

**Burn Model System
National Data and Statistical Center**

STANDARD OPERATING PROCEDURE (SOP) #110

SOP # 110	Title: BMS Genomic Study (DNA Isolation from Buccal Swabs)	
Approved: BMS Project Directors		Effective Date: 2/17/2022
Attachments: None		Revised Date: 1/26/2026
Forms: None		Review Date:
Review Committee: BMS Project Directors		

Introduction:

This procedure establishes standard operating procedures for DNA isolation from cells from Buccal (cheek) swabs collected at a participating Burn Model System (BMS) center and processed at the Northwest Regional Burn Model System (NWRBMS) at Harborview Medical Center. NWRBMS led the module project that initiated the DNA data collection during the 2017-2022 funding cycle and for the purposes of this SOP is considered the BMS DNA Isolation and Storage Site. Because this SOP lays out processes that involve the NWRBMS as the BMS Center processing the buccal swab data, if the NWRBMS's participation is discontinued or if another center takes over the role of BMS DNA Isolation and Storage Site, this SOP will be revised to account for procedures at the new BMS DNA Isolation and Storage Site. See item VI below for more information about necessary steps if a new BMS DNA Isolation and Storage Site is needed.

Background:

Integration of genetic data is increasingly being used to develop what is known as precision care for patients. Understanding genetic risk factors for patients living with burn injuries might facilitate prediction of recovery trajectories including development of hypertrophic scars, neuropathic pain, depression or post-traumatic stress. Combining genetic information with premorbid characteristics, injury, and early responses to injury will create a unique repository that will allow us to better understand contributions to physical, cognitive, and emotional outcomes and perhaps identify modifiable targets to improve outcomes during the early treatment phase. Given reports that individuals who have experienced a burn injury have higher levels of depression and other mental illness than the general public¹⁴ and patient reports of limited mental health resources - especially in underserved areas, identifying genetic risk factors for at-risk patients could allow earlier prediction of psychological challenges and allow us to target therapeutic interventions earlier. A repository of DNA samples might leverage the BMS National Database as a tool to study comprehensive predictors of burn injury outcomes in a large longitudinal population sample; as such, addition of biological samples may facilitate future hypothesis-driven studies of associations between genetic profiles and burn injury recovery trajectories. In the future, this genetic databank may help to personalize medical and treatment options in both acute and rehabilitation phases of burn care. These new data could allow development of precision medicine approaches that address each patient with a burn injury as a biologically unique individual.

Purpose:

To establish standard operating procedures for obtaining consent and for ensuring optimal sample collection and processing to provide high quality and a sufficient quantity of DNA for downstream analysis.

Scope:

BMS Centers that participate in the BMS Genomic Study and collect and process Buccal Swab Samples for DNA isolation and the BMS National Data and Statistical Center (BMS NDSC).

Responsibilities:

The research staff responsible for obtaining and processing buccal swabs.

Precautions:

Observe biohazard precautions for all steps of this protocol.

Reagents and Equipment:

- Buccal Swabs: Puritan™ PurFlock™ Ultra Flocked Swabs (25-3306-U), ThermoFisher Catalog Number 22-029-612
- KingFisher™ Duo Prime magnetic particle processor and consumables
ThermoFisher Catalog Number 5400110
(2) Deep-well 96 plate ThermoFisher Catalog Number 95040450
(1) Duo Prime 12-tip comb ThermoFisher Catalog Number 7003500
- MagMAX™ DNA Multi-Sample Ultra 2.0 Kit
Applied Biosystems/ThermoFisher Catalog Number A36570
- Ethanol 100% (molecular biology grade) used to prepare Wash Solution II
- Wash Solution II: 80% EtOH prepared with nuclease-free H₂O; stored in 518 fume hood
- Phosphate Buffered Saline (PBS, pH 7.4); stored in 518 fume hood
- Nuclease-Free Water
- Plate shaker in room 510 set to 900rpm (~10th or 11th setting)
- Plate heating block in room 510 set to 65°C
- NanoDrop 2000 ThermoFisher Catalog Number ND-2000
- PPE such as nitrile gloves and lab coat
- Vortexer

Procedures:

I. IRB approval and informed consent

The informed consent process for genetic data is separate from the BMS National Longitudinal Database (NLDB) informed consent process. However, some centers may have two consents (one for the NLDB and one for the Genomic Study) combined in one consent form packet. Others may have completely separate consent forms for each of the studies. Genetic data is considered an optional add-on data collection for participants of the NLDB. Each BMS Center will maintain IRB approval and consent forms for the genetic data collection at their site. The genetic data is to be collected when a participant provides informed consent for the buccal swab, and is collected one time (rather than at each follow-up timepoint). Consent for genetic data collection and swab data collection can occur at any time point.

II. Sample buccal swab collection (brief description/overview)

Participants are limited to BMS NLDB participants (newly consented into the study or who have previously provided consent and are providing follow-up data for the BMS NLDB) who are over the age of 18 years. Those participants who have provided the separate written, informed consent or consent online for DNA data collection can either be mailed a swab collection kit, including a postage paid envelope addressed to NWRBMS or BMS staff can supervise the buccal swab collection in person. Swab collection procedures involve the following:

- a. Confirm with participants that they have i) not consumed food or beverages (water is fine) and ii) consumed nicotine in the 30 minutes prior to collection of the cheek swab.
- b. Participants will be instructed to thoroughly rinse their mouths with water prior to swabbing.
- c. The swab is removed from the package (holding the tip above the breakpoint).
- d. The applicator tip is inserted into the mouth and rubbed firmly along the inside of both cheeks for 30 seconds per side (total of 60 seconds).
- e. After sample collection, participants carefully place the swab sample in its original packaging.
- f. Label the swab with the BMSGENE # (see section V, REDCap Data Entry Process, for more information on the BMSGENE#) using a permanent marker and then tape over the ink so it does not smear.
- g. Samples are sent to the NWRBMS by participants or by the BMS Center who collected the sample.
- h. An online video is available that details each step of sample collection and can be accessed at <https://youtu.be/oSvMEyslWtY>
- i. The NWRBMS developed an infocomic with instructions for sample collection and can be used during procedures or mailed to participants. The infocomic can be found in this SOP's appendix.

III. Mailing Swabs to NWRBMS

- a. Regardless of if a swab is being sent from a BMS center to the NWRBMS or from a participant to the NWRBMS, the packaging will include the following:
 - i. Padded envelope
 - ii. NWRBMS address:
"[insert name of Northwest Regional Burn Model System research coordinator]
Harborview Medical Center
325 9th Ave, Box 359796

Seattle, WA 98104"

- iii. Return address: BMS center's address even when it is sent by a participant
- iv. "Human Except Specimen" sticker (or handwritten) on the outside of the envelope.
- b. When a BMS Center mails a swab collected in-person, they will email the NWRBMS with the date and BMSGENE#.
- c. If a swab is sent from one of your participants, email the NWRBMS team to inform them of when you mailed the swab to the participant.
- d. When the NWRBMS receives a swab, they will email the appropriate center with the date it was received.

IV. Sample Intake Process at NWRBMS

- a. After the buccal swab sample is received at NWRBMS, will track the date the sample was received and store sample in its' collection tube in a -80°C freezer
 - i. Optimal time for DNA extraction is within 4 weeks of receipt. Time between receipt and isolation will be calculated by entering date of receipt and date of isolation in REDCap as part of the sample quality assurance process
- b. **DNA isolation from Buccal Swab:** Process samples using the MagMAX™ DNA Multi-Sample Ultra 2.0 Kit by following the instructions noted in NWRBMS site specific SOP for genetic data collection and isolation. An abbreviated version of the site-specific procedures follows:
 - 1. Prepare samples and digest with Proteinase K
 - 2. Perform DNA isolation and purification using KingFisher™ Duo Prime
 - 3. Bind the gDNA
 - 4. Process the plate on the KingFisher™ Duo Prime Magnetic Particle Processor.
 - 5. The following values are recorded:
 - Values for 260 nm (DNA), 280 nm (Protein), and 260/280 ratio
 - 260/280 RATIO should be between 1.8 and 2.0
 - 260/230 RATIO should be between 1.8 and 2.2
 - 6. Please also refer to specific guidelines and protocol in the user guide for MagMAX™ DNA Multi-Sample Ultra 2.0 Kit

https://assets.thermofisher.com/TFS-Assets/LSG/manuals/MAN0017205_MagMAX_MultiSampleUltra2_BuccalSwabs_UG.pdf

V. REDCap Data Entry Process

- a. After swab is collected at a BMS Center or a swab is mailed to a participant for collection the BMS Center where the swab was collected should enter the following information into the *REDCap BMS Genetic Info Database*:
 - i. Assign a BMS Gene # to each individual sample. The BMS Gene # starts with the letter that represents the BMS institution that collected the sample (e.g. A-University of Washington/NWRBMS; B-Boston; C-UTSW; D-UTMB, E-USC) , followed by the numerical code that starts with "0000#" replacing the "#" symbol with the appropriate number that represents the consented participant. E.g. E-00001. The MSID of the participant
 - ii. Buccal swab collection method (Collected in Person or by Mail)
 - iii. Date that the swab was mailed to the participant (if applicable)
 - iv. Date of collection for in person swabs (if applicable)

- b. After DNA processing, the NWRBMS Center will enter the following information into the *REDCap BMS Genetic Info Database*:
 - i. Date that the buccal swab arrived in the mail (if applicable)
 - ii. Date that the buccal swab was processed/DNA was isolated.
 - iii. 260/280 and 260/230 Ratio
 - iv. DNA concentration as expressed in ng/mL (nanograms per milliliter)
 - v. Final DNA elution volume expressed in µL (microliters)

VI. BMS DNA Data Usage and Analysis

- a. The BMS DNA data that has been extracted from the buccal swabs is stored until such a time that a genetic analysis is identified that a BMS Center or Centers wants to conduct. The expenses of conducting a genome-wide association study (GWAS) or a SNP – PCR analysis are not covered by existing BMS funds and will need to be budgeted for by the group doing the analysis.
- b. The BMS NDSC funding does not include analysis of the DNA. It is the responsibility of the BMS Center/s initiating the analysis to find the proper expertise for conducting the bioinformatic analysis.
- c. Data sharing: The BMS DNA data will not be shared until it has been sequenced. The BMS and the BMS NDSC will work with external researchers who are interested in SNP-PCR analyses using BMS data on an as-needed basis to develop data use agreements and procedures for data sharing.

VII. BMS DNA Data Transfer Procedures

In the event that NWRBMS is no longer able or available to store the genetic data and another BMS Center assumes the duties of the BMS DNA Isolation and Storage Site:

- a. If another BMS Center plans to take over these duties, this SOP must be edited to account for the procedures of the new BMS DNA Isolation and Storage Site. Additionally, the following issues must be addressed:
 - a. The genetic data is classified as specimens that are regulated by state and federal laws. The samples will be sent from NWRBMS to the new BMS DNA Isolation and Storage Site and will involve crossing state lines with human samples and must be arranged ahead of the transfer of BMS DNA Isolation and Storage Site duties.
- b. For more information on transferring human specimens see this article:
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6777724/>

Training requirements:

Each center's institution may have specific trainings that are necessary. For example, all NWRBMS lab staff handling human swab samples must complete the following UW online courses:

Bloodborne Pathogens for Researchers

<https://www.ehs.washington.edu/training/bloodborne-pathogens-researchers-online>

Biosafety Training

<https://www.ehs.washington.edu/training/biosafety-training-online>

Managing Laboratory Chemicals

<https://www.ehs.washington.edu/training/managing-laboratory-chemicals-online>

Compliance:

All current BMS Centers and any BMS longitudinal follow-up centers (if applicable) who collect Buccal swab samples as part of the Burn Model System National Longitudinal Database.

References:

NWRBMS Site Specific Module: Genetic Predictors of Functional Outcomes after Burn Injury

NWRBMS Collaborative Module: Genetic Predictors of Functional Outcomes after Burn Injury

User guide for MagMAX™ DNA Multi-Sample Ultra 2.0 Kit

https://assets.thermofisher.com/TFSAssets/LSG/manuals/MAN0017205_MagMAX_MultiSampleUltra2_BuccalSwabs_UG.pdf

History:

--Updated on 1/26/2026 to add more detail and clarify procedures.

Review schedule:

At least every 5 years.