Cottage Health
GOLETA VALLEY | SANTA BARBARA | SANTA YNEZ VALLEY

Entities: (check all that apply) ☒**Cottage Health** ☒**SBCH** ☒**GVCH** ☒**SYVCH** ☒**PDL** ☒**HBC**			
Policy Title:	Conduction of External Clinical Research		
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Owner Title:	VP, Research & CRO	**Owner Approval Date:**	12/2022
Committee Approval:		**Committee Approval Dates:**	
VP Approval:	Richard Beswick, PhD, MBA	**VP Approval Date:**	12/2022
Departments Affected:	Cottage Health Research Institute, Institutional Review Board		

GOAL

To establish guidelines for the conduction of Clinical Research by a Collaborating Independent Investigator or Collaborating Institutional Investigator ("external Research") within and outside of a Cottage Health facility.

POLICY

Institutions holding an Office for Human Research Protections (OHRP)-approved Federalwide Assurance (FWA) may extend a permissible mechanism for one or more research protocols – the applicability of its FWA to cover two types of collaborating investigators: Collaborating **Independent** Investigators and Collaborating **Institutional** Investigators.

As a general procedure, external research sites performing Greater Than Minimal Risk activities within a Cottage Health facility will require management by the Cottage Health Research Institute (CHRI). Conversely, external Research that includes Less Than Minimal Risk activities within a Cottage Health facility do not require management by CHRI. However, this type of research does require operational oversight by SBCH IRB.

External Research that includes Less Than Minimal Risk activities outside of a Cottage Health facility do not require management by CHRI but are welcome to utilize the services of the Santa Barbara Cottage Hospital Institutional Review Board (SBCH IRB) as the IRB of Record.

DEFINITIONS

Assured Institution: An institution with an accepted and approved FWA with OHRP. Employees and agents of the institution holding the FWA are covered whenever they are involved in the conduct of research covered by the FWA. All individuals performing institutionally designated activities and acting on behalf of the institution, or exercising institutional authority or responsibility are considered employees or agents of the institution.

SBCH IRB: Santa Barbara Cottage Hospital 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.

Collaborating Independent Investigator:

a) Not otherwise an employee or agent of the assured institution;
b) Conducting collaborative research activities outside the facilities of the **assured** institution; and
c) Not acting as an employee of **any** institution with respect to his or her involvement in the research being conducted by the assured institution.

Collaborating Institutional Investigator:

a) Not otherwise an employee or agent of the **assured** institution;
b) Conducting collaborative research activities outside the facilities of the **assured** institution;
c) Acting as an employee or agent of a **non-assured** institution with respect to his or her involvement in the research being conducted by the **assured** institution; and
d) Employed by, or acting as an agent of, a ***non-assured institution*** that does not routinely conduct human subjects research.

Engagement of an institution in research: In general, an institution is considered *engaged* in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. In applying this guidance, it is important to note that at least one institution must be determined to be engaged in any non-exempt human subjects research project that is conducted or supported by HHS (45 CFR 46.101(a)).

Expanded Access: Sometimes called “compassionate use”, expanded access is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

Federalwide Assurance (FWA): A documented commitment by an institution to comply with the requirements in 45 CFR 46. All institutions “engaged” in research are governed by the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects (45 CFR 46). Research that is conducted or supported by a federal department or agency must obtain an FWA that is accepted and approved by OHRP.

Greater Than Minimal Risk: the probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Individual Investigator Agreement (IIA): A written agreement between an institution and a collaborating investigator who will be engaged in the institution's non-exempt human subjects research. The IIA describes each party's responsibilities for research conduct and oversight.

Less Than Minimal Risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

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.

Sub-Investigator (Sub-I): any Key Research Personnel who plays a significant role in the conduct of the Clinical Research study.

PROCEDURE

1. **FWA Coverage**
    - **a.** Individual Investigator Agreements (IIA) will be completed, signed, and kept on file by SBCH IRB, for all collaborating investigators who request SBCH IRB as the IRB of record for their research.
    - **b.** The IIA is a co-signed agreement between the collaborating investigator and the Cottage Health Institutional Official, who is specifically named as such on the FWA.
    - **c.** The co-signed agreement binds the collaborating investigator to compliance with:
        - **i.** State and federal laws and regulations regarding research, including, but not limited to, the terms of Cottage Health's FWA;
        - **ii.** Cottage Health Institutional and CHRI policies and procedures; and
        - **iii.** SBCH IRB review and findings.
    - **d.** SBCH IRB executes an IIA with all collaborating investigators in order to provide them with regulatory instruction and to receive their assurance that they will conduct research in accordance with the laws, regulations and institutional and SBCH IRB policies.

2. **Types of External Research and Oversight Requirements**
    a. Greater Than Minimal Risk Activities to the Subject
        i. Type A: Greater Than Minimal Risk activities that occur within a Cottage Health Facility
            1. Oversight: Required to be managed by CHRI
            2. Example: Private medical corporation conducting sponsored clinical trials regardless of the nature of the procedure performed

        ii. Type B: Greater Than Minimal Risk activities that occur outside of a Cottage Health Facility
            1. Oversight: Not required to be managed by CHRI; SBCH IRB can serve as the IRB of Record
            2. Example: Expanded Access protocols conducted by a private or affiliated medical corporation

            Note: Other than Expanded Access, SBCH IRB cannot review Greater Than Minimal Research conducted outside of a Cottage Health facility.

b. Less Than Minimal Risk Activities to the Subject
    i. Type A: Less Than Minimal Risk activities that occur within a Cottage Health Facility
        1. Oversight: Not required to be managed by CHRI; operational oversight is required by SBCH IRB
        2. Example: Private of affiliated medical corporation conducting sponsored clinical trials with Less Than Minimal Risk activities occurring within a Cottage Health facility

    ii. Type B: Less Than Minimal Risk activities that occur outside of a Cottage Health Facility
        1. Oversight: Not required to be managed by CHRI; SBCH IRB can serve as the IRB of Record
        2. Example: Less Than Minimal Risk Research conducted outside of a Cottage Health facility by a private or affiliated medical corporation

External Research that requires CHRI management
It is the responsibility of CHRI to coordinate the use of hospital facilities and to determine costs and staffing needs required for the intervention. In addition, CHRI negotiates all contracts and billing associated with the Clinical Trial.

Therefore, regardless of whether or not SBCH IRB or another IRB is used, the investigator must contact CHRI as soon as possible in order to initiate the setup of the various operational requirements and/or to begin negotiation of the CTA. The investigator shall not circumvent CHRI responsibilities related to study start-up by coordinating procedures directly with hospital staff or specific departments.

Research that does not require CHRI management
The investigator is required to complete an SBCH IRB application. SBCH IRB will determine what type of application is appropriate for the proposed research. SBCH IRB will either serve as the IRB of Record for the study, or will waive purview, but maintain operational oversight.

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Key Words:	Research Engagement, External Clinical Research		
Related Policies:			
Previous Review Dates:		**Previous Revision Dates:**	
Superseded:	On-Site and Off-Site Research, Research Approved by Other IRBs		
Regulations/ Standards References:	This policy currently reflects: • Office of Human Research Protections (OHRP) Guidance on Engagement of Institutions in Human Subjects Research, October16, 2008.		