Retrospective Chart Review Research Requirements

Requirements to Collect Data from TMH Medical Records

The record review/access must be conducted by an individual who would normally have access to the records as part of the patient’s routine clinical care, and is not a member of the investigational team and is provisioned for research access.

OR

a) An Honest Broker (HB) will be required to access TMH charts/records.
b) The HB must be a qualified TMH employee who cannot be part of the research team. If you do not have a TMH privileged employee to perform HB responsibilities, TMH will assign an Honest Broker and charges will be rendered for services.

Step 1: Review the following guidelines to decide if your proposed research is eligible for Exempt or Expedited Review and whether or not you are authorized to conduct the research. Research based on reviews of patient records is subject to IRB review. The method for and the type of data to be collected will dictate the category of IRB review that is appropriate:

- Exempt [45 CFR 46.101], or
- Expedited [45 CFR 46.110 and 21 CFR 56.110].

Note
Submit ALL CHART REVIEW PROPOSALS to the IRB prior to initiation. The IRB has the final authority to determine a study’s exempt or expedited review category.

Exempt Category: Review of existing patient records may be considered exempt if the data is collected without identifiers or a link to identifiers, and there is no possible way to go back later to the records.

In most cases, a retrospective chart review that does not record identifiers falls under the following allowable exempt category:

“Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.”

Expedited Category: Retrospective review of patient records involving the collection of identifying information or when a link to the data source is kept require expedited review.
Step 2: Discuss your data collection plan, HB requirement/assignment/and training with the Honest Broker Office: 850-431-2522.

Step 3: Complete Retrospective Chart Review Research Application.

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<th>Forms Required for Retrospective Chart Review Research</th>
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<td>☐ Form 1: Proposal Cover Sheet /Signature Sign Offs (contact IRB Office for Instructions)</td>
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<td>☐ Form 2: Protocol Summary</td>
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<td>☐ Form 3: Conflict of Interest Disclosure Questionnaire for Research (One per investigator/key personnel)</td>
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<td>☐ Form 4d: Application for Approval of Retrospective Chart Review Research</td>
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Enclose Supporting Documents: (as applicable)

- **Full Protocol**: This is the detailed plan describing the objectives, study design, methodology, inclusion/exclusion criteria, statistical plan, subject/confidentiality protection measures, etc.
- **List of all variables and PHI** that will be extracted from medical records
- **Data Collection Sheet**
- **Form DUA**: Data Use Agreement (If applicable)
- **Resume/CV/Bio-sketch** for each person associated with the study
- **Certificate**: Human Subject Protection Education (CITI/NIH/Other Ethics Training) for each key person associated with the study
- **Form 5a**: TMH Hospital Resource Utilization *(if TMH Nursing, Lab. Pharma or other resources i.e. finance, IT services etc. are utilized)*
- **Form 6**: Fee Form
- Any Other Relevant Documents:

Step 4:

1. Submit the complete application packet (one hard copy- printed single sided only) to the IRB Administrator, IRB at TMH, Tallahassee Memorial HealthCare, 1310 Magnolia Drive, Tallahassee, FL, 32308.
2. An electronic copy of the complete application packet must be forwarded to the IRB Administrator at IRB@TMH.ORG. For questions, please contact IRB Office at 850-431-5676.