**Introduction:**
This policy and procedure addresses the established criteria to determine eligibility for enrollment and participation in the BMS National Database (NDB).

**Purpose:**
To institute standard inclusion / exclusion criteria for identifying and enrolling potential subjects into the NDB.

**Scope:**
Current BMS centers which are identifying and enrolling subjects into the NDB.

**Responsibilities:**
BMS staff responsible for identifying and enrolling subjects into the NDB (e.g., BMS researchers or clinicians, research assistants, study coordinators).

**Policy**
As of 8/1/2009, the study group criteria for the BMS NDB is as follows:

**Case Definition:**
A patient with a burn injury at one of the Burn Model Systems Centers is eligible for participation in the BMS NDB if:
1. They are a patient with a burn injury that is treated at one of the NIDRR-funded BMS Centers.
2. They meet the criteria listed below;
3. They sign a Consent Form;
4. They agree to scheduled follow-up assessments at 6, 12, 24 months, and every five years post-burn.
Inclusion Criteria for Model System Burn Patient

1. >=10% TBSA, >=65 years of age and with burn surgery for wound closure;
2. >=20% TBSA, 0-64 years of age and with burn surgery for wound closure;
3. Electrical high voltage/lightning with burn surgery for wound closure;
4. Hand burn and/or face burn and/or feet burn with burn surgery for wound closure; OR

Met Burn Model System inclusion criteria prior to the change in such criteria that was made on 8/1/2005 (for tracking follow-up of already enrolled subjects)

And;

• Received primary treatment in the Burn Model System Center from the time of burn (outpatient or inpatient) for primary burn wound closure.
• Surgery for closure of burn wound must occur within 30 days of burn injury (effective date of this criterion: 8/13/2013).
  - Autografting is considered wound closure; those patients that have only xenografting or allografting are not eligible.
  - As of 2010, frostbite/cold, TENS/Steven Johnson, abrasions, necrotizing fasciitis, meningococcemia, and other skin disease are not eligible types of burns to be included in the national database. Therefore, the burn etiologies that are eligible to be included are: fire/flame, scald, contact with hot object, grease, tar chemical, hydrofluoric acid, electricity, radiation, UV light, flash burn, and other burn (other burn includes road rash, abrasions, steam burns, etc).
• In addition to acute care, will be provided comprehensive rehabilitation services at the Burn Model System Center, including: physiatric, physical, occupational, recreational, psychological, vocational, or other traditional rehabilitation therapies throughout the care of the burn injury.
  - If there is reasonable expectation that follow-up care at the model system can occur, the patient will be enrolled.
  - Once the patient meets inclusion criteria and is enrolled into the study, the subject should be retained even if she/he is subsequently transferred to another facility or moves to a different catchment area.

Training requirements:
Staff who are responsible for recruitment and enrollment of subjects into the BMS NDB should be familiar with these criteria.

Compliance:
Only participants that meet these inclusion criteria will be enrolled into the BMS NDB. These criteria should be reported in publications related to analysis of the NDB data, but do not need to be stated exactly as above.

References:
None
History:
1/2/2014—Edited to clarify which types of burns are eligible and not eligible.
4/14/2014—Edited to clarify what types of burns are included in “other burns” and clarify some wording issues.

Review schedule:
At least every 5 years