MONTEFIORE MEDICAL CENTER
ADMINISTRATIVE POLICY AND PROCEDURE

SUBJECT: RESEARCH BILLING POLICY

NUMBER: JF17.1

OWNER: FINANCE

EFFECTIVE DATE: 07/2017

REVISED DATE: SUPERSEDES:

07/2017

CROSS REFERENCE: Administrative Policy and Procedure JM03.1 Devices, Medical, Use when not approved by the FDA for General Marketing

Policy:

Montefiore Medical Center seeks to comply consistently and fully with all laws, regulations and contractual obligations pertaining to the billing of research-related charges for patients covered by Medicare, Medicaid and other third party payors. Laws and regulations include: Medicare, Medicaid and state insurance laws addressing coverage and payment for clinical services. Contractual obligations include: obligations under contracts with the sponsor of the clinical research and contracts with third party payors. The goal of this policy is to ensure appropriate billing of all research-related charges for services provided at Montefiore.

Scope:

This policy applies to all human subject research conducted in whole or in part at Montefiore. All principal investigators and hospital staff involved in conducting human subjects research, providing care to research patients or billing for services provided to research patients must comply with this policy. This policy applies to clinical trial services billed by Montefiore and to professional services billed by principal investigators to third party payors or patients.

All patients enrolled in a trial meeting the requirements (investigational trials and those observational trials having charges that are billed back to the study/sponsor) to be available in EPIC, the Electronic Medical Record System (EMR) are required to be enrolled in the study under their actual name and current demographic information. Aliases will not be used for study patients in Epic.

I. ALLOCATION OF RESPONSIBILITY

Accountability for compliance rests primarily with the Principal Investigator conducting the research for the following:

1. Identification of Covered Services. The Principal Investigator must review the clinical protocol, applying the coverage principles described below to clinical trials, in order to determine which services would be covered by third party payors Medicare, Medicaid or commercial payors and which services are not.
2. **Coverage of Costs.** The Principal Investigator must ensure that all services that cannot be billed to third party payors are covered by the research sponsor or funding agency and that the clinical trial agreement clearly identifies the services paid by the sponsor or funding agency.

3. **Implementation.** The Principal Investigator must ensure that: (1) Upon IRB approval, all research protocol information is recorded in the Velos Clinical Trial Management System (CTMS) and that protocol activation is documented in Velos as soon as a study is activated. (2) All clinical trial participants are recorded in the Velos system immediately upon signing of the informed consent. (3) The appropriate patient status for each study (e.g. “Informed Consent Signed”, “Screening”, “Enrolled”, “Active on Treatment”, “Off Study”, etc.) has been documented in Velos and appears in EPIC when the patient is scheduled for any research visit. (4) Dedicated internal accounts are established for services that cannot be billed to third party payors; and (5) Services that cannot be billed to third party payors are identified.

Research involving health care services cannot be conducted unless a dedicated account has been created for each research subject. Hospital staff is responsible for the appropriate billing of technical fees once a research subject and a research service has been identified by the Principal Investigator. Responsibility for billing rests with the clinical department in which the test or procedure is performed.

4. **Coverage Analysis or Medicare Coverage Analysis (MCA).** Is required for all clinical trials for any tests, procedures and interventions performed on human subjects that will be billed to third party payors. The MCA will assist in determining the eligibility of a clinical trial for Medicare coverage and a review of the protocol to determine which items and services can be reimbursed by Medicare. The MCA will ensure that billing for both Standard of Care/routine costs and research only procedures is appropriately in compliance with legal requirements. If the trial does not qualify for an MCA, PI or designee must perform a coverage analysis (appendix XXX) prior to contract and budget negotiations. The final CA must be uploaded in the attachment section of Velos.
II. GENERAL PRINCIPLES FOR THIRD PARTY PAYOR COVERAGE OF RESEARCH-RELATED CHARGES

Principal Investigators and hospital staff should be aware that different coverage principles apply to research-related services depending upon the third party payor and, in some cases, the circumstances and nature of the clinical trial itself. Below is a summary of the general principles that apply for Medicare, Medicaid and commercial insurance. Coverage of particular services, however, will depend on the specific scope of benefits under the government programs or commercial insurance.

A. Medicare

Medicare has three sets of principles that determine coverage of health care services provided in a clinical trial: (1) general coverage principles applicable to all health care services; (2) specific and more generous coverage principles established by a Medicare Clinical trial policy (issued July of 2007 which apply to health care services provided in certain clinical trials; and (3) specific coverage principles that apply to clinical trials investigating medical devices under an investigational device exemption. A Principal Investigator must determine which Medicare principles apply in order to assess what services will be covered under Medicare.

1. General Clinical Trials. Medicare coverage of health care services provided in the context of many clinical trials will be determined by generally-applicable coverage principles. Medicare will pay for certain services if the services are not paid for or provided without charge by another source (such as federal research grants, pharmaceutical company, research sponsor and private insurers).
   a. Medicare will cover medically necessary services that represent standard care and that would be covered outside the context of a clinical trial.
   b. Medicare will not cover services related to the use of a non-covered service. Medicare therefore, will not reimburse for services related to follow-up care and complications of non-covered services, which require treatment during a hospital stay in which the non-covered service was performed. Complications that arise after discharge from a hospital stay, however, may be covered.
   c. Medicare will not cover items and services that are not medically necessary to diagnose or treat a condition (i.e., costs incurred for research purposes over and above standard care). For example, Medicare will not pay for any medical services provided solely as a result of a patient’s participation in a research trial, including administration of an experimental drug, any lab or diagnostic tests whose purpose is monitoring the patient for effects of the research drug or collecting data for the protocol.

2. Trials Covered under the Clinical Trial Policy. The Clinical Trial Policy on Clinical Trial Services (CTP) mandates that Medicare pay for the routine costs of qualifying trials if the services are not paid for or provided without charge by another source (such as federal research grants, pharmaceutical company, research sponsor, and private insurers).
a. **What is a qualifying trial eligible for coverage under the Clinical Trial Policy?**

i. Trial must be to evaluate a Medicare benefit. (Note that Medicare currently does not cover most outpatient self-administered drugs so that clinical trials evaluating most outpatient self-administered drugs are not qualifying clinical trials. Coverage for services provided clinical trials evaluating most outpatient self-administered drugs is discussed separately below.)

ii. Trial must have therapeutic intent. (The trial must not be designed exclusively to test toxicity or disease pathophysiology.)

iii. Trial must enroll diagnosed beneficiaries rather than healthy volunteers (except that healthy patients may be enrolled in order to have a proper control group in trials of diagnostic interventions).

iv. Trial must have certain desirable characteristics or be “deemed” to have those characteristics. The only trials that currently meet this requirement are trials that are:

   ➢ Funded by the Centers for Medicare & Medicaid Services, National Institutes of Health, Centers for Disease Control and Prevention, Agency for Healthcare Research and Quality, Department of Defense, and Department of Veterans Affairs; or

   ➢ Conducted under an investigational new drug application (“IND”) reviewed by the Food and Drug Administration or is a drug trial exempt from having an IND. The sponsors of both IND trials and IND-exempt trials under 21 CFR 312.2(b)(1) must identify themselves by e-mail to clinicaltrials@cms.hhs.gov.

b. **What services are covered by Medicare as routine costs of qualifying trials under the Clinical Trial Policy?** The following services are covered by Medicare as routine costs of qualifying trials under the CTP:

i. Items or services that are typically provided absent a clinical trial (e.g., medically necessary services provided consistent with the standard of care);

ii. Items and services required for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent);

iii. Items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications;

iv. Items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.

c. **What services are not covered by Medicare as routine costs of qualifying trials under the Clinical trial Policy?** The following services are not covered by Medicare as routine costs of qualifying trials under the CTP:

i. The investigational item or service (unless the item or service that is the investigational focus would be covered outside the clinical trial as standard of care)

ii. Items and services:

   ➢ For which there is no Medicare benefit category (e.g., custodial care, cosmetic surgery, or most preventive care other than screening tests or vaccines that enjoy a specific coverage mandate);

iii. Which are statutorily excluded (e.g., hearing aids, eyeglasses, most outpatient self-administered drugs);
iv. That fall under a national non-coverage policy e.g., the national coverage
decision for percutaneous transluminal angioplasty (PTA) permits coverage for
PTA of the carotid artery concurrent with carotid stent placement when
furnished in FDA-approved protocols of Category B investigational devices used
under an investigational device exemption);
v. Items and services furnished solely to satisfy data collection and analysis needs
that are not used in the direct clinical management (e.g., monthly CT scans for a
condition usually requiring only a single scan when the sole purpose of the
additional CT scans is data collection for the protocol)
vi. Items and services customarily provided by the research sponsors free of charge
for any enrollee in the trial or for which sponsor has specifically paid, or
vii. Items and services provided solely to determine trial eligibility.

3. Special Medicare Coverage Issue: Outpatient Self-Administered Drug Trials. Most
outpatient self-administered drugs are not covered by Medicare and therefore most
drug trials will not qualify for coverage under the CTP and will not have many services
that qualify for coverage under general Medicare coverage principles.
a. What outpatient drugs are covered by Medicare?
i. Outpatient drugs that are covered include the following:
   ➢ drugs that are not usually self-administered;
   ➢ blood cloting factors;
   ➢ drugs used in immunosuppressive therapy;
   ➢ erythropoeitin for dialysis patients;
   ➢ certain oral anti-cancer drugs and Group C cancer drugs; and
   ➢ oral anti-nausea drugs when used in certain situations.
ii. For clinical trials of drugs that fall within the Medicare coverage categories,
research-related services are billed in accordance with the principles (CTP or
general) applicable to other trials of a Medicare covered benefit, as outlined
above.
b. What services are covered in outpatient drug trials even if the drug is not covered?
The following services provided in outpatient trials of self-administered drugs may
be covered even if the drug itself is not covered:
i. Medically necessary visits, such as the initial visit in which the patient is first
   enrolled in the trial and subsequent visits that are routine care for the patient.
ii. Items or services provided for complications not contemplated in the protocol.

4. Trials Involving Investigational Devices. Refer to Administrative Policy and Procedure
JM03.1 for billing for medical devices that have not been approved by the FDA.

B. Medicaid
Medicaid will not reimburse for medical care and services that are
investigational or experimental in nature. Medicaid will reimburse for services that represent
medically necessary standard care.

C. Commercial Payors
Coverage of research-related services by commercial insurers or managed care plans varies and
depends on the contract between the insurer/plan and member. Principal investigators should
advise patients covered by commercial insurance to discuss in advance with their commercial insurers or managed care plans what will be covered if they are enrolled in a clinical trial. The Principal Investigator must receive written confirmation from the insurance company and/or patient concerning that coverage prior to enrollment of the patient in a protocol.

**STEPS TO BE FOLLOWED BY PRINCIPAL INVESTIGATOR or DESIGNEE**

**A. Trial registration:**
1. Clinical Trial registration is required. Obtain an IRB number in IRIS (Einstein IRB) or IRB Manager (BRANY) by starting the application inclusive of the core requirements. Central/External IRB studies require a record in IRIS. Registration will automatically establish a record in Velos. Enter as much information as possible into the appropriate IRB system in order to prevent the need for duplicate data entry into the Velos system. The PI and/or designee (Regulatory Coordinator) will be notified immediately to (1) complete the protocol information in Velos, (2) upload all pertinent documents (draft budget, contract, MCA/CA etc. and (3) set the study status to “Ready for Admin Review”.

**B. Study Calendars:**
1. Study calendars are built for visit tracking and management of research related finances billable to the research sponsor or funding agency. In partnership with the PI or designee, BRANY and OCT will build the calendar and billing matrix in SMART (BRANY) or Velos (OCT) in accordance with the approved protocol, contract and budget.

**C. Study Activation in Velos**
1. Study Activation Checklist: It is the responsibility of the PI to ensure that the Study Activation Checklist is completed in Velos and that the study is activated in Velos before any protocol can be activated in EPIC
   a. To complete the checklist, all requested information must first be entered into the Velos system and appropriate access rights and roles must be assigned to all members of the study team that will require access in both EPIC or Velos – as per the Velos SOP

Information included in this checklist that must be entered/verified in the Velos system before activation include:

a. Regulatory Summary Information
   i. Study Personnel Access Rights: Roles assigned such as PI, Clinical Sub-I, Non-Clinical Sub-I, Study Coordinator etc. will determine access to patient data
   ii. All Study Status Dates including ACTIVE/ENROLLING

b. **BRANY Classic and IRIS IRB Studies:** Upon IRB approval of the protocol, the PI and the designated Primary/Regulatory Coordinator will receive an email notification indicating that the Study Activation Checklist must be completed in the Velos system. (Most information will have already been pulled in to Velos via the interface but all outstanding data must be completed and verified in Velos.

c. **External IRB Studies:** Upon notification of IRB approval from the external IRB, the PI or designated Primary/Regulatory Coordinator must document the IRB Approval status in the Velos system in addition to completing the Study Activation Checklist in the Velos system.

**D. Patient Association to the Study** *
2. Immediately upon signing of consent, associate the patient to the study and document the “Initial Consent Signed” Status as per Velos Policies and Procedure Documentation. This will
associate the patient to the study in EPIC and allow the provider to associate all orders with
the study to ensure proper billing. The date entered in this status record will populate the
Active Start Date for the patient in Epic.

3. Record all appropriate status records (e.g. Screening, Screen Fail, Consented, Enrolled, etc.)
in a timely fashion to ensure appropriate billing association of all procedures.

4. If a study calendar exists in SMART or Velos, link it to the patient immediately at screening.
Abide by the SMART or Velos policies on patient calendar association.

E. Recording Visit Status:

1. Status Records*: At each visit evaluate and record any new patient status in
   Velos (e.g. Enrolled, Active on Treatment, Off Treatment, Off Study etc.). Status must be
documented in a timely fashion and recorded in chronological order in order to ensure
the status will flow to EPIC and direct the bills to the appropriate billing queue. It is the
responsibility of the PI to ensure the data are entered appropriately and verified in EPIC
at each visit.

2. Status Dates*: Active Start Date/End Date in EPIC determine routing of billing charges.
   a. The 'Initial Consent Signed" status date in Velos will dictate the Active Start Date in
      EPIC. Once recorded, this date should not be changed. The “Screen Failure” or “Off
      Study” Status date in Velos will dictate the End Date in EPIC. If a patient rescreens,
      the “Reconsented” status must be entered to indicate to EPIC that the patient is
      linked once again to the study.
   b. Recording Visit Activity: Billing calendars are built based on the MCA or CA and
define the billing queue to which research charges are dropped. Document
   completion of all events (procedures) and visits in SMART (BRANY) or Velos (OCT) in
   accordance with system policies.

F. BILLING CALENDARS AND ROUTING OF RESEARCH CHARGES

A. Determines which costs are covered by sponsor and which are covered by
third party payors. The Principal Investigator must ensure that all costs of a clinical trial
are covered by the sponsor or third party payors. The Principal Investigator or designee
must work with the designated research office to negotiate acceptable rates with the
sponsor for services covered by the sponsor’s payment.

1. Sponsor or Funding Agency: The Principal Investigator must determine, in coordination
with sponsor/funder, which costs will be covered by the grant or payment, by
performing a CA or MCA. The clinical trial or grant agreement should clearly identify
those costs.
   a. Determine whether the grant or payment will cover all costs associated with the
   study, including the study drug or device. If all costs are covered, no claims for
   services can be billed to Medicare, Medicaid or commercial payors.
   b. Determine whether the grant or payment will cover some (but not all) costs
   associated with the study. If some costs are covered, these costs should be
   specifically identified. The grant or payment must cover costs for all services not
   billable to third party payors.
   c. Upload final CA or MCA document(s) to the attachment section of Velos

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2. Third Party Payors: The Principal Investigator must determine what services may be covered by Medicare, Medicaid or commercial payors – these will generally be the medically necessary routine care costs.

   a. Determine which Medicare principles apply (i.e., whether clinical trial qualifies for coverage under CTP and whether the trial involves a Category A or Category B device)
   b. Determine what coverage principles apply for other third party payors.
   c. Ensure that any procedural requirements for claims under the CTP (e.g., registration of drug trials) or the Medicare investigational device exemption regulations (e.g., application for coverage determination for Category B device) are met to obtain the most comprehensive coverage.

3. Clinical trial/grant agreement: Clinical trial or grant agreement(s) require negotiation, approval, and signatory execution on behalf of the Institution by the respective research office. Research offices include Biomedical Research Alliance of New York, Office of Clinical Trials, Office of Grant Support, or the Office of Research Sponsored Programs; refer to clinical research guidelines for additional guidance. Negotiation and approval of the agreement includes approval of the research rates and payment terms.

B. SCHEDULING PATIENT VISITS
   1. Patient visits will be scheduled in Epic.
   2. To associate a visit with the study the patient must first be associated to a study. Patients will be associated to the study with their current patient status; the status will be updated throughout the study as necessary.
   3. Patients will be scheduled for research encounters in EPIC and the study will be associated to the visit prior to or during the visit.

C. ORDERING TESTS/PROCEDURES/REFERRALS BILLABLE TO THE STUDY/GRANT
   The following procedures must be followed by the Principal Investigator (or designee) when ordering/scheduling any research-related test or procedure that should be billed to and paid by the research sponsor/grant or funding agency.

   1. Prior to the start of the study the Principal Investigator (or designee) will meet with ancillary departments to discuss the study, and come to an agreement for necessary services and charges for the service.
   2. Research related lab tests performed by the Montefiore Pathology Department, as well as procedures and referrals performed at Montefiore that are to be billed to the sponsor/grant or funding agency will be ordered in Epic and associated with the study when the order is placed.
   3. When ordering tests, procedures or referrals that are not billable to the sponsor/grant or funding agency, and deemed standard of care (SOC) the Principal Investigator (or designee) will place the order in Epic and not associate it to the study.
   4. When study patients arrive at ancillary sites for service the front desk associates must ensure the research association is made if the service is to be billed to the sponsor/grant or funding agency.
   5. Once a study is completed, the Principal Investigator (or designee) is responsible for notifying all parties that the study is closed.
D. Patient Informed Consent. Informed consents (and advance beneficiary notices) should accurately inform potential subjects about their responsibility for any costs that may not be covered by the sponsor or third party payers, including co-payments. In order to ensure this requirement is met, language in the clinical trial or grant agreement must be finalized prior to finalizing the language in the informed consent document. Patient informed consents, amendments and all updates that the patient has signed should be scanned and be available in Epic. The original consent will be retained in the patient’s study records.

V. DOCUMENTATION GUIDELINES

The patient’s participation in a clinical trial must be documented in the medical record. If the trial meets the criteria to be built into Epic (EMR) the patient’s participation must be recorded in Epic. Documentation in the medical record/EMR must substantiate: (1) whether the item or service was medically reasonable and necessary; and (2) whether the service can be billed to a third party payer. The documentation in the medical record must clearly substantiate the purpose for each research-related item or service. If an item or service changes from billable to the grant to billable to the third party, the change and the reason for that change must be documented. The trial name and sponsor must be included in the medical record/EMR.

VI. BILLING AND CODING GUIDELINES

A. Billing

1. All billing to third party payors for specific services must comply with published Medicare and Medicaid regulations and contract requirements for commercial third party payors and research sponsors or funding agencies.
   i. Routine care billing to commercial third party payors transpires in EPIC.
   ii. Research billing for non-routine care services billable to the research sponsor/grant or funding agency are managed in SMART (BRANY), Velos (OCT) or Banner (Research Finance/Department); refer to each administrative office’s policy on invoicing, payment, reconciliation and fund transfers.

2. A research patient must, like all other patients, be responsible for deductibles and co-payments. Investigators may not induce patients to participate in clinical trials and forego standard therapy by promising to waive these payments. Nor may the investigator offer as an enrollment incentive any free items or services to patients unless these items or services are customarily provided without charge to patients not enrolled in clinical research. (This does not prohibit, however, hardship discounts when applicable.)

3. If the patient has Medigap insurance, the patient must pay coinsurance for any costs that Medicare covers (including what Medicare pays in the context of a clinical trial).
B. General Coding. As indicated above, all research-related services must contain the diagnosis code Z00.6 along with any other diagnosis code required depending on the patient’s condition. This code serves the purpose of identifying research encounters.

C. Coding under the Clinical Trial Policy. Claims submitted for services or items that constitute the routine patient care for a qualifying clinical trial under the CTP must identify the items and services with specific modifiers and ICD-10-CM Diagnosis codes. All claims for services (hospital or physician) must be submitted with the “Q1” procedure code modifier (denoting an item or service provided as routine care in a Medicare qualifying clinical trial). The Q1 procedure code modifier and the ICD-10-CM diagnosis code (where applicable) serves as the provider’s attestation that the service meets the Medicare coverage criteria.

D. Physician Services.
1. The ICD-10CM code Z00.6 (examination of participant in a clinical trial) is appended to every clinical trial claim, inpatient or outpatient, in the secondary diagnosis-code position for patients being treated for a diagnosed disorder. It is placed in the primary position for healthy volunteers.
2. Modifier Q0 (zero) - is used to identify items and services that are being investigated as an objective within a study.
3. Modifier Q1 - identifies items and services for necessary routine patient care.

E. Hospital Services
1. The ICD-10-CM code Z00.6 (examination of participant in a clinical trial) is listed as the secondary diagnosis on the claim for all services.

2. Specific HCPCS codes now exist for hospital outpatient services provided under clinical trials. Two “G codes” exist for use in reporting services furnished in hospital outpatient departments:
   a. G0293- Non-covered surgical procedure(s) using conscious sedation, regional, general or spinal anesthesia in a Medicare qualifying clinical trial, per day.
   b. G0294- Non-covered surgical procedure(s) using either no anesthesia or local anesthesia only, in a Medicare qualifying clinical trial, per day.

F. Coding in Investigational Device Trials. Claims for a Category B device that has been approved for coverage by the Medicare contractor and services “related to” the Category B device must include the Q0 (zero) modifier and the IDE number.

G. Review of Research and Non-Research Related Charges in Epic
When a patient is associated to a study in Epic (EMR) a review process must take place to ensure all charges are being routed to the correct payor. The Principal Investigator (or designee) is responsible for reviewing all patient charges found on the “Patients needing research billing review” report in Epic. This review must occur at minimum, on a weekly basis for all studies having active participants.

Review process:
1. To perform this review the coverage analysis or Medicare coverage analysis and budget are used as a guide to assess where the charges should be directed, to the research guarantor or patient/insurance account.
2. Each patient encounter and all services are reviewed to ensure they are being directed correctly, to the research guarantor account or to the patient/insurance. Corrections are made if charges are not directed to the appropriate payor.

3. Research related charges:
   a. charges to be paid by the study, indicate “bill to study” in the charge review report in Epic
   b. charges to be paid for by insurance/patient, a modifier type is chosen, Investigational/Device (Q0) or Routine (Q1).

4. Non research-related charges:
   a. charges that are not research related (SOC) are marked “not research related” and routed to the insurance/patient account.

5. The account is marked as reviewed and the charges are routed to the appropriate guarantor account. Diagnosis codes and modifiers are automatically added to the claim.

VII. COMPLIANCE

A. All Principal Investigators and hospital staff must attend mandatory training on Montefiore’s research billing compliance policies and procedures. The training, which will be held at least annually, will explain the research compliance policies and procedures in place at Montefiore and inform each individual about his/her accountability and the expectations for performance. Montefiore will conduct ongoing monitoring and audits to evaluate compliance with this and related compliance and research policies and procedures.

B. Violation of Montefiore’s research compliance policy or the failure to comply with applicable laws, regulations and contractual obligations can prevent Montefiore from obtaining the appropriate reimbursement for services provided, and, more importantly, can expose the hospital and any individuals involved to civil and criminal penalties, including exclusion from participation in federal health care programs. Any concerns about compliance should be reported to the or, as with any compliance concern, reported through the Montefiore Compliance Hot Line at (800) 662-8595. Upon report of suspected noncompliance, Montefiore staff will investigate the conduct in question to determine whether a violation of applicable laws or the requirements of our compliance program has occurred, and if so, take appropriate steps to correct the problem. Concerns must be reported to ensure issues are investigated and appropriate corrective action taken.

VIII. Auditing

The Compliance Program will conduct reviews and audits of clinical items and services provided to study Subjects (patients) and monitor Compliance with applicable billing requirements in accordance with Federal and State regulations. Reviews and audits may be conducted on a random basis or in response to an allegation or violation. All associates are required to cooperate fully with any reviews/audits.

A. Monitoring Procedures: Documents that may be reviewed, but not limited to include:
   • Contracts (Clinical Trial Agreements)
   • Coverage analysis or Medicare Coverage Analysis
   • IRB Applications
   • Research Protocol
B. Reviews: The Compliance Department will review the subject’s account to determine if:

- The charges are study or non-study related
- The charges have been allocated to the proper internal accounts
- The charges are billed to the appropriate entity (Sponsor/Insurance)
- The charges were not double billed by the institution
- The items and services were correctly coded (ICD/CPT)
- Items and services that were SOC were documented, coded and billed as appropriate.
- Review of the consent document will also be conducted to determine that subjects were appropriately informed regarding costs to be incurred.

All non-compliant billing queries will be documented and reported to the Compliance Department. As appropriate corrective actions or a corrective action plan will be implemented.

IX. Research Pricing Policy

For hospital-related costs to be paid by the sponsor, the charge master amount is used and a factor applied based upon the identity of the sponsor. For federal sponsored clinical trials the NIH published rates should be applied. The factor for industry sponsored trials is derived from third party payer recovery rate data and is currently 35% percent.

For professional service fees, the research fee schedule is used. For federal sponsored trials, the amount payable by Medicare is used to value the professional fees. For professional fees incurred on industry sponsored trials, use the research fee schedule as a reference to negotiate an acceptable amount of reimbursement. It is preferred that the amount per the fee schedule be accepted by the potential sponsor.

This established rate structure ensures consistent pricing and budgeting for the research community. All research budgets should be reviewed and approved by the Office of Clinical Trials (OCT) to ensure consistency. All rate exceptions which are more than 10% below the proposed rates for services which have a charge of $1000 or greater should be escalated for discussion by the Executive Director, OCT to the VP, Finance prior to approval. This formal process ensures that equitable rates are applied across the institution in a non-discretionary and compliant manner.