I. POLICY

Use of the OnCore application is vital for the support of clinical research patient tracking, compliance, patient billing, and study financial management. OnCore integrates with the Epic EHR as a single “source of truth” for patient association with clinical trials.

Required Use

Human subject clinical trials with a Prospective Reimbursement Analysis (PRA) conducted at any Johns Hopkins Medicine site or external affiliated entity by a Johns Hopkins Medicine Faculty Principal Investigator.

II. PURPOSE

The Johns Hopkins University School of Medicine (SOM) will use OnCore, a clinical trial management system (CTMS), to serve as an enterprise-wide platform to manage clinical research and facilitate fiscal and operational compliance with all relevant requirements. The School of Medicine intends to fully leverage OnCore’s capabilities and system integrations to improve efficiency and ensure compliance.

III. DEFINITIONS

<table>
<thead>
<tr>
<th>Clinical Trial Management System</th>
<th>The OnCore Clinical Trial Management System (CTMS) is Johns Hopkins Medicine’s official registry of participants in a research study for any Hopkins location.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant</td>
<td>In this document, the term participant denotes a research human subject. It is a person who voluntarily participates in a human research study after giving informed consent.</td>
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</tbody>
</table>
A Principal Investigator is the primary individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research.

Document resulting from the systematic review of a clinical research study protocol, draft contract and sponsor budget, proposed Informed Consent Form (ICF) cost language and other study documents, such as Notice of Grant Award (NOGA), Investigator’s Brochure (IB) and information regarding the FDA status of the investigational item(s); for the determination of cost delineation (research vs. standard clinical care) of items and services performed as part of consenting subject’s participation in the clinical research or clinical trial.

IV. RESPONSIBILITY

School of Medicine faculty and staff involved in clinical research are individually responsible for understanding this policy, participating in any required training, fulfilling recordkeeping requirements, seeking clarification when questions arise, and responding in a timely manner to requests for information associated with internal audits and investigations.

Clinical Research Support Services (CRSS)

- Closely coordinates with the PI and study team to develop a detailed schedule of events and procedures, equipment, items, services, and human participant visits required to carry out the schedule of events
- Ensures that a detailed PRA is completed for all mandatory human subject research studies regardless of funding source, identifying items and services that can be billed to insurance versus items that cannot
- For supported departments, develops and negotiates final budget directly with sponsor and/or Clinical Research Organization (CRO)

Clinical Research Billing Compliance (CRBC)

- Conducts clinical research billing quality assurance activities

V. PROCESS

DATA ENTRY

Data entry standards within OnCore apply to any Human Subject Protocols (HSP) with any activities that could generate a charge to either a study budget or participant insurance coverage. The following elements for each HSP apply:

a. Protocol Console Minimal Footprint Met
b. Calendar of events (specifications)
c. Study Budget
d. Calendar event validation
e. Calendar events, including additions or corrections for missed elements must be recorded within two (2) business days of visit date
f. Study status update
g. Participant status changes must be recorded within two (2) business days of the precipitating change event
h. Sponsor Invoicing
i. Payment reconciliation for Sponsor Invoicing

VI. REVIEW CYCLE
Three (3) years

VII. APPROVAL

<table>
<thead>
<tr>
<th>Electronic Signature(s)</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Mark Sulkowski</td>
<td>10/03/2023</td>
</tr>
<tr>
<td>Senior Associate Dean for Clinical Trials</td>
<td></td>
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