Utah Suicide Mortality Research Study (USMRS) Resource Request Operating Procedures

1. Purpose

These procedures govern the submission, review, and approval of all requests to use USMRS resources. Every investigator or investigative team must follow this process for each grant submission that proposes to use USMRS resources and each distinct project that produces a tangible outcome (e.g., preliminary data, feasibility study, publication, conference presentation, clinical guideline, or quality-improvement study).

NOTE: One application may **not** cover multiple separate projects.

2. Prerequisites

Before submitting a grant proposal or resource request application involving USMRS resources:

1. ALL team members must have a current signed USMRS Memorandum of Understanding (MOU) on file with the USMRS Program Manager.

2. For requests involving public-facing products (e.g., presentations, posters, manuscripts):
   - **All team members** must be approved as co-investigators on the relevant IRB protocol(s) and maintain up-to-date CITI certification.
   - The project team must ensure and document that the requested data elements and proposed analytical procedures are covered by the IRB. This ensures the request aligns with the Utah Department of Health and Human Services (UDHHS) Data Sharing Agreement (DSA).
     View IRBs [here](#).

3. Basic grant information as detailed in the USMRS grant submission application form proposing use of USMRS resources must be submitted to the USMRS Advisory Group (AG) for review **at least 30 days prior** to the internal University of Utah grant submission deadline (OSP or other funding agency deadline for non-OSP submissions)

- The 30-day USMRS AG grant review must take place to make an awarded grant eligible for any USMRS resources.

Note: If USMRS data is needed to prepare the grant submission, a separate resource request must be submitted.

3. Application Process

1. Review Available Resources

   a) Data Resources: The USMRS Data Core will keep up-to-date data inventories, including data dictionaries and years of coverage for each data field.

   b) *Bio samples: As of the fall of 2025 Collection and use of biological samples is pending a decision from Utah DHHS. The process for requesting resources that relate to biospecimens and the data generated from these will be updated when the Data Sharing Agreement with UDDHS has been updated.*

   c) Feasibility questions can be answered during this initial review stage with the Data Core, Lab Care and other USMRS AG members.

2. Consult the Study Tracking Sheet

   a) Review the "USMRS Study Tracker" to identify existing studies/projects. This helps avoid duplication, ensures alignment with ongoing efforts, and may reveal opportunities for collaboration.

3. Complete the Application
   a) Grant Submissions proposing use of USMRS Resources:
      i) Basic grant information proposing use of USMRS resources must be submitted **at least 30 days prior** to the internal University of Utah grant submission deadline (OSP).
      ii) Complete and submit the online grant submission form available here. (Note: We recommend using the word version of the form to prepare your responses before submitting, as the online form does not allow you to save your progress)
4. USMRS Resource Requests (Currently for Data Only)
   a) Complete and submit the resource request application form available here. (Note: We recommend using the word version of the form to prepare your responses before submitting, as the online form does not allow you to save your progress)

4. Review Process

The review process is interactive and iterative. Optional suggestions for enhancement may be offered throughout any steps of the review process.

Step 1: USMRS Program Manager Screening

Timeline: Within 1–2 business days of receipt of application

USMRS Program Manager will verify regulatory compliance through ensuring:

- All team members have a current, signed MOU on file.
- IRB and CITI certification requirements are met for all team members, as applicable.
- When required, documentation is provided confirming that the relevant IRB protocol covers the requested data elements and analytical design.
- Current investigator projects are compliant with USMRS policies.

Step 2: USMRS Advisory Group Review

Timeline: Within 3 weeks of receipt of application

All requests will be reviewed by a subset of the USMRS Advisory Group Governance Committee and the Data Core Director. External experts will be consulted as needed. This process will be overseen by a designee from the University of Utah Office of Compliance and Integrity. Reviewers will consider the following when evaluating the data request:

- **Feasibility**: Availability of the data and resources necessary to address the study aims and the potential scientific or translational benefit weighed against the scarcity of resources.
- **Minimum Necessary:** Are the data being requested the minimum necessary to conduct the study?
- **Scientific Rigor**: Soundness of scientific premise, methods, and hypothesis(es) and/or feasibility of implementation plan.
- **Impact**: Scope, potential benefits, and appropriateness of the proposed study based on project type, scale, and experience level of the investigator(s) (for example, seeking grant funding, clinical, public health, adding to body of knowledge, and quality improvement).
- **Benefit back to USMRS resource**
- **Ethical Considerations:** Potential interpretations of data and adherence to community/lived-experience guidance.
- **Ensure compliance:** All UDHHS and stakeholder requirements are met.

- **Duplication**: Degree of overlap with ongoing USMRS projects.
- **Team Capacity**: Sufficiency of expertise/ capacity within the proposed study team.
- **Training opportunities:** Consideration of support of and/or training opportunities for early career individuals.

NOTE: If the request is coming from a member of the USMRS AG Governance Committee they will be required to recuse themselves from the review process.

Step 3: Feedback and Revision (within 4 weeks of receipt of resource request)

Written feedback (and an in-person or virtual debrief, if possible/needed) will be shared with the individual who submitted the data request. The feedback will indicate if the request has been:

- Approved as is
- Approved with revisions
- Request for resubmission that addresses concerns of reviewers
- Declined

Revisions and Resubmissions

- Revisions will generally be minor, and the request will be approved based on the revisions being made and submitted within 15 days.
- Resubmissions may include any aspect that stems from the review process described in step 2. Feedback will include the aspects of the request that did not meet the criteria with suggestions for a resubmission.

Declined Requests

- If the request is declined written rationale for the denial, referencing specific unmet criteria will be provided. The applicant may request clarification or reconsideration.
- If the applicant does not agree with the decision, they may submit a formal appeal.
  - To appeal a declined data request, a written appeal should be submitted to the USMRS program manager within 15 days of receiving the data request denial notice. It should include:
    - Study tracking number and name of the data requester
    - Description of concerns
    - Supporting documentation (e.g., application materials,

09/03/2025

feedback received)

- The USMRS AG and the designee from the Office of Compliance and Integrity will review the appeal within 15 days. If unresolved, the appeal will be escalated to the OVPR for final review.

NOTE: Exceptions to the Review Timeline will be considered on a case-by-case basis.

5. Upon approval of the resource request application

- **For Preliminary/feasibility** resource requests the project PI will be required to certify and sign the USMRS certification for preliminary resource use
(Sent to PI Within 1 day of approval)
- **For presentation/poster submissions, manuscript** and other public facing products the project PI must sign and agree to the terms of the University of Utah DUA on behalf of all members of the study before data release.
(Can take up to 4 weeks from data request approval date to be fully executed)
- **For Grant Plans/Applications** a letter of support from USMRS will be shared with the PI stating that USMRS is engaging in a collaborative agreement with the study team (within 1 day of approval)

6. Data Availability

- Requested data will be made available to the investigator(s) once all parties have signed the USMRS certification for preliminary resource use or the DUA.
- Detailed data safeguarding requirements are outlined in the USMRS MOU.

7. Study Tracking

- All resource applications—approved or declined—are logged by the Program Manager. A summary is maintained in the USMRS Study Tracker, accessible to all USMRS members for transparency and coordination.
- The study tracker will indicate that a representative from OME has reviewed and acknowledged the resource request.
- All materials that will be published as a public facing product must be submitted to the RGE for review prior to submission.
- Final copy of research products are required to be submitted to the USMRS

09/03/2025

program manager. All submitted materials will be maintained confidentially.

- As a recipient of USMRS resources, you will be expected to participate in periodic check-ins with the USMRS Program Manager. These check-ins are designed to support your work and ensure effective use of USMRS resources. They may include:

  - Confirming ability to access USMRS resources.

  - Discussing any data-related issues or discrepancies that should be shared with USMRS.

  - Receiving updates from USMRS regarding new information or changes to existing data.

  - Providing timelines or updates on expected drafts of manuscripts or publications for USMRS review.

8. Resource Retention and Archiving

- All data will be archived and auditable per specifications at: https://osp.utah.edu/policies/handbook/award-management/records-retention.php