Entities: (check all that apply) ☒Cottage Health ☒SBCH ☒GVCH ☒SYVCH ☒PDL ☒GPC ☒CSC			
Policy Title:	Cottage Health Institutional Review Board		
Policy Number:	8013-SW01	**Original Policy Effective Date:**	06/1997
Last Review Date:	08/2018	**Last Revision Date:**	08/2018
Owner Title:	Executive Vice President & Chief Operating Officer Director, Acute Care Services	**Owner Approval Date:**	08/2018
Committee Approval:		**Committee Approval Dates:**	
VP Approval:	Steve Fellows, COO Ed Wroblewski, MD, CMO	**VP Approval Date:**	08/2018
Departments Affected:	Patient Care Areas		

GOALS

To establish guidelines for securing Cottage Health Institutional Review Board (CH IRB) acknowledgment and/or approval for individuals wishing to conduct research, research-related activities, and/or data / specimen collection activities involving a Cottage Health facility.

POLICY

Guidelines for conducting research at Cottage Health must be strictly followed in order to maintain compliance with state and federal regulations regarding research involving human subjects. CH IRB is an appropriately constituted group, and has an established Federalwide Assurance with the Federal Office of Human Research Protections (FWA00000147).

DEFINITIONS

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.

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research, obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information. Human subject research extends to specimens collected from a living individual. These specimens include blood, tissue, organs or organ parts, excreta, hair and nail clippings, and any other specimen collected from an individual. Human subject research further extends to all information about an individual, including that which may be obtained from a patient's medical record.

PROCEDURE

CH IRB as mandated by federal regulations, provides guidance and oversight of research conducted at a Cottage Health facility. As such, CH IRB is required by law to review all research conducted at CH, even when CH IRB purview responsibilities are relinquished to another institutional review board.

Various applicable research studies and/or related activities include:

1. Clinical trials using investigational drugs or devices;
2. Use of Humanitarian Use Devices;
3. Medical record reviews;
4. Access to, and collection of, patient database and/or registry information;
5. Quality assurance projects which fulfill certain criteria; and
6. Specimen and tissue analysis and/or tissue banking.

If ANY information is collected, compiled, and/or analyzed on a human being in any CH facility, and that information is to be shared with others outside the CH facility (presented, printed, published, or collected into a database), the CH IRB office should be contacted in order to classify the project (e.g. quality improvement, evaluation, Evidence Based Practice, research, etc.) and to determine the appropriate mechanism of approval / exemption to allow the project to proceed.

Projects may qualify for various review requirements. Some projects may be considered exempt from further CH IRB review. However, **it is the responsibility of CH IRB, and not the investigator to make the official determination.**

CH IRB approval must be granted before any part of a research study may commence. Retroactive CH IRB approval for projects that are already in progress or that have been completed is against federal regulations.

All individuals wishing to conduct research must first complete an application provided by CHRI. Upon contacting CHRI, the investigator will receive an application along with an IRB number.

After the completed application is received from the investigator, CHRI will determine what reviews the study will require. A study may receive up to four types of review.

1. All studies involving human subjects will require CH IRB review. For studies requiring Full Board CH IRB review, the investigator is required to present the study to CH IRB. The investigator is notified with the date and time for this presentation.
2. All studies conducted, in part or in whole, at a CH facility shall receive operational and financial review by CHRI to determine what services and personnel will be required of the CH facility, and to estimate the cost of the study to the CH facility.
3. All studies conducted, in part or in whole, at a CH facility receive budget and contractual review by CHRI to determine if the legal and financial requirements of the CH facility are met.
4. Studies may receive an additional scientific review upon request of CH IRB.

For more information regarding research or application requirements, contact CHRI.

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Key Words:	CH IRB, Research, Human Subjects Research, Data Collection, SpecimenCollection, Piloting, Exploring, Investigation, Regulations		
Related Policies:	8013-IRB01; 8013-IRB06; 8013-IRB11		
Previous Review Dates:	04/06, 10/08, 01/09, 08/11, 05/14, 12/14, 01/17	**Previous Revision Dates:**	06/07, 01/17
Superseded:			
Regulations/ Standards References:	21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812, 45 CFR 46		