MCW Office of Research
Standard Operating Procedure

Research-Related Professional Billing Compliance

Unit: Research Systems; MCW Office of Research

Applies to: MCW Faculty/Staff/Students involved in human research who perform research activities which result in billable professional services.

PURPOSE: The purpose of this Standard Operating Procedure (SOP) is to provide guidance to ensure consistency with compliant research billing practices. By doing so, minimizing financial risk to clinical trial participants along with financial and non-compliance or litigation risk to the institution.

In accordance with Centers for Medicare & Medicaid Services Clinical Trial Policy (NCD 310.1) qualified billing of research related procedures, items and services may occur.

SCOPE: This applies to all faculty and staff involved in research at the Medical College of Wisconsin (MCW), Froedtert Hospital (FH), Children's Wisconsin (CW) and Versiti/Blood Center of Wisconsin, who will perform research activities which result in billable professional services by MCW.

DEFINITIONS:

Facility: (Medicare Part A) entity where medical procedures, testing, technical support, or medical equipment for the purpose of clinical or non-clinical (research) care of a diagnosed disease or medical condition are conducted.

Provider: (Medicare Part B) licensed individual (may or may not be clinical trial investigator) with expertise qualifying for the practice clinical or non-clinical (research) care of a diagnosed disease or medical condition.

Study encounter: Clinical trial visit, procedure, or other event which has the potential for generation of a billable service.

Clinical Physician Services (CPS): MCW entity responsible for the professional billing of clinical or non-clinical services on behalf of MCW providers.

Coverage Analysis: Document indicating determination of the appropriate payor for procedure, item or service used for a clinical trial.

Clinical Trial Agreement (CTA): Legal agreement (contract) between MCW and the clinical trial sponsor governing responsibilities and conduct of the clinical trial for all involved parties.

National Clinical Trial (NCT) #: The eight-digit clinicaltrials.gov number represents a unique study identifier. Clinicaltrials.gov is a web-based resource designed to increase transparency in research and to provide public access to information regarding clinical trials.

Investigational Device Exemption (IDE): An FDA-approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for the purpose of conducting investigations of that device. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the clinical trial is initiated. This approval is represented by a unique study identifier referred to as the **IDE number**.

Investigational New Drug (IND): An FDA-approved investigational new drug exemption (IND) grants permission that a new drug, agent, or biologic may be used in humans prior to FDA review of clinical data to determine that a particular product is safe and effective for a specific use. The FDA permission is evidenced by the assignment of an IND number by the FDA or the granting of an IND exemption.

Research-Related: A procedure, investigational device or event used or completed specifically for the purpose of a clinical trial.

Study Only (ST): Procedures, investigational device or events used or completed for a clinical trial which are ***not billable a third-party payor (insurance)***, which will be billed to the clinical trial.

Investigational/Device (I/D): Procedures, investigational device or events used or completed for a clinical trial which ***are billable to a third-party payor (insurance)***. These procedures occur because the patient is in the clinical trial. The difference may simply be related to frequency or timing of this procedure when compared to routine care procedures.

Routine Care (RC): Procedures, investigational device or events used or completed as routine clinical care for a clinical indication, and will be used for the clinical trial purposes, and **are billable to third-party payor (insurance).** These procedures would occur if the patient was not involved in the clinical trial.

Procedures:

1. Guided by the coverage analysis for each clinical trial, delegated research personnel will complete the **MCW Human Research Charge Notification (**Human Research Charge Notification**)** when either facility or provider billable services have been generated, within 24 hours of the encounter.

2. Guided by the coverage analysis of this clinical trial, for each procedure, investigational device or event properly indicate bill to “study” or “patient / insurance.” For items billed to “patient / insurance” properly apply (I/D) Investigational/Device or (RC) for Routine Care on the **MCW Human Research Charge Notification** form. These acronyms are reflective of the terminology used by CPS for charge processing.

3. Once completed, the **MCW Human Research Charge Notification** Qualtric form will be submitted to CPS via the submit button at the end of the form, within 24 hours of the encounter.

4. Properly completed **MCW Human Research Charge Notification** forms require completion of all fields pertinent to the clinical trial. This does include the project NCT number, and IND or IDE (device only) numbers when appropriate.

5. Submission of the Qualtric form will trigger a copy of completed form to be forwarded to Study Coordinator email address entered on the form. Include the Notice of Submission email of the **MCW Human Research Charge Notification** in participant research folder as documentation of efforts to maintain compliance with MCW best research billing practices.

Compliance:

By following the guidance of this MCW SOP for research billing practices, the study investigator can avoid the following significant issues:

- Billing for services which have been indicated in the CTA to be paid by the sponsor.
- Billing for services that are for research only purposes.
- Billing for services which were promised to be free to the participant in the informed consent.
- Billing Medicare for services which are part of a non-qualifying clinical trial.

Consequences of fraudulent billing include:

- Criminal penalties.
- Civil Fines.
- Loss of governmental funding.
- Institutional penalties / PI disbarment.

References:

CFR 42 Chapter IV Subchapter B Part 405 Subpart B (https://ecfr.io/Title-42/Part-405/Subpart)

Medicare Claims Processing Manual Chapter 32 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1418CP.pdf)

Supporting Documents:

MCW Human Research Charge Notification