

GENESYS REGIONAL MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

INSTRUCTIONS FOR COMPLETING THE NEW RESEARCH PROJECT APPLICATION

*Note: For Research guidance, forms, IRB meeting dates, and contact information refer to:
Genesys Website: www.genesys.org– search "research".
Details on how to electronically submit this research in IRBnet.org– are on the last page of this
application and the Genesys website.*

The investigator must complete the attached "New Project Application Form" and submit it electronically. Attach a complete copy of the study protocol, the informed consent and any other pertinent documents (*i.e., investigator's brochure, questionnaires, advertisements, letters to subjects, HIPAA or HIPAA Waiver etc.*) as indicated in the application. **The Principal Investigator and all Co-Investigators must electronically sign the application in IRBnet.org.** Templates of most forms can be found on the Genesys website and the IRBnet.org form library.

The application and all documents should be submitted via:

www.IRBnet.org
to Genesys Health System - Institutional Review Board
Located: Office of Research – Room 2442
Genesys Regional Medical Center
One Genesys Parkway
Grand Blanc, MI 48439
810 606 7722 – Office of Research

The IRB Board meets monthly. (2nd Wed of every month)
Applications must be received prior to deadline to be place on the next months agenda -
Refer to Genesys website for exact IRB dates and submission deadline dates.

Note: In the case of student or resident research, refer to the Medical Education Research Committee (**MERC**) **web page** (www.genesys.org – MERC) for application forms and submission instructions.

APPLICATION TO THE GENESYS REGIONAL MEDICAL CENTER INSTITUTIONAL REVIEW BOARD FOR APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS

NEW PROJECT

This application must be completed for all new projects submitted to the Institutional Review Board for review. **This form does not supersede or replace a formal written protocol.**

PROJECT IDENTIFICATION

1. Current date:
2. Title of Project:
3. Principal investigator's name, academic degree, title, department and affiliation
4. Principal investigator's address, telephone number, facsimile number and e-mail address:
5. Co-Investigators' names, academic degrees, titles and affiliations
6. Research coordinator(s) assigned to the project, address(s), and telephone number(s):
7. Sponsor (paying) of the project (if applicable):

INTRODUCTION:

1. Describe the study - the background and rationale:
If this is a clinical study, describe what phase - explain standard therapy and state how the research will alter standard therapy. If a new drug or medical device is involved, explain the results of previous animal/human studies, including the risks and benefits reported in the literature. If a questionnaire is to be used, include information supporting its validity and reliability.

2. What is the overall goal of this research? State specific aims, hypothesis, objectives, etc.
3. Exactly where will the study be conducted (e.g., inpatient unit, outpatient clinic, private office, GRMC, WFC or EFC)?

STUDY POPULATION:

1. Describe the subjects or groups that will comprise the study population and give the number of subjects to be included in each group. (Experimental, control, etc.)
For each group, please include information on **age range**; (i.e. 18-75) sex; ethnic background; health status (e.g., healthy subjects, patients with certain disorders, critically ill requiring intensive care, etc). How many subjects are expected to be enrolled at Genesys?
2. Outline the inclusion criteria for subjects in each group. (i.e. Subjects 18 and older)
3. Outline the exclusion criteria for subjects in each group.
4. Do subjects belong to any category involving special ethical or legal concerns?
(Children under the age of 18;(must have a child assent form) pregnant women; fetuses; mentally incompetent; questionable state of mental competence or consciousness; prisoners or other institutionalized persons; and others who are likely to be vulnerable. If yes, please indicate the categories involved, and for each special category, provide rationale and justification for inclusion).
5. Describe how subjects will be recruited and by whom for the study.
(For each subject group, please indicate method of how subjects are approached to be recruited, e.g., physician referral, clinics, hospitals, general public, etc. If media advertisements, posters, announcements, brochures, letters, etc., will be used for recruitment, text of such materials must be approved by the Institutional Review Board. ***Please append text of the advertisement, brochure, letter, etc.***)

6. Will any subject's recruitment incentives be offered by the study sponsor or investigator? If yes, describe the nature of the incentive and justification for offering the incentive.

METHODOLOGY:

1. In lay terms, provide a concise, but complete, summary of how you will collect information or do procedures?
Please summarize the protocol and include information on the type or nature of each procedure (e.g., labs, X-rays, catheterization, biopsy, duration of each procedure; how many times and at what intervals each procedure or medication will be carried out; any hospitalization; frequency and number of ambulatory clinic visits; arrangements for long-term follow-up, etc.)
2. Will any of the treatment, procedures or other interventions be carried out solely for the purposes of this research? If yes, please itemize.
3. Does the research treatment procedures or other interventions that the subjects will receive, differ from standard or customary health care?
If yes, for each procedure please provide the following information: Type or nature of the modifications; extent of the modification; any resulting increase in the length or frequency of the procedure; any increased risk due to the modification; and any increase in the number of clinic visits or duration of hospitalizations.
4. Will the investigators carry out the planned experiments, treatments, or interventions themselves?
If no, please indicate the arrangements for implementation by qualified personnel.
5. Do any of the procedures *require special* training or certification by the investigators or other personnel who will be performing the procedure? If yes, for each treatment or intervention that requires special skills (e.g. cancer chemotherapy, arterial cannulation, tissue biopsy), please identify the qualified investigator. If yes, please indicate the type of training and/or certification, and how this will be accomplished.

6. Will blood be removed from the subjects for the purposes of this research?
If yes, please indicate the following: Route and method of removal; frequency of removal; total volume to be removed in milliliters – (Teaspoons for Informed Consent) in the case of children under the age of 12, volume of blood to be removed - expressed as a percentage of total blood volume; and total time span involved.

7. Will any tissues or organs be removed from the subjects for the purposes of this research? If yes, please indicate the following: Type of tissue or organ; method of removal; size or weight to be removed; frequency of removal; whether the tissue is to be removed solely for research purposes; and whether the material to be removed may be used commercial purposes. (If commercial use is contemplated, indicate the nature of the disclosure to be made to the subjects).

8. Will the subjects complete any questionnaires or surveys?
If yes, please indicate the following: Number of questionnaires to be completed; type or nature of each questionnaire; total time required to complete the questionnaires; and frequency of their administration- who will collect or handle the questionnaires/surveys. ***Please append a copy of each questionnaire. – (Include what to do with questionnaire when finished on forms)***

9. Will records containing previously collected information or data on the subjects be reviewed? (i.e. old records) If yes, please indicate the types of records, time frame and the nature of the information or data to be reviewed.

DRUGS, BIOLOGICS AND/OR DEVICES TO BE STUDIED:

1. Will investigational drugs, biological materials or substances (including placebo) be administered to the subjects? If yes, for each investigational material ***please attach the "investigator's brochure" prepared by the manufacturer.*** It should include the following information: Name or code number: type or chemical nature; (supplier); dosage and frequency of use; route of administration or application; total duration of use; relevant Investigational New Drug (IND) exemption numbers; and status of approval or exemption by the US Food and Drug Administration (FDA).

2. Will commercially available drugs, biological materials or substances be administered or applied to the subjects for the purposes of this research?
If yes, for each test item please indicate the following: Generic and trade names; (supplier); dosage and frequency of use; route of administration or application; total duration of use; and whether it is to be used for a purpose which was not approved or authorized by the FDA.

3. Will the study involve the use of any investigational devices? If yes, for each device **please attach the "investigator's brochure" prepared by the manufacturer**, and provide the following information: Name or code number; type of device; (supplier); presumed function or action; dosage and frequency of use; route of application; total duration of use; relevant Investigational Device Exemption (IDE) numbers; and status of approval or exemption by the FDA, as indicated above for investigational drugs. Equipment must be inspected by the Biomedical Engineering Department prior to use.

4. Will commercially available devices be used? If yes, for each device please indicate the following: Trade names; supplier; function or action, frequency of use; route of administration or application; total duration of use; and whether it is to be used for a purpose which is not authorized by the FDA.

5. Will radioisotopes be administered to the subjects? If yes, for each radioactive compound please indicate the following: Chemical nature; amount of radioactivity and frequency to be administered; route of administration; and total duration of administration. Describe any special precautions that should be taken by health care personnel, patient and/or others with whom the patient may come in contact.

6. Will the subjects be exposed to radiation or any type of X-rays? If yes, please indicate the type of exposure and the total dosage to be delivered for the purposes of this research. Describe any special precautions that should be taken by health care personnel, patient and/or others with whom the patient may come in contact.

7. Will the subjects receive any organs, tissues or cells from other humans?
If yes, please specify the measures planned to prevent the transfer of undesirable elements. Specifically confirm that each human donor or the materials themselves will be tested for human immunodeficiency virus (HIV) and that no material from positive donors, or that no positive material will be used. (Please note that Michigan law requires a subject's prior written consent to non-anonymous HIV testing.)

RISKS AND BENEFITS OF THE RESEARCH

1. Does any aspect of this research impose upon the human subjects or the public any physical, psychological, social, legal or other potential risks or inconveniences? If yes, **please itemize** and describe each risk or inconvenience; assess seriousness of the risks; and assess the risks in comparison to any alternative treatments or interventions. The risks may include injury, discomfort, death, extension of hospital stay, deprivation of a treatment of established efficacy, breach of confidentiality, attracting attention of the public or news media, etc. (Be sure to include all risks in the Informed Consent)
2. What measures will be taken to minimize the potential risks or inconveniences? For each risk or inconvenience indicated above, please specify measures to be taken to protect the subjects or to minimize the impact or occurrence; of adverse effects; for monitoring the data to be collected to ensure the safety of subjects. If women of childbearing age are among the subjects, specific measures must be taken to avoid harm to fertility potential, undetected fetuses, or breast-fed children.
3. Describe the risks and inconveniences mentioned above in relation to the potential benefits. Please justify the risks in relation to the anticipated benefits to the subjects, and in relation to the importance of knowledge that may reasonably be expected to result from the research.

PROCEDURES FOR OBTAINING THE INFORMED CONSENT OF THE HUMAN SUBJECTS

1. How will informed consent of subjects be obtained and documented? Will anyone other than the investigators themselves obtain the informed consent? Where, when and who will obtain the informed consents and ensure that subjects will have time to consider participation. Please append the informed consent documents and/or the verbal text for oral consent. Note: All consents must be at an 8th grade reading level for the general public.
2. If subjects belong to a special or ethical category or have any legal concerns, what measures will be taken to ascertain that the informed consent will be adequate. (e.g., involvement of parents, legal guardians, or next of kin in the consent process; obtaining assent from children capable of assenting, other language issues etc.) Subjects under age 18, require a child assent form

COSTS OF THE RESEARCH

1. Will the subjects or their health insurance be charged for expenses in conjunction with any of the treatments, procedures, or tests that are to be performed solely for the purposes of this research? (e.g., extended use of the catheterization laboratory, increase in duration of hospitalization, additional office or clinic visits, additional labs, x-rays, tests etc.) If yes, please identify each cost item and amount – also disclose this information in the informed consent of this potential liability.
2. Will costs or expenses be incurred by Genesys Health System during this project? If yes, describe in detail.
3. Is there a source of funds to cover the costs of this research? If yes, provide information:
4. To what extent are funds, in whole or part, benefit Genesys for its participation in this project?

DATA MANAGEMENT

1. What measures will be taken to assure anonymity or confidentiality of the subjects' records and how will such records be secured? (e.g., HIPAA rules applied, collection of unidentifiable data or use of code numbers, master code sheet, kept in locked area. etc.)
2. Who will have access to the data and to the subjects' records? (e.g., representatives from the study sponsor, FDA, private monitoring firms, co-investigators, study coordinators, staff, etc. How are you meeting HIPAA requirements regarding protected health information?)
3. Please describe any efforts that have been made to coordinate this study within departments of Genesys. (e.g., contact with Research Office, coordinate laboratory, pharmacy, approval of department head; nursing, contact with Medical Staffing Office.)

4. Describe the plan for statistical analysis of the data. Include how the sample size was determined. (Refer to Office of Research for assistance, if needed)

Conflict of Interest

1. Does the Primary Investigator or Co-Investigator have any conflict of interest by participating in this research project? – If yes, describe in detail. (For a complete definition of COI concerning research – refer to the IRB website – at www.Genesys.org –research)

PROJECT SUMMARY

Please give a concise, but complete, summary of what you propose to do, what benefits you hope to derive and how do they outweigh the risks involved. For the benefit of the non-medical members of the Committee, please try to use as few technical and medical terms as possible.

See next page for instructions on how to submit this research to the IRB board.

How do I submit my research to the IRB for review using the www.IRBnet.org electronic system?

Print this page for reference

Step 1 **Connect** to the internet –www.IRBnet.org

Step 2 - **Log in** – First time users – click

- “NEW USER REGISTRATION,” complete the user profile
- Accept terms of IRBnet.org
- Select "Genesys Regional Medical Center" for location
- Create and Remember your password -
- Now, Go to your email - you will have received an email from IRBnet.org
- To **activate “click” the link** - then sign into IRBnet.org – then go to step # 3.

OR **if you already have registered** – just Log in “www.IRBnet.org” using your user name and password and select Study Manager to find your study.

Step 3 - Click - **CREATE NEW STUDY** and fill in the information - Title of study

Step 4 - Click - **STUDY DESIGNER** to attach IRB forms - All IRB –forms are located in form library drop down menu or on the Genesys website– –Select type of document – and browse & attach each form.

Need to stop and come back to this process?

Step 5 - Click - **SAVE** – You “Save” the forms to your computer - you may complete and edit at a later time.

Step 6 - Click - **SHARE THIS STUDY** – Select anyone who you would like to have access to your research – (i.e. Co-investigators) Note: (To “share” your research with someone, they must be registered in IRBnet.org)

Step 7 – To **SEND a quick e-MAIL** – Use only for a quick email to anyone on your research team, or IRB Coordinator- (This stage is optional.) This does not submit your research

Step 8 – **Mandatory** – **SIGN STUDY** – - Your “Electronic” signature is accepted as a legal signature – All Co-Investigators must “sign” the study.

Once all documents are attached –and the study is ready in final form -

Step 9 – **Mandatory** - Click – **SUBMIT THIS STUDY** – Select “Genesys IRB” in the “Search for Organization” drop menu -Be sure all documents are attached and in final version prior to submitting. – Once “SUBMIT” is clicked – the research cannot be edited unless – you contact the IRB Office to unlock the study.

YOU MADE IT!

Step 10 –Click – Study **OVERVIEW** – To review what has been sent – study will be under “Pending Review” status until the IRB votes at the next meeting

*An electronic IRB - email will be sent to your **email** notifying you of the IRB receiving your research study – A letter will be sent, after the meeting date – with the IRB decision.