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Policy No:	1 CLN 061	Effective Date: 04/15/2012

OBJECTIVE
To clearly define the in-patient and out-patient billing compliance requirements for all clinical research occurring at DMC facilities.

SCOPE
All DMC employees, agents and medical staff members, and all other persons involved in human subjects research conducted at, or including the provision of services by, any DMC-owned or-controlled site or facility.

DEFINITIONS

Billing Coverage Analysis (BCA): a systematic review of protocol-related documents (protocol, contract, patient consent form, budget) to determine if all the patient care costs in a study are covered by the study sponsor, other funding sources, or qualify for reimbursement by third party payers. Medicare's expanded coverage of clinical trials provides increased opportunities for reimbursement.

Qualifying Clinical Trial: clinical research under which Medicare permits billing for routine costs of trial when the involved items and services are otherwise available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision.)

Clinical Research Office (CRO): the DMC Clinical Research Office has responsibility for the ethical practices and billing oversight of clinical studies at DMC Facilities.

POLICY
All clinical services rendered during the course of a research study shall be billed to the appropriate third party payer, individual or company in compliance with applicable contracts, and state and federal regulations. A billing coverage analysis (BCA) shall be conducted by the DMC Clinical Research Office for every study with clinical events.

PROVISIONS

1. Research Review and Approval

A. All human subjects research conducted at a DMC site or facility OR involving DMC resources OR conducted by or with the assistance of DMC employees, agents or medical staff members must be approved by the DMC and its Institutional Review Board (IRB)

B. Prior to study implementation, investigators conducting studies that include clinical events must complete and return a billing compliance grid and a billing analysis survey to the DMC Clinical Research Office (CRO). The billing compliance grid identifies all clinical services, drugs, devices, treatments and tests that are considered part of the study and delineates those that are standard of care and those that are investigational. In addition, the grid must include the name and address of the responsible party to be billed for each research-specific service, drug, device, treatment and test. The billing analysis survey is used to help determine if the clinical study is considered a 'qualifying clinical trial' according to Medicare Billing Rules.

C. During the course of an approved study, all study amendments, continuations and/or study closure/termination documents submitted to the IRB must be uploaded to the study's DMC Research Review record.

2. Billing Compliance

A. The investigator shall ensure that the correct research charges have been included in the research budget. Prior to finalizing the study budget with the sponsor, the investigator shall contact the study sponsor to obtain the CPT-4 (out-patient) and/or ICD-9 (inpatient) codes for the research-specific clinical services.

B. After such codes have been obtained, the investigator shall contact the appropriate hospital finance department to obtain the research charge for the codes. For all clinical services, the investigator will include these codes and charges in the final study budget. In some studies, University Labs and the Investigational Pharmacies may have separate billing accounts and the investigator will work with those departments to ensure appropriate billing consistent with their processes.

C. Contracts between a sponsor and the entity conducting the research (WSU or DMC), should not be finalized until the DMC Clinical Research Office and DMC Finance approves the research charges for the itemized services/tests. The DMC Clinical Research Office is responsible for the research billing compliance review, study account monitoring, and study participant enrollment.

D. In order to initiate and conduct a research study at the DMC, the following actions must occur:

i) The study Principal Investigator or Research Coordinator shall submit a study application to the DMC Research Review Website. If the protocol includes research-specific clinical services, the PI will be sent a billing information worksheet that must be completed and submitted to the CRO along with a copy of the study schedule of clinical events or study calendar.

ii) After the BCA has been completed a Senior Clinical Auditor will contact the investigator to discuss the results of the billing coverage analysis and the process for billing research services at the DMC. A DMC grant pathway number for the study is assigned. This number is unique to each study and must be used when ordering any clinical research test/procedure/service.

iii) Upon approval of the study by DMC and the IRB, the investigator must upload the IRB approval letter to the DMC Research Review record. This action will signify that the study has been activated and is approved for enrollment of research participants and billing of research services at a DMC facility.

iv) Patient enrollment information must be submitted to the CRO. The patient enrollment form for each research participant must be submitted within 24 hours of consent to clinicalresearch@dmc.org. All information submitted to the CRO should include the grant pathway number for the study.

3. Oversight and Monitoring of Compliance

A. Each Department Chair or Executive Director of the Department/Institute where human subject research is conducted is responsible for establishing an environment for clinical research that is compliant with all policies and regulations governing the conduct of research – including those instituted by the WSU Institutional Review Board (WSU) and the DMC.

B. It is the responsibility of the Principal Investigator (PI) to understand and comply with clinical research billing rules and procedures, to maintain up-to-date documents and records related to the research study and to make such documents available to the DMC, as requested. When submitting a study with clinical events for DMC Research Authorization, the PI, or his/her designee, must submit a copy of the study protocol, patient consent form, budget for clinical items, contract (or section describing sponsor-covered clinical items), and the IRB Protocol Summary Form. The PI shall determine what is conventional care and shall assure that all clinical research charges are ordered on a research account pathway or special insurance code assigned to the study by the DMC Clinical Research Office.

C. The Research Team (including coordinators, nurses, technicians, managers, residents, fellows), whether they are DMC or WSU employees, is responsible for compliance with all provisions of this policy. Each team member is to monitor compliance with applicable billing rules.

D. Any Employee (WSU or DMC) who becomes aware of noncompliance with this policy is expected to report the incident to their supervisor, the DMC Clinical Research Office or to the DMC Compliance Hotline.

E. The DMC Clinical Research Office (CRO) is responsible for review and approval of research studies, billing compliance and oversight. In conjunction with DMC Patient Financial Services, Revenue Cycle, Patient/Grants Accounting and hospital finance departments, the DMC CRO will provide Principal Investigators and their staff with budget and billing information and education on research compliance procedures.

F. The DMC Regulatory and Governance Office reviews contract language and planned utilization of resources at the DMC. This office has the authority to approve, or deny, us the DMC facilities or resources for research. The authorization for research letter shall be signed by the authorized officials of the Regulatory and Governance Office and the Clinical Research Office at DMC. A study may not commence until final IRB approval is provided.

G. The DMC Compliance Office, in conjunction, with DMC Clinical Research, and Internal Audit departments, will perform audits of clinical services provided to research study participants in order to monitor compliance with this policy and applicable medical research billing requirements.

REFERENCES

1. CMS National Coverage Decision on the Routine Costs of Clinical Trials (310.1), 2000 and 2007.
2. 1 CLN 050 Subjects in Research
3. 2 MED 400 Investigational Drug Control

ADMINISTRATIVE RESPONSIBILITY

The DMC EVP/Chief Medical Officer and the DMC EVP/Chief Operating Officer shall have administrative responsibility for this policy. The System Executive Director, Clinical Research Office has administrative day-to-day responsibility for this policy.

APPROVAL

This policy has been approved and is duly authorized by DMC management. The posting of the policy on the DMC intranet signifies that it is in full force and effect.

NEXT REVIEW DATE

May 2015

KEY SEARCH WORDS

Billing; research; pathway

Please check one:

This policy is: X New ☐Reviewed ☐Revised *(If* Revised *box is checked complete* Changes *Section below)*