**Children's Hospital and Health System, Inc.**
**Administrative Policy and Procedure**

This policy applies to the following entity(s):

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| ☒ Children's Hospital of Wisconsin | ☒ Children's Hospital of WI-Kenosha | ☒ Children's Hospital of WI-Fox Valley |
| ☐ Children's Medical Group | ☐ Children's Health Education Center | ☐ Seeger Health Resources |
| ☐ Children's Hospital Foundation | ☒ Surgicenter of Greater Milwaukee | ☒ Children's Research Institute |

# SUBJECT - Research: The Process of Conducting Research on Human Subjects at Children's Hospital of Wisconsin and Affiliates

## POLICY

Children's Hospital of Wisconsin (CHW) is committed to adhere to the Federal Guidelines for the Conduct of Research on Human Subjects. CHW has filed a Federal-Wide Assurance with the Department of Health and Human Services Office of Human Research Protections covering CHW main campus, CHW-Fox Valley, CHW-Kenosha, the Surgicenter of Greater Milwaukee and Children's Research Institute, CRI (the CHW Affiliates). The following policies and procedures pertain to the conduct of research at CHW affiliates. Please refer to related Human Research Review Board Policies and Procedures, HRRB Administrative Policies.

**DEFINITION of RESEARCH:**
*"A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Common Code, Section 46.102*

## CATEGORIES OF RESEARCH AND THE REVIEW PROCESS

(Refer to HRRB Policies and Procedures for definitions and examples of research categories)

**I. Exempt:**
1. Situations in which no subject identifying information has been recorded or can be linked to the subject.
2. Need approval only of the Chair of the Research and Publications Committee/Human Rights Review Board.

**II. Expedited:**
1. Research where the risk to the subjects is minimal or essentially non-existent.
2. Needs approval only of the Chair of the Research and Publications Committee.
3. Does not need to be reviewed by the Research and Publications Committee/Human Rights Review Board.
4. Requires submission of full protocol and Consent Form.

**Exempt and expedited research** will be reviewed and approved by the Chairperson or designee within 5 days of receiving the request. Unapproved protocols will be reviewed at the next meeting of the Research and Publications Committee/Human Rights Review Board.

**III.** **Full Review (involves risk to subjects):** All interventions that present risks to human study subjects, children and adults.

NOTE: The Chair of the Human Research Review Board according to federal policy determines the category of research.

## PROCEDURE

1. All research conducted in CHW Affiliates facilities that involve children, parents or staff must be reviewed and approved by the Human Research Review Board of the CHW Medical/Dental staff. The chair of the HRRB or his/her designee has the authority to grant permission for expedited and exempt research. Investigators conducting research without approval will be subject to disciplinary action, which may include suspension of Medical Staff privileges or termination of employment.

2. Only the following individuals may serve as the principal investigator in the conduct of clinical research at CHW Affiliates: CHW Affiliates Medical/Dental staff member in good standing, CHW Affiliates employee, or CRI Investigator. Students, residents, and fellows must have a CHW medical/dental staff member, CHHS employee, or CRI Investigator listed as a co-principal investigator or co-investigator on the study team. If a study requires patient care tests, procedures or medications and is conducted at a CHW Affiliates site, a member of the Medical/Dental Staff or employee of CHW Affiliates must serve as a principal investigator for the study. *Non-Medical/Dental staff members,* who are approved by Children's Research Institute, may independently serve as a principal investigator on studies that do not involve medical or surgical tests, procedures or medications.

3. Investigators planning research involving Children's Hospital and Health System (CHHS) employees as subjects must review the research with the Director of Human Resources in order to determine the appropriateness of research for the targeted employee group. Confidentiality and communication surrounding the research also will be reviewed. A letter of support from the Director of Human Resources is required.

4. In order to maintain the scientific integrity of the research and the rights of subjects, any potential conflict of interest for the principal investigator or member of the research team must be disclosed to the Human Research Review Board at the time of protocol submission. Conflict of interest includes, but is not limited to: partial ownership of a sponsoring company, stock in the company or financial profit by conducting the research. The Chair of the Research and Publications Committee has the right to request and review the contract between the Investigator and the sponsoring agency. (Please refer to HRRB Policy HRRB - Conflict of Interest Financial Disclosure.doc").

5. All Investigators and related research staff who are not CHW or Children's Hospital and Health System (CHHS) employees or members of the Medical/Dental Staff but are conducting clinical research with CHW patients and families must comply with the CHHS standards and

regulatory requirements for safety and health. (see Policy: Verification of Clinical Research Staff and Students.doc ). They may be required to complete a verification form.

6. Investigators must have written final approval from the Chair of the HRRB of CHW before beginning the study.

7. In many instances, the use of treatments, drugs and devices for research purposes may not be charged to third party payers. The Investigator is responsible for complying with all Medicare and Medicaid Policies regarding financial reimbursement for research related treatments, devices and drugs. Complex studies may require a formal coverage analysis to determine what services are covered and what services may not be billed to third party payers.

   Investigators are responsible for identifying in the HRRB registration form all hospital services that are not routine clinical services and non-therapeutic that will be required to perform the research study. All such services, including use of facilities, must be included in a study budget and paid for by the study sponsor or the investigator.

   All Investigators requiring hospital resources to conduct the research that will not be billed to insurance are to meet with the Respective Department Director(s)/Manager(s) to identify required services and determine the exact charges for those services. The investigator must consult with the CRI Finance Manager to complete the full budget for hospital services and obtain sign-off on the study budget that includes Hospital services.

8. Ancillary services will not set up methods and procedures which are not part of their existing line of services. If reference lab services are required, the investigator may send out those labs independently with no CHW Lab involvement or charges, or may send them out through the CHW Lab. CHW Lab will apply the standard mark up fee for send-outs and then apply the research discount when billing the research study.

   Pharmacy must review all drug studies. The Pharmacy Director will determine where study drugs may be stored within the hospital. Any investigators storing and dispensing study drugs outside of the CHW Pharmacy will comply with all applicable regulatory requirements.

9. Obtaining research consent and authorization: The principal or co-investigator is responsible for assuring that the on-going process of informed consent is done in accord with Federal Regulations (45 CFR 46. 116; 117 and 21 CFR 50.25, 50.27). In addition, the principal investigator is responsible for assuring confidentiality through compliance with the HIPAA Privacy Rule requirements for research.

10. In situations where an FDA approved device is being used as part of the study and there is no Hospital policy regarding the use of the device, the investigator must clearly describe, in the Protocol, the procedure for using the device.

11. If a CHW Affiliate is providing any service as part of the study protocol, or if any part of the study protocol is taking place in CHW Affiliates' clinical space, the study subject must be registered as a CHW Affiliate patient. This includes study subjects who are seen only for research purposes. Study subjects completing questionnaires or dropping off samples do not need to be registered.

12. Principal Investigators must keep signed consent forms and study records in a locked and secure site. Copies of signed consent forms must be given or sent to the family. A copy of the signed consent, assent (if applicable), and HIPAA Authorization must be placed in the study subject's medical record if they are registered as patients at CHW Affiliates.

13. Investigators are required to adhere to guidelines established by the Human Research Review Board of CHW regarding the submission of research protocols for approval, and the submission of Continuing Reviews. (See related HRRB Policies and Procedures HRRB - Continuing Review.doc ).

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Jon E. Vice, President CHHS, Inc.