



102 Guidelines and Strategies for TBIMS National Database Recruitment & Consenting	
Approved: TBIMS Project Directors	Effective Date: 10/01/2008
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Review Committee	SOP Committee

Introduction:

The TBIMS use established procedural steps to recruit and consent potential 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:

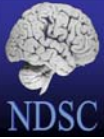
TBIMS staff responsible for recruiting and consenting into the NDB (e.g., TBI researchers or clinicians, research assistants, study coordinators).

Procedural steps:

Who should be approached for consent?

- All individuals who meet the inclusion criteria – all potential subjects eligible should be approached regardless of immigration status, residence, language barriers, 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?



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- A member of the clinical team
- Coercion consideration: Clinicians should be aware that, in the clinician –patient relationship, the clinician may hold potential “power” or the perception of power over the patient. See further information below.
- 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 reapproach until three months post-discharge from TBIMS inpatient rehabilitation facility.

What if consent/participation is refused?

- Politely ask if the person will tell you the reason for refused consent.
- Record as refused consent and do not reapproach.

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.
 - 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



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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
- Copy on chart
 - Caution: Clarify with your IRB as each local project and IRB may have unique considerations and requirements, especially regarding chart copies of study consent forms.

Coercion

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

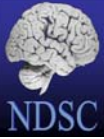
- Understand your subject population pool. (this may be especially important for minority populations – i.e. that there are over 500 Native American tribes and over 100 dialects spoken among Asian American Pacific Islanders).
- Establish rapport and trust in the program and staff
- Ensure that all recruitment 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.

Cultural considerations in approaching for consent:

There is little literature that examines specific approaches for different cultural experiences. Be aware that there are large variations in response to American medical and research culture within ethnic/cultural/racial groups. For newer arrivals to this country, this may be their first experience with informed consent. The following are some considerations that might be helpful for recruitment of subjects in the Model Systems. Please remember that although culture may play a role in some people's decisions, this is not universal and each person should be considered uniquely for any concerns they may express.

1. African American culture:

- Patients may have distrust of medical research in particular because of well-known historical abuses in this area. Discuss the details with the patient AND family on the safeguards to prevent abuse of research participants.
- Unless invited to do otherwise, greet the patient with a formal title (Mr., Mrs.)
- Take special care to have congruent verbal and non-verbal communication. Be attentive.



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2. Latino culture:

- Ask the potential participant who they want to be involved in decision-making about research. When possible, engage the whole family.
- Shake hands and greet the participant by name. Older persons should be called by Señor or Señora.
- People may avoid eye contact with health care professionals as a sign of respect.
- When a person nods, they are not agreeing with you but rather demonstrating that they are listening.
- Silence may be a sign of not understanding or disagreeing.
- Mexican culture: Use title and full name on first meeting. Demonstrating warmth and attentiveness is very important. Often the mother is in charge of health care.

3. Russian culture:

- Decisions are often made by the elders in the group; there are no gender preferences for decision-making. Ask who should be involved in the decision to join a research study.
- Direct eye contact is acceptable and firm handshakes appreciated.

4. Vietnamese culture:

- The family spokesperson is often the person who speaks the best English. This may not be the decision-maker in the family. Ask who should be involved in decision-making.
- There may be alternative explanations for medical symptoms, such as imbalances in body systems, or a feeling that there should be direct cause and effect relationships. You may need to explore what the potential participant understands about their condition.
- Handshakes are appropriate between men. Women do not shake hands.
- Respect is shown to authority figures by a gentle bow and avoiding eye contact.

5. Somali culture:

- Be aware of cultural beliefs about the causes of illness (“evil eye” and associations between illness and actions) that may impact their understanding of the research.
- Men shake hands with men, women with women.
- Often the male of the household is the spokesman for the family.
- Much of the country is Muslim; a common greeting is “salaym-alekhum” or “peace be with you”.

6. Ethiopian culture:

- Women are considered inferior to men.
- Family ties are strong.
- Medicine in Ethiopia tends to be more “personal” and less “business-like”.



7. Hasidic/ orthodox Jewish culture:

- Avoid shaking hands with people of the opposite gender.
- Direct eye contact may be taken as rudeness. It is more comfortable for Hasidic Jews to look down or off to the side when engaging in conversation (particularly with the opposite sex).
- Caregivers/ physicians who are of the same gender as the patient are strongly preferred wherever possible. It may be helpful to reassure the patient/ family that the research does not involve any physical contact or medical type of procedure.
- People whose first language is Yiddish may omit the words “please” and “thank you,” instead expressing courtesies through voice inflection and body language. Be careful not to misinterpret this as lack of consideration.

Cultural Competence Tidbit compiled by Angela Sauaia, MD, PhD

Did you know that:

- ...the main issue in cultural competence is to NOT make assumptions about a person? Did you feel the pressure to memorize traditions, beliefs and attitudes of different cultures and communities? Cultural experts tell you to simply ASK your person. The LEARN model may help:¹

Listen with sympathy and understanding to the person’s perception of the problem

Explain your perceptions of the problem and your strategy for treatment.

Acknowledge and discuss the differences and similarities between these perceptions.

Recommend treatment while remembering the person’s/patient’s cultural parameters.

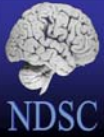
Negotiate agreement. Understand the person’s/patient’s explanatory model so that the medical treatment fits in their cultural framework.

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.



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References:

Berlin EA, Fowkes WC, Jr. A teaching framework for cross-cultural health care. Application in family practice. *West J Med* 1983; 139(6):934-938.

History:

- 1) Version used to create this SOP = 04/01/07
- 2) Transferred to SOP template and approved by SOP Review Committee = 9/16/08
- 3) Added stop time for attempting consent as 3 mos post-discharge = 10/01/08.
- 4) Review approved by Planning Committee and Project Directors = 12/12/08.

Review schedule: At least every 5 years.