Texas Health Research and Education Institute

Research Administration Process Manual (RAPM)

Version 1.0

Property of Texas Health Resources

Copying or using this document other than by Texas Health Resources employees or Medical Staff for Texas Health Resources or Medical Staff business purposes is strictly prohibited without the written permission of Texas Health Resources.
## Revisions Table

<table>
<thead>
<tr>
<th>Manual Version</th>
<th>Approved By</th>
<th>Date Revised</th>
<th>Effective Date</th>
<th>Summary of Revisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Jessica Derr, Director</td>
<td>N/A</td>
<td>04/01/2016</td>
<td>Original Version</td>
</tr>
<tr>
<td></td>
<td>Research Administration</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Effective Date: 04/01/2016  
Approved By: Jessica Derr, Director Research Administration
# Table of Contents

<table>
<thead>
<tr>
<th>Sections</th>
<th>Current Effective Date</th>
<th>Page(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Study Coverage Analysis</td>
<td>04/01/2016</td>
<td>4-7</td>
</tr>
<tr>
<td>2. Research Participant Notification</td>
<td>04/01/2016</td>
<td>8-11</td>
</tr>
<tr>
<td>3. Research Participant Visit Tracking</td>
<td>04/01/2016</td>
<td>12-15</td>
</tr>
</tbody>
</table>
1. Study Coverage Analysis

A. Scope:

I. Applicable Entities:

This process applies to the Texas Health Resources (Texas Health) member hospitals and Texas Health Physicians Group (THPG). They will be referred to as THR Entity or THR Entities.

This process does not apply to Texas Health joint venture entities.

II. Applicable Departments:

This process applies to any and all departments conducting or participating in a research study.

B. Purpose:

The purpose of this process is to establish a consistent, well-defined, and comprehensive analysis that is performed on every research study conducted at a THR Entity or THR Entities.

C. Process Statement(s):

I. A Study Coverage Analysis (SCA) and its applicable attachments is required on each research study conducted, which meets any of the following criteria:
   - Could possibly require the admission (inpatient or outpatient) at a THR Entity or Entities, of a patient on a research study, regardless of where the study is being conducted
   - Will use the services or staff of a THR Entity regardless of payer or conventional care determination
   - Will access the data of any THR Entity or any THR Entity patient(s)
   - Will access the premises of a THR Entity.

II. An SCA must be completed, by the research team, in the form, process, and/or system designated by Research Administration.

III. An SCA must be complete, accurate (to the best of the research teams’ knowledge) and signed by all parties prior to the Institutional Approval and release of the research study.

IV. After the execution of an SCA, it will be considered the plan to conduct the study, and the Principal Investigator will ensure the SCA is followed according to plan.
D.  Process Guidance:

I.  Elements:

1.  Demographic Information (staff, location, protocol, summary, NCT #, IRB #, etc.)
2.  Qualified Clinical Trial (QCT) determination
3.  THR Entity engagement
4.  Identification and Verification of protocol required services
5.  Identification and Verification of funding source(s)
6.  Identification and Verification of Device/Drug Information (Source, Origin, Recipient, Storage, funding, etc.)
7.  Notification Assurance
8.  Research Administration Internal Use (required agreements, forms, appendices, coding, etc.)

II.  Attachments:

1.  Attachment A: Coverage Grid; required on each study that is funded and/or requires coding of a THR entity patient account
2.  Attachment B: Drug Information; required for a study that has investigational or research-related medication(s), regardless of coverage determination
3.  Attachment C: Device Information; required for a study that has investigational or research-related device(s), regardless of coverage determination
4.  Attachment D: Supporting Documentation; optional documentation used to support the study coverage analysis, which may include but is not limited to: THR charge sheet, National Coverage Decision determination documentation, correspondence with research team or study funding source regarding coverage determinations, data reports, etc.

III.  Signatures and Assurances:

1.  Each SCA must be signed by each the following: Principal Investigator, the study coordinator or designated project manager/lead, and the Director of Research Administration or his/her delegate.

2.  Each study that requires coding and/or the adjustment of charges will require an additional initial and date of the Principal Investigator. By initialing, the Principal Investigator is specifically acknowledging and providing his/her assurance that they will follow the policies and procedures for notifying Research Administration of an enrolled research patient.
IV. Changes/Deviations:

1. If any changes or deviations from the SCA occur after release and approval of the study, the Principal Investigator will be required to notify Research Administration immediately upon becoming aware of the change or deviation. If necessary, the SCA may be amended and signed by original and applicable signatory parties.

E. Definitions:

**National Coverage Decision (NCD):** a United States' nationwide determination of whether Medicare will pay for an item or service.

**Qualified Clinical Trial (QCT):** When evaluated and documented prior to the start of a study, Medicare will cover associated routine and expanded patient care costs for items and services that are reasonable, necessary, and within the scope of a Medicare benefit category. Although private payers and Medicare Advantage Plans generally follow Medicare, this policy does not include them and a separate pre-authorization for the research procedures, items, and or services may be required.

**Research Team:** The personnel listed on any of the following: the Institutional Review Board Application, the FDA form 1572, and/or the delegation of authority log.

**Study Coverage Analysis (SCA):** A document and a process to systematically review a research study to determine location, personnel, research items, services, procedures, and other required documents associated with the study. The analysis is required to ensure the proper identification of research patients as required by governmental policies (i.e., Medicare), the proper billing and invoicing as required by applicable payers, and the proper distribution of funds to the appropriate service providers.

F. Responsible Parties:

I. **Principal Investigator**

   1. Provide and Validate information for the accurate completion of the SCA process, forms, and attachments.
   2. During the study, follow the SCA as a study plan.
   3. Notify Research Administration of any changes or deviations from the SCA.

II. **Research Coordinator/Project Lead**

   1. Assist Principal Investigator and Research Administration Staff in the accurate completion of SCA forms and attachments.
   2. Notify Principal Investigator and Research Administration of any changes or deviations from the SCA.
   3. Assist Principal Investigator and Research Administration Staff in the accurate completion of amendments to the SCA process and/or forms.
III. **Research Contract/Grant Specialist**

1. Facilitate and coordinate SCA process.
2. Assist Research Team and Research Administration Staff in the accurate completion of SCA forms and attachments.
3. Ensure complete execution of forms and attachments.
4. Coordinate and ensure execution of amendments to the SCA process and/or forms.

IV. **Research Finance Analyst**

1. Assist Research Team and Research Administration Staff in the accurate completion of SCA forms and attachments.
2. Assist Research Team and Research Administration Staff in the accurate completion of amendments to the SCA process and/or forms.

V. **Research Billing Analyst**

1. Assist Research Team and Research Administration Staff in the accurate completion of SCA forms and attachments.
2. Assist Research Team and Research Administration Staff in the accurate completion of amendments to the SCA process and/or forms.

VI. **THR Entity**  
(Including but not limited to: Central Business Office, Supply Chain, Hospital departments, etc.)

1. Assist Research Administration Staff in the accurate completion of SCA forms and attachments in regards to staffing needs, pricing, storage, supplies, etc.
2. Research Participant Notification

A. Scope:

I. Applicable Entities:

This process applies to the Texas Health Resources (Texas Health) member hospitals and Texas Health Physicians Group (THPG). They will be referred to as THR Entity or THR Entities.

This process does not apply to Texas Health joint venture entities.

II. Applicable Departments:

This Process applies to any and all departments conducting or participating in a research study at THR Entity/Entities.

B. Purpose:

The purpose of this process is to establish a consistent and effective means by which to facilitate the identification of THR Entity patients who are participating in a research study at a THR Entity that requires billing or coding of the account.

This process is intended to ensure charges are billed to the appropriate party, as indicated on the Study Coverage Analysis (SCA), the Informed Consent, and the Clinical Trial Agreement (as applicable).

C. Process Statement(s):

I. Prior to the start of a Qualified Clinical Trial (QCT), the research team will be provided with a Subject Admissions Form (SAF).

II. The research team will complete and submit, via fax/email, to Research Administration an SAF form for each visit identified on the SAF. The SAF will be sent within 24 hours of the research participants’ admission to THR Entity. This form must be faxed each time there is an admission to a THR Entity.

III. If the participant is required to sign an informed consent form (ICF), a fully executed ICF must accompany the SAF, each time the participant is admitted. A copy of the ICF must also be placed on the participants’ medical record, in addition to a progress note indicating the participant is enrolled in a research study.

IV. After receipt of the ICF (if applicable) and the SAF, Research Administration will work with the Central Business Office (CBO) and Health Information Management (HIM) to ensure the participant account is accurately coded and charges match the SCA.

V. The SAF must be followed explicitly and any deviations must be approved by the payor and Research Administration prior to the service being provided.
VI. The research team must also send monthly enrollment logs for each study that has an SAF, to ensure no participants have been missed. The enrollment logs should be sent to Research Administration on the 25th of each month.

D. Process Guidance:

I. Elements:

1. THR entity label; if a label does not exist, the financial account number and the medical record number must be written on the SAF.
2. Participant demographic information (date of consent, date of service, date of birth, full name)
3. Study identifying information (IRB number, National Clinical Trial Identifier number - NCT #, PI, Study Coordinator)
4. Visit number and THR Entity location
5. Procedures/Services/Supplies (with quantities, dates, and charge code)
6. Coding (i.e., REV624, CC30, Z00.6, etc.)
7. Comments/Deviations
8. Research Administration Internal Use (instructions and checklist as needed)
9. Research Team Signature (required)
10. Participant Signature (preferred but not required)

II. Attachments:

1. ICF: The fully executed ICF should accompany the SAF

III. Signatures and Assurances:

1. Each SAF must be signed by the research team member conducting the applicable visit. Although not required, it is preferred the participant sign the SAF as documentation that they understand and acknowledge the services of the study.
2. By signing the SAF, the research team member is providing his/her assurance that they have notified Research Administration of a participant admission at a THR entity and they have ordered and documented the appropriate procedures/services/supplies.

IV. Changes/Deviations:

1. If any changes or deviations from the SAF occur Research Administration must be notified immediately.
2. The research team will obtain prior approval from Research Administration and the payor prior to the change. The research team will also document why the change was required.
3. If the deviation from the SAF is due to protocol changes, a change in the plan, etc. that will affect future participants, the SAF will be amended and the latest version will be used after the amendment.
4. If a deviation is not approved prior to the service/procedure being performed, and the change cannot be paid for by the payor, the PI and/or the research team will...
be responsible for the difference in cost between the planned procedure and the actual procedure performed.

E. Definitions:

Qualified Clinical Trial (QCT): When evaluated and documented prior to the start of a study, Medicare will cover associated routine and expanded patient care costs for items and services that are reasonable, necessary, and within the scope of a Medicare benefit category. Although private payers and Medicare Advantage Plans generally follow Medicare, this policy does not include them and a separate pre-authorization for the research procedures, items, and or services may be required.

Research Team: The personnel listed on any of the following: Institutional Review Board Application, the FDA form 1572, and/or the delegation of authority log.

Study Coverage Analysis (SCA): A document and a process to systematically review a research study to determine location, personnel, research items, services, procedures, and other required documents associated with the study. The analysis is required to ensure the proper identification of research patients as required by governmental policies (i.e., Medicare), the proper billing and invoicing as required by applicable payers, and the proper distribution of funds to the appropriate service providers.

F. Responsible Parties:

I. Principal Investigator

   1. Provide and Validate information for the accurate creation and completion of the SAF.
   2. During the study, follow the SAF as a study plan.
   3. Notify Research Administration of any changes, deviations, and/or amendments from the study and/or the SAF.

II. Research Coordinator

   1. Assist Principal Investigator in the accurate completion of SAF.
   2. Notify Principal Investigator and Research Administration of any changes, deviations, ad/or amendments from the study and/or the SAF.
   3. Assist Principal Investigator and Research Administration Staff in the accurate creation and completion of amendments to the SAF.

III. Research Contract/Grant Specialist

   1. As they are made aware, notify Research Administration staff of any changes to the study (protocol, contract, budget, etc.) as they may affect the SAF.

IV. Research Finance Analyst

   1. As they are made aware, notify Research Administration staff of any changes to the study (protocol, contract, budget, etc.) as they may affect the SAF.
2. Assist Research Team and Research Administration Staff in the accurate creation of the SAF.
3. Assist Research Team and Research Administration Staff in the accurate completion of amendments to the SAF.

V. Research Billing Analyst

1. Create the SAF and amendments as necessary.
2. Ensure the accurate and timely completion of the SAF by the research team.
3. Train and educate as necessary if there are compliance issues regarding this process.

VI. THR Entity
(Including but not limited to: Central Business Office, Supply Chain, Hospital departments, etc.)

1. Assist Research Administration Staff in the accurate implementation of the SAF.
3. Research Participant Visit Tracking

A. Scope:

I. Applicable Entities:

This process applies to the Texas Health Resources (Texas Health) member hospitals and Texas Health Physicians Group (THPG). They will be referred to as THR Entity or THR Entities. This process does not apply to Texas Health joint venture entities.

II. Applicable Departments:

This process applies to any and all departments conducting or participating in a research study, financially managed by Texas Health Research & Education (THRE).

B. Purpose:

The purpose of this process is to establish a consistent and effective means by which to track research participants to ensure accurate financial management (accounts receivable and accounts payable) of studies managed by THRE.

This process is intended to ensure charges are billed to the appropriate party, as indicated on the Study Coverage Analysis, the Informed Consent, and the Clinical Trial Agreement (CTA) (as applicable).

C. Process Statement(s):

I. Prior to the start of a study, a Study Coverage Analysis (SCA) will be completed and executed by the research team. The SCA and its attachments will include the appropriate service location and providers.

II. The Research Administration (RA) staff will build the study into the Clinical Trial Management System (CTMS) used by RA. This will include the financial payables and receivables as well as the visits and the providers.

III. The research team will enter the participant (and all demographic information) and each visit into the CTMS within 5 business days of the service being provided.

IV. THRE accounting and RA will invoice and/or pay at the beginning of each month, for services performed in the previous month. Monthly activities include, but are not limited to: Patient Stipend Payments, Principal and Sub Investigator’s Payments, other third Party service provider payments, invoicing to Sponsor, inter-departmental/inter-entity transfers, etc.

V. If there are any issues or changes with the following, the research team needs to notify Research Administration immediately to resolve the issue: overall study design in the CTMS, the listed provider and/or location of a procedure or service, any change (addition, removal, etc.) to a procedure or service, and/or a change to the participant visit once it has been submitted.
VI. Entry into the CTMS does not replace the Research Participant Notification Process. These are two separate process, both of which must be done, as applicable to that study.

VII. Research Administration personnel will perform internal audits. Upon notification of an audit and upon request, the research team will be asked to provide documentation to support the data entered into the CTMS. This information may include, but is not limited to: participant source documentation, Electronic Data Capture (EDC) reports, lab results, physician office records, monitoring reports, etc.

D. Process Guidance:

I. Elements:

1. Review the study in the CTMS, with RA, prior to the enrollment of the first patient.
2. Make changes corrections as needed until the study is accurate in the CTMS.
3. Register/Enter participant into the CTMS. Be sure to include all demographic data in order for RA to contact the participant if necessary.
4. Enroll participant in the appropriate study.
5. Enter visit information into the CTMS within 5 days of the visit being performed. Visit Information should be comprehensive and accurate. If a procedure was not done, indicate a reason in the comment section of the applicable procedure.
6. If there are additional procedures that were done and not listed in the CTMS and/or if there have been changes that affect future visits and/or patients, contact RA to ensure changes are reflected for future visits.
7. Use notes and comments to clearly communicate any important information about a visit and/or procedure.
8. Contact RA if changes need to be made once a visit has been submitted. Any changes after submission could affect payments or invoicing that was already done and therefore must be cleared and corrected by RA.

II. Attachments:

1. None. ** Note: all source and EDC documentation are considered to be support documentation and may be required upon request.

III. Signatures and Assurances:

1. None. ** By signing the Study Coverage Analysis and entering the study into the CTMS, the research team member is agreeing to follow this process to the best of their ability and notifying RA as needed to prevent errors in the financial management of a study.

IV. Changes/Deviations:

1. If any changes or deviations from the study occur RA must be notified immediately.
2. The research team will obtain prior approval from RA and the payor prior to the
change. The research team will also document why the change/deviation was required.
3. If the change/deviation is due to protocol changes, a change in the plan, etc. that will affect future participants, RA will be notified immediately so the study can be amended.
4. If a change/deviation is not approved prior to the service/procedure being performed, and the change cannot be paid for by the payor, the PI and/or the research team will be responsible for the difference in cost between the planned procedure and the actual procedure performed.

E. Definitions:

Clinical Trial Agreement (CTA): The agreement signed by the research team, PI, or other site personnel that outlines the conduct of the study. It will include the budget.

Electronic Data Capture (EDC): The system used to input de-identified data to submit to outside sources (i.e., pharma/device companies, data analysts, etc.)

Research Administration (RA): The department within THRE that oversees the administration of the study: budget, contract, compliance, participant account coding, and accounting (in conjunction with THRE accounting)

Research Team: The personnel listed on any of the following: Institutional Review Board Application, the FDA form 1572, and/or the delegation of authority log.

Source Documentation: The first place of documentation that a procedure or service occurred.

Study Coverage Analysis (SCA): A document and a process to systematically review a research study to determine location, personnel, research items, services, procedures, and other required documents associated with the study. The analysis is required to ensure the proper identification of research patients as required by governmental policies (i.e., Medicare), the proper billing and invoicing as required by applicable payers, and the proper distribution of funds to the appropriate service providers.

F. Responsible Parties:

I. Principal Investigator

1. Provide and Validate information for the accurate creation and completion of the study in the CTMS.
2. During the study, follow the study plan as indicated in the CTMS and the SCA.
3. Notify RA of any changes, deviations, and/or amendments of the study.

II. Research Coordinator

1. Register all new participants in the CTMS and link them to the appropriate study in the CTMS.
2. Enter accurate and complete visits into the CTMS.
3. Notify Principal Investigator and RA of any changes, deviations, and/or amendments to the study.

III. Research Contract/Grant Specialist

1. As they are made aware, notify RA staff of any changes to the study (protocol, contract, budget, etc.).

IV. Research Finance Analyst/Other RA financial support staff

1. Build the study in the CTMS according to the CTA, Budget, SCA, and other applicable RA agreements (Service agreements, hospital agreements, etc.).
2. As they are made aware, make any changes to the study, in the CTMS, (i.e., protocol, contract, budget, etc.) as they may affect the study financials.
3. Train and educate research team on how to input into CTMS and re-train as necessary upon the discovery of errors or issues.

V. THRE Accounting/Research Billing Analyst

1. Invoice and make payments according to the CTMS data.

VI. THR Entity

(Including but not limited to: Central Business Office, Supply Chain, Hospital departments, etc)

1. Assist RA Staff in the accurate billing and invoicing of the study financials via documentation of procedures, notification of outstanding payments, denials, etc.