

Genesys Health System - Institutional Review Board Request for Exemption

Submit this form with any supporting documentation to the IRB via electronic submission at www.IRBnet.org – Call the IRB Office 810 606 7722 for any assistance or refer to the Genesys webpage –www.genesys.org - search “research” for additional instructions or forms.

Project Title: _____

Project Leader & Title: _____

List all Co-Leaders: _____

Dept/Address: _____

Phone: _____ EMAIL: _____

PLEASE NOTE: Federal regulations require IRB review of all human subjects' research. Some categories of research are difficult to discern as to whether they qualify as human subject “exempt” research. Therefore, the IRB has established policies and procedures and the following Exemption Form to assist in this determination -

A. Exempt Category Selection

According to FDA regulations, “Exempt” research must meet one of the following six categories:

YOU MUST “CHECK” ONE OR MORE OF THE FOLLOWING:

Category 1: 45 CFR 46.101(b) (1)

- EVALUATION/COMPARISON of Educational strategies, curricula or classroom management methods -** 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. This exemption category cannot be used for FDA regulated research. Will identifiers be retained?
- No Yes *If yes, describe the educational setting in which the research will be conducted.*

Category 2: 45 CFR 46.101(b) (2)

- EDUCATIONAL TESTS, SURVEYS, INTERVIEWS, OR OBSERVATIONS of Public Behavior** 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 human 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. This exemption category cannot be used for FDA regulated research. **Research that uses survey procedures, interview procedures, or observation of public behavior when the investigators participate in the activities being observed cannot be granted as “Exempt”.**

Category 3: 45 CFR 46.101(b) (3)

- Educational test, Surveys, Interviews, or Observations of Public Behavior - PUBLIC OFFICIALS OR CANDIDATES FOR PUBLIC OFFICE (not approvable under Category #2)** This study involves elected or appointed public officials or candidates for public office and the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter, Note: How the identifiable information will be maintained must be clear in the research plan. This exemption category cannot be used for FDA regulated research. Describe how subjects may be identified or are at risk, or state the federal statute that allows the confidentiality of the subject to be maintained throughout the research and thereafter.

Category 4: 45 CFR 46.101(b) (4) –

- COLLECTION OR STUDY OF EXISTING DATA – Documents, Recorded, Specimens**
Secondary data analysis - All data must be pre-existing at the start of this research project (retrospective data only). In the research plan, identify inclusion dates (a start date is not mandatory, but the end date must be earlier than the date this project is submitted for review).
Data is publicly available (identifiers may be retained and the research plan explains how they will be protected.) Or
Data will be recorded in such a way that individuals can not be identified directly or indirectly or through identifiers inked to the subject at any time during the study. (No identifiers within the research data files, medical records numbers, or other identifiers with a key.) This exemption category cannot be used for FDA regulated research.
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.

Category 5: 45 CFR 46.101(b) (5)

- RESEARCH & DEMONSTRATION PROJECTS – Federal department or agency research and demonstration projects for evaluation of public benefit/service programs.** Research and demonstration projects which are conducted by or subject to approval of Federal Departmental or Agency heads (such as the Secretary of HHS), 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; (iv) possible changes in methods or levels of payment for benefits or services under those programs. This exemption category cannot be used for FDA regulated research.

Proof of approval by Department/Agency Head is attached. Yes No

Note: This exemption applies to federally funded projects only and requires authorization or concurrence from the funding agency. Additionally, specific criteria must be satisfied to invoke this exemption. Also, this exemption category does not apply if there is a statutory requirement that this project be reviewed by an IRB or if the research involves physical invasion or intrusion upon the privacy of subjects.

Category 6: 45 CFR 46.101(b) (6) and 21 CFR 56.104(d)

- FOOD QUALITY EVALUATION & CONSUMER ACCEPTANCE STUDIES – (no additives or safety questions)**
Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome food, 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 FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

- **STOP** - If the project does not meet one of the above categories, submit your protocol using the “IRB Research Application” form found at www.genesys.org – search: IRB (Note: All resident or medical student research projects must use the IRB “MERC Research Application” and will not be considered for “exempt” consideration.)
- **STOP** - Projects/Research involving any vulnerable population such as: Children (18 & under), Prisoners, Pregnant Women or Special Needs population are not eligible for “exempt” consideration by GHS – Institutional Review Board.)
- **CONTINUE** to Section B – Page 3 – If this project does meet one of the six categories above.

B. Project/Study Information/Plan:

1. Give a brief synopsis of the project, specific aims or goals, including background information to understand the risk/benefits and the need for this project:
2. Describe the **subject population**/ type of data/specimens to be studied. Give ages of population (i.e.>18-<75)
3. What are the date parameters (start date and end date) of data extraction for this project?

C. Project Detail/Source of Data

1. Describe the plans for recruitment of subjects or data? How will you specifically obtain or collect the information needed for this project? (Will identifiable records, specimens or data be used?)
2. Describe how data will be kept private and stored.
4. List who will have access to this information:
5. Is there any "link" that could allow the data/specimen(s) to be re-identified?
 No Yes If "Yes" Explain
6. Does this study involve the collection of data in existing medical records or data often referred to as "on-the- shelf" public data?
 No Yes If "Yes" Explain
7. List all variables that will be collected to conduct this project:
OR attach - A data collection sheet or spreadsheet that contains all collected variables- (Diagnosis, demographics, lab values, etc)

D. Process & Procedures:

1. Describe the recruitment process, including any advertisements, to be used for this study. – Attach any advertisements – flyers, etc:
2. Will any procedures be done to subjects during this study?
3. Where exactly will this project be conducted? What office, campus or department?

E. Project Information:

1. Is this study affiliated with any other IRB-approved studies that you know of?
 No Yes
If "Yes", please list the IRB who reviewed the study and submit the IRB approval letter.

2. Is this proposal associated with a grant or contract?
 No Yes If yes, provide details:

3. Will this research project involve any other Genesys personnel or departments?
 No Yes If yes, list the department/person(s) who have given permission for the data to be collected:

4. Conflict of interest: Is there any way in which the investigator(s) might benefit by an individual participating in this project or completion of the project in general. (Do not describe academic recognition, such as publication, or salary commensurate with the grant/contract for the professional effort required for the conducting the project.)
 No Yes If yes, describe COI:

5. Attach any HIPAA training verification or NIH Human Protection Certificates for all participating investigators on this project. – Refer to Website: <http://phrp.nihtraining.com/users/login.php> - for training certificate –attach in IRBnet.org

If data will be shared outside of the Genesys Health System with any other organization or health agency – please submit a Data USE AGREEMENT -signed by both parties

Project Leader/Investigator Statement of Compliance:

I certify that all key project personnel, including myself have completed the NIH required training on human subject's protection.

I agree to a continuing exchange of information with the IRB including the requirements to obtain IRB approval before making any changes to the study that would change the category of exemption, change risk level, type of data collected or type of research. I would provide progress reports to the IRB, if requested. The data collected for this project will not be used for any other purposes not stated in this application.

I understand I may not proceed with the research without first receiving a written "Exempt" letter from the GHS Intuitional Review Board (IRB).

Signature of Project Leader/Investigator and Co-Investigators:

(Electronic signature in IRBnet.org is required)

Project Leader/Investigator -Signature

Title/Date

Co-Investigator - Signature

Title/Date

Co-Investigator - Signature

Title/Date

Office Use Only:

Date of Receipt: _____

Review Assignment: _____

Reviewer Comments:

Review Status: _____

IF "Exempt" status is approved – the IRB will retain a copy of the application and submitted attachments – This project will be "exempt" (not required) for IRB annual continued review.

An IRB letter will be sent – acknowledging the review of this project.

****No data may be collected until the IRB has approved this study/project in writing.**