

GENESYS REGIONAL MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD
MEDICAL EDUCATION RESEARCH COMMITTEE -**MERC**

INSTRUCTIONS FOR COMPLETING THE NEW PROJECT APPLICATION

Complete this form for all Genesys Residents, Interns or Medical Student research projects and electronically submit along with any other pertinent documents such as:

- Study protocol or this application
- Informed consent, if needed – Use Genesys template on IRB web page - forms
- Data collection tool –list all data items — Age, gender, vitals, etc.
- Attach copy of surveys
- Attach questionnaires
- Advertisements – flyer – cards – phone script, radio or TV script
- Any letters to subjects or physicians.
- HIPAA or HIPAA Waiver form must be submitted.
- Answer all questions - Indicate N/A for non-applicable

This application and all documents must be submitted electronically via www.IRBnet.org from any web-based computer. –Detailed instructions on how to submit your research are on the last page of this application. And can also be found on the IRB or MERC webpage: www.genesys.org -Search engine - “Research” –click on MERC FORMS

MANDATORY - Prior to submitting your research application for MERC review, your Program Director or Program Research Faculty must electronically sign this form or a scanned attached copy.

****Research applications must be received one week prior to the meeting date – Most MERC meetings are held on the 3rd Monday of each month at 8:15 AM - Room 3452Classroom**

Residents are encouraged to attend the MERC meeting to present their research study. You will be notified in writing of the board’s approval or other recommendations of the study. Dr. Mark Vogel, PhD., IRB & MERC Chairman can be reached at 810-715-4320

Remember you and all co-investigators must electronically sign in the IRBnet.org submission system.

NIH Human Protection training certificate is required with the submission of this application: Researchers must complete the following computer module training: <http://phrp.nihtraining.com/users/login.php>

To meet with Director of Research, Kim Barber, PhD. or the Research Pharmacist, please contact the Office of Research to schedule an appointment. 810 606 7722 –

Need help, Contact Candy Rainwater, CIM – IRB Administrative Coordinator 810 606 7722 ----- Fax number: 810-606-5882

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

STATEMENT OF INVESTIGATOR

Investigators are required to ensure that the protocol is conducted as written and that any changes in the protocol or consent are submitted to and approved by the Genesys Regional Medical Center Institutional Board prior to any research being conducted. Investigators must promptly submit any serious adverse reactions, unexpected events or deaths to the IRB Chairperson and appropriate regulatory agencies within 72 hours of occurrence.

**APPLICATION TO THE GENESYS REGIONAL MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD –MERC - Medical Education Research
Committee -- FOR CONSIDERATION OF APPROVAL OF RESEARCH
INVOLVING HUMAN SUBJECTS**

NEW PROJECT

This application must be completed for all new projects submitted to the Institutional Review Board –MERC 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, title, department and/or residency program.
4. Principal investigator's: Genesys Beeper/telephone number, fax number and e-mail address:
5. Co-Investigators' names, Beeper/telephone number, fax number and e-mail address - academic degrees, titles and affiliations
6. Corporate Sponsor of the project (if applicable):

INTRODUCTION:

1. Describe the study – the background and rationale
 - If this is a clinical study, 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.
 - If known, state the type of research – (i.e. research is prospective – plan to use an informed consent form or a retrospective – chart review.

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 clinics, private office GRMC, EFC, WFC) ?

STUDY POPULATION:

1. Describe the type or group of subjects that will comprise the study population.
 - Give the number of subjects to be included in each group. (Experimental, control, etc.) For each group, please include information on the **age range**; sex; ethnic background; health status (e.g., healthy subjects, patients with certain disorders, critically ill requiring intensive care, etc)
 - If you are not sure of the number of subjects needed – contact Dr. Kim Barber, Director of Research for assistance.

2. Outline the inclusion criteria for subjects in each group.
 - Include age range of subjects (i.e >18 yrs old)
Note: Research including children (ages 7 to <18) – will need a child assent form
 - Include what type of health conditions

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; 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. Is there the potential for the enrollment of prisoners in this study? If yes, special consideration is required by federal regulations.

6. Describe how subjects will be recruited for the study.
 - For each subject group, please indicate the source of the subjects, e.g., physician referral, clinics, hospitals, general public, etc., and the method of recruitment. If media advertisements, posters, announcements, brochures, letters, etc., will be used for recruitment, must be reviewed.
Please attach the advertisement, brochure, letter, etc.

7. Will any subject's recruitment incentives (such as money or gifts) be offered by a 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 briefly summarize the plan of this protocol
 - Include how information will be obtained, such as the type or nature of each procedure - how often will subjects be seen, what tests will need to be done. (e.g., labs, X-rays, biopsy, medication or placebo duration).

2. Will any of the research treatment procedures, test, procedures or other interventions be carried out solely for the purposes of this research?
 - If yes, please itemize

3. Does the research treatment or interventions differ from standard of care?

4. Will any of the investigators carry out the planned experiments, treatments, or interventions themselves?
 - If no, please indicate the arrangements for implementation by qualified personnel or indicate no experimental treatments will be conducted.

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, 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 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/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.
 - Give instructions - what to do with the questionnaire when completed
 - How will questionnaires be kept confidential
 - ***Please attach a copy of each questionnaire.***
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, and the nature of the information or data to be reviewed.
 - Also, list this information on the HIPAA or HIPAA waiver form

FOR DRUGS, BIOLOGICS AND/OR DEVICE RESEARCH:

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.*** The investigational material should include the following information: Name or code number; type or chemical nature; source (supplier); mechanism of action; 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; source (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 is not authorized by the FDA.

3. Will the study involve the use of any investigational devices?
 - If yes, for each device **please append the "investigator's brochure" prepared by the manufacturer,** and provide the following information: Name or code number; type of device; source (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; source (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, confidentiality, other potential risks or inconveniences?
 - If yes, **please itemize** and describe each risk or inconvenience; assess seriousness of the risks; (minimal to great risk) and assess the risks in comparison to any alternative treatments or interventions. (ie. Risk of confidentiality is minimal)
 - The risks may include injury, discomfort, death, extension of hospital stay, deprivation of a treatment of established efficacy, **confidentiality**, attracting attention of the public or news media, etc.

2. What measures will be taken to minimize the potential risks or inconveniences?
 - For each risk or inconvenience indicated under F-1, please specify measures to be taken to protect the subjects or to minimize the occurrence; provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the 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.
 - What provisions for monitoring the data are being done to ensure the safety and confidentiality of subjects.

3. Describe the risks and inconveniences mentioned above in relation to the potential benefits.
 - Please justify the risks versus the anticipated benefits to the subjects, and the importance of knowledge that may reasonably be expected to result from the research.

PROCEDURES FOR OBTAINING THE INFORMED CONSENT OF THE HUMAN SUBJECTS - (If unsure an "Informed Consent" form is required? - Contact the Office of Research for assistance.)

1. How will informed consent of subjects be obtained and documented? Will anyone other than the investigators obtain the informed consent?
 - Please attach the informed consent documents and/or the verbal text for oral consent.
 - Where, when and who will obtain the informed consents and ensure that subjects will have time to consider participation.

2. If subjects belong to a category of special, ethical or legal concern, what measures will be taken to ascertain that the informed consent will be adequate ethically and legally?
 - (e.g., involvement of parents, legal guardians, or next of kin in the consent process) Subjects under age 18, require a child asset form.

(Please note, Informed Consents must be at an 8th grade reading level, define all medical terms for the general public)

COSTS OF THE RESEARCH

1. Will the subjects or their health insurance be charged for any 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., additional labs, x-rays, increase in duration of hospitalization, additional office or clinic visits, additional tests, etc.)
 - If yes, please identify each cost item and amount, and justify the assignment of the burden. Please indicate whether the informed consent document discloses this potential liability.

2. Will there be costs in conducting this research?
 - If yes, describe in detail and what is the source of funds to cover the costs of this research?

3. What costs or expenses will be incurred by Genesys Health System during this project?
4. To what extent are funds, in whole or part, beneficial to Genesys for 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 & or use of code numbers, master code sheet, will data be locked/stored. 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, hospital staff, etc.)
3. Please describe any efforts that have been made to coordinate this study within Genesys staff/departments involved.
 - (e.g., contact with Research Office, Nursing Administration, Pharmacy, Laboratory, approval of department head; Physician Office, 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 Con-Investigators 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.)

PUBLICATION:

1. Any study proposing to test or compare a treatment (drug or device) or a procedure that is designed as a prospective clinical trial must be registered with the government at the website titled **ClinicalTrial.gov** in order to be considered for publication in any peer-reviewed scientific journal. This registration must occur before the first subject is enrolled in the study.
Do you intend to register your study proposal with ClinicalTrial.gov?
Yes No N/A

PROJECT SUMMARY

Please give a concise, but complete, brief summary of what you propose to do, what benefits you hope to derive and how do they outweigh the risks involved. What is the research goal or question you are trying to answer? For the benefit of the non-medical members of the Committee, please try to use as few technical and medical terms as possible.

Next page –see instructions for submitting to the Medical Education Research Committee MERC – for review.

MERC – Medical Education Research Committee

Resident-Student Research

How do I submit my research to the board for review?

Applications are submitted electronically at www.IRBnet.org – Follow Directions below

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”
- Remember your password –
- Go to your email address and **activate “click” the link** to get going in IRBnet.org –

OR If you already have registered - just - Log in “www.IRBnet.org” using your user name and password - if you have forgot your password –click – “forgot my password” it will be sent to your email.

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

Step 4 - Click - **STUDY DESIGNER** to attach IRB-MERC forms - All IRB –MERC forms are located in form library drop down menu or the genesys.org website for IRB - – Choose “MERC Application form” – fill-out the application and save to your computer then - just “Browse” and “Attach” forms -

Need to stop and come back to this process?

Step 5 - Click - **SAVE – You** can “Save” the forms to your computer. You may complete and edit at a later time. – When they are completed - just “Browse” and “Attach” forms -

Step 6 - Click - **SHARE THIS STUDY** – Select anyone who you would like to have access to your research. (ie. Program Director, Co- Investigators, Dr. Kim Barber, Director of Research and Candy Rainwater, IRB Coordinator - -Note: (To “share” your research, they must be registered in IRBnet.org)

Step 7 – Click “SEND” – Use only for a quick email or note to anyone on your research project or IRB Coordinator, - (This is optional) Note: This does not submit your research – see below – **SUBMIT THIS STUDY**.

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

Once all documents are attached and signed and in their final form – you are ready to “Submit”

****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 – IRB Coordinator – 606-77222

Step 10 – To review what was sent - Click – **Study OVERVIEW** – study will be under “Pending Review” status until the MERC votes at the next meeting. YOU MADE IT!

*An electronic IRB email will be sent to your **email** notifying you of the IRB decision and recommendations. A formal letter will then be sent or put in your mailbox at Genesys.