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Human Subject Protection Newsletter

Focus on excellence in Research at Mount Carmel

ADDRESSING THE NEEDS OF RESEARCHERS, COORDINATORS AND IRB MEMBERS, AND PLANTING THE SEEDS OF HUMAN SUBJECT COMPLIANCE.

Properly Registering Your Research Patient for Services/Procedures at a Mount Carmel Facility

By now all of you should have received your stack of green Research Registration Forms. These forms were sent to all Principal Investigators/Coordinators to use when registering their patients for research related services at a Mount Carmel facility.

Once a patient, who will be receiving services at a Mount Carmel facility (inpatient or outpatient), is enrolled into a study the Principal Investigator or his/her research coordinator **must** complete the Research Registration Form and instruct the patient to bring the form with them to the facility where the services will be provided. The research subject should present the form to the Registration Personnel at the time of registration.

The purpose of this form is to properly identify patients as research

patients, which in turn facilitates the billing process. This form must be completed each time a research patient comes to a Mount Carmel facility to receive any services related to the study, whether services are standard of care (but part of the research) or strictly for research purposes.

When scheduling your patient for services at Mount Carmel, tell the individual doing the scheduling that this patient is a research patient and indicate that they will be bringing their "Research Registration Form" with them at the time of their services.

You should keep a copy of the "Research Registration Form" for your records and fax a copy to the Human Subject Protection Office.



The use of this form will be built into the Human Subject Protection audit process. Prior to each audit, we will be asking you for a list of study patients. Their account will be accessed and a copy of the form must show up in Mount Carmel's electronic medical record.

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Investigators and other members of the study staff (study coordinators, research assistants) may **NOT** accept money or other bonuses as incentives to recruit or refer patients to research studies. "Kick backs" are against the law!

Compliance Corner

1. Q: What should a well-integrated human research program consist of?

A: A human subject protection program that is full integrated consists of IRB members, IRB administrative staff, investigators, community and subject input, institutional oversight, and good policies and procedures.

2. Q: What is the difference between "practice" and "research" or between "program evaluation" and "research"?

A: "Practice" consists of interventions designed to enhance the well-being of a patient or client. "Program Evaluation" consists of standard questionnaires or procedures designed to evaluate the effectiveness of standard, non-experimental programs. The purpose of program evaluations is for administrative review, not to answer a research question.

"Research" is designed to test hypotheses, permit conclusions to be drawn and thereby develop or contribute to generalize knowledge.

Research and practice can be carried out together, as can program evaluation and research. However, as a rule, if there is any element of human-subject research in an activity, then that activity should be described in a protocol and submitted to the IRB.

3. Q: What is the worst that can happen if you do not request IRB approval?

A: Aside from potential ethical implications for the subject and for the investigator, bypassing IRB review brings other risks:

Students

- Funding may be withheld: Many funding programs will not release funds without IRB approval.
- Dissertation or thesis work will not be accepted: Graduate students must present evidence of IRB approval for their projects involving human subjects. Thesis or dissertation work will not be accepted without it.
- Degrees may not be awarded for work based on non-IRB-reviewed projects. Articles may not be published: Many professional journals require evidence of IRB approval when considering articles for publication.

Faculty and Staff

- Funding may be withheld: Federal sponsors and many private sponsors require IRB approval as a condition of funding. Sponsors may postpone review of proposals for which IRB review is not complete/pending at the time of proposal submission. Some sponsors will not release funds for the investigator's use without IRB approval.
- Articles may not be published: Many professional journals require evidence of IRB approval when considering articles for publication.
- The Office for Human Research Protections and the Food & Drug Administration have the authority to halt all federally funded projects involving human subjects, should either of those federal agencies determine that Mount Carmel research activities are not appropriately reviewed.

4. Q: Can I still participate in a research project if I have financial or other connections to it?

A: A conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations, such that an independent observer might reasonably question whether the individual's professional actions or decisions are influenced by considerations of personal gain, financial or otherwise.

Investigators (or their family members) who have a substantial financial interest in the outcome of the research must, during the consent process, disclose the conflict to potential subjects. This includes providing a written disclosure on the consent form to explain and document the disclosure. The management plan for the conflict of interest will be noted by the IRB, which will determine whether it is appropriate, given the level of risk to subjects.

No IRB member may participate in the review of any study on which he or she is an investigator or co-investigator, or where a potential for conflict of interest exists.

**SMART
INVESTING IN
YOUR RESEARCH
TEAM!
Education at
citiprogram.org**



The CITI program is a web-based training program on issues relating to human subjects research. It is currently the educational standard for human subject research in hundreds of institutions nationwide, including Mount Carmel. It was developed by experts in the "IRB community" and contains modules on topics such as informed consent, vulnerable populations, ethical principals of research, and IRB regulations. Each module has a short quiz at the end to assess understanding. The CITI format is "open-book" – you may refer back to the text at any time while taking the quiz.

Properly Registering Your Research Patient for Services/Procedures at a Mount Carmel Facility

If the auditor finds that the "Research Registration Form" has not been utilized, your protocol is subject to suspension until the situation has been remedied.

It is Mount Carmel's policy that all clinical services rendered during the course of a research study are billed appropriately; either to the sponsor, a third party, or individual in compliance with applicable state and federal regulations.

To ensure that the study related procedures are billed appropriately, investigators and research teams are required to take the following steps for all outpatient services or ancillary testing incurred by a research protocol that are reimbursed by a research grant or contract.

Principal Investigator's Responsibility

It is the Principal Investigator's responsibility to complete the Research Registration Form and ensure that it is presented at the time of registration. It is also the Principal Investigator's responsibility to indicate that the patient is participating in a research study at the time of scheduling.

It is the Principal Investigator's responsibility to determine whether a service is billable to the subject or third party payer through a review of the study budget. These responsibilities may be delegated to a research coordinator or administrator; however the PI remains ultimately responsible. This information must be provided to the Human Subject Protection Office by providing a copy of the signed clinical trial agreement indicating the sponsor's obligations and a copy of the clinical trial budget. These items must be submitted at the time the research protocol is sent for IRB review.

Key Definitions

Billable Costs: These are costs incurred by the research protocol for services that are not being paid for by the research grant or contract. They are billable to the subject or third party payer. The research informed consent document must discuss that the subject and/or insurance will be responsible for these costs.

Non-Billable Costs: These are costs incurred by the research protocol for services that are being paid for by the research grant or contract. These costs are not billable to the subject or third party payer. The informed consent document should state that these services are being provided free of charge.

Date of Enrollment: A subject is considered enrolled in a research study the date that informed consent has been obtained.

NOTE:

1. Research procedures reimbursed by a research grant or

contract may not be billed to a subject and/or their insurance carrier.

2. It is the research team's responsibility to know which procedures and visits are required and covered by the research grant or contract. All clinical trial budgets must indicate which services are billable or non-billable.
3. It is the research team's responsibility to convey the information regarding covered and non-covered services to the Human Subject Protection Office by providing a copy of the signed clinical trial agreement (contract) and the study budget.

Outpatient Process for hospital or office based procedures:

1. The investigator/study coordinator identifies that the subject is appropriate for the study and obtains informed consent.
2. The investigator/study coordinator determines whether or not the procedures are being paid for by the grant or contract by reviewing the detailed study budget.
3. The investigator/study coordinator schedules the patient for services at Mount Carmel.
 - a. Complete the Research Registration Form.
 - b. Indicate when scheduling that patient is a research patient.
 - c. Keep a copy of the Research Registration Form for your records and give the "green" form to the patient. Fax a copy of the green form to the Human Subject Protection Office.

When Patient Arrives for Visit (date of service)

1. Patient will be registered following normal hospital procedures.
2. The investigator/study coordinator will provide the subject with a green "Research Registration Form" which the patient will present to the registrar.
3. Registration will enter all the patient's primary insurance information and assign plan code 049999. The Research Registration Form will be scanned into ChartMaxx.

Procedure for Inpatient Services including Hospital Admissions

It is the Principal Investigator's responsibility to:

- Notify admitting when a research patient has been admitted or when a patient becomes a research subject after admission.
- Determine what costs are billable to the subject or third party payer through a review of the study budget/contract, reason for hospitalization, and protocol requirements.

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These responsibilities may be delegated to a research coordinator or administrator; however the PI remains ultimately responsible.

Admitting Procedure:

1. The patient will be registered following normal hospital procedures. If this is a planned admission, Investigators **must** contact admitting prior to the day of admission.
2. The Investigator/study coordinator will provide admitting with the Research Registration Form and indicate that the patient is a research patient.
3. Admitting will record the following information to ensure research services are correctly billed: Enter all the patient's primary insurance information and assign plan code 049999.

Process for those hospitalized specifically for research:

1. The Investigator/study coordinator identifies that the patient is appropriate for the study and obtains informed consent.
2. The Investigator/study coordinator determines whether or not the hospitalization is being paid for by the grant or contract by reviewing the detailed study budget.
3. If the Investigator/study coordinator determines the hospitalization is required by protocol and covered by the study budget and therefore non-billable he/she **must notify admitting** either prior to hospitalization or if already hospitalized at the time the patient becomes a research subject (day they sign consent document); provide admitting with a Research Registration Form and provide a copy of the signed consent document for the medical record. Both the Research Registration Form and the consent document will be scanned into ChartMaxx.

Process for those hospitalized for medical necessity unrelated to research protocol (example: patient on a hip protocol admitted for heart problem):

1. The Investigator/study coordinator determines whether or not hospitalization is related to the protocol and covered by the grant, study budget or contract.
2. If the Investigator/study coordinator determines that hospitalization is related and covered by the grant, study budget or contract and is billable.
 - a. Notify admitting and provide a Research Registration Form and copy of the signed consent document.
3. If it is determined that the hospitalization is unrelated to the protocol and billable to the subject or third party payer, the investigator/ study coordinator

determines:

- a. If the patient has insurance and that proper authorization is obtained.
- b. If the patient lacks insurance or insurance won't cover the procedure/hospitalization ensure that the consent form advises the subject that the procedure or hospitalization is not covered.

Research Registration Forms may be obtained by calling the Human Subject Protection Office at 614-546-4325 or emailing irb@mchs.com.



The Human Subject Protection Office has a Billing and Budget Planner that can be utilized to:

- determine the budget for your research protocol,
- determine which services are billable to the patient or a third party payer, and
- determine which services are billable to the contract or study budget.

Call 614-546-4325 or email irb@mchs.com for a copy.

The Nonaffiliated IRB Member

According to 45 CFR 46, an IRB must have a diverse membership. This means that the IRB can not be comprised entirely of physicians, nurses, other scientists, non-scientific members or nonaffiliated members (community members). The nonaffiliated member may not be employed by the institution nor may any of their immediate family members. Ideally, a nonaffiliated member has no scientific knowledge so that he/she brings the true perspective of a volunteer research participant.

The nonaffiliated member contributes to the IRB review process:

- by giving consideration to the risks and benefits of a study. Using information provided by the medical experts, the community member can review the risk/benefit ratio and make determinations about the ethical appropriateness of the study.
- by looking at the inclusion/exclusion criteria. This criteria also weighs into the risk/benefit analysis and the community member can look at this criteria to determine if the inclusion/exclusion criteria has an ethical basis.
- by balancing the conversation. The unaffiliated community member is truly an independent member of the committee and can give an honest opinion without fear of reprisal.
- by giving consideration to the consent document. Perhaps the community member does not understand the consent documents and the words used within, the overall feel of the document, and the process used to obtain consent. If the community member is uncomfortable or does not understand, the same may be true for a research participant.

"It is essential that the research community come to value the ethics of research as central to the scientific process." – National Bioethics Advisory Commission

All the issues above are items included in the Belmont Report. Although the nonaffiliated member may not be as familiar with research or scientific procedures, he or she does provide perspectives essential to sound ethical reviews of protocols. With this in mind, the nonaffiliated member should be encouraged to voice his/her opinion and ask questions at IRB meetings. There have been suggestions that IRBs should have up to 25% of their membership as nonaffiliated members, the role of the nonaffiliated member and the importance of their contribution will only continue to grow.

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We're on the Web!

See us at: <http://www.mountcarmelhealth.com>
(Click on the icon "For Medical Professionals" on the right side of the screen. When the page opens click "Research" in the drop down menu on the left side of the screen.)