Entities: (check all that apply) ☒**Cottage Health** ☒**SBCH** ☒**GVCH** ☒**SYVCH** ☒**PDL** ☒**GPC** ☒**CSC**			
Policy Title:	Investigator Responsibilities		
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Committee Approval:		**Committee Approval Dates:**	
VP Approval:	Richard Beswick, PhD, MBA	**VP Approval Date:**	08/2018
Departments Affected:	Cottage Health Research Institute, Institutional Review Board		

GOALS

To detail Cottage Health Institutional Review Board's (CH IRB) human subjects research requirements for investigators.

POLICY

In addition to information contained in CH IRB's policies, this policy is designed as a guideline to investigators regarding some of the basic requirements related to human subjects research.

DEFINITIONS

CH IRB: Cottage Health Institutional Review Board

CHRI: Cottage Health Research Institute

Clinical Research: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product/s, and/or to identify any adverse reactions to an investigational product/s, and/or to study absorption, distribution, metabolism, and excretion of an investigational product/s with the object of ascertaining its safety and/or efficacy. A specific clinical research project is referred to as a study.

CRC: The primary Clinical Research Coordinator acts as the point of contact for all study related matters, both from the Sponsor and from clinicians. The CRC will be familiar with the study requirements, relevant regulations and study documentation including the study protocol, CRFs and any other relevant study specific documentation.

Key Research Personnel: Principal Investigator, Sub-Investigator, Study Coordinator and any individual performing various tasks related to the conduct of human subjects research activities. Such involvement would include:

- Obtaining information about living individuals by intervening or interacting with them for research purposes;
- Obtaining identifiable private information about individuals for research purposes;
- Obtaining the voluntary informed consent of individuals to be subjects in research; and
- Studying, interpreting, or analyzing identifiable, private information or data for research purposes

Principal Investigator (PI): The person responsible for the conduct of a Clinical Research study at the study site. The Principal Investigator is the responsible leader of the team.

Regulatory Coordinator: The primary point of contact between the Sponsor and/or CRO and CH IRB. The Regulatory Coordinator's primary concerns are with regulatory documents and submissions to CH IRB.

Sponsor: An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a Clinical Research study.

PROCEDURES

1) General Requirement
The investigator is responsible for following the study plan outlined in the CH IRB application while adhering to the Individual Investigator Agreement and institutional and departmental policies.

2) Investigator Agreement
Researchers wishing to conduct research at a CH facility or wishing to use CH IRB, must first sign and return the Individual Investigator Agreement, attesting to having read all of the materials referenced in the Investigator Agreement. (Please refer to policy, *Federalwide Assurance and Individual Investigator Agreements,* for more information.)

3) IRB Approval of Research
Investigators may not use more than one IRB for approval, continuing review and amendments to any one given study. Each IRB has its own requests and requirements. Moreover, each IRB has specific consent form criteria. Use of more than one IRB could result in multiple active versions of the consent form (regulations stipulate only one current, IRB-approved version of the consent form may be in use at any given time).

Principal Investigators are responsible for securing CH IRB approval or a written waiver of oversight for research involving human subjects for any of the following studies conducted, in whole or in part, at a Cottage Health facility:

1. Studies conducted, supported, or otherwise subject to regulation by any Federal Department or Agency that takes appropriate administrative action to require IRB review.
2. Any clinical investigation involving a test article which must meet the requirements for prior submission to the Food and Drug Administration (FDA).
3. Procedures done within the context of a research study which would not ordinarily be done to meet the needs of the patient, including but not limited to the collection of identifiable private information or the collection of data through intervention or interaction with human subjects; the use of human organs, tissue, or body fluids of individually identifiable human subjects; or the graphic, written, or recorded information derived from individually identifiable human subjects.

4. Withholding medical treatment for the purpose of a study such as the use of a placebo. (This does not apply to cases covered by the Natural Death Act).

4) Human Subjects Research Education Requirements

CH IRB requires documentation of human subjects research training for all researchers and key research personnel for any project that involves human subjects (for both full board or expedited reviews). Key study personnel are those individuals involved with identifying, consenting, treating potential research participants, interacting with personally identifiable data, and/or those involved with applying to and interacting with CH IRB. **A research study will not receive final CH IRB approval until all key research study personnel have submitted documentation of human subjects research training.**

CH IRB provides training via the Collaborative Institutional Training Initiative (CITI) Human Subjects Research Training education program. Investigators are assigned specific training to best meet the needs of the type of research being conducted. For external investigators, training via the National Institutes of Health (NIH) Research Involving Human Subjects Training education program is also accepted.

Cottage Health Research Institute (CHRI) and CH IRB also provide on-going educational opportunities in the form of written materials, presentations, computer-based training modules, and quality assurance post approval reviews. (Please refer to policy, *CH IRB Education of Key Research Personnel,* for more information.)

5) Ongoing Communication with CH IRB, CH, and Participants

A. The use of investigational drugs shall be in accordance with applicable state and federal laws and regulations, and policies adopted by CH, CHRI, and the CH Pharmacy.
B. All changes which occur in the study must be submitted to CH IRB for review and approval prior to implementation. Investigators may not implement any protocol changes without prior CH IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects. Changes include all protocol amendments, revisions to the Investigator's Brochure, consent form documents, in key personnel, any new or updated patient facing materials, and any new or updated recruitment methods Investigators are required to notify CH IRB of any noteworthy events, activities, occurrences, or reports (regulatory or otherwise) that may take place during the course of a study. Reportable events, include, but are not limited to:

    1. Adverse events *(*see policy, *Adverse Event Reporting*, for more information*)*;
    2. Findings from sponsors, monitors, or other reviewers;
    3. Complaints or concerns from participants; and
    4. Any other unexpected problem or event that may occur.

D. It is the Principal Investigator's responsibility to do everything possible to eliminate any confusion, misinformation, stress, physical discomfort, or other harmful consequences the participant may have experienced as a result of his/her participation in the research.

6) Conflict of Interest

Investigators are obligated to inform CH IRB of any conflict of interest, real or perceived, pertaining to the research to be conducted. Various conflict of interest regulations exist, depending upon the funding source and whether or not the research involves an FDA-regulated agent. Applicable Financial Disclosure Statement(s) are included in each study's initial and continuing review. Conflict of interest must be disclosed on the participant's informed consent document if the value received from the sponsor exceeds a designated amount. (Please refer to

policies, *Managing Conflicts of Interest in Research* and/or *Financial Conflict of Interest in PHS Funded Research,* for more information.)

7) Participant Identification Cards

It is recommended that investigators involved in research studies providing ongoing drug treatment or the implantation of a medical device make available identification cards for research participants containing pertinent information regarding their enrollment in a research study. Participants are to be provided with an identification card at the time of enrollment and are to be instructed to show the card to other healthcare providers (i.e. other physicians caring for the patient) and upon admission to any hospital. The purpose of the card is to alert other individuals providing medical care to the patient of his/her participation in a research study.

1. Investigators may develop and supply their own identification cards, as long as they meet CH IRB approval.
2. Some sponsors provide their own patient identification cards for investigators to use. The investigator should provide CH IRB with the sponsor's identification card for review and approval as part of the CH IRB application.

8) Signed Consent

A copy of the signed and dated consent document, which includes the State of California Experimental Subject's Bill of Rights and the Authorization for Use or Disclosure of Health Information, shall be provided to the research participant or his/her legally authorized representative who signed the document on the participant's behalf. A copy of the signed consent form shall also be included in the patient's medical record at the time of enrollment onto the study.

A patient's enrollment in a research study shall be noted by way of a "flag" in the patient's electronic medical record at the time of study enrollment. Each time s/he is admitted to the hospital while the patient is still on study, the key study personnel will receive a notification to alert the research coordinator or the investigator/s of specific information (admission, discharge, or transfer) which may be important in the care or intervention of the research participant. (Please refer to policy, *Informed Consent Guidelines for Research*, for more information.)

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Superseded:			
Regulations/ Standards References:	21 CFR 54; 21 CFR 56; 42 CFR 50, Subpart f; 45 CGR 46; 45 CFR 94; CA Health & Safety Code, sections 24170-24179.5: *Protection of Human Subjects in Medical Experimentation Act.*		