Regional One Health

# Research at Regional One Health

**Please be advised that this policy was printed on 6/25/2015 at 10:54:49 AM and may be out of date.
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## Policy

Regional One Health is committed to excellence in teaching, research and patient care. These activities are to be conducted with the highest ethical standards. For research studies involving human subjects, Regional One Health is guided by the ethical principles regarding human subjects in research and adheres to applicable laws, regulations and guidelines, including those of the Food and Drug Administration (FDA), the Office for Human Research Protection and the State of Tennessee. Research activity is also governed by Health Insurance Portability and Accountability Act (HIPAA) Privacy regulations.

These policies apply to all clinical research activities, regardless of the source of funding, which in whole or in part:

1. Are conducted using any property or facility of Regional One Health.
2. Involve the use of non-public information to identify or contact human research subjects or prospective research subjects that are patients of Regional One Health or any of its affiliate facilities.
3. Involve human subjects in research.

No clinical research may be conducted until the project has been reviewed and approved by both the University of Tennessee Health Science Center (UTHSC) Institutional Review Board (IRB) and Regional One Health's Office of Medical Research (OMR). This requirement applies not only to clinical trials but also to any research studies that qualify for exempt status as determined by the IRB.

A study or project approved by a non-UTHSC-IRB must be submitted to the UTHSC-IRB for review and approval prior to written approval by Regional One Health.

## Purpose

To assure that research conducted at Regional One Health may attain the goals desired and complies with these policies and procedures, as well as applicable federal, state and local laws and regulations.

## Process

## Related Documents

None

## TJC

## Approved By

**Van Werkhooven, Maria E.** - *Department Head*
**8/22/2014 2:35:02 PM**

**Benink, Eric H.** - *Executive/VP*
**11/26/2014 7:58:21 AM**

**Sumter, Rob** - *COO Approval*
**12/4/2014 10:37:46 AM**

Regional One Health

# Office of Medical Research

**Please be advised that this policy was printed on 6/25/2015 at 10:53:44 AM and may be out of date.
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## Policy

The role of the Office of Medical Research (OMR) is to coordinate, encourage and facilitate research conducted at Regional One Health; and to serve as a resource to investigators and their research teams.

The OMR is the primary contact with the University of Tennessee Health Science Center Institutional Review Board (UTHSC-IRB).

The OMR operates under the guidance and direction of the Chief Medical Officer (CMO)/Senior Vice President for Clinical Affairs.

## Purpose

To ensure that research is conducted in accordance with high ethical standards; and to ensure compliance with applicable state and federal regulations, as well as Regional One Health's institutional policies.

## Process

The duties of the OMR shall include:

1. Review clinical trial operations, facilitate communication with the UTHSC-IRB, resolve issues and develop or review clinical research operating policies and procedures.
2. Communicate with the UTHSC-IRB as needed.
3. Provide pricing for rate requests submitted by investigators for services to be provided by Regional One Health under contract.
4. Utilizing UTHSC-IRB resources, gather, review and prepare the documents submitted by Investigator for research studies for review by the CMO.
5. Coordinate the evaluation of study applications by the UTHSC-IRB and the OMR.
6. Facilitate the contract approval process for services to be purchased by the investigator, and any special arrangements required to conduct the study.
7. Request legal and financial review of all study contracts and contract amendments.
8. Provide written notification and pertinent information to the investigator regarding whether a research study is approved.
9. Provide written notification and pertinent information to the departments at Regional One Health providing services for new research studies.
10. Provide notification to Regional One Health's Chief Financial Officer (CFO), Accounting Services Department (ASD) and UTHSC Grants & Contracts Office (or other institution, when applicable) of

those approved research studies for which Regional One Health will provide services chargeable to research accounts.

11. Provide to the ASD a copy of the Regional One Health's approval letter for each study (Confirmation of Approval of Research Activity) for which Regional One Health is expected to provide research services, a copy of the contract, along with the UTHSC contract number, account number, department and name and address of person to whom the invoice should be directed.
12. Coordinate with investigator's research staff and Regional One Health's department of Patient Financial Services (PFS) to receive timely patient enrollment information and identification of research related tests, procedures and other services.
13. Review Research Order Entry and Billing reports, and study coordinator reports, as applicable, to confirm that patient accounts are not charged for research tests and procedures, referring any discrepancies to PFS for resolution.
14. For non-pharmacy services, the OMR will provide to the ASD on a monthly basis the following information for the previous month, for each active research study, as applicable: patient identification, charges, procedure performed, service date, invoice total, IRB #, UTHSC account number, UTHSC contract number. Regional One Health's Investigational Drug Pharmacist is responsible for providing billing information to the ASD for all research-related pharmacy services.
15. Coordinate with research study staff and the UTHSC-IRB staff to maintain current records in the OMR on all open studies being conducted at Regional One Health.
16. Maintain copies and a computer database of research records. Copies will be maintained in compliance with Regional One Health's Records Retention policy (see **Related Documents** below for link to *Records Management* policy).
17. Provide reports to Regional One Health's CMO, Administration and departments providing research services as needed.

## Related Documents

Medication Use - HR22 - Investigational Drug ServiceRecords Management

## TJC

None

## Approved By

**Van Werkhooven, Maria E.** - *Department Head*
**8/22/2014 2:25:19 PM**

**Benink, Eric H.** - *Executive/VP*
**11/20/2014 4:15:06 PM**

**Sumter, Rob** - *COO Approval*
**11/23/2014 1:39:57 PM**

Regional One Health

# Institutional Review Board

**Please be advised that this policy was printed on 6/25/2015 at 10:55:43 AM and may be out of date.
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## Policy

Regional One Health has designated University of Tennessee Health Science Center (UTHSC) to review research involving Regional One Health through the UTHSC's Institutional Review Board (UTHSC-IRB). The UTHSC-IRB will identify projects subject to full review, expedited review and those which are exempt from IRB review. The UTHSC-IRB will be responsible for notifying the Office of Medical Research (OMR) of any IRB-approved research activity which involves Regional One Health's patients, records, services, or facilities prior to its initiation. Approval must be obtained from both the UTHSC-IRB and Regional One Health's OMR prior to a study's initiation at Regional One Health.

The UTHSC-IRB will be responsible for the general conduct of research at Regional One Health, including compliance with all applicable regulations and requirements regarding the conduct, enrollment, consents, and record keeping for such studies.

However, Regional One Health reserves the right to disapprove any research activity which, in its sole discretion, (i) is not consistent with the hospital's mission; (ii) does not adequately protect the rights and welfare of human subjects; or (iii) is to involve an investigator who does not meet the qualifications as described in Research Policy # 2446.001 (*Investigator Qualifications*) or has failed to comply with these policies and procedures.

## Purpose

An IRB is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans. In the United States, the Food and Drug Administration (FDA) and Department of Health and Human Services regulations have empowered IRBs to approve, require modifications in planned research prior to approval, or disapprove research. IRBs are responsible for critical oversight functions for research conducted on human subjects that are scientific, ethical, and regulatory.

The IRB has the authority to approve, require modifications in or disapprove all research activities that fall within its authority as specified by both the federal regulations and local institutional policy. It makes an independent determination to approve or disapprove research activity based on its assessment that the following requirements are satisfied (45 CFR § 46.111):

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by **§46.116**.

5. Informed consent will be appropriately documented to the extent required by **§46.117**.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

## Process

## Related Documents

Investigator Qualifications45 CFR Part 46 Protection of Human Subjects

## TJC Approved By

None

**Van Werkhooven, Maria E.** - *Department Head*
**8/22/2014 2:31:21 PM**

**Benink, Eric H.** - *Executive/VP*
**11/26/2014 8:01:11 AM**

**Sumter, Rob** - *COO Approval*
**12/4/2014 10:41:28 AM**

Regional One Health

# Approval of Research Activity

**Please be advised that this policy was printed on 6/25/2015 at 10:57:00 AM and may be out of date.
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## Policy

All research must be approved by Regional One Health's Office of Medical Research (OMR), in writing, prior to initiation. The OMR will be responsible for obtaining the express authorization of Regional One Health's Chief Medical Officer (CMO) and/or any other authority required by Regional One Health for the approval of any research. Research must be scientifically sound, have University of Tennessee Health Science Center Institutional Review Board (UTHSC-IRB) approval and be consistent with Regional One Health's mission. Regional One Health reserves the right to withhold approval of any research activity.

## Purpose

To assure Regional One Health is informed of all research activity conducted within its facilities and that research is in compliance with Regional One Health's policies and procedures, as well as applicable federal, state and local laws and regulations.

## Process

Any Investigator desiring to conduct research must submit the following information for each study to the OMR at least thirty (30) days prior to the study's proposed initiation:

1. Completed Regional One Health's *Application for Approval to Conduct Research* form (see **Related Documents** below for link to form). This form can also be downloaded from Regional One Health's website: **http://www.regionalonehealth.org/employees-and-physicians/research/**.
   - For research proposed to be conducted by non-credentialed physicians such as residents; non-physicians such as physician extenders and nurses, a faculty member of University of Tennessee Health Science Center (UTHSC) must be named as co-principal investigator.
   - For chart review activities in the context of research, when patients can not be reasonably contacted for consent, investigators must obtain a waiver of Health Insurance Portability and Accountability Act (HIPAA) Privacy authorization from the Institutional Review Board (IRB). Investigators must have a UTHSC-IRB-approved waiver of HIPAA Privacy authorization whenever patient charts are to be screened to identify patients who might be eligible for inclusion in a study.
   - The federal Certificate of Confidentiality, if any is involved, for the study.
2. If applicable, a study-specific, written contract for clinical research hospital services between Regional One Health and the institution. Rates for research-related services are available from the OMR. If no services are to be provided by Regional One Health, this should be stated in a cover letter (sample wording, "This will confirm our understanding that no services will be performed at Regional One Health

which are chargeable to this Study; therefore, there will be no reimbursement to Regional One Health from ___Name of Institution___ for services.").

3. Cover letter which clearly states the role of Regional One Health in the study and any special arrangements to be made. If necessary, the cover letter should also clarify any of the above items.
4. Such other information or supporting documentation as may be requested by the OMR.

The UTHSC-IRB makes accessible to Regional One Health's OMR the investigator's electronic application and all documents related to the study, the IRB letter of approval, and, if applicable, any IRB-approved documents (e.g., informed consent form or questionnaire).

Once all of the required materials have been received and reviewed by the OMR (Completed Application), the OMR will notify the Principal Investigator if additional information is needed or of its decision within thirty (30) days. Research studies may not be initiated, and subjects may not be enrolled, prior to written approval by Regional One Health .

Questions concerning research activity should be directed to the OMR at Regional One Health .

All IRB-approved projects have an assigned IRB number which will be used by Regional One Health to identify the research protocol in the patient record, and in billing the research account for research-related tests and procedures which may have been contracted to Regional One Health .

## Related Documents

Investigator ResponsibilitiesMedication Use - HR22 - Investigational Drug ServiceForm 1-application For Approval (2014-02).docx

## TJC Approved By

None

**Van Werkhooven, Maria E.** - *Department Head*
**8/22/2014 2:26:51 PM**

**Benink, Eric H.** - *Executive/VP*
**11/20/2014 4:30:12 PM**

**Sumter, Rob** - *COO Approval*
**11/23/2014 1:44:20 PM**

Regional One Health

# Dispensing Drugs Administered in Clinical Trials or Other Investigative Studies

**Please be advised that this policy was printed on 6/25/2015 at 9:32:32 AM and may be out of date. Always refer to The MED's Intranet for the most current copy.**

## Policy

All medications required by a research protocol must be administered through Regional One Health's Department of Pharmacy. This applies to inpatient and outpatient studies. Any exception to this requirement must be approved in advance and in writing by the Chief Medical Officer (CMO) and the Director of Pharmacy. A copy of this documentation will be maintained with the study-specific research file in Regional One Health's Office of Medical Research (OMR).

## Purpose

To comply with general hospital policy and Standards of The Joint Commission (TJC).

## Process

## Related Documents

Medication Use - HR22 - Investigational Drug Service

## TJC

None

## Approved By

**Van Werkhooven, Maria E.** - *Department Head*
**8/22/2014 2:28:54 PM**

**Benink, Eric H.** - *Executive/VP*
**11/26/2014 8:58:02 AM**

**Sumter, Rob** - *COO Approval*
**12/4/2014 10:45:16 AM**

Regional One Health

# Investigator Qualifications

**Please be advised that this policy was printed on 6/25/2015 at 10:57:47 AM and may be out of date.
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## Policy

Investigators applying for research or conducting research must have the appropriate skills, medical training, credentialing, experience, and privileges to conduct research at Regional One Health. The Medical Staff Services Department maintains current credentialing files on all licensed professional clinical staff who have privileges at Regional One Health. The Office of Medical Research may require investigators or those subject to investigators' direction and control, to provide additional information and documentation that demonstrates qualifications to provide service for said research.

The University of Tennessee Health Science Center Institutional Review Board (UTHSC-IRB) will determine that investigators and those subject to their direction and control are sufficiently qualified to conduct proposed research. The UTHSC-IRB will certify that all investigators and key research personnel have received training in human subjects protection, and are current in this certification.

The primary investigators will be responsible for the research activities of co-investigators and those participating in the research.

If invasive methods (e.g., blood draws) are a part of the research protocol, a co-Principal Investigator must be identified who is both a UTHSC faculty member and a physician with privileges at Regional One Health and credentialed to practice in the specialty where the research is to be conducted.

For chart reviews and non-invasive protocols, co-Principal Investigator can be an individual who is a UTHSC faculty member at Regional One Health. Because a Regional One Health-credentialed Principal Investigator (PI) will be identified for each research project, faculty/student investigators operating under the supervision of the PI will not need to seek independent credentialing from Regional One Health in order to conduct research at Regional One Health.

Regional One Health reserves the right to prohibit an investigator from performing research, if in its sole discretion, such action is necessary under the existing circumstances.

## Purpose

To assure that investigators are fully qualified to undertake the proposed research activity.

## Process

| Related Documents | TJC | Approved By |
|---|---|---|
| Institutional Review Board | None | |

**Van Werkhooven, Maria E.** - *Department Head*
**8/22/2014 2:33:06 PM**

**Benink, Eric H.** - *Executive/VP*
**11/26/2014 7:59:53 AM**

**Sumter, Rob** - *COO Approval*
**12/4/2014 10:39:33 AM**

Regional One Health

# Investigator Responsibilities

**Please be advised that this policy was printed on 6/25/2015 at 10:58:35 AM and may be out of date.
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## Policy

1. Investigators will submit the required documentation for research approval to the Office of Medical Research (OMR) no less than thirty (30) days prior to the study's proposed initiation date and comply with all applicable laws regulations and these policies and procedures.
2. Investigators will bear the primary responsibility to obtain University of Tennessee Health Science Center Institutional Review Board (UTHSC-IRB) approval for study protocol, advertisements, informed consent and other applicable study documentation before initiation of study as set forth in the *Approval of Research Activity* policy (see **Related Documents** below for link to policy). They will notify the UTHSC-IRB and Regional One Health of changes to the study, provide progress reports as required by the UTHSC-IRB and Regional One Health, but no less frequently than annually; final study report; and promptly report adverse events to Regional One Health's OMR, the UTHSC-IRB and appropriate sponsor. Investigators will adhere to the provisions of the clinical trial protocol approved by the UTHSC -IRB unless approval is obtained for changes to the study or otherwise required of the safety and welfare of participants.
3. Investigators will assume the responsibility for supervising, training and educating personnel involved in the study including Regional One Health's staff. Personnel requiring training will be identified by the investigator or designated research nurse. Training will be coordinated by the investigator or designated research nurse with Regional One Health's staff educator assigned to the clinical area where research is planned. Documentation of training will be maintained by Regional One Health staff educator.
4. Identification of and arrangements for all services to be provided by Regional One Health must be made prior to initiation of the study by the investigator or his designee through the OMR.
5. Notify all physician groups, laboratories or other entities that may provide clinical services to an enrolled research subject.
6. All research staff involved in a study at Regional One Health must be approved by Regional One Health. University of Tennessee Health Science Center (UTHSC) students/residents are not required to be separately approved to engage in research activity, but must work under the supervision of a faculty member credentialed at Regional One Health.
7. Registered nurses who are approved as research associates at Regional One Health may engage in clinical nursing functions supporting the research protocol within the scope of their professional license. In compliance with Regional One Health policy and accreditation requirements, research nurses who desire to engage in clinical functions for research protocols are responsible for completing a satisfactory competency assessment on the same schedule as Regional One Health-employed nurses.
8. Research personnel will comply with existing hospital policies limiting their access to only those patient records for which they have authorization, to the minimum necessary information needed, and for which

the protocol has specified a need to know. This will apply to all sources of patient information, including computer systems operated by Regional One Health.

9. Investigators, Co-Investigators, and those subject to the investigators' direction and control, will securely maintain in their respective departments adequate and accurate medical records and case histories for each study, including recording all ordered or required tests, protocol, and procedures ordered and designated by the study. The records must identify each patient enrolled in the study at the initiation of each study, as well as the end date of that patient's participation. The information will include the principal investigator's name, the IRB Number, and any additional information necessary to identify the applicable study, investigation, the study purpose of the research, and orders for services.
10. Investigators will ensure that any services or procedures that are ordered specifically for the study be identified individually in the medical records in accord with the *Ordering and Identification of Procedures to be Charged to Research Accounts* policy (see **Related Documents** below for link to policy).
11. All orders for research purposes, in compliance with the IRB-approved protocol, must comply with Regional One Health's Medical Staff Bylaws (located under the Departmental tab on the hospital's intranet), and be authenticated by the ordering practitioner, or another practitioner allowed to prescribe who is involved in the patient's care, within forty-eight (48) hours. Research nurses may only enter orders into the patient's electronic medical record related to the research project; physician orders for standard clinical care may not be entered by a research nurse, as privileges of a research nurse are restricted to research.
12. For studies which do not involve a service contract with Regional One Health, when specimens are collected by the PI, approved research personnel, or Regional One Health employees, the medical record should contain documentation regarding this. Documentation should be entered as either:
    - A Physician Order: including the specific collection requirements (i.e., amount to be collected into specified collection container), per protocol IRB #, and the PI name; this order may be entered into the patient's electronic medical record by a physician, or entered by a research nurse and co-signed by a physician), or as
    - A *Research - Progress Note*(electronic form): specifying, i.e., that x.x mL blood was collected for the study (per protocol IRB #, the PI name); this may be completed by whoever collects the specimen or by the research nurse.

      **Note**: This should be done each time a specimen is collected.

## Purpose

To assure Regional One Health is fully informed of research activity in its facilities; can comply with federal and state regulations; has sufficient information to ensure patients who are research subjects are not billed for research-related tests paid for by a sponsor; and can bill the investigator or the research account for research-related services.

## Process

1. Submit to the OMR a completed Regional One Health *Application for Approval to Conduct Research* (see **Related Documents** below for link) to obtain written approval before initiation of study. **Note**: The UTHSC IRB office in its electronic IRB application system will make accessible to Regional One

Health's OMR all study related documents, letter of IRB approval and IRB-approved documents, as applicable.

2. Obtain proper written informed consent from each study subject prior to participation in the study; place copy of signed informed consent form on each patient's medical record.
3. Record enrollment of the subject in the research study (use electronic forms, i.e., *Research - Documentation of Consent Discussion* or *Research – Progress Note*) in the patient's electronic medical record (EMR) on the day of enrollment. If the free-text *Research - Progress Note* form is used, documentation should include, at minimum, the following statement:
    a. Patient has been enrolled in a research study: '_TITLE_' ; PI Name, IRB Protocol #.
    b. Note must indicate if the study involves use of investigational medications.
    c. To further document and facilitate clarification of any future questions regarding the consenting process, the investigator should use the "*Research - Documentation of Consent Discussion*" form, recording that the study was explained, questions were answered (if any), subject agreed to participate and signed the consent form, and a copy of the signed consent form was given to subject. This documentation should be made by the person obtaining consent. The accumulation of these notes over a period of time will document the consent process.
4. Submit an update of patient enrollment to the OMR using a customized *Verification of Patient Enrollment* form within 48 hours of enrollment (see **Related Documents** below).
5. Research study coordinators should enter research orders for inpatient study subjects into the Research module/order entry of the EMR. In the event there is no study coordinator to enter research orders into the EMR, the investigator may be trained to do so or must otherwise coordinate with the OMR, submitting a completed customized *Verification of Services for Billing* form to the OMR within 48 hours of the order, each time research services are ordered (see **Related Documents** below).
6. Report serious adverse events promptly to Regional One Health's OMR, the IRB, and appropriate sponsor. A copy of the report required by the UTHSC IRB will suffice for Regional One Health's OMR.
7. Notify the OMR upon completion of the study and including the following information (**Note**: The UTHSC-IRB makes available to Regional One Health's OMR the electronic termination report.):
    a. Date of Project Termination;
    b. Number of Research Subjects Enrolled;
    c. Status of Enrolled Subjects:
        - Number of Completing Study:
        - Number Discontinued Due to Noncompliance:
        - Number Discontinued Due to Adverse Events:
        - Number Lost to Follow-up:
        - Number Deceased:
    d. Did any subjects experience any reportable unexpected adverse events? Yes *____ No ____
        - **Note**: * If this blank has been checked, attach explanation of same.
    e. Submit a brief narrative of overall results with respect to efficacy and safety with specific attention to the original purpose of the project.

## Related Documents

Approval of Research ActivityMedication Use - HR22 - Investigational Drug ServiceOrdering and Identification of Procedures to be Charged to Research AccountsForm 1-application For Approval (2014-02).docxForm C-verification of

## TJC Approved By

None

**Van Werkhooven, Maria E.** - *Department*

Patient Enrollment (2014-03) (2).docxForm D-verification of Services (template) (2014-03).xlsx

*Head*
**8/22/2014 2:26:10 PM**
**Benink, Eric H.** - *Executive/VP*
**11/20/2014 4:20:54 PM**
**Sumter, Rob** - *COO*
*Approval*
**11/23/2014 1:40:52 PM**

Regional One Health

# Research Documentation for HIPAA Compliance

**Please be advised that this policy was printed on 6/25/2015 at 10:44:07 AM and may be out of date.
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## Policy

Investigators conducting research at Regional One Health will comply with Regional One Health policies governing compliance with the Health Insurance Portability and Accountability Act (HIPAA) documentation requirements.

## Purpose

To assure that Regional One Health is able to account for uses and disclosures of protected health information (PHI) for research purposes. A waiver of HIPAA Privacy Authorization granted by the Institutional Review Board (IRB) for any part of a study protocol does not diminish or eliminate the responsibility of the healthcare provider, as custodian of the medical records, to be accountable for uses and disclosures of PHI in those records.

For research uses and disclosures of PHI, an IRB may approve a waiver or an alteration of the Authorization requirement in whole or in part. A complete waiver occurs when the IRB determines that no Authorization will be required for a covered entity to use and disclose PHI for a particular research project. A partial waiver of Authorization occurs when an IRB determines that a covered entity does not need Authorization for all PHI uses and disclosures for research purposes, such as disclosing PHI for research recruitment purposes. An IRB may also approve a request that removes some PHI, but not all, or alters the requirements for an Authorization (an alteration).

## Process

Circumstances in which the IRB may grant a waiver of HIPAA privacy authorization and/or a waiver of informed consent include the following:

- To screen current patients' medical records for eligibility for a study.
- To collect data for prospective observational studies involving only data collection when patients are not competent to consent and a Legally Authorized Representative (LAR) is not readily available.

Examples of scenarios when investigators should document:

- To determine eligibility of a **current** patient for inclusion in a prospective observational study, even though investigators might not collect the data until later - make a notation on the electronic form "*Research - Progress Note*" at the time of the eligibility review.
- To conduct a prevalence study wherein data is collected from medical records of all patients on a given day in a specific hospital unit - make a notation on the electronic form "*Research - Progress Note*" for each patient.

- To determine eligibility of a **current** patient for inclusion in a clinical trial, regardless of whether the patient is deemed eligible or later consents to participate - make a notation on the electronic form "*Research - Progress Note*".

The investigator or other research staff reviewing the medical record of a current patient should document on the electronic form "*Research - Progress Note*" that he/she reviewed record for potential study inclusion. This should be done for all patients whose records are accessed, regardless of whether they are ultimately enrolled in the study. Below is recommended verbiage:

> Medical record reviewed for eligibility of patient for inclusion in research study, "____Study Title____", IRB # _____, P.I. _____.

When a medical record of a current patient is accessed to determine whether the patient qualifies for inclusion in a study, and subsequently to collect data, under an IRB-approved waiver of informed consent and waiver of HIPAA privacy authorization, the following verbiage is recommended:

> Medical record reviewed for data collection for research study, "____Study Title____", IRB # _____, P.I. _____.
>
> **Note**: This applies **only** to records of patients who are currently hospitalized or in a clinic for an appointment. This does **not** apply to retrospective studies, as the Health Information Management (HIM) Department tracks access to stored records. Do **not** make any notation in charts filed in the HIM Department.

**Research on Decedents' Protected Health Information:** To use or disclose PHI of the deceased for research, Regional One Health is not required to obtain an authorization from the personal representative or next of kin, or a waiver of authorization. However, the researcher who is seeking access to decedents' PHI must present:

1. written representation that the use and disclosure is sought solely for research on the PHI of decedents,
2. written representation that the PHI for which use or disclosure is sought is necessary for research purposes,
3. proof of identity and qualifications of the researcher, research organization, university, institution, or government agency, who is conducting scientific, medical, or public health research including, the name of the principal investigator if other than the applicant for the data, as well as the location where the research will take place; and
4. documentation of the death of the individuals whose PHI is sought.

Acceptable forms of proof of death include: obituaries, death certificates, recognized sources that can be documented, written media or police file evidence that indicates a person is deceased.

More than one document showing proof of identity may be required at the discretion of Regional One Health.

## Related Documents

Medication Use - HR22 - Investigational Drug Service

## TJC

None

## Approved By

**Van Werkhooven, Maria E.** - *Department Head*
**8/22/2014 2:35:32 PM**

**Benink, Eric H.** - *Executive/VP*
**11/20/2014 4:11:43 PM**

**Sumter, Rob** - *COO Approval*
**11/23/2014 1:37:57 PM**

Regional One Health

# Informed Consent for Participation in Research Activity

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## Policy

The informed consent forms utilized at Regional One Health for research studies must be approved by the University of Tennessee Health Science Center (UTHSC) Institutional Review Board (IRB) as part of the approved research study application. See UTHSC-IRB website for UTHSC-IRB policy governing informed consent (**http://www.uthsc.edu/research/research_compliance/IRB/docs/sops/SOP05.pdf**) and for guidance see “Consent Form Templates” at **http://www.uthsc.edu/research/research_compliance/IRB/consent.php**.

The investigator, or an IRB-approved member of the research team, must obtain signed informed consent of the subject or the subject's legally authorized representative prior to involving the subject in a research study. A copy of the fully executed informed consent form documentation will be included in each subject’s medical record.

It is the responsibility of the investigator to discuss the research study with the subject (or legally authorized representative), to provide the required elements of informed consent, and to properly inform the subject of his/her rights as a research subject. The electronic form “*Research - Documentation of Consent Discussion"* in the Electronic Medical Record (EMR) should be used to document the elements of the discussion. Consent forms must indicate the name of the person providing the information and date and time the form is signed.

The consent form must clearly define which tests or hospital services related to the study will be paid for by the sponsor and what will be the financial responsibility of the subject. (see **Related Documents** below for link to *Guidelines*)

No informed consent, whether oral or written, may include exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. (45 CFR § 46.116 and 45 CFR Pts. 160 and 164)

Informed consent must embody the general requirements issued by the U.S. Department of Health and Human Services for the protection of human research subjects.

## Purpose

To document a study subject’s voluntary participation in a research study.

## Process

## Related Documents

Guidelines to Appropriate Financial Obligations Language (rev 2014)

## TJC Approved By

None

**Van Werkhooven, Maria E.** - *Department Head*
**8/22/2014 2:30:49 PM**

**Benink, Eric H.** - *Executive/VP*
**11/26/2014 8:57:24 AM**

**Sumter, Rob** - *COO Approval*
**12/4/2014 10:42:14 AM**

Regional One Health

# Ordering and Identification of Procedures to be Charged to Research Accounts

**Please be advised that this policy was printed on 6/25/2015 at 11:01:29 AM and may be out of date.
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## Policy

Services ordered by the investigator or those subject to the investigator's direction and control, and provided by Regional One Health, including tests, pharmaceuticals and procedures shall be sufficiently identified to Regional One Health to ensure the proper allocation and billing for said services. Orders entered for research purposes shall comply with Regional One Health's Medical Staff Bylaws (located on the hospital's intranet under the Departmental tab, Medical Staff Services and Clinical Privileges).

## Purpose

1. To inform Regional One Health of study-related services ordered for a research subject and to assure that a research subject's hospital account is not charged for research-related services that are funded by the study sponsor.
2. To assure that research orders are entered in compliance with Medical Staff Bylaws.

## Process

1. Patient should be identified in the Electronic Medical Record (EMR) as a research subject, with the principal investigator and Institutional Review Board (IRB) number of project identified.
2. Research tests and procedures to be provided by Regional One Health and which must be charged to a research account of an approved study should be ordered from the list of Research tests and procedures available in Computerized Provider Order Entry (CPOE).
3. The order may be entered in CPOE by a physician, a nurse practitioner or the research nurse coordinator. All orders entered by the research nurse must be authenticated by a physician.
4. Patient enrollment information must be submitted to the Office of Medical Research (OMR) on the study -specific Verification of Patient Enrollment form. (see **Related Documents** for generic *Enrollment Form*)

## Related Documents

Investigator ResponsibilitiesForm C-verification of Patient Enrollment (2014-03).docx

## TJC Approved By

None

**Van Werkhooven, Maria E.** - *Department Head*
**8/22/2014 2:33:47 PM**

**Benink, Eric H.** - *Executive/VP*
**11/20/2014 4:13:29 PM**

**Sumter, Rob** - *COO Approval*
**11/23/2014 1:38:53 PM**

Regional One Health

# Financial, Reporting and Billing Responsibilities

**Please be advised that this policy was printed on 6/25/2015 at 11:02:33 AM and may be out of date.
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## Policy

The Accounting Services Department (ASD) of Regional One Health will be responsible for billing for research services provided by Regional One Health . The ASD will retain research billing records in a manner consistent with Regional One Health's records retention policy (see **Related Documents** below for link to *Records Management* policy).

## Purpose

To assure Regional One Health is paid for all research-related services performed for a study protocol, according to the contract executed between the institution and Regional One Health and to ensure that proper claims processing protocols are maintained.

## Process

1. The Office of Medical Research (OMR) will provide the current research rates for services or procedures for a proposed research study, as requested by the research staff. Regional One Health's pharmacist assigned to research studies shall provide Pharmacy rates.
2. The OMR shall provide to the Accounting Services Department (ASD) a copy of the approval letter for each study (Confirmation of Approval of Research Activity) for which Regional One Health is expected to provide research services, and a copy of the contract, including the contract number, account number, and department (if applicable), and name and address of person to whom the invoice should be directed.
3. The OMR will perform an analysis of billing coverage before the contract is signed and before any subject is registered in the trial. The OMR will determine who are the potential payers for trial services and follow policies/procedures for the registration and tracking of all research subjects.
4. The OMR will coordinate with investigators and their research staff for timely notification of patient enrollment to the OMR; and timely identification of research related tests, procedures and other services, to be submitted to the OMR.
5. For non-pharmacy services, the OMR will provide to the ASD on a monthly basis the following information for the previous month, for each active research study, as applicable: patient identification, charges, procedure performed, service date, invoice total, IRB #, account number, contract number and to whose attention the invoice should be directed. **Note**: If Pharmacy services are utilized for a research study, the Regional One Health pharmacist assigned to research studies will submit the same information as listed above to the ASD.

6. The ASD will prepare an invoice for each institution for the respective department's charges for the previous month, referencing the title of the project, the investigator's name, the IRB number, and the account number and contract number (if applicable). This invoice will be sent to the respective department or institution.
7. The ASD will submit monthly statements to the responsible institution or department for payment no later than the 15th day of the month following the month in which the services were provided.
8. Subsequent notices of payment due will be forwarded if payment is not received within thirty (30) days. If payment is not received within ninety (90) days of billing, the Accounting Office will notify the OMR.
9. When payment is received, the ASD will credit the income to the department where the services were provided.

## Related Documents

Records ManagementRecords Retention and Management

## TJC Approved By

None

**Briggs, Judy M.** - *Additional Approver*
**11/25/2014 6:59:06 PM**

**Van Werkhooven, Maria E.** - *Department Head*
**8/22/2014 10:48:47 AM**

**Benink, Eric H.** - *Executive/VP*
**11/20/2014 4:25:12 PM**

**Sumter, Rob** - *COO Approval*
**12/4/2014 10:44:21 AM**

Regional One Health

# Financial, Reporting and Billing Responsibilities to Medicare

**Please be advised that this policy was printed on 6/25/2015 at 11:03:13 AM and may be out of date.
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## Policy

Regional One Health's Patient Financial Services will be responsible for billing Medicare for patients who are participating in clinical trials in accord with Medicare principles.

- Reference: Medicare Claims Processing Manual - CMS Pub 100-04 > Chapter 32 69.1, et seq, Billing Requirements for Clinical Trials (Effective January 1, 2002), Centers for Medicare and Medicaid Services (Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

## Purpose

To assure that proper Medicare claims processing protocols are maintained.

Medicare will cover the routine costs of qualifying clinical trials as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. The coverage requirements for routine costs of qualifying clinical trial services are contained in The National Coverage Determinations Manual, Section 310.1.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service, itself;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.

## Process

1. The Medicare beneficiary's medical record must include the following information: trial name, sponsor and sponsor-assigned protocol number. Effective for clinical trial claims received after January 1, 2014, providers must begin to report an 8-digit clinical trial number.
2. Enter clinical trial and non-clinical trial services on separate line items when billing both types of services on the same claim.
3. For services furnished by Regional One Health to Medicare beneficiaries, who are healthy, control group volunteers participating in qualifying diagnostic clinical trials, are to be coded/billed on the in the following manner:
   - Institutional providers billing clinical trial service(s) must report a diagnosis code of V70.7 in the secondary position (or in the primary position if the patient is a healthy, control group volunteer) and a condition code 30 regardless of whether all services are related to the clinical trial or not.
   - Condition code 30 (qualifying clinical trial) is reported at the claim level.
   - Diagnosis code V70.7 (Examination of participant in clinical trial) is reported as the secondary diagnosis.
   - "QV" procedure code modifier (only for **outpatient** claims submitted by institutional providers) is reported at the line item level.
4. QV modifier is line item specific and must be used to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare covered clinical trial. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed using the QV modifier. Items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using the QV modifier.
5. When billed in conjunction with the V70.7 diagnosis code, the QV modifier will serve as the provider's attestation that the service meets the Medicare coverage criteria (e.g., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation).
   - For Outpatient Prospective Payment System (OPPS)claims, providers must report a token charge for a no cost item in the covered charge field along with the applicable Healthcare Common Procedure Coding System (HCPCS) modifier (e.g., modifier - FB) appended to the procedure code that reports the service provided to furnish the no cost item, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing no cost items under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of the Medicare Claims Processing Manual.
6. For clinical trial billing requirements for patients enrolled in a managed care plan, please refer to Section 69.9 of the Medicare Claims Processing Manual.

## Related Documents

http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.htmlNational Coverage Determination - Clin Trials (310.1)R2758CP - Aug 9-2013

## TJC Approved By

None

**Briggs, Judy M.** - *Additional Approver*
**11/25/2014 6:57:58 PM**

**Van Werkhooven, Maria E.** - *Department*

*Head*
**8/22/2014 2:29:51 PM**
**Benink, Eric H.** - *Executive/VP*
**11/20/2014 4:24:28 PM**
**Sumter, Rob** - *COO*
*Approval*
**12/4/2014 10:43:24 AM**

Regional One Health

# Reimbursement

**Please be advised that this policy was printed on 6/25/2015 at 9:40:20 AM and may be out of date.
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## Policy

Payment for services provided by Regional One Health will be submitted to Regional One Health promptly upon receipt of statements.

Rates for the aforesaid services will be established by Regional One Health's Office of Medical Research (OMR), in accordance with the Research Agreement between the respective institution and Regional One Health, and should be requested by the investigator prior to initiation of the study.

## Purpose

To fulfill obligations set forth in each study-specific contract.

## Process

## Related Documents

## TJC

None

## Approved By

**Van Werkhooven, Maria E.** - *Department Head*
**8/22/2014 2:34:17 PM**

**Benink, Eric H.** - *Executive/VP*
**11/26/2014 7:59:00 AM**

**Sumter, Rob** - *COO Approval*
**12/4/2014 10:38:27 AM**

Regional One Health

# Compliance Audit

**Please be advised that this policy was printed on 6/25/2015 at 9:40:56 AM and may be out of date.
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## Policy

As part of its annual audit plan, Regional One Health's Department of Corporate Compliance will conduct a systematic and independent examination of research activities and related documentation.

## Purpose

To determine whether the research-related activities were properly conducted, according to Regional One Health's policies and procedures governing research.

## Process

## Related Documents

None

## TJC

## Approved By

**Van Werkhooven, Maria E.** - *Department Head*
**8/22/2014 2:27:25 PM**

**Benink, Eric H.** - *Executive/VP*
**11/26/2014 8:58:37 AM**

**Sumter, Rob** - *COO Approval*
**12/4/2014 10:46:00 AM**