

# Memorandum of Understanding (MOU) Utah Suicide Mortality Research Study (USMRS)

This agreement is entered into and effective as of [INSERT DATE], by and between the Utah Suicide Mortality Research Study (USMRS) Advisory Group and [RESEARCHER NAME], [Department, University/Institution Name].

## **Purpose**

The purpose of this Memorandum of Understanding (MOU) is to support both existing and new researchers in the appropriate, productive, and ethical use of the valuable resources provided by the Utah Suicide Mortality Research Study (USMRS). This document outlines the roles and responsibilities of researchers, as well as those of the USMRS Advisory Group (AG), to foster a transparent and collaborative research environment.

USMRS is committed to improving our understanding of factors associated with risk of or resilience to suicide mortality, with the eventual goal of saving lives and improving the quality of life, both in Utah, and potentially more broadly. The intent of this MOU is to ensure that the resources made available by the Office of the Medical Examiner (OME) are used in a sustainable, feasible, efficient, ethical, and compliant manner. It also aims to support efficient tracking and management of research progress and resource utilization; encourage engaged, informed co-creation; enhance research rigor; and promote the dissemination and translation of findings into public health and research practices with guidance from individuals with lived experience and other key stakeholders.

This MOU applies to all users of USMRS resources including USMRS AG members, and all prospective users regardless of position (e.g., faculty, student, staff, affiliate).

#### **About USMRS**

The USMRS was formed on an interdisciplinary basis to promote greater collaborative research opportunities aimed at studying risks contributing to deaths by suicide in Utah. Since the late 1990s, USMRS has grown and evolved through a unique and ongoing collaboration with the Utah Department of Health and Human Services (UDHHS), particularly through foundational data and sample contributions from the Office of the



Medical Examiner (OME). This data and sample contribution enables access to valuable information on individuals who have died by suicide.

#### Data Resources

USMRS data derived from OME autopsies, and additional securely linked data including demographics, electronic health records, environmental and geographical exposures, social determinants of health, genealogical, and genetics. The USMRS data core is committed to keeping data documentation comprehensive, current, and accessible.

# Biological Samples

USMRS samples currently include dried blood spots, DNA, viably frozen skin biopsies, fibroblast cultures, hair samples, and a limited amount of fresh frozen and formalin fixed brain tissue. The USMRS lab core maintains up-to-date information about sample types, storage locations, and sample quality/amounts. (NOTE: Collection and use of biological samples is currently pending Utah DHHS decision)

# People

The USMRS team is made up of a multidisciplinary group of individuals that include researchers and clinicians across UU departments and at Intermountain Health, policy makers, UDHHS professionals, and individuals with lived experience. The USMRS strives to foster a transparent and collaborative environment for all participants to engage in meaningful and ethical research. Investigators must be aware of ongoing projects and are encouraged to co-create and co-implement research initiatives.

USMRS Advisory Group (AG)
 Established in 2025 the USMRS AG provides strategic oversight of the USMRS project funded by the OVPR.

# Governing statutes and permissions governing samples and data

The use of data and biological samples associated with the USMRS is governed by multiple legal statutes, institutional agreements, and oversight processes:

## 1. Legal Authority for Samples:

<u>Utah Code section 26B-8-202</u>, specifies that the medical examiner is authorized to "retain tissues and biological samples . . . for scientific purposes."



## 2. Data and Sample Transfer Agreement:

Access to data and samples from the OME is governed by a formal Data Sharing agreement (DSA) between USMRS/ University of Utah and the UDHHS (OME).

# 3. Data Transfer and Management:

Data are securely transferred from OME to the <u>Utah Population Data Base</u> (UPDB) and linked to additional data by UPDB honest data brokers. Linking identifiers are removed and a limited use dataset is securely transferred to the USMRS Data Core Manager for research purposes, in compliance with ethical and privacy standards.

# 4. IRB Oversight and Approvals

Access to and use of USMRS data acquired through the UDHHS DSA (item 2 above) is also contingent upon approvals by ethics and oversight boards, including:

- Institutional Review Boards (IRB) of the UU, Intermountain Health (IH), and the Utah Department of Health and Human Services (UDHHS)
- The UPDB's governing body, the Resource for Genetic and Epidemiologic Research (RGE)

# 5. Publication Review Requirement

In accordance with <u>Utah code USC 26B-8-217(6)(f)</u>: any individual or entity that references or analyzes medical examiner data in a publication must additionally allow the OME to review the material prior to public release.

# 6a. USMRS/UU Data Use Agreement (DUA)

Access to USMRS data is contingent upon signing a DUA with USMRS/UU and adhering to all aspects of the agreement to ensure compliance with all applicable statutes and institutional policies.

# 6b. USMRS/UU Material Transfer Agreement (MTA)

Access to USMRS biological samples is contingent upon signing an MTA with USMRS/UU and adhering to all aspects of the agreement to ensure compliance with all applicable statutes and institutional policies. (NOTE: Collection and use of biological samples is currently pending Utah DHHS decision)



## **Institutional Review Board (IRB) Requirements**

All individuals who intend to access USMRS data and/or biological samples—or who are involved as part of the investigation or implementation teams—must be listed on at least one of the following approved overarching USMRS IRB protocols. Amendment(s) will be pursued to support proposed research if needed. If the proposed work includes new data element(s) with substantially different requirements for regulatory oversight, a new umbrella sub-study IRB may be considered, as recommended by VPR, RGE, and IRB leadership.

# To ensure compliance, users must:

- Be approved on one of the USMRS overarching IRBs and document sections that cover approval of necessary data elements and analytical design as an attachment to any data requests.
- Keep CITI (Collaborative Institutional Training Initiative) training current and up to date.

## Approved IRBs:

USMRS Overarching Umbrella IRB

IRB\_00044244; NOTE: This IRB is also mirrored in an Intermountain Health IRB and UDHHS IRB. These IRBs are annually reviewed by their organizational IRB committees.

# USMRS Sub Study Umbrella IRBs

IRB\_00133374: Specific to extra regulatory requirements for storing and processing notes in health records

IRB\_00144804: Specific to extra regulatory requirements for storing and processing geographical data

Researchers are responsible for verifying and documenting their IRB status together with the USMRS Program Manager and IRB co-PIs. The IRB co-PIs will be responsible for enforcing ongoing compliance with all ethical and institutional requirements.



### Rights to data usage

All users of USMRS resources are reminded that research funding is awarded to institutions—not to individual investigators. As outlined by <a href="the-U.S. Office of Research">the U.S. Office of Research</a> <a href="Integrity">Integrity</a> and <a href="UU policy">UU policy</a>, data and other research products (including intellectual property, patents, etc.) generated from funded research are considered institutional assets.

Accordingly, no data elements derived from funded research using USMRS resources are the property of any individual researcher. Instead, such data become part of—and contribute to—the broader USMRS dataset, which serves as the foundation for this research, and which made the funding possible. Data access and usage are governed by the UDHHS/OME Data Sharing Agreement and the UU, with additional oversight by the USMRS AG, in accordance with institutional policies and state statutes.

In alignment with principles of responsible data stewardship, researchers are expected to:

- Ensure that data generated through USMRS can be effectively reused by others in ways that are transparent and not overlapping with other ongoing work.
- Provide adequate metadata and documentation to facilitate transparency and reproducibility.
- Deposit data products and datasets with the USMRS Data Core and Program
   Manager, facilitating documentation and sharing of results and sharing of relevant
   datasets with USMRS-affiliated teams, when appropriate and compliant.
- Ensure appropriate storage and use of all data products in accordance with established policies and procedures (described in detail below).

Any misuse of data or violation of data usage rights may result in suspension or revocation of access to USMRS data and biological samples.

## **Operating procedures**

The USMRS AG has developed several operating procedures to guide the request, review, and approval of USMRS resources. These procedures aim to ensure sustainable compliance with regulations, enhance innovation and impact through co-creation, facilitate ethical research through diverse perspectives, and ensure rigor through initial and ongoing cross-checking of data and design elements. Procedure details are organized as follows:



- Data Access
- Sample Access (NOTE: Collection and use of biological samples is currently pending Utah DHHS decision)
- Personnel Access
- External Contracts
- Incident Management
- Project tracking

These operating procedure documents will be updated at least annually. Users of USMRS resources should be familiar with the content of these documents that can be viewed at the <u>USMRS Stewardship Materials website</u>.

# **Data and Sample Application Request**

As per the operating procedures USMRS has developed applications to request access to data and to request access to samples.

Users of USMRS resources should be familiar with the request applications available at the USMRS Stewardship Materials website.

## **DUA and MTA**

A new DUA or MTA is required of each approved data or sample request that will result in a research product (publication, presentation, grant proposal, policy guidelines, etc.). One request cannot be used to cover multiple separate projects. The DUA and MTA can be viewed at <u>USMRS Stewardship Materials website</u>.

#### **Data Safeguarding**

To ensure the integrity, confidentiality, and appropriate use of USMRS data, the following data security protocols must be observed:

Secure Storage
 All data must be stored and accessed exclusively on institutionally approved and secure systems. Access to these systems will be limited to the proposed project timeline. Use of unapproved storage solutions is prohibited. Data may not be downloaded.



- Access Restrictions
  - Data will only be accessed and shared with users who have been explicitly approved through the appropriate IRB and RGE protocols and Data Use Agreements (DUAs).
- Archiving of Completed Projects
   Upon project completion, finalized datasets must be transferred to the USMRS past projects archive for long-term storage and reference. This ensures data continuity, accountability, and accessibility for future review.

Any misuse of data or violation of data usage rights may result in suspension or revocation of access to USMRS data and biological samples.

# Required recognition, acknowledgement, and review of research products

All publications, presentations, grant applications, and any other public products that utilize USMRS data, samples, or infrastructure must include formal acknowledgment of the following contributors and partners:

- Utah Office of the Medical Examiner: at least one co-author from the OME must be included where appropriate; if co-authorship is not appropriate, an OME/UDHHS representative must be allowed to review the research product, and acknowledgment is required.
- All publications must go through the formal RGE Publication/Publicity Review prior to publication.
- Appropriate USMRS co-authors must be included where appropriate as dictated by sample use, data use, and study design. Co-authors must be notified early in the development of the research product (ideally at its inception); a generous amount of review time and a collaborative, non-coercive review process of final drafts is expected of researchers.
- Utah Population Database (UPDB) acknowledgment is required <u>Acknowledging UPDB</u>.
- Acknowledgments of other contributing entities must be included as appropriate (e.g., Core labs, significant contributors).
- Funding Sources must be acknowledged as appropriate.
- At least one co-author from Intermountain Health must be included where appropriate.

Failure to include appropriate acknowledgements may result in suspension or revocation of access to USMRS data and biological samples.



Researcher/Investigator	Utah Suicide Mortality Research Study Advisory Group Governance Committee Load Representative
Signature:	Committee Lead Representative.  Signature:

Name:

Title: Title:

Name:

Department: Department:

Date: Date

Please email <a href="mailto:emily.sullivan@hsc.utah.edu">emily.sullivan@hsc.utah.edu</a> to request an official Memorandum of Understanding (MOU) for signature.