Burn Model System

National Data and Statistical Center

STANDARD OPERATING PROCEDURE (SOP) #102

SOP #102	**Title:** Guidelines for BMS National Database Recruitment, Consenting, Discharge Data Collection, and Withdrawal of Participants
Approved by: BMS Project Directors	**Effective Date**: 4/14/2014
Attachments: Appendix A: Best Practice Guidelines for Recruitment and Consent	**Revised Date**: 9/18/2025
Forms: None	**Review Date**: 10/23/2020
Review Committee: BMS Project Directors	

Purpose:

SOP #102: Guidelines for BMS National Database Recruitment, Consenting, and Withdrawal of Participants implements procedural steps for recruiting and consenting potential participants into, or withdrawing them from, the BMS National Database (NDB).

Scope:

Applies to all current BMS Centers who are recruiting and consenting participants into the NDB.

Responsibilities:

For Implementation:

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

For Oversight:

- Directors of BMS Centers and staff from the Burn National Data and Statistical Center (BMS NDSC).

Procedures:

Identifying Potential Participants

All individuals who meet the inclusion criteria should be approached regardless of immigration status, residence, language barriers, etc. as established by the BMS Center's IRB requirements. See further information about conducting a successful recruitment campaign in *Appendix A*. **Note**: The inclusion criteria for the BMS is established in *SOP #101: Identification of Subjects for the Burn Model System National Database.* It is important for all individuals who meet study criteria to be approached so that we can accurately assess the population of the BMS as compared with the eligible population.

Approaching Potential Participants

1. Potential participants may be approached by an IRB approved member of the clinical team **OR** an IRB approved member of the research 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 about coercion in *Appendix A*. Members of the research team may have a better understanding of the parameters of data collection and the research projects.
2. A potential participant may initiate contact with the research or clinical teams.

Language Barriers

Centers should use local institutional resources and policies for providing translation for the consent process when the patient and/ or consenting family member who requires assistance with English.

Capacity to Provide Consent

Centers should be aware of their individual IRB procedures for determining the capability of an individual to give informed consent.

Time frame for Approaching Potential Participants

Potential participants should be approached and subsequent informed consent pursued when they are in acute care and have been stabilized and are capable of informed consent.

Time frame for Discharge Data Collection from Consented Participants

Data collection of discharge information (i.e., Form I) can occur prior to acute care discharge, but should occur after participants have been stabilized and are capable of providing the information about where they will be discharged to and other information on Form I. Discharge data collection should occur within the same window as consent (i.e., within 30 days of discharge from the model system clinical unit (either from the acute care unit or inpatient rehab unit). Date of discharge from the BMS clinical unit qualifies as day one.

Refusal to Participate

If a potential participant refuses consent/participation, the study coordinator should record the refused consent, collect data on the Patient Status Form, and the individual should not be re-approached. The refusal should be reported on the Patient Status Form and in the online data entry system (REDCap) so that response rate can be computed.

Annual Re-consent

Formal annual re-consent is not required unless the IRB monitoring human subjects' protection for the BMS Center requires it. However, note that consent is an ongoing process. At the beginning of each 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.

Withdrawal from the Study

A participant may refuse further participation or decide to withdraw from the study at any time. If this happens,

- *Clarify the individual's intent*, that is, do they want to withdraw completely or do they want to engage in selective non-participation (selective non-participation is when a participant declines to participate in the current follow-up period but not the entire study).
- If a participant withdraws, the participant should be *recorded as withdrawn* from further BMS follow up data collection and no further data collection or contact should occur.

Refusal to Respond to Specific Questions

A participant may choose not to answer a specific question, set of questions, or participate for a specific follow up interval, and 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.

Storing and Documenting the Signed Consent Form

1. Original, signed consent should be stored according to individual center IRB requirements.
2. A copy of the signed consent form should be stored in BMS Center research files.
3. A copy of the signed consent form should be left with the participant/parent proxy.
4. A copy of the signed consent form may be added to the patient's chart; ***however*** clarify with the local IRB as each local project and IRB may have unique considerations and requirements, especially regarding chart copies of study consent forms.

Consent Data Collection in the BMS Patient Status Form

"Consent at discharge for follow-up" is the section in the Patient Status Form that should be filled out for all patients that meet eligibility criteria: people who <u>do</u> consent to the study, people who are eligible to participate but choose not to, and people who are eligible but non-consentable (i.e., people with language barriers, etc.). Definitions for this section of the patient status form are as follows:

Consent at discharge for follow-up?

1. Yes, consented

- If a patient agrees to participate in the study and signs the required consent form (or provides verbal consent where this is allowed by the IRB), they are considered enrolled in the study.
- The data should be entered in the Patient Status Form as 1-Yes, consented.

2. No, did not consent/refused (do not collect date of birth or date of burn, but do collect burn and birth years). Some examples include:
    - When a patient gives a clear indication of refusal prior to reviewing the consent form.
    - When a patient decides not to participate after reviewing the consent form.
    - When a patient expresses interest and is provided a consent form but never signs or returns it.
3. No, did not consent/missed (do not collect date of birth or date of burn, but do collect burn and birth years:)
    - Missed is a category for people who were eligible for participation but were not approached for the study prior to 30 days post discharge.
    - This can also include patients that leave the hospital against medical advice (AMA).
4. Eligible but unable to consent (severe cognitive impairment due to dementia, TBI, etc) (do not collect date of birth or date of burn, but do collect burn and birth years):
    - Centers should be aware of their individual IRB procedures for determining the capability of an individual to give informed consent.
    - This also includes patients that passes away before they can consent. In these cases, data should be entered as 4-Eligible but unable to consent.
5. Eligible but unable to consent (language barriers) (do not collect DOB or Date of Burn)
    - Centers should use local institutional resources and policies for providing translation for the consent process when the patient and/ or consenting family member who requires assistance with English.

Training requirements:

None is required across Centers; Centers should implement Center specific training as needed to follow these procedures

Compliance:

All BMS Centers, follow-up centers, and the NDSC will comply with this procedure.

References:

None

History:

12/23/2022—Edited to clarify that discharge forms (i.e., Form I) can be collected prior to discharge from acute care. Also edited to clarify why all eligible patients should be approached.

9/18/2025—Edited to add definitions for enrollment statuses on Patient Status Form and to clarify timeframe of discharge data collection.

Review Schedule

At least every 5 years.

Appendix A: Best Practice Strategies for

Recruitment and Consent

Understanding Coercion in the Recruitment Process

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 the clinician may hold 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 who has been approached for research purposes 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 (especially as it relates to racial/cultural differences).
- Establish rapport and trust in the program and staff
- Ensure that all recruitment staff are 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 language groups.
- Explain <u>real</u> benefits of participation in clinical research (contribution to science,

advance new learning). 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 (transportation issues, etc.).
- Distribute an educational packet or brochure that includes information about BMS in general and information about your specific project. This could include MSKTC produced Fact Sheets, etc.
- Obtain business cards for research and clinical staff.

References:

Traumatic Brain Injury Model System Standard Operating Procedures 102a "Guidelines and Strategies for National Database Recruitment and Consent."