Standard Operating Procedure (SOP)

SOP number: SOP CW AHC 257	**SOP Name:** Research Billing Compliance
Location: *Company-Wide Policies	**Responsible Department:** Research Services
SOP Owner/Executive Owner: Executive Director of Research Services	**Original Creation Date (If applicable):** Not Set
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I. SCOPE: This standard operating procedure (SOP) applies to all employees and agents of AdventHealth and AdventHealth Medical Group (AHMG) who conduct human subjects research, provide Billable Patient Care Items or Services related to a research study protocol, or perform clinical research billing. That includes, but is not limited to, Research Services Personnel, Research Personnel, clinical providers serving as research investigators, employees involved in the registration of research participants, ordering, coding, or billing of research related Billable Patient Care Items or Services.

II. PURPOSE: This SOP describes the process that must be followed to ensure Billable Patient Care Items or Services designated as part of a research protocol, are billed, in compliance with applicable laws, regulations, the Centers for Medicare & Medicaid Services (CMS) requirements, as well as institutional policies and procedures, study related documents, and grant and contractual obligations.

III. QUALIFIED PERSONNEL: Employees, Research Personnel, and AdventHealth agents

IV. TRAINING: Collaborative Institutional Training Initiative (CITI): Clinical Trial Billing Compliance (CTBC) module and other assigned research billing compliance training specific to role and AdventHealth Research Institute (AHRI) policies and procedures

V. SUPPLIES & EQUIPMENT: CITI, clinical trial management system - Clinical Conductor (CTMS), IRBNet, ALN, SharePoint and Epic access, study budget document, Coverage Analysis (CA), study informed consent document (ICF). Access to applications and documents will vary depending on role and responsibilities.

VI. PROCESS/PROCEDURE:

A. Required Training: mandatory research billing compliance training will consist of:

1. CITI CTBC module required upon hire as part of orientation and every 3 years.
2. AHRI, Office of Research Integrity and Compliance (ORIC) assigned training specific to AHRI research billing processes required upon hire for AHRI staff, dependent upon role, when added to a study team for clinical providers (physician and advanced practice provider investigators), and every 3 years.
   a) AHRI training will include information on associated research billing guidelines and instruction on institutional processes to ensure proper billing of research related clinical trial participant services/items.
   b) There are two separate training versions for AHRI research billing institutional

processes, one for clinical providers/physician investigators and another for AHRI staff and non-providers.

c) Training will be available to all staff but is not mandatory for the following non-AHRI staff: Employees involved in the registration of research participants, ordering, coding, or billing of research related Billable Patient Care Items or Services.

3. Re-training may be required when significant changes to federal regulations, CMS rules and/or institutional policy affect investigator requirements, or when an Individual is found non-compliant with this policy.
4. Epic system training will be required by appropriate research personnel, to include ORIC Epic Research Billing Review (Epic RBR) team, research billing analysts, and others depending on their role and responsibilities.
5. All applicable Research Personnel listed on a Delegation of Authority (DOA) log (or research personnel log) must complete required research billing compliance training prior to the study being granted Institutional Clearance, noting that any non-research personnel as defined below, who are required to be added to the log by an industry sponsor are not required to complete this training.
6. Attendance of mandatory training is documented and monitored for compliance. Completion will be tracked by AHRI, Research Services

B. Study start up processes impacting research billing compliance:

1. Office of Sponsored Programs (OSP):

a) OSP will complete a billing risk assessment to determine if a CA or Billing Grid (BG) is necessary. This process takes the following into consideration:

i. The study is a clinical trial with clinical items/services

ii. There is a national coverage analysis available for the study

iii. AHRI is accepting payment from sponsor for 100% of all clinical items/services included in the study

iv. The study is not a clinical trial and does not have any clinical items/services (such as retrospective chart reviews and, observational registries)

b) All clinical trials with clinical items/services will have either a CA or a BG based on completed risk assessment.

c) Identification of study type: The study type is determined during the OSP billing risk assessment process. The budget team identifies the study type in the internal budget spreadsheet for the CTMS team to reference. The CTMS team enters the study type in the CTMS build which interfaces and maps to the Epic research record. The study type in Epic determines whether the patient charges enrolled in that specific study are directed to the Epic RBR report in Epic and held until the Epic RBR team review is completed. The available study types in Epic and the corresponding billing hold statuses are as follows:

i. Interventional - charges held and routed to Epic RBR

ii. Observational - charges released and not routed to Epic RBR

iii. Expanded Access – charges released and not routed to Epic RBR

d) Execution of Physician Payment Letters (PPLs): PPLs are required for providers who will perform the research required clinical services/procedures that are not considered billable and are identified as part of the budget process. PPLs are executed prior to the identified provider(s) performing any study related clinical activities with enrolled patients for that specific study. The execution of all required PPL's must be completed prior to granting institutional clearance for a study.

e) As providers participating in study activities are identified during the study intake feasibility assessment, their employment status is determined as AdventHealth or non-AdventHealth employed providers, documented and communicated to the study team by including the information in the internal budget document.

f) Review of informed consent language: Review the subject injury, patient cost, and patient payment sections of the draft ICF provided by the regulatory team. Complete final review of the cost section ensuring the institutional required cost language is present and there are no conflicts with the sponsor provided cost language. Upon review communicate approval or needed revisions to the regulatory specialist.

g) Document concordance. After the clinical trial agreement (CTA), or grant agreement, CA or BA, internal budget and ICF are finalized, OSP is responsible for ensuring consistency across these documents prior to providing Institutional Clearance for study activation.

2. Centralized Regulatory Team:

a) Informed consent language: The regulatory specialist will compare the sponsor provided cost information to the institutional required cost language to ensure all required information is present and there and there are no directly conflicting statements. OSP will provide final review prior to submitting to sponsor and IRB for approval. Any revisions to sponsor provided informed consent language must be approved by the sponsor as applicable prior to IRB submission.

b) Activate study in Epic (refer to Epic Tip Sheet-Updating Research Record Statuses in Epic, referenced below):

i. Upon confirmation by the regulatory team that the study may be activated obtaining institutional and study sponsor approvals, the Epic research record must have 1.) the billing status set to "active" and 2.) the study status updated to an active study status type prior to enrolling patients in the study. Active study statuses include:
   - recruiting
   - enrolling by invitation
   - active, not recruiting
   - suspended

ii. The study must be in an active study status to link a patient to an Epic research record to trigger the charges to be held and sent to the Epic RBR report.

3. Study Team:

For all providers identified as non-AdventHealth employed or independent providers, the study team must ensure a billing contact in that provider's office is established and communicate with them regarding the new study prior to study activation. ORIC research billing compliance analyst may assist in establishing the contact person and share with appropriate study team members.

4. Study Intake:
    a) Identification of providers who will perform study protocol required clinical items/services and therefore may need a PPL developed and executed prior to study initiation. This information is communicated to OSP to ensure PPLs are fully executed during the study start-up process. Study intake team should copy OSP budget team on email with providers and then follow-up with specific items for the budget.
    b) Investigational Device Studies
        i. The research study intake team may need to submit to local Medicare administrative contractor (MAC), requesting approval to bill for all investigational device exemption (IDE) studies prior to study activation depending on the AdventHealth facility location and the local MAC region for that facility.
        ii. Upon national or local MAC approval, a token charge creation request should be made to the AdventHealthchargemaster support team to ensure the investigational device is not charged to or reimbursed by the research participant or research participant's health insurance.
        iii. For devices billable to insurance, the IDE number issued by the Federal Drug Administration (FDA) should be attached to each device Epic all procedure (EAP) in Epic to ensure this is billed with charges to each clinical trial participants insurance per Medicare guidelines.

C. Study Amendments
    1. Amendments that could impact research billing compliance may include but not limited to, amendments to the research protocol, CTA, budget, CA, BG, or the ICF.
    2. Each applicable amended study document must be reviewed to determine if any study start up processes listed below are impacted:
        a) Document concordance due to changes required in any of the following: CTA, Budget, CA, ICF, etc.
        b) CTMS study type
        c) New PPL
        d) Addition of any new non-AdventHealth providers
    3. If it is determined that the amended document does impact the above, make necessary adjustments and communicate the changes to all applicable parties.

D. Patient Enrollment - Study Team
    1. Upon patient enrollment, the research study team must complete the following steps to ensure research participant charges are held and routed to the Epic RBR report:

a) Upon consenting a patient to a clinical trial, the patient must be linked in Epic to the corresponding research record as soon as possible, no later than 7:00pm local time on the day of consent.

b) Link each research visit to its associated Epic research record the same day the patient completes the visit, no later than 7:00pm local time.

2. When research visits include clinical items/services performed by non-AdventHealth providers, the study team must communicate with the established contact in the external provider's billing office at the following timepoints as applicable:

a) Upon consent of non-AdventHealth provider patient

b) Each date of service a non-AdventHealth provider sees patient for research, (communicate each research visit)

E. Epic RBR:

1. Charges of research participants who are linked to a research record in Epic are routed to the Epic report titled "Patients Needing Research Billing Review" for the Epic RBR team to conduct a 100% review of all research patient charges. The 100% charge review includes all AdventHealth, AHMG or AdventHealth Imaging Center (AHIC) generated hospital and professional charges.

2. Research participant's services/items that appear on the patients needing Epic RBR report are investigated and marked as reviewed by the Epic RBR team.

3. The Epic RBR team utilizes CTMS data, the CA, BG, budget documents, and the research protocol to conduct their review.

4. The Epic RBR team is tasked with determining whether the research participant's charges are research related. Any charges determined to be non-related to research will be billed to patient/insurance per AdventHealth/AHMG/AHIC standard process.

5. For all charges determined to be related to a research study, the Epic RBR team will delineate those charges as follows:

a) Routine care charges: Billable to patient/patient's insurance and should include CMS required research compliance indicators as appropriate.

b) Research sponsor reimbursed charges: Reviewed by the research finance team who are tasked with ensuring all sponsor reimbursed charges are invoiced or paid.

F. Third Party Billers – File extracts will be created and transmitted securely by revenue cycle AdventHealth Information Technology (AIT) to third-party billers as appropriate. The file extracts will:
1. Separate and remove non-study related charges
2. Separate study related charges that should be billed to AdventHealth Research Institute (AHRI) that are being reimbursed by the study sponsor
3. Indicate the charges that are study related charges and should be billed to patient/patient's insurance (following Medicare rules for deemed and qualifying clinical trials) and will include the National Clinical Trial number to be added to the claim

G. Maintenance of Statuses in Epic (Study, Billing, and Patient Statuses):
1. Study status responsibility: The centralized research regulatory team is responsible for

updating the study status in Epic for each individual study. When the study is terminated or completed, the study status should be updated to an inactive status upon study closure with the IRB of record. Inactive study statuses include:

a) not yet recruiting

b) terminated

c) completed

d) withdrawn

2. It is important that all patients enrolled have completed all study visits that include clinical items/services prior to updating the study status to an inactive status.
3. Billing status responsibility: The regulatory team is responsible for updating the billing status to "completed" upon study closure with the IRB of record. The billing status should only be switched to "completed" when charges are no longer being generated for the study. Upon changing the billing status to "completed" the action cannot be undone.
4. Patient status responsibility: The clinical operations study team is responsible for ensuring patient study statuses are maintained in Epic and updated in a timely manner. When the patient's participation in the study has ended and no further study visits will occur with that patient, their study status should be updated in Epic to reflect their completion of study participation.
5. For long term mortality studies, when a patient completes the treatment phase of the study and enters into a survivorship follow up phase (completed the investigational intervention phase and are only being followed to determine their survival status) at that time the patient status may be updated to "survivorship" patient status. The survivorship phase of each study (when applicable) will be identified in the survivorship column of the CA (previously referred to as survival follow up column in the CA). Additionally, changing the patient status to "survivorship" will not impede the ability to continue to bill the study sponsor for study related costs and invoiceable items, including future survivor status follow-up visits.
6. Statuses should be updated preferably within 48 hours of knowledge of the status change.

H. Reporting and Review of Research Billing Compliance Inquiries, Concerns, or Research Participant Complaints:

1. The research billing compliance analysts will assist the Research Personnel and billing teams with the update/correction of any research related billing issues that are billed out of the AdventHealth Epic billing system.
2. This will include research related services/items billed by AdventHealth and any AHMG or AHIC practice indicated on the AHMG provider power business intelligence report.
3. When corrections are identified that require reversing charges made to patients or insurance providers, the research billing compliance analysts will ensure the charges are reversed in a timely manner.

I. Enforcement actions may include one or more of the following:

1. Human subjects research that does not comply with this policy, may not receive Institutional Clearance and may not begin the study or utilize hospital services in

support of the study.

2. AdventHealth or reviewing IRB suspension or hold of associated study(ies) involved.
3. Employee discipline or other administrative actions as appropriate.
4. Requirement to develop and complete a corrective and preventative action (CAPA) acceptable to ORIC. Additional training and education may be required as part of the CAPA.

I. DEFINITION(S): For capitalized terms not defined in this policy, refer to CW AHC 106 Billing Compliance in Clinical Research Policy.

For abbreviations not defined in this policy, refer to CW AHC 102 Abbreviations in Research.

Delegation of Authority (DOA): A comprehensive list of study staff members and the duties that have been delegated to them by the principal investigator used by the study team, sponsor, and IRB to confirm who is listed as Research Personnel of a study.

Epic Research Billing Review (Epic RBR): RBR allows for review of the charges related to a research study patient's account when linked to a research record within Epic. The RBR team can review and classify charges as related to research and/or review system classified charges and evaluate whether those designations are correct utilizing applicable resources. Upon verifying whether the charges are related to research, next, for research related charges, the RBR team will determine if the charges are routine care charges to be billed to patient/patient's insurance, or if the charges are research sponsor reimbursed charges and should be billed to the study. After completing their analysis, the RBR team will correct any mistaken system assigned classifications, and then mark the charges as reviewed allowing those charges and accounts to be billed. All charges determined not related to research will be released to be billed to patient/insurance per standard process.

Non-Research Personnel: Ancillary individuals who may interact with research subjects during a research study, but only within the scope of his/her regular employment capacity. Involvement in the research study of this level merits neither professional recognition nor publication privileges. Individuals do not contribute to the design, governance or analysis of the study. Individuals are not recognized as Research Personnel and are not required to be listed on the DOA log. (Examples include but are not limited to: Bedside nurse completing standard of care procedures, Infusion Nurses (starting and monitoring the infusion), Phlebotomist, ECG technician, Radiologist or Radiology Technician, Pathologist, Lab Personnel, Nutrition Services, Pharmacy (if applicable)).

Physician Payment Letters (PPLs): A document memorializing a provider's agreement to perform specific clinical services as part of a clinical trial that is externally funded, and the agreed upon fair market value rate for the service. To be effective, the PPL must be executed prior to the provider performing any agreed upon clinical services for the given study.

VII. EXCEPTION(S): See CW AHC 101 Research Oversight

VIII. REFERENCE(S):

Medicare Clinical Trials Policy - National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)
Medicare Benefit Policy Manual, Ch. 14
Federal False Claims Act, 31 U.S.C. §§ 3729 – 3733
Anti-Kickback Statute, 42 U.S.C. § 1320a- 7b(b)
Physician Self-Referral Law, 42 U.S.C. §1395nn
NCD 310.1 - Routine Cost in Clinical Trials
Medicare Coverage Related to Investigational Device Exemption (IDE) Studies
Pub 100-04 Medicare Claims Processing – Chapter 32, Section 68.1
Pub 100-04 Medicare Claims Processing – Chapter 32, Section 68.2
Updating Research Study Status | Epic Training Documentation

IX. RELATED DOCUMENT(S) / ATTACHMENT(S):

Research Oversight
Billing Compliance in Clinical Research Policy
Abbreviations in Research
Human Research Protection Program
Research Personnel