

# GENESYS HEALTH SYSTEM – POLICY

## EXEMPT RESEARCH

The regulations do not specify who at an institution may determine that research is exempt under [45 CFR 46.101\(b\)](#). However, the United States Department of Health and Human Services Protection of Human Subjects (OHRP) recommends that, because of the potential for conflict of interest, investigators not be given the authority to make an independent determination that human subject's research is exempt. It is recommended, Institutions should implement exemption policies that most effectively address the local setting and programs of research. OHRP recognizes that this may result in a variety of configurations of exemption authority, any of which are acceptable assuming compliance with applicable regulations. OHRP notes that the Health & Human Services retains final authority as to whether a particular human subject's research study conducted or supported by HHS is exempt from the HHS regulations.

### **Genesys Health System Exempt Policy:**

IRB Chairman or his designee in consultation with the Director of Research and IRB Coordinator has the authority to make the determination if research meets the criteria to be considered "EXEMPT" from IRB review.

Sufficient information must be submitted to the IRB Chair for exempt consideration. Such as:

- IRB Genesys "Exempt" application
- Study Plan or Protocol
- Data collection instruments (if applicable)
- Grant/contract proposal (if applicable)
- GHS Departmental or Director approval where research will be conducted (i.e. Director of Nursing)
- Any additional information GHS staff or IRB Chair may request
- Consent form or Information Sheet (if applicable)
- Any applicable HIPAA forms
- Proposed advertisements
- Letters of support
- Conflict of Interest disclosure

**Exempt Research (45 CFR 46.101(b) - Categories** *GHS will not consider an EXEMPT category for research involving prisoners, children (minors under age 18) Pregnant Women or any other vulnerable populations.*

*Note: All Resident or Fellowship research projects will not be considered for "Exempt" consideration –Refer to: Medical Education Research Committee (MERC)*

According to the Federal Regulations, “Exempt” from IRB review, must meet one of the following six categories:

**The following categories are established by regulation as exempt research:**

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under #2, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. –  
**Note: To qualify for this exemption, the data, documents, records, or specimens must be in existence before the project begins. Additionally, under this exemption, an investigator (with proper authorization) may inspect identifiable records, but may only record information in a non-identifiable manner.**
5. Research and demonstration projects which are conducted by or subject to the approval of the federal government, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the federal government.

## **GHS EXEMPT Research Process**

- Submission of an “Exempt” application and all documents must be sent to the IRB Coordinator via electronic submission using “IRBnet.org”.
- The IRB Coordinator will forward all documentation to the IRB Chair and Director of Research.
- The Project Leader is responsible for responding to any of the IRB Chairman questions and issues in a timely manner.
- Once all information is received, the IRB Chairman determines whether the project meets the requirements for approval of exempt status.
- IRB Coordinator sends a written confirmation verifying the status of the research, if it meets the exempt criteria or should be forwarded for IRB review.
- If approved, the “Exempt” research will then be reported to the full IRB at the next convened meeting
- Records will be kept in the IRB Office – for a period of ten years as all other research records.

Also in consideration:

- Proposed changes to an exempt study, that could potentially affect the study’s exempt status, must be submitted to the IRB Office and IRB Chair review.
- If proposed research involves Protected Health Information (PHI), HIPAA regulations still apply, even if the GHS IRB Chairman has determined that the research is exempt.
- The IRB Chairman reserves the right to request a higher level of review at his discretion.
- The IRB Chair may contact the PI for any clarification needed and documents the issues discussed with the PI.

The categorization of human subject’s research as "exempt" from IRB review is intended to streamline IRB procedures with no diminution of protection for human subjects.