Acronym/Term	Definition
AAHRPP	Association for the Accreditation for Human Research Protection Programs
Accrual	In OnCore, accrual is counted when a subject has a status of On Study with an On Study date.
AE	Adverse Event
A-TRU	Adult Translational Research Unit
Billing Grid	The OnCore product generated as a result of the Act of Coverage Analysis. A Billing Grid is generated for both Qualifying and Non-Qualifying Clinical Trials. The Billing Grid nomenclature will replace the MCA/SIG nomenclature used by OCRICC with protocols initiated prior to the initiation of the OnCore Financials Process.
Budget Appendix or Attachment	Identifies the payment or reimbursement terms associated with completion of clinical trial activities. Usually identifies the Bill to address required for invoice set-up and generation.
Budget Procedures	Subject-related events included in the budget, which do not need to appear on the protocol or subject calendars. For example, CRC time per visit.
CA	Coverage Analysis
CDA	Confidential Disclosure Agreement
CFR	Code of Federal Regulations
Charge Master	Central source for procedure Current Procedural Terminology (CPT) codes, a description of the procedure associated with each CPT code, and location specific technical and professional pricing for that procedure. Charge Master Events include Protocol Related Events, Procedures, Labs and Budget Procedures.
CIR	Center for Imaging Research
CITI	Collaborative IRB Training Initiative
CLIA	Clinical Laboratory Improvement Amendments
COC	Certificate of Confidentiality
Console	OnCore word that describes a section of the software: protocol, subject, or financial console
Coverage Analysis (Act of)	Determination whether a clinical trial meets Medicare 310.1 criteria for a “Qualifying Clinical Trial” which allows routine care costs, along with reasonable and necessary items and services used to diagnose and treat complications arising from participation in that clinical trial to be billed to Medicare. Items and services not meeting this criteria will be billed to sponsor or the

Acronym/Term	Definition
	research subject. This determination then establishes the financial plan that drives post-approval billing compliance activities.
CPS	Clinical Physician Services (CPS). MCW professional and facility billing group.
CRA	Clinical Research Administration
CRF	Case Report Form
CRO	Contract Research Organization or Clinical Research Organization
CRPC	Clinical Research Process Content – an Epic-OnCore interface that allows OnCore calendar and billing grid data to flow from OnCore to Epic.
CTA/CSA	Clinical Trial Agreement/Clinical Study Agreement, documents the legal language and responsibilities related to trial conduct.
CTCAE	Common Terminology Criteria for Adverse Events
CTO	Clinical Trails Office
CTRC	Clinical Trials Research Center
CTSI	Clinical and Translational Science Institute
CV	Curriculum Vitae
CVECHO Core	Cardiovascular Echo Core Lab
CVEKG Core	Cardiovascular EKG Core Lab
DCR	Data Clarification Request
DOA	Delegation of Authority (Research)
DSMB	Data and Safety Monitoring Board
DSMP	Data Safety Monitoring Plan
EAP	Epic Procedural Code
EHR	Electronic Health Record
EIRC	Eye Institute Research Center
EMR	Electronic Medical Record

Acronym/Term	Definition
Event	An event is a subject procedure, regulatory procedure or other task completed for the purpose of the clinical trial.
FDA	Food and Drug Administration
FED	Federal Rate Base
FH	Froedtert Health
FH-IDS	Froedtert Health Investigational Drug Services
GCO	Grants and Contracts Office
GCP	Good Clinical Practice
HB	Hospital Billing
HRPP	Human Research Protection Program
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDC	Indirect Costs
IDE	Investigational Device Exemption
IDS	Investigational Drug Services
IIP or IIT	Investigator Initiated Protocol/Trial
IND	Investigational New Drug (OnCore PC Console)
IND	Industry Rate Base (OnCore Financials)
Indirect Rate	Indirect Rate is not a specific study event; however, does represent the general cost of doing the business of the clinical trial. A federal requirement that can change over time, with the minimum rate set by MCW Finance. Is accounted as a percentage on top of every dollar spent on a clinical trial visit. Also referred to as F&A (Facilities & Administrative cost), it is not considered overhead. At MCW, applied to all expenses charged for each study fee except the Initial IRB Fee and OCRICC fee.
INV	Investigator Initiated Rate Base
Invoiceable Items	Events that appear in the invoiceable items list, ready to be added to an invoice
IRB	Institutional Review Board

Acronym/Term	Definition
LAR	Legally Authorized Representative
MCA	Medicare Coverage Analysis
MCP	Medical College Physicians
MCTA	Master Clinical Trial Agreement
MCW	Medical College of Wisconsin
Milestones	A milestone defines a specific protocol or subject-related event that can be invoiced according to a study payment schedule. In OnCore speak, a milestone represents all procedures that can occur at a single timepoint during the study. An example would include all procedures completed at a single visit.
MoP	Manual of Procedures
MRN	Medical Record Number
MSM	Medical Safety Monitor
NCI	National Cancer Institute
NCT Number	National Clinical Trials Number in ClinicalTrials.gov
NIH	National Institute of Health
NOA	Notice of Agreement
Occurred	Research subject visit status – most important status that generates invoiceable items
OCRICC	Office of Clinical Research and Innovative Care Compliance (FH). OCRICC has oversight responsibility for any clinical research activities involving Froedtert Health clinical space, including facilities, services, staff and billing compliance as a result of research activities.
OHRP	Office of Human Research Protection
OSR	Outside Safety Report
Parameters	OnCore Financial settings that are used to define the rules that will govern financials activities for a specific clinical trial (protocol).
Pass Thru Items	Procedures or events that are invoiced as a line item (not part of a milestone).
PB	Professional Billing
PI	Principal Investigator

Acronym/Term	Definition
Procedure Alternative	When occurring a visit select from one of the list of procedure alternatives
Protocol Items/ Protocol Related Events	Protocol Related (Administrative) events identify the tasks or events that relate to the operation of the trial (including but not limited to Study Start-up, Florence or OnCore fees, IRB fees, Advertising fees, Monitoring, and Pharmacy fees). These events occur when study submission or budget related activities begin through the duration of the trial and can be incurred even without a single subject accrual.
Protocol No.	Protocol identifier in OnCore
PTE	Pass Through Entity
P-TRU	Pediatric Translational Research Unit
QA	Quality Assurance
QCT	Qualifying Clinical Trial
R	Research Related Procedure Designation – if viewed in an OnCore protocol or subject's calendar
Rate Base	Financial Console Parameter (rate base) in OnCore, choose from FED-federal, IND-industry, or INV-investigator initiated.
RBC	Research Billing Compliance
RPE	RPE interface (Retrieve Process for Execution) – interface between oncore and epic
RR	Re-consent required
S	Standard of Care Procedure Designation – if viewed in an OnCore protocol or subject's calendar
SAE	Serious Adverse Event
SIG	Study Invoicing Grid
SOC	Standard of Care
SOE (Schedule of Events)	The sponsor protocol table of events that identifies which procedures/events will occur at each clinical trial visit. The use of the SOE to indicate SOC vs. Research events for OCRICC application will be replaced by use of the OnCore Billing Grid for all protocols included in the OnCore Financials Console, this applies for both New and Legacy studies.
SOP	Standard Operating Procedures
SUB	Subaward

Acronym/Term	Definition
Subject Milestone Items	Milestone items appear on the invoiceable items list after the visit for that milestone is marked occurred.
Subject Related Events	The Subject Related events are those associated with the subject procedures or calendar. Subject Related events would be found in Procedures or Labs tab in OnCore Financials.
Subject Status	Research subjects always have a status to designinate where they are in the life of the study. Some status designations automatically create an invoiceable item.
SWF	Salaries, Wages and Fringe
Trigger	In OnCore Financials, triggers are configured on protocol related events which can be set to automatically create invoiceable items or allow study personnel to create invoiceable items from the CRA Console.
Unplanned	Visit Variation where a visit is added – additional visit
Variable	OnCore selection for a protocol related event, ie: can this event be invoiced more than one time? If so, it is variable.
Visit Overrides	The function which enables the ability to set the set the billing designation and negotiated cost for the same procedure differently depending on the visit.
Visit Variation	Changes to the setup for a subject visit. Missed or additional items.
WDL	Wisconsin Diagnostic Laboratories
Withholding	Field in OnCore Financials parameters per protocol. Represents a specific percentage of per procedure reimbursement held from MCW until a CTA defined timepoint in the future, most often database lock. Withholding is inconsistent with MCW Best Practice, if sponsor requests withhold amount >5% contact the Office of Research.