiate a NSR device trial or hold an IDE (see the Research Description Section of the IRB Application).

FDA CONTACTS: Contact the IDE section of the Office of Device Evaluation (ODE) 301-796-5640 or 800-638-2041 cdrhide@fda.hhs.gov or CDRH Manufacturer's Assistance 800-638-2041, 301-796-7100, DSMICA@CDRH.FDA.GOV.

To obtain a written risk determination from FDA, submit correspondence labeled "Study Determination" in triplicate to USFDA, CDRH, Document Mail Center – IDE Document Mail Center WO66-G609, 10903 new Hampshire Ave., Silver Spring, MD 20993-0002. Content and submission information is available at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf (pg 20)

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Section C: Device Management, Accountability, Registration, Training, and Qualifications to Administer

(***MUST COMPLETE*** *– attach additional pages if contents exceed space provided in below text fields)*

NOTE: The IRB requires periodic quality improvement reviews (QIR) for investigational device accountability. If your protocol is selected for a device accountability QIR, you should expect an on-site evaluation of policies and procedure for storage, control, dispensing, accountability, and monitoring.

1. Describe how dispensing of the investigational device(s) will be controlled including policies and procedures for, control, dispensing, and accountability:

PI and study personnel will be responsible for the receipt (validation of lot, serial, model, unique identification numbers), logs, shipping records, and secure storage with access limited to study personnel. Upon receipt will will ensure the device(s) labeling clearly states "investigational use" and includes any applicable warnings or precautions. We will follow the manufacturer/sponsor's standard procedures to randomize, dispense, and document subject receipt of study device. Each subject will be dispensed either the standard or study device, labeled with his/her unique randomization number. Subjects will be educated regarding device use, precautions, potential adverse events. We will maintain accountability records, inventory management, and sponsor correspondence. The control and accountability records will be made available for monitoring by the sponsor representative. Devices returned from subjects will be recorded and returned to the sponsor along with unused inventory at the conclusion of the study. Accountability records from initial receipt to final disposition will be maintained in the regulatory files.

*The ORI QI Resources website provides a Device Accountability SOP template and sample study logs (See Investigational Device Accountability Log)

2. Indicate where the devices will be stored and how access to the device(s) will be limited to prevent unauthorized access (e.g., *secure, locked storage; signage designating device as HUD or investigational*):

The device will be stored separate from clinical inventory, in the Principal Investigator's research office. Access is limited to essential research personnel. The storage cabinet, shipping containers, and each individual device are clearly labeled as investigational with study protocol ID.

3. Indicate if specific qualifications or training is required for study personnel to use or administer the device, (The CITI Humanitarian Use Device Course* may be required at the discretion of the IRB for new HUD users):

Advanced training is not required to administer the device. Basic use instructions will be provided to the subjects. Use does not involve calibration, batteries, maintenance procedures or electrical safety.

*For information/access to the required HUD training, see the ORI mandatory training website.

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4. If the Principal Investigator (PI) or sub-investigator does NOT have training or experience related to the proposed study with this device, indicate plans to obtain or augment applicable qualifications or expertise:

The PI and study personnel have extensive experience using the device according to the FDA cleared and off-label indication in a clinical setting. Medical device incidents, including those resulting from malfunctions of the device, will be detected, documented, and reported to the sponsor throughout the study. All Unanticipated Adverse Device Events will be promptly reported to the UK IRB according to the IRB Policy on Unanticipated Problem and Safety Reporting (http://www.research.uky.edu/ori/SOPs_Policies/2-AE_policy.pdf).

5. For "applicable clinical trials" initiated after March 7, 2012, FDA regulations require the informed consent document to include a specific statement informing subjects about trial registration and availability of trial data on clinicaltrials.gov.

   If study is registered on clinicaltrials.gov, do all informed consent documents associated with the study include the specific statement?

   ◉ **Yes** ○ **No** ○ **N/A** (e.g., not an "applicable clinical trial")

Definitions

Medical Device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes (*Federal Food, Drug, and Cosmetic Act).*

Nonsignificant Risk device investigation is one that does not meet the definition for a significant risk study.

Significant Risk device study is defined [21 CFR 812.3(m)] as a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. *Note: A significant risk device study requires an Investigational Device Exemption (IDE) be approved by FDA.*

Humanitarian Use Device (HUD) [21 CFR 814] is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year. The statute and the implementing regulation (see 21 CFR 814.124(a)) require IRB review and approval before a HUD is used in a facility. For use of a HUD in *emergency, off-label/compassionate, and investigation situations* refer to the UK "Humanitarian Use Device SOP" [PDF] and the "IRB Summary Medical Devices: Humanitarian Use Devices" [PDF]. For more information on HUDs and Humanitarian Device Exemptions (HDE) Regulations see the FDA HDE Regulation Question and Answers guidance.

Treatment IDE [21 CFR 812.36] is a device that is not approved for marketing may be under clinical investigation for a serious or immediately life-threatening disease or condition in patients for whom no comparable or satisfactory alternative device or other therapy is available. During the clinical trial or prior to final action on the marketing application, it may be appropriate to use the device in the treatment of patients not in the trial under the provisions of the FDA Early Expanded Access program as a Treatment or Compassionate Use. See the UK Medical Device SOP [PDF] for guidance.

ADDITIONAL GUIDANCE MATERIALS:

FDA Frequently Asked Questions about Medical Devices (2006)

Significant Risk and Nonsignificant Risk Medical Device Studies (2006)

IDE Responsibilities for Sponsors and Investigators of SR and NSR Risk Device Studies

FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations (draft 2013)

CDRH Learn Online Presentations –Clinical Studies/IDE

Additional FDA resources including In-Vitro Devices & Mobile Medical Applications, etc.

Principal Investigator: **Date:**

Study Title: Sample Clinical intervention of a New Indication for an FDA Cleared Medical Device compared to a Standard Control in Humans

Study Drug Form

For studies designed to test:

- **a drug, biologic**; or
- other **compounds or products** intended to affect structure or function of the body, and/or
- **dietary supplements** used to diagnose, cure, mitigate, treat, or prevent disease,

please complete and attach this form under the Study Drug Information section of your E-IRB application. If your study involves multiple drugs, complete applicable sections (and attach additional forms if needed) for each drug being investigated.

Where instructions in this form indicate to attach additional materials (e.g., product information or FDA correspondence), please use the "Protocol/Products Attachments" button under the *Additional Information/Materials* section of your E-IRB application to attach them.

Section A: Complete for EACH drug, biologic, or compound tested in this study.

DRUG NAME *(include generic and trade name if applicable):*	**STUDY DOSE** *(indicate if study dose exceeds maximum approved dose or maximum dose used in prior studies):*	**DOES INVESTIGATIONAL PLAN PERMIT DOSE ADJUSTMENTS?**	**ROUTE OF ADMINISTRATION** *(e.g., oral, topical, etc.):*	**APPROVAL STATUS**
		◯ No ◯ Yes *If yes, describe or reference protocol.*	☐ Check if combination drug/device product	☐ FDA Approved or legally marketed product ☐ FDA Approved/ Unapproved use ☐ Not FDA Approved ☐ Unsure

Attach a copy of the investigator brochure, approved labeling, package insert, and/or drug monograph (e.g., Micromedix, PDR).

Principal Investigator: **Date:**

Study Title: Sample Clinical intervention of a New Indication for an FDA Cleared Medical Device compared to a Standard Control in Humans

Section B: Applicability of Investigational New Drug (IND) Regulatory Requirements

Under FDA regulations, research that involves use of a drug other than the use of a marketed drug in the course of medical practice, must have an IND, unless the study meets one of the exemptions from the IND requirement [21 CFR 312.2(b)].

Complete the following to document that the study is either:

1) Exempt from IND requirements, or

2) Subject to IND requirements and being conducted under a valid IND

Attach any applicable FDA correspondence.

To assist you in determining which category applies to your study, see FDA guidance for determining whether human research studies may be exempt from IND requirements or IND Exemptions for Studies of Lawfully Marketed Drugs or Biological Products for the Treatment of Cancer**.**

Consultation with the FDA may be required at the discretion of the IRB. FDA contact information is available below.

CATEGORY 1: STUDY IS EXEMPT FROM IND REQUIREMENTS

The following are categories of studies that may be "Exempt" from IND requirements. Specific criteria or conditions within each category must be met to qualify for exemption.

Indicate if the drug(s) used in this study meets any of the following IND Exemption categories and attach any available supporting documentation from the FDA or the Sponsor. **Specific criteria or conditions within each category must be met to qualify for exemption from IND requirements**. If unsure if a drug used in this study meets an exemption category, you are responsible for consulting category-specific guidance below or checking with the FDA in order to determine whether an IND is required.

I. Study involves an FDA Approved drug product and ALL of the following are true. If ANY of the following statements are "false", you are responsible for consulting FDA to determine whether an IND is or is not required.

1. (●) True ( ) False The drug is lawfully marketed in the United States.
2. (●) True ( ) False The results of the investigation are NOT intended to be reported to FDA as a well-controlled study in support of a new indication for use or intended to be used to support any other significant change in the labeling for the drug.
3. (●) True ( ) False The investigation is NOT intended to support a significant change in the advertising of a lawfully marketed prescription drug product.
4. ( ) True ( ) False The investigation does NOT involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product*

Principal Investigator: **Date:**

Study Title: Sample Clinical intervention of a New Indication for an FDA Cleared Medical Device compared to a Standard Control in Humans

******The study may involve an unapproved use as long as change does not significantly increase risk or decrease acceptability of risk. For guidance regarding FDA's interpretation of* ***dose, population, or route of administration changes that may significantly affect risk****, see the FDA Guidance regarding determining if research may be conducted without an IND [PDF] or FDA IND Guidance for Marketed Cancer Treatments [PDF].*

5. ◯ True ◯ False The research is conducted in compliance with IRB review (21 CFR 56), informed consent (21 CFR 50), and marketing and promotion limitations described in 21 CFR 312.7.

II. Other Potential Exemption Categories:

☐ Each of the following exemption categories has specific conditions or criteria that must be met in order to qualify for exemption from IND requirements. If the study meets any of the following exemption categories, you are responsible for consulting FDA guidance and/or checking with FDA to confirm the specific criteria are met in order to be exempt from IND requirements.

☐ Testing of select in vitro diagnostic biological products that meet the required conditions (see regulation for required conditions 21 CFR 312.2).

☐ Select Bioavailability or Bioequivalence Studies (see FDA guidance for dose limitations and required conditions).

☐ Select types of Cold Isotopes (see FDA guidance for types and required conditions).

☐ Dietary supplements, botanicals, or other substances designated as generally recognized as safe (GRAS) for use in food may be exempt from FDA IRB and IND regulations **if** study is intended only to evaluate effect on structure or function of the body. Studies designed to evaluate a supplement's ability to diagnose, cure, mitigate, treat or prevent disease are considered to be FDA regulated and are NOT exempt from IND submission requirements. (see FDA guidance for details). See FDA IND guidance for revised information on which supplement studies require an IND. Refer to FDA Guidance Structure/Function Claims, Small Entity Compliance Guide for examples of structure/function effects.

☐ Electronic nicotine delivery systems (e.g., e-cigarettes) research may not require an IND if testing does NOT involve a therapeutic purpose. A study designed only to evaluate an effect on structure or function in the body may be exempt from IND requirements. An IND would be required if the intent of the study was to evaluate a product's ability to diagnose, cure, mitigate, treat or prevent disease. If the study examines the product's ability to aid smoking cessation, cure nicotine addiction, prevent relapse, or mitigate withdrawal symptoms, the sponsor-investigator should submit an IND or consult with FDA regarding need for an IND. See FDA and NIH Guidance.

III. If available, attach correspondence from FDA or commercial sponsor indicating that IND is not indicated for this study.

Principal Investigator: **Date:**

Study Title: Sample Clinical intervention of a New Indication for an FDA Cleared Medical Device compared to a Standard Control in Humans

CATEGORY 2: STUDY IS SUBJECT TO IND REQUIREMENTS

Studies that do not meet an exempt category above require submission of an IND to FDA.

If study involves a drug product subject to IND requirements, indicate the status of the IND application and attach documentation as indicated.

☐ IND submitted and pending FDA approval or 30-day clearance period

☐ IND approved by FDA

Record IND number and IND holder on Study Device Section of E-IRB Application and attach one of the following documents to validate IND number:

- Written communication from commercial sponsor printed with number
- Commercial sponsor protocol printed with number
- Written communication from FDA (required for investigator holding the IND★★)

☑ IND not applicable (e.g., study involves drugs exempt from IND requirements).

☐ Confirmation obtained from FDA or commercial sponsor indicating that IND is not indicated for this study.

★★**Sponsor-Investigator Training**: IRB policy requires completion of Sponsor-Investigator Good Clinical Practice Training for investigators who hold an IND (see the Research Description Section of the IRB Application).

FDA Contact Information –Contact the Chief, Project Management Staff, in the review division for the applicable therapeutic area if unsure about exemption from IND requirements. Organizational charts and contact information is available at:

- DRUGS,
- CDRH Division of Drug Information: 888-463-6332, 301-796-3400, druginfo@fda.hhs.gov,
- BIOLOGICS 301-827-2000,
- CBER Manufacturer's Assistance 800-835-4709, 301-827-1800, Industry.Biologics@fda.hhs.gov

Section C: Study Drug Management Accountability, Registration, Training & Qualifications to Administer

[21 CFR 312.57]

(**MUST COMPLETE -** *attach additional pages if contents exceed space provided in below text fields*)

(MUST COMPLETE - attach additional pages if contents exceed space provided in below text fields)
Note: Inpatient studies are required by hospital policy PH08.04.025 to utilize the Investigational Drug Service (IDS) Room A03.101 UK Medical Center (859) 218-5562. Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

1. Describe how drug(s) will be handled including policies and procedures for receipt, storage, control, dispensing, and accountability:

Investigational Drug service (IDS) will be responsible for receipt, storage, control, dispensing, and accountability of study drug. IDS will follow the sponsors automated system for randomization and drug assignment and inventory. IDS will make accountability records available for review by monitor representatives of the sponsor.

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2. Describe any procedures in place to prevent drug dispensing and/or administration errors:

IDS handles dispensing, labeling, and packaging the study drug in containers clearly marked with the subject's unique study ID. Study personnel authorized to dispense study drug on the PI's task-delegation log, cross-check to ensure the identifiers on the dispensed study drug matches the subject's identifiers before disposing to the subject.

3. If the Principal Investigator (PI) or sub-investigator does NOT have training or experience related to the proposed study with this drug product, indicate plans to obtain or augment applicable qualifications or expertise:

Both the PI and sub-investigators responsible for research-related medical decisions, per the study task-delegation log, are licensed MDs specializing in the trial's therapeutic area. All have clinical experience with the standard treatments. The PI has received study-specific training at the sponsor's investigator meeting. Copies of the protocol and investigator's brochure have been provided to all sub-investigators. All additional study personnel will receive additional training and instruction from the sponsor at the site initiation visit scheduled (__).

4. For "applicable clinical trials" initiated after March 7, 2012, FDA regulations require the informed consent document to include a specific statement informing subjects about trial registration and availability of trial data on clinicaltrials.gov. If study is registered on clinicaltrials.gov, do all informed consent documents associated with the study include the specific statement?

(●) **Yes** ( ) **No** ( ) **N/A (e.g., not an "applicable clinical trial")**

Definitions and Additional Resources

Drug (Food Drug and Cosmetic Act) = "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . ." and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) may also be considered drugs within the meaning of the FD&C Act. It is important to note that the *drug* definition is not limited to compounds intended for therapeutic purpose but also includes compounds intended to affect structure or function of the body without regard to influence on a disease process. [Source 2010 FDA Investigational New Drug Applications (IND) Guidance]

FDA Regulations - 21 CFR 312 (drug) & 21 CFR 600 (biologics)

2013 FDA Guidance - Investigational New Drug Applications (INDs): Determining Whether Human Research can be Conducted Without an IND

2004 FDA Guidance on IND exemptions for marketed products in cancer treatment

FDA information for Sponsor-Investigator's submitting an IND

An Introduction to Investigational Drugs for non-research personnel

ICH Good Clinical Practice (GCP) Consolidated Guidance, 4.6 Investigational products

FDA Botanical Dietary Supplements FAQ & Botanical Drug Product Guidance

Additional FDA resources including alternative medicine products, inspections, etc.