ADMINISTRATIVE POLICY MANUAL

Subject: Research Studies – Financial and Administrative Operations

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Approved by:	Vice President of Finance/CFO
Responsible Parties:	Senior Executive Director of Finance
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Policy:

(See last page for list of definitions used in this document)

The purpose of this policy and procedure is to ensure that there are proper oversight and monitoring procedures in place for the budgeting, billing, and financial reporting of clinical services provided under a clinical trial, and to ensure that funds received through the conduct of clinical research are administered in accordance with organizational policies, sponsor requirements and federal regulations.

This policy applies to all research studies conducted within Peninsula Regional Medical Center including to any human subjects' research involving research induced medical interventions and research-related patient charges generated from medical, behavioral, social science, outcomes and health services research, regardless of funding source (industry sponsor, federal grant, collaborative group, or other source). Specifically, this policy applies to any study that involves a non-FDA approved drug, device, or off-label use of an FDA-approved drug; a study involving FDA approved drugs; a study which involves a clinical intervention, such as a laboratory test or surgical procedure; and to any health services research performed at Peninsula Regional Medical Center (PRMC) including Peninsula Regional Medical Group (PRMG).

The Protocol Assessment Committee (PAC) has review and approval authority at PRMC. However, the final study protocol approval is obtained through the appropriate IRB (WIRB, JHH, or Copernicus). It is the responsibility of the principal investigator to carry out the approved studies as outlined by the clinical protocol.

In the state of Maryland, in accordance with rate regulation, we are required to bill and collect full charges in all regulated areas; we are not permitted to discount or accept less than charge in research studies. Some charges are not state rate regulated. These include physician services and off-site services; we are permitted to accept less than charge for these services. It is our policy to ensure that we cover our costs associated with research studies.

PRMC uses tax exempt bond finance borrowing as a way to finance buildings in order to provide mission driven services to our community. Bond finance regulations require that we use physical space that was built with tax exempt financing, and has not yet been fully repaid, almost exclusively for our non-profit use. Space used for research studies may be considered private use of bond space. Private use is limited to an extremely small percentage of total usage and must be tracked and reported to the Internal Revenue Service.

Department executive directors, directors, and their management team are responsible for knowing external regulations and internal policies related to research studies conducted in their areas and are responsible to conform to such regulations and policies.

Principal Investigators are responsible for:

- Ensuring appropriate billing according to payor coverage limitations and rules;
- Ensuring that the clinical trial agreement (CTA), or a detailed cost assignment/budget spreadsheet, clearly articulates which medical items/services required by the protocol are funded by the sponsor or grant;
- Ensuring the informed consent form (ICF) correctly reflects which services are routine care, which items/services the patient is financially responsible for, and which items are provided by the sponsor;
- Ensuring consistency between the ICF and the CTA/budget with regards to sponsor funding and patient financial responsibility (including responsibility for treatment for research-related injuries);
- Ensuring there are proper oversight and monitoring procedures in place within the research team for the billing of medical services provided under the clinical trial;
- Obtaining the permission from the fiscal intermediary/carrier to bill Medicare for device trials.

*If the principal investigator is not employed by PRMC, the director of the area serving the research patient is responsible to ensure all principal investigator responsibilities are completed.

The following financial guidelines must be met in order for a study to be considered for approval:

- Ability to determine Medicare and FDA status of the specific study
- Ability of the Principal Investigator for the study to identify patients having services at PRMC, at off-site locations, or within the PRMG
- Ability to differentiate charges billable to Medicare or other health insurance from charges to be paid for or billed to the study sponsor
- Evaluating the financial feasibility to determine the financial impact of the study:
  - Full charge payment for regulated services
  - Acceptable payment for unregulated services
  - Acceptable payments for professional fees, for employed and non-employed physician services
- Determine the potential revenue and potential expenses of the study
- Contract review and approval by the PRMC legal department
- Does not adversely affect our tax exempt bond financing for private use of space

Potential Conflict of Interest – if the physician performing the study related services is the Principal Investigator of the investigational research study; there may be the perception of a potential conflict of interest. The PAC will determine what study related consents and conflict of interest forms must be presented to the patient.

Procedure:

STUDY START-UP

When a study is under consideration and on track to present to the Protocol Assessment Committee (PAC) to request approval:

The research nurse or director of the appropriate department will submit the proposed budget for review and approval by the Senior Executive Director of Finance or designee. This will begin the review process to determine if the study meets financial guidelines for review by PAC and appropriate IRB (see Attachments I and II).

If the trial "qualifies, as per Attachment I or II," then PRMC may bill Medicare and other insurers for the "routine costs" of that trial which includes:

- Items and services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent);
- Items and services required solely for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications;
- Items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service; and,
- Routine care items/services.

The following are specifically excluded from the definition of "routine costs" and are not billable to Medicare:

- The investigational item or service itself, unless it is otherwise specifically covered by an NCD, a LCD or CED;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly computed tomography scans for a condition usually requiring only a single scan);
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial; and,
- Items and services provided solely to determine whether a potential participant meets the trial inclusion or exclusion criteria. The "standard-of-care" work-up to determine appropriate clinical management of the patient is, however, billable.

MEDICARE: See information Attachments I and II (it is the responsibility of all parties in this policy to ensure current Medicare guidelines are known and implemented).

OTHER THIRD PARTY PAYORS: Commercial health insurance plans and other government programs (such as Medicaid, etc.) also may have coverage limitations for clinical trial participants. Consult with plan contacts to determine coverage availability.

Clinical Trial Agreements (CTA):
Clinical Trial Agreements (CTAs) should explicitly detail the charges for a clinical research study and the extent to which the sponsor is funding patient clinical services, including payment for research-related injuries. If the CTA (including any attachments) does not specifically identify what services the sponsor is funding, the PI must have another document which clearly identifies what clinical services the sponsor is funding. All rates charged to sponsors in a study budget for medical items or services must meet HSCRC

criteria and be at fair market value. The rate can also reflect research personnel time in addition to the charge for the actual item/service if their time is not also a separate budget line item.

1. The Research Nurse responsible for the study or the Department Director sends the research contract to the legal office for review.
2. The legal office reviews and provides changes/feedback to the Research Nurse who is responsible for gaining agreement and new contract to support the legal requirements.
3. No study may begin without the legal office's approval of the study contract; the contract may not be fully approved until the budget is approved as per this next section of procedure. The legal office will advise the PAC chair of the approval or concerns.
4. Only the CEO or designee may approve a study contract (including JHHC affiliated contracts).
5. A copy of the final, executed clinical trial agreement must be provided to the Senior Executive Director of Finance before the study begins.

Study budget/financial assessment:

1. The Research Nurse responsible for the study or the Department Director sends the Managed Care Analyst the protocol and informed consent form (ICF).
2. The Managed Care Analyst (analyst) builds the schedule of assessments in Excel based on the information the sponsor has provided in the protocol.
3. The Analyst schedules a meeting with the Research Nurse to discuss each service that is needed for the study per patient. Prior to the meeting the Analyst obtains the current regulated charges for services that are included within the study such as labs, CT, MRI, Pathology, Nuclear Medicine, Radiology, etc.
4. The Research Nurse and the Analyst review each service. If it is a regulated service the Analyst obtains the PRMC charges. If it is an unregulated service, the Analyst uses historical studies as examples to determine the charge that will be incorporated into the budget. The unregulated charges involved are office visits and consultations, reviewing the patient's medical history, adverse event evaluations, etc.
    - Each service is determined to be within the normal routine patient care or outside the normal standard. If within the normal routine care, the charges associated with these services are the responsibility of the patient's health plan or the patient if uninsured. If outside the normal routine care, these service charges are the responsibility of the study sponsor.
5. Also included in the budget proposal are the non-patient related costs (IRB fees, Nurse Coordinator fee, storage fees, etc.).
6. The budget is then developed using the study schedule of services, charges, and other costs, and reviewed by the Research Nurse (or the Department Director if the Research Nurse is not an employee of PRMC), Senior Executive Director of Finance and the Analyst. After reviewing the budget proposal with the Senior Executive Director of Finance, the Analyst makes any necessary changes to the budget proposal.
7. The Analyst then forwards the budget proposal to the Research Nurse. The Research Nurse forwards the budget proposal with the CTA provided by the sponsor to be reviewed by the PRMC legal team. After it is reviewed by the PRMC legal team, the Research Nurse forwards it to the sponsor.
8. Note that in the case of a Johns Hopkins affiliated study, the budget is provided to PRMC from Johns Hopkins who develops a comprehensive budget for the total study which may cross multiple hospital sites. PRMC will accept or request budget changes; once agreement is met, JHHC will submit to the study sponsor.

STUDY INITIATION

1. The Research Nurse or the Department Director will alert the Senior Executive Director of Finance that a study has been opened for enrollment and will notify Finance each time a subject is enrolled including patient name, demographic information, study name, and expected PRMC services.
2. The Principal Investigator or his/her designee will maintain an active list of open studies and enrollees. This listing will be submitted monthly to the Managed Care Analyst using the attached template. (See Attachment III)
    - The Analyst will determine if the study list is in agreement with studies previously identified and approved and pose any questions/concerns back to the Department Director.
    - Once the monthly list is determined to be in agreement, the list is uploaded to the Finance iPortal site under Investigational Studies.
        - This provides study information to registration, billing, and accounting who all have responsibilities in the study process (no patient names are included in the summary report). Registration and billing responsibilities are within the hospital and also within the PRMG Medical Group.
3. This report will show the type of study, formal study name, physician investigator, expected number of patients, study start date and projected end date, whether the study includes services that are billable to the sponsor vs. the patient's health insurance, and who the study contact person is.
4. The Department Director is responsible for notifying (in writing) the Managed Care Analyst when a study is fully concluded. The analyst will move the study to a new file identified as "Completed Studies" indicating that no new patients will be enrolled and that existing patients have completed all services under the study with the exception of required continued reporting.
5. The Principle Investigator/Research Nurse and/or his or her designee is responsible for ensuring that for every patient receiving services at PRMC under a study, the "Research Order Form" form ID = NUR-656 is completed and becomes part of the medical record in the medical center imaging system (HPF) for each study service.
    - This form is the basis for the financial billing office to identify study patients and assures that the appropriate party is billed.
    - This form does not replace ANY other order form either electronic or paper -- all other physician order forms are required to meet clinical and other operational needs.
    - If the patient is presenting for outpatient testing, the patient should have the normal physician order plus the research order form. The Registrar will scan both into the HPF system (the Research Nurse is responsible for providing the patient with the research order form and instructing the patient to bring it to the medical center or service site on their date of service) or form may be faxed to the Patient Registration area at PRMC.
    - If the patient is an inpatient or observation patient, the Research Study Nurse is responsible for placing the research order form on the patient chart which will follow the record to be scanned into HPF upon patient's discharge.

Billing – Hospital Charges:

Once a participant enrolls in a clinical research study, his/her insurance may limit coverage for their medical care, even if that care would otherwise be considered routine care. Third-party payors, such as Medicare, Medicaid, other governmental programs and commercial insurance plans, have differing coverage limitations and

billing requirements. The research team and billing personnel must be aware of these limitations and requirements and take them into consideration when negotiating funding with sponsors and when ensuring compliant billing.

PRMC cannot bill a third-party payor or patient for the following:

- Items/services for which the sponsor has agreed to pay;
- Items/services provided free of charge by the sponsor to PRMC or affiliate, and;
- Any items which are promised for free in the Informed Consent Form.
- All applicable deductible, co-payment and co-insurance rules apply to services which are billable to a patient's insurance. These deductibles, co-payments, and co-insurance must be paid by the patient and cannot be waived, except in accordance with applicable policies pertaining to waivers for indigent patients.

The AR Resolution Supervisor or designee monitors an HPF work queue that shows every patient where a research order form exists in the HPF system (which by procedure should be every patient receiving service under a study).

- The Supervisor or designee reviews the services indicated on the order form in comparison to the study financial protocol and determines whether to bill the patient's health plan, the patient if uninsured, the study sponsor, or JHHC.
- If charges are able to be identified (by using the study protocol and/or budget) as "bill to sponsor or JHHC" those charges will be billed separately from the health insurance responsibility.
- If charges are unable to be identified, the full itemized bill will be sent to the Research Nurse and he/she will determine study related charges. The Research Nurse will return the bill indicating responsible party to the billing office. The billing office will then submit to the health insurance or study sponsor as appropriate and indicated.
- Any question remaining about who the responsible payment party is will be referred to the Director of Patient Financial Services or designee.
- The Principal Investigator and/or his or her designee will send a "no-pay" itemized bill for every study patient to the Research Nurse or Director responsible for the study. This will be used by that area to track services provided and to determine payments for non-employed physician professional fees as noted below.
- Study sponsor is responsible for all charges that Medicare deems not covered or not payable thru the Medicare program.

6. Billing – Professional Fees for PRMG

- The AR Resolution Supervisor or designee will send a copy of the research order form to the PRMG administrative office.
    - The PRMG Supervisor reviews the services indicated on the order form in comparison to the study financial protocol and determines whether to bill the patient's health plan or the study sponsor, or JHHC.
    - If charges are able to be identified as "bill to sponsor or JHHC" those charges will be billed separately from the health insurance responsibility.
    - If charges are unable to be identified, the bill will be sent to the Research Nurse and he/she will determine study related charges. The Research Nurse will return the bill indicating responsible party to the

billing office. The billing office will then submit to the health insurance or study sponsor as appropriate and indicated.
    - Any question remaining about who the responsible payment party is will be referred to the Director of Patient Financial Services or designee.
    - Study sponsor is responsible for all charges that Medicare deems not covered or not payable thru the Medicare program.

7. Payments
    - Payments from health plans including Medicare are made thru the normal payment process and on remittance advices.
    - Payments from the sponsor or from JHHC are received as miscellaneous/other operating income and may be received by the medical center Cashier or the department responsible for the study.
        - If received by the medical center Cashier, the cashier will deposit to Other Operating Income – Research Studies and send a copy to the Research Nurse responsible for the study or to the Department Director if the Research Nurse is not employed by PRMC.
    - If check is received by the Research Nurse or department, the check will be hand delivered to the medical center Cashier for deposit as above; the department will make a copy of the check for further processing.
    - Once the Research Nurse or Department Director receive a check either directly or from the medical center Cashier; they will determine if any amount is due to PRMG or any non-employed physician/ physician group for professional charges under the study (note: they will be able to refer to PRMC detail bills previously provided in order to make this determination). For example, a chest x-ray always requires professional reading and a payment for that reading will need to be made to the radiology group.
        - Any amount due to PRMG or another physician/physician group will require an AP check request form. The form must include a detailed description of what the payment is and a copy of the sponsor check.
        - The AP office will prepare and send the check directly to the physician as indicated on the pay to line of the request form. The general ledger account will equal the other operating – research study account as above.
        - If the patient is to be paid travel costs, the Research Nurse or Department Director will complete the required information/documents as per medical center policy on payment to research participants.
    - The medical center Cashier is responsible to determine if any account exists in the hospital or physician billing systems and for applying payment to these accounts under normal processing steps.

QUARTERLY DATA NEEDED ON THE RESEARCH STUDIES

1. At the conclusion of each quarter the department director responsible for the study with information provided by the Research Nurse must provide a list of patients that received services under a study (whether or not the services were chargeable) during the prior quarter. The report will include the patient's account number, study that the patient was in, date of service, and services provided. This report will be provided to the Managed Care Analyst who compiles and provides a quarterly and cumulative fiscal year-to-date report. (See Attachment IV)
    - Copies are distributed to the following for financial and account clearing purposes:

- AR Resolution Supervisor or designee – to review accounts for appropriate billing and payment posting
- PRMG Billing Manager or designee – to review accounts for appropriate billing and payment posting
- Hospital Cashier – to review accounts for appropriate payment posting
- Senior Executive Director of Finance – for reporting
- Director of Accounting – for 990 tax reporting
- Director of Budget, Cost, and Reimbursement – for HSCRC monitoring

ANNUAL REPORTING

The Director of Accounting is responsible for tracking the use of bond space as allowable or private use space and for reporting appropriately on the 990 tax form.

Data from the above reporting is used to determine whether the study has used space financed by a tax exempt bond. If such space has been used the percentage of such space to total space must be determined and reported on the 990 form. The finance department along with the legal department monitors the use of private use space and ensures the percentage is within the allowable corridor.

DEFINITIONS:

PI – is the Principal Investigator; this is the physician responsible for the study and was named by the sponsor. In the case of Johns Hopkins Health Care (JHHC) affiliated studies, there is a JHHC PI and a PRMC principle investigator.

Research Nurse – works closely with the physician investigator. If the Research Nurse is employed by PRMC, they have direct responsibilities to meet this administrative policy; if the Research Nurse is not employed by PRMC, they remain responsible to meet this administrative policy and the Department Director of the area where the research is being conducted is responsible to ensure that all research study nurse requirements are fulfilled.

Sponsor – is the entity that promotes the research study and engages the PI to conduct the study. The sponsor is generally responsible for payments to the PI and/or PRMC for study specific costs; the sponsor may be a pharmaceutical company, a device company, a cancer cooperative group, or other entity engaging studies for clinical research.

Clinical Trial Agreement (CTA) – is an agreement between the organization and an industry sponsor.

Coverage with Evidence Development (CED) – A National Coverage Decision (NCD) which first requires development and capture of additional patient data to supplement standard claims data in order to obtain Medicare coverage of the item or service.

Informed Consent Form (ICF) – The consent document which a participant signs prior to being enrolled in a clinical trial.

Investigational Device Exemption (IDE) – Issued by the FDA, it allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a premarket approval application or a premarket notification (510(k)) submission to FDA.

Approved by:

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Bruce Ritchie
Vice President of Finance/CFO

Attachment I

(It is the responsibility of all parties under this policy to know and implement changes to Medicare regulations) – This attachment is informational only.

MEDICARE REIMBURSEMENT FOR RESEARCH (Other than IDE device trials):
This section applies to all research studies other than device trials with a Category A or B IDE. Medicare coverage rules for devices with an IDE are explained in the following section. The Medicare program under a NCD and other regulations issued by the CMS covers the "routine costs" of "qualifying clinical trials." Even if a trial does not "qualify," Medicare will still pay for routine care services and any reasonable and necessary items and services used to diagnose and treat complications arising from participation in the study. Even if the only items/services in a trial which are not funded by the sponsor are routine care services, PIs must still analyze whether the trial "qualifies" for coverage due to special coding requirements. In addition to determining whether the trial qualifies, each PI is also responsible for determining which medical services fall within CMS's definition of "routine costs."

In order to be considered a qualifying trial, it must meet all of the following criteria:

- Evaluates a Medicare Benefit – The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g. physician's services, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).

- Has a Therapeutic Intent – The trial must have a therapeutic intent (i.e., the trial must, to some extent, assess the effect of the intervention on patient outcome). Trials that are conducted exclusively to test toxicity or disease pathophysiology are not covered under Medicare's policy.

- Enrolls Diagnosed Beneficiaries – Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

- Deemed Trials – Under the NCD, trials must have certain desirable characteristics. At present, trials which fall under one of the following are "deemed" to have these characteristics:
    - Funded or supported by centers of cooperative groups that are funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), Department of Defense (DOD), and Department of Veterans Affairs (VA);
    - Conducted under an investigational new drug application (IND) reviewed by the Food and Drug Administration (FDA); or,
    - Drug trials that are exempt from having an IND under 21CFR312.2(b)(1)

Attachment II

(It is the responsibility of all parties under this policy to know and implement changes to Medicare regulations) – This attachment is informational only.

MEDICARE REIMBURSEMENT FOR IDE-DEVICE TRIALS:
The extent to which Medicare covers items, services, or the investigational device involved in a device trial depends on the category of the device. For trials involving a device with an IDE from the FDA, however, it is required that the PI submits a request to the local Medicare fiscal intermediary/carrier requesting coverage prior to billing for anything related to the trial. If the PI does not submit a request, then the organization cannot bill for any items or services required by the protocol.

For Category A devices: These are experimental investigational devices for which the initial questions of safety and effectiveness of the device have not been proven (FDA Class III). For these trials, the organization cannot bill Medicare for the device itself, but may be able to bill for services related to the use of the device if the devise is used to diagnose, monitor or treat an "immediately life threatening disease or condition." The types of services which may be billed are the same as "routine costs" discussed above for drug trials. CMS defines "immediately life threatening disease or condition" as "a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment."

For Category B devices: Non-experimental investigational devices for which the initial questions of safety and effectiveness have already been proven even though the device may not yet be approved by the FDA (FDA Class I and II). In these cases, the device itself may be billable, in addition to services incident to its use, taking into consideration factors such as medical necessity, frequency, acceptable medical standards and appropriate setting.

MEDICARE DOCUMENTATION REQUIREMENTS:
The trial name, name of sponsor, and the sponsor-assigned protocol number must be documented in the patient's medical record and must be provided if requested for a medical review. A copy of the participant's ICF must also be made available if requested for medical review.

MEDICARE MANAGED CARE PLANS:
Payment for routine care clinical trial services furnished as part of a "qualified" trial to beneficiaries enrolled in Medicare managed care plans will be made on a fee-for-service basis by the Medicare contractors that process fee-for-service claims. The same coverage rules apply to these plans. The payment amounts will be based on the applicable Medicare fee schedules for such services.

Claims related to IDE trials (Category A and Category B) and claims for routine care services related to "non-qualifying" clinical trials are to be submitted to the Medicare Advantage plan for prior approval to determine if they are covered.