Introduction:
The TBIMS use established procedural steps to recruit and consent potential participants in the TBIMS National Database (NDB) including strategies and considerations for recruitment and consent.

Purpose:
To institute standard procedural steps for recruiting and consenting potential subjects into the NDB.

Scope:
Current TBIMS centers which are recruiting and consenting participants into the NDB.

Responsibilities:
TBIMS staff responsible for recruiting and consenting into the NDB (e.g., TBI researchers or clinicians, research assistants, study coordinators).

Procedural steps:
Who should be approached for consent?
- All individuals who meet the inclusion criteria and are identified through the NDB sampling procedures (SOP 103) – potential subjects are eligible regardless of immigration status, residence, language barriers, anticipated or actual length of stay, ease of follow up etc. as established by the center’s IRB requirements.
- Centers should use local institutional resources and policies for providing translation for the consent process when the patient and/ or consenting family member does not speak English.
- Persons with TBI &/or their SO (if the individual with TBI does not have capacity for consent)
- Centers should be aware of their individual IRB procedures for determining the capability to give informed consent.
Who can approach potential participants?

- A member of the clinical team
- A member of the research team
  - HIPAA consideration: At some institutions, interpretations of HIPAA regulations may require that permission for research staff contact be given by the potential participant/SO to a member of the clinical team
  - Members of the research team may have a better understanding of the parameters of data collection and the research projects.
- A potential participant may initiate contact with the research team.

When should potential participants first be approached and subsequent informed consent pursued?

- Acute care hospital (if it is known that the person will be transferred to the TBIMS inpatient rehabilitation facility) or acute rehabilitation hospital.

When do you stop approaching for consent?

- Continue to re-approach until nine months post-discharge from TBIMS inpatient rehabilitation facility.

What if consent/participation is refused?

- Record as refused consent and do not re-approach.

Is formal annual re-consent needed?

- No, unless your IRB requires it. Consent is an ongoing process. At the beginning of each annual follow-up contact it is generally a good idea to briefly review the project, the reason for the call and what will be asked, and to confirm permission to proceed with the contact.
  - A participant may refuse further participation or decide to withdraw from the study at any time. If so;
    □ Clarify their intent: withdrawal or selective non-participation.
    □ If withdrawn, the participant would be recorded as withdrawn from further model system follow up data collection and no further data collection or contact would occur.
    □ A participant may choose not to answer a specific question, set of questions, or participate for a specific follow up interval, but still be allowed to participate in other data collection and subsequent years. In this situation the participant would still be considered a model system participant and not withdrawn.

Documentation and storage of signed consent form:

- Copy of consent to research files
  - Your local IRB/privacy office may be a helpful resource to learn about storing consent forms in a manner that maintains privacy
- Copy of consent to participant/SO
Coercion
Any research involving human subjects is guided by regulations provided in CFR Title 21 regarding the proper consent process. For example, Data Coordinators, Clinicians and Investigators should be cautious when approaching subjects and their families and not be coercive when discussing their participation in the TBIMS. We recommend referencing resource materials that will help navigate these regulations, such as, http://www.clinicalresearchresources.com/books/bookstore.html and http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm

What is coercion?
- Coercion is the practice of compelling a person to behave in a certain way (whether through action or inaction) by use of threats, intimidation or some other form of pressure or force.
  - Clinicians should be aware that in the clinician–patient relationship that the clinician may hold a potential “power” or perception of power over the patient
  - Although overt coercion is easy to spot (and to avoid), clinicians should also be aware of more subtle influences on the patient approached for research by a trusted member of his/her clinical team. For example, a patient may think “This has to be okay because my doctor wants me to do it” and thus fail to think carefully through the risks and benefits.
  - Patients commonly believe that they will benefit personally from research or that the research project is part of clinical care, even when told otherwise. Being offered participation in a research project by a clinical team member may further blur the boundaries and exacerbate confusion about the nature of the research.

- Tips to avoid coercion or unintended pressure:
  - Have the clinician ask the patient if he/she can be approached by a research staff person in order to discuss potential research projects, and have the research staff person explain and obtain written consent.
  - Don’t put too much focus on monetary incentives.
  - Don’t promise any direct benefit.

- These points should not be interpreted to mean that clinicians should not be involved in recruitment. On the contrary, clinicians are often in the best position to answer questions the potential participant may have about the study. Referring the patient to a clinician for the purpose of explaining the research is not considered coercive (as long as the patient has not already declined participation.)
Strategies for a Successful Research Recruitment Campaign

- Understand your subject population pool. (this may be especially important for minority populations – i.e. that there are over 500 Native American tribes and over 100 dialects spoken among Asian American Pacific Islanders).
- Establish rapport and trust in the program and staff
- Ensure that all recruitment staff is properly trained and that their skills are assessed regularly.
- Promote awareness of the project.
- Promote interaction with direct-care staff.
- Secure translators for commonly seen ethnic groups.
- Explain real benefits of participation in clinical research (contribution to science, advance new learning). Note: Don’t overplay the expected project benefits.
- Enhance the capability and perceived self-efficacy of potential participants to participate (this has proven very effective in the minority populations).
- Understand the needs, fears, and attitudes of participants about research and their condition.
- Help participants solve problems interfering with participation.
- As opportunities present themselves, help participants meet needs not directly related to your research project.
- Take an educational approach to project involvement and recruitment.
- Distribute an educational packet or brochure that includes information about TBI in general and information about your specific project.
- Obtain business cards for research and clinical staff.
- Leave MSKTC flyers in patient’s room.

Considerations in approaching elderly patients/caregivers for consent:

- Address the person as “Dr.” or "Mr." or "Mrs." or "Ms." unless they tell you to call them by their first name.
- Ask patient’s permission to include caregiver in discussion.
- Continue to include patient in conversation (eye contact, etc.) even if the caregiver is acting as proxy.
- Be sure that all parties can hear you and see you.
- Speak slowly, allowing time for information to be processed.
- After explaining study, offer to leave the consent with them to review, letting them know that you will return at an established time to follow up.

Training requirements:
Whatever your TBIMS center or IRB requires (e.g., HIPAA training, IRB training, Cultural Competency/Diversity training).
Compliance:
Comply with institutional/IRB policies and procedures. Each Model System will review specific procedures and policies regarding recruitment and consent with the NDSC during the quality support visits.

References:

History:

<table>
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<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>04/01/2007</td>
<td>Version of inclusion criteria used to create this SOP</td>
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<tr>
<td>09/16/2008</td>
<td>Transferred to SOP template and approved by SOP Review Committee</td>
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<tr>
<td>10/01/2008</td>
<td>Added stop time for attempting consent as 3 months post-discharge</td>
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<tr>
<td>12/12/2008</td>
<td>Revised definition with approval of Planning Committee and Project Directors</td>
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<tr>
<td>06/19/2011</td>
<td>Changed the time to consent from 3 months post discharge to nine</td>
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<tr>
<td>01/01/2013</td>
<td>Removed bullet regarding collection of reason for refused consent</td>
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<tr>
<td>02/19/2018</td>
<td>Added “Leave MSKTC flyers in patient’s room.” to list of strategies.</td>
</tr>
<tr>
<td>10/01/2019</td>
<td>Removed Cultural Considerations</td>
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<tr>
<td>08/27/2020</td>
<td>Added note about sampling for NDB enrollment</td>
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Review schedule: At least every 5 years.