Policy Identification Number		
Policy Title	Prospective Reimbursement Analysis (PRA) for Clinical Research	
Classification	University MUSC Hospital Authority (MUHA) MUSC Physicians Research	
Approval Authority	University Research Council	
Responsible Entity	Office of Clinical Research, Office of the Vice President for Research	
Policy Owner	Royce R. Sampson, Director, Office of Clinical Research	

# I. Policy Statement

This Policy describes the shared responsibility for performing the Prospective Reimbursement Analysis (PRA) in the development of the Study Billing Plan for all clinical research studies regardless of sponsor funding source (i.e., extramural industry funding, extramural non-profit or government funding, and/or intramural funding).

## II. Scope

This Policy applies to all MUSC entities and persons involved in human subjects' research. Pls have primary responsibility for submitting all human subjects' studies to the Office of Clinical Research (OCR) for PRA review prior to participant enrollment and ensuring that the Study Billing Plan is followed in compliance with applicable law and this policy.

# III. Approval Authority University Research Council

# IV. Purpose of This Policy

The purpose of this Policy is to ensure enterprise-wide research billing compliance through the Prospective Reimbursement Analysis (PRA) review process.

#### V. Who Should Be Knowledgeable about This Policy

All MUSC enterprise employees engaged in human subjects' research as described in the U.S. Department of Health and Human Services' guidance document entitled "Engagement of Institutions in Human Subjects Research." All MUSC enterprise employees who are involved in research billing including, but not limited to, Revenue Integrity, Epic-Information Solutions (IS), Epic Research, MUHA and MUSCP Compliance, Research Administration Offices, University Compliance, and Clinical Service Providers.

## VI. The Policy

All human subjects research studies are required to have a PRA review to ensure compliance with federal billing regulations. All studies determined by IRB review to be IRB Exempt will be automatically deemed as PRA Exempt. A PRA review includes an objective analysis of all MUSC Health services and funding sources associated with a research study and a determination of what can and cannot be billed to third party payers using the National Coverage Determinations (NCDs) and the Local Coverage

Policy ID Number	
Policy Title	Prospective Reimbursement Analysis (PRA) for Clinical Research
Date Approved	5/6/2019

Determinations (LCDs) adopted by the Centers for Medicare and Medicaid Services (CMS), as well as clinical care guidelines. The PRA is used by the MUSC Health Revenue System as the source of truth to ensure items are billed correctly to third party payers, the patient, or the study account. The final determination on which items and services during a research study are billable to Third-party payers or patients, as may be reflected in a PRA, is an institutional decision of the MUSC enterprise and not the decision of a study team member.

Upon PRA approval, all studies with MUSC Health services will be entered into Epic by the OCR PRA team and the Epic Research team will create the required research orders. All studies with orderable services will receive a simple Epic order set that contains a pick list of orders as determined by the PRA.

Industry-sponsored human subjects research studies will be assessed a fee for the PRA review.

# VII. Special situations

There may be unusual situations with research-related billing that may require additional considerations by the OCR Director, MUSC Research Leadership and Legal Counsel.

## VIII. Sanctions for Non-compliance

Clinical research investigators are ineligible to initiate their studies or to utilize MUSC Health services for the purposes of their research without PRA review and approval. Principal Investigators that do not comply with this policy will have their studies put on hold until identified research compliance issues are resolved. The Principal Investigator and/or his or her department will be responsible for any financial consequences resulting from non-compliance. Research billing compliance issues will be reported to the Principal Investigator, Department Chair and Administrator, and Medical University of South Carolina (MUSC), Medical University Hospital Authority (MUHA), and/or MUSC Physicians (MUSCP) Compliance Officers as appropriate and a Corrective Action Plan will be developed. Repeat compliance issues will be reported to the Vice President for Research, Chief Physician Executive, Associate Provost for Regulatory Compliance, and Legal Counsel as appropriate.

# IX. Related Information

#### A. References, citations

"Engagement of Institutions in Human Subjects Research," U.S. Department of Health and Human Services, <a href="https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html">https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html</a>
"Routrine Costs in Clinical Trials," Centers for Medicare and Medicaid Services' National Coverage Determination 310.1

#### X. Communication Plan

This Policy will be posted on the Institutional Research Policy website with a link on the Office of Clinical Research (OCR) website and will be distributed through the Vice President for Research list serve.

# XI. Definitions

Define key terms used within the policy.

Policy ID Number		
Policy Title	Prospective Reimbursement Analysis (PRA) for Clinical Research	
Date Approved	5/6/2019	

- Clinical Research Clinical Research aims to advance medical knowledge by studying people, either through direct interaction or through the collection and analysis of blood, tissues, or other samples.
- Corrective Action Plan (CAP) Includes a description of a compliance issue, plan of action to
  address the issue including the responsible person(s), and the recommended preventative
  action to avoid reoccurrence. CAPs will be reviewed with the OCR Research Compliance
  Committee comprised of MUSC, MUHA and MUSCP Compliance Officers and the OCR. Plans will
  be escalated to the OCR Advisory Board and the Institutional Compliance Committee as
  determined appropriate by the OCR Research Compliance Committee.
- Coverage Analysis is a systematic review of all procedures listed in the study protocol's schedule
  of events to determine which ones are 'billable' and the correct responsible party to receive the
  bill.
- Coverage Determinations Determining the appropriate funding source for each MUSC Health service, whether research study account or third-party payer, as outlined by the study documents and CMS and clinical practice guidelines.
- Epic The electronic health record system utilized by MUSC.
- Human Subjects Research Research involving a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information.
- Prospective Reimbursement Analysis (PRA) A detailed review of the research protocol, related documents, and Medicare coverage guidelines to determine probable reimbursement in the context of the National and Local Coverage Determinations. See Coverage Analysis
- Study Billing Plan A document that contains the study billing calendar and includes the MUSC Health services associated with the clinical research study and the coverage determinations.
- Third-party Payer An entity (other than the the research study ) that reimburses and manages healthcare expenses. Third-party payers include insurance companies, governmental agencies, and employers.

XVI. Review Cycle
This Policy will be reviewed every 3 years.

XVI. Approval History
List original approval date and subsequent review dates

Approval Authority	Date Approved
University Research Council	

XVII. Approval Signature
The policy is signed by the President of MUSC.

Policy ID Number		
Policy Title	Prospective Reimbursement Analysis (PRA) for Clinical Research	
Date Approved	5/6/2019	
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