



**CHRONIC VENOUS THROMBOSIS: RELIEF WITH ADJUNCTIVE
CATHETER-DIRECTED THERAPY
(THE C-TRACT TRIAL)**

Health Economic Study

APPENDIX H



TO: C-TRACT Trial Research Coordinators

FROM: Kate Vilain, Data Coordination Manager
Erin Notestein, Clinical Research Associate
Elizabeth Magnuson, ScD, Director
Health Economics and Technology Assessment (HETA) Group at MAHI

SUBJECT: C-TRACT Health Economic Study

The C-TRACT Trial includes an **Economic** study. This start-up packet provides a brief overview of this study, along with instructions to help make this component a success at your hospital.

Included in this packet are the following:

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We look forward to working with you throughout the duration of the study. If you have any questions or concerns, please do not hesitate to contact me at (816) 932-5480 or at kvilain@saint-lukes.org, or Erin Notestein at (816) 932-5328 or at enotestein@saint-lukes.org.

Sincerely,
Kate Vilain



C-TRACT CLINICAL TRIAL

Health Economic Study (Non-VA sites)

Introduction to the Economic Component of the C-TRACT trial

The C-TRACT trial includes an economic component. Analysis will be conducted on medical resource use data already collected by the Research Coordinator on the case report forms, in conjunction with billing data collected by the Health Economics and Technology Assessment (HETA) group at the Mid America Heart Institute (MAHI) of Saint Luke's Hospital. These billing data include UB-04 (Medicare summary) forms or the equivalent, as well as itemized hospital bills. These two items will be collected directly from the billing offices of participating, non-VA hospitals by the HETA team at MAHI for any inpatient hospital admission incurred by subjects during the C-TRACT trial.

During the informed consent process, non-VA patients will be asked to provide personal information and permission for MAHI to obtain these hospital billing records. A Medical Billing Release authorization form ("MBR form") is used to capture this personal information and must be signed by the patient in order for MAHI to collect patient billing data. Personal information collected on the MBR form will be entered into a secure database, designated for the HETA Group, at MAHI. Further instructions and information on our data confidentiality procedures are included in this document.

The HETA group hopes that this transition will be simple and will relieve some of the burden of data collection for the site Research Coordinators. We look forward to working with you!



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Health Economic Study (Non-VA sites)

Site Research Coordinator's Responsibilities for Economic Component

1. Patient Accounting Contact

Establish a specific contact person in the Patient Accounting Department, complete the Patient Accounting Contact Form on the next page and email it to MAHI. This only needs to be done one time.

Inform the Patient Accounting Contact that they will be receiving correspondence from MAHI regarding the hospital bills we will need for the C-TRACT trial.

2. Medical Billing Release

Ensure that the MBR is filled out completely and accurately at the time of study consent for every single patient. The form must be signed and dated by the patient or proxy. Email the MBR to MAHI as per the instructions at the bottom of the MBR form, give a copy to the patient, and retain the original on-site.

That's it! The HETA team will do the rest!



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C-TRACT Patient Accounting Contact Form

As part of the **C-TRACT trial Health Economic study**, we need a contact person from your site's patient accounting department. Please inform this person that MAHI will be sending them a list of requested hospital bills (UB-04 formulations or equivalent, and itemized bills) for the C-TRACT trial on a regular basis (usually monthly).

Please complete the information below and email it to enotestein@saint-lukes.org.

_____ Site #	_____ Site Name
_____ Name of Patient Accounting Contact	_____ Phone number
_____ E-mail address of Patient Accounting Contact	_____ FAX number
_____ Name of Research Coordinator	
_____ E-mail address of Research Coordinator	

If you run into difficulties or have questions, please contact Erin Notestein at (816) 932-5328 or via email (above).



C-TRACT CLINICAL TRIAL

Health Economic study (Non-VA sites)

Instructions for the Medical Billing Release Form

- By completing and signing the C-TRACT Medical Billing Release MBR form (see sample on the next page), patients in the Study provide their personal information to MAHI and provide consent that this information can be used to collect hospital billing records for admissions through the end of their follow-up period.
- The Medical Billing Release will be provided to you as a separate document from this packet, for ease of use. MAHI or the Sponsor can provide you a new file if necessary.
- Because of the private nature of the information collected, it is necessary that the MBR form adhere to the guidelines set forth by HIPAA. The required components of a HIPAA authorization, and their locations in the MBR form, are described in Appendix A.

Instructions. The Medical Billing Release form must be:

1. Filled in completely at the time of the patient's consent. Fields for the patient name, DOB and patient's Social Security number must be filled in. This is necessary in order to properly identify the patient's bills in the billing office at your site.
2. Signed and dated by the patient or proxy.
3. Emailed directly to the HETA Group at MAHI as soon as possible. Attention: Erin Notestein (enotestein@saint-lukes.org).
4. One **photocopy** should be given to the patient, and **the original kept on site**.

Note: If for any reason a patient refuses to sign the MBR form, please complete the header with the Site # and Patient #, and slash through the form or write "Patient Refused" across the remainder of the form. Follow the above directions for submitting this form to us.



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Subject Confidentiality Procedures at Saint Luke's MAHI

The Health Economics and Technology Assessment (HETA) team adheres to the following guidelines to ensure the confidentiality of all patient information:

- The Medical Billing Release form is created to be compliant with all HIPAA regulations.
- All Medical Billing Release forms and/or patient bills mailed to MAHI will be delivered directly to the appropriate HETA team member by the mailroom.
- Personal information collected on the Medical Billing Release form will be entered into a highly secured database at MAHI, separate from all clinical data, and this information will be used solely to request outstanding bills.
- All Medical Billing Release forms received at MAHI will be stored by Study/site/patient number in a locked file cabinet within the HETA office space. The HETA Data Collection Manager (Kate Vilain) and the Clinical Research Associate assigned to C-TRACT bill collection (Erin Notestein) are the only people who will have access to the file cabinet. No clinical data will be stored with these documents.
- All itemized and UB-04 Bills received at MAHI will be labeled with the following information: Study Name, Site Number, Patient Number, and Initials. Once this information has been recorded on the bill, the patient name, address, and any additional personal information will be blacked out by the HETA team. Bills will be stored by study/site/patient number in locked file cabinets within HETA office space that requires an access code for entry. No clinical data will be stored with these documents. A copy of the MAHI Data Management Policy and Procedures document, which details our policies and procedures for handling protected health information (PHI) with the highest regard for maintaining security and confidentiality, can be provided upon request.

**If you have any questions or comments, please contact Erin Notestein at
(816) 932-5328 or via email at enotestein@saint-lukes.org.**



C-TRACT CLINICAL TRIAL

Health Economic study (Non-VA sites)

Questions and Answers

How is confidentiality maintained?

Patient confidentiality is given the highest priority at HETA. Billing information is used only to extract the cost of procedures. Our database is highly secured and separate from clinical data. All paper information is stored in a locked file cabinet. Only two HETA members working on the C-TRACT trial have access to the file cabinet and the billing information. A copy of the MAHI Data Management Policy and Procedures document, which details our policies and procedures for handling PHI with the highest regard for maintaining security and confidentiality, can be provided upon request.

My facility will not release patient names or social security numbers. Can we still participate in the economic analysis?

Yes. Direct bill collection by HETA is meant to save time for coordinators, and it requires collection of patient names and social security numbers. If your facility will not release these data, site Research Coordinators can collect inpatient billing information directly, redact identifiers and replace them with site and patient study IDs, and send them to HETA. All charges on the bills must be visible. Note that no patient-level or site-level charge data will be released outside of HETA, even to the study Sponsor, and all charge data will be destroyed 5 years from the end of study follow-up.

If this is the preferred method of bill collection for your site, please contact the HETA team as soon as possible to alert them of the situation. You will receive separate instructions on how to collect bills from the accounting department, label them, and forward them to MAHI.

If the patient is transferred or readmitted to another hospital as part of the episode of care, do I have to contact that hospital and get the billing information?

For the majority of sites, no. If a patient is admitted to a hospital and then transferred to a second hospital, either that same day or on another day, you should fill out two Subsequent Hospitalization forms. One form should be completed for each hospital to which the patient is admitted, if it is within the same episode of care. HETA will contact any outside (non-study) hospitals visited by the study patient during the episode of care, and use the Medical Billing Release form to collect the billing information.



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Questions and Answers (cont.)

However, if your site will not allow HETA to collect bills directly (will not provide a signed MBR), you will be responsible for contacting all outside hospitals and requesting the necessary billing information.

I have a patient who does not want to release their social security number (SSN) on the MBR. Can I still submit the MBR?

As long as the patient is willing to release their date of birth and full name, and sign the MBR, we will attempt to collect their bills. Please note (and share with the patient, if helpful) that:

- The MBR will be transmitted securely and be stored in a dedicated, highly secure physical location with limited access, and permanently destroyed following the study.
- The SSN is the only certain unique identifier for a patient. It is possible for multiple persons to share both the same name and DOB. Obviously this is unlikely to occur at one facility, but we request the SSN in order to be absolutely sure that we are requesting bills for the correct person.
- The bills collected for the trial will (also) contain the patient's SSN. We immediately redact it and all other identifying information so that no patient's PHI is ever apparent on a bill. It is in all of our best interest to comply with HIPAA and protect patient confidentiality.

Let us know if you have any additional questions regarding the economic study!

APPENDIX H



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Appendix A: HIPAA Requirements and MBR Language

HIPAA requires a statement of...	Excerpt from MBR to comply with this requirement:
- What information will be used or disclosed	"... I authorize...MAHI... <u>to use the above information [Patient's Name, Date of Birth, and Social Security Number]...</u> "
- The purpose of the requested use or disclosure	"The C-TRACT trial will gather data in order <u>to assess the medical care costs</u> of endovascular therapy for treatment of post-thrombotic syndrome ."
- Who may disclose the information	"... I authorize... MAHI... to use the above information (Patient's Name, Date of Birth and Social Security Number) to collect medical bills <u>from the patient accounting department at any hospital I am admitted to during my time in the C-TRACT trial.</u> "
- To whom the information will be disclosed.	"...I authorize <u>authorize the Mid America Heart Institute (MAHI), as the Economic Core Lab for the C-TRACT trial,</u> to use the above information (Patient's Name, Date of Birth and Social Security Number) to collect medical bills..." <u>"The information will not be disclosed to any outside party."</u>
- The patient's right to refuse to sign the authorization	"...I understand that I have the right to: 1) <u>refuse to sign</u> this document"
- The patient's right to revoke the authorization	[I understand that I have the right to:] "2) <u>withdraw this Authorization</u> at any time by giving written notice to the address listed at the bottom of this form, with the knowledge that this action will not affect any information collected before the notice of withdrawal..."
- The patient's right to receive a copy of the authorization	[I understand that I have the right to:] "3) <u>receive a copy of this Authorization.</u> "
- The form must contain an expiration date.	"4. This Authorization expires on ____/____/____ (five years from date signed)."
- The form must contain an individual's or proxy's signature and date.	"7. Patient signature _____ 8. Date ____/____/____"
- The form must be written in plain language.	The MBR form is written clearly in plain language for the patient to understand.



C-TRACT CLINICAL TRIAL
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MAHI Contacts for the Economic Component of the C-TRACT trial

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