JOHNS HOPKINS MEDICINE	**The Johns Hopkins University School of Medicine** **Office of Clinical Trials**	**Policy Number**	CCR006
		Effective Date	5/21/2024
	Subject Medicaid Attestation for Qualifying Clinical Trials	**Pages**	3
		Revised	

I. POLICY

A signed and completed *Medicaid Attestation Form* must be part of each research participant's electronic medical record for all research studies that are determined to be qualifying and for which the participant's primary insurance is Medicaid or a Medicaid product.

II. BACKGROUND

Medicaid amended a section of the ***Consolidated Appropriations Act***[1] to mandate coverage of routine costs for clinical trials. This process also requires that institutions collect a "Medicaid Attestation Form" for all research participants with Medicaid (and its alternative plans) enrolled in a qualifying clinical trial as defined by the regulation. The regulation has been in effect since January 1, 2022. The state of Maryland released guidance on compliance with the rule on April 22, 2022.

III. DEFINITIONS

Electronic Health Record (EHR) - an electronic version of a patient's medical history, that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that person's care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports. [2]

Legal Medical Record (LMR) – Documentation of healthcare services provided to or used in the care of an individual and contains the identification unique to the patient. The legal medical record contains information needed to support the patient's diagnosis and condition and justify the patient's care, treatment, and services (JHH Legal Medical Record Policy- HIM004)

Principal Investigator (PI) – A principal investigator (PI) is the researcher, usually a doctor or other medical professional, who leads the clinical research team and, along with the other members of the research team, regularly monitors study participants' health to determine the study's safety and effectiveness. A PI is primarily responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of clinical research.[3]

Research Coordinator (CRC) – Manages and conducts the day-to-day activities of a clinical trial. The Principal Investigator (PI) determines the CRC's specific responsibilities and works closely with the CRC. In general, the CRC ensures the clinical study maintains accordance with the protocol, applicable regulations, and Good Clinical Practice (GCP) and Institutional Review Board (IRB) requirements. Beyond administrative duties, the responsibilities of a CRC may include acting as a liaison for the clinical site, ensuring staff are properly trained per the protocol, recruiting and/or registering participants,

maintaining study guidelines, and collecting and/or reviewing the data or review before it is entered into a study database.[4]

Qualifying Clinical Trial - According to the Medicaid regulation a qualifying clinical trial is must be described in section 1, 2, or 3 below:

1. The study or investigation is approved, conducted, or supported (which may include funding through in-kind contributions) by one or more of the following:

- National Institutes of Health (NIH) [includes National Cancer Institute (NCI)]
- Centers for Disease Control and Prevention (CDC)
- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Medicare and Medicaid Services (CMS)
- A cooperative group or center of any of the entities described above or the Department of Defense (DOD) or the
- Department of Veterans Affairs (VA)
- A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants
- The Department of Veterans Affairs, the Department of Defense, or the Department of Energy as long as the study or investigation has been reviewed and approved through a system of peer review that is determined by the Secretary of Health and Human Services (Secretary) to meet both of the following criteria:
    - Comparable to the system of peer review of studies and investigations used by the National Institutes of Health
    - Ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review; **or**

2. The study or investigation is conducted under an investigational new drug exemption under section 505(i) of the Federal Food, Drug and Cosmetic Act, or an exemption for a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act; **or**

3. The study or investigation is a drug trial that is exempt from being required to have an exemption as described in section 2 above.[1]

IV. RESPONSIBILITIES

It is the ultimate responsibility of the study Principal Investigator to ensure that all Medicaid Attestations sent to him/her and the research team are completed, signed, and available in the electronic health record.

The Research Coordinator and/or Research Nurse is responsible for making certain that the Medicaid Attestations are completed and signed by the Principal Investigator. It is the responsibility of the team member(s) with Epic Research Coordinator *with Scanning* or Research Coordinator with *Scheduling and Scanning* job roles and security to scan the signed form into Epic's Media tab.

The Office of Research Billing Compliance (CRBC) is responsible for monitoring the consent of research participants with Medicare and primary insurance and sending an Epic in-basket to the study team. CRBC will also monitor that the Medicaid Attestations are available in Epic's Media tab.

V. PROCEDURE

1. A report that identifies active or potential research participants with primary insurance of Medicaid will be run and reviewed by the Office of Clinical Research Billing Compliance (CRBC).
2. Based on the report, an Epic In-basket message will be sent to the Research Coordinator and/or Research Nurse as identified by the OnCore Clinical Trial Management System (CTMS). The message will be set up with a one-week reminder for follow-up.
3. The In-basket message contains a link to the Medicare Attestation and instructions on how to complete the form.
4. The form must be printed and signed by the Principal Investigator. No electronic signatures are **not** permitted.
5. The Medicaid Attestation must be scanned/uploaded into Epic's Media tab with the document type "Research Medicaid Attestation" and using a description that starts with the IRB number.
6. Once the form is scanned, it will drop from CRBC's report thus stopping the monitoring efforts.
7. A follow-up In-basket message will be sent to the research staff after one week.
8. If the form is not completed withing two weeks, this matter will be escalated to leadership and more frequent reminders will be sent.

VI. REFERENCES

1. Consolidated Appropriations Act (2021) https://www.congress.gov/116/plaws/publ260/PLAW-116publ260.pdf
2. CMS. (2023, September 6). *Electronic Health Records*. https://www.cms.gov/priorities/key-initiatives/e-health/records
3. National Center for Advancing Translational Sciences. (n.d.). *Principal Investigator.* https://toolkit.ncats.nih.gov/glossary/principal-investigator/
4. National Center for Advancing Translational Sciences. (n.d.). *Clinical Research Coordinator.* https://toolkit.ncats.nih.gov/glossary/clinical-research-coordinator/

VII. REVIEW CYCLE

One (1) Year

VIII. APPROVAL

May 21, 2024

Mark Sulkowski, MD
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Date