

Memorandum of Agreement – UDOH Cover Sheet

Revised on July 13, 2020

1. Routing Contact and Phone: Michael Staley, (801) 816-3869
2. Program Contact and Phone: Michael Staley, (801) 816-3869
3. Agreement Name: Utah Suicide Genetic Research Study (USGRS) – OME
4. Vendor Name: University of Utah
5. Effective Date: Date of last signature
6. Termination Date: June 30, 2025
7. General Purpose of Agreement: This agreement allows the Office of the Medical Examiner to share limited data regarding decedents who were suspected to have died by suicide with the USGRS via an honest broker (Utah Population Database). The purpose of sharing this data is to aid in determining suicide risk and risk prediction via genetic and epidemiological inquiry.
8. NOTE: The SharePoint DSA system is not operational.

Approval

Reviewer	Signature	Date
Michael J. Staley, Suicide Prevention Research Coordinator		09/25/2020
Erik D. Christensen, Chief Medical Examiner		09/30/2020
Francesca Lanier, Chief Privacy Officer	<i>Francesca Lanier</i>	10/01/2020
Micah Vorwaller, Assistant Attorney General	<u>MICAH A. VORWALLER</u> <small>MICAH A. VORWALLER (Oct 1, 2020 08:55 MDT)</small>	10/01/2020
Janae Duncan, Director, Division of Disease Control and Prevention		10/02/2020

-END-

UTAH DEPARTMENT OF HEALTH DATA SHARING AGREEMENT

This data sharing agreement is by and between the Utah Department of Health, Office of the Medical Examiner (OME) (“Department”) and the Utah Suicide Genetic Research Study team (USGRS) at the University of Utah (“Recipient”). The purpose of this agreement is to establish conditions, safeguards, and requirements under which the Department agrees to disclose data to Recipient and to ensure the confidentiality and security of all such data.

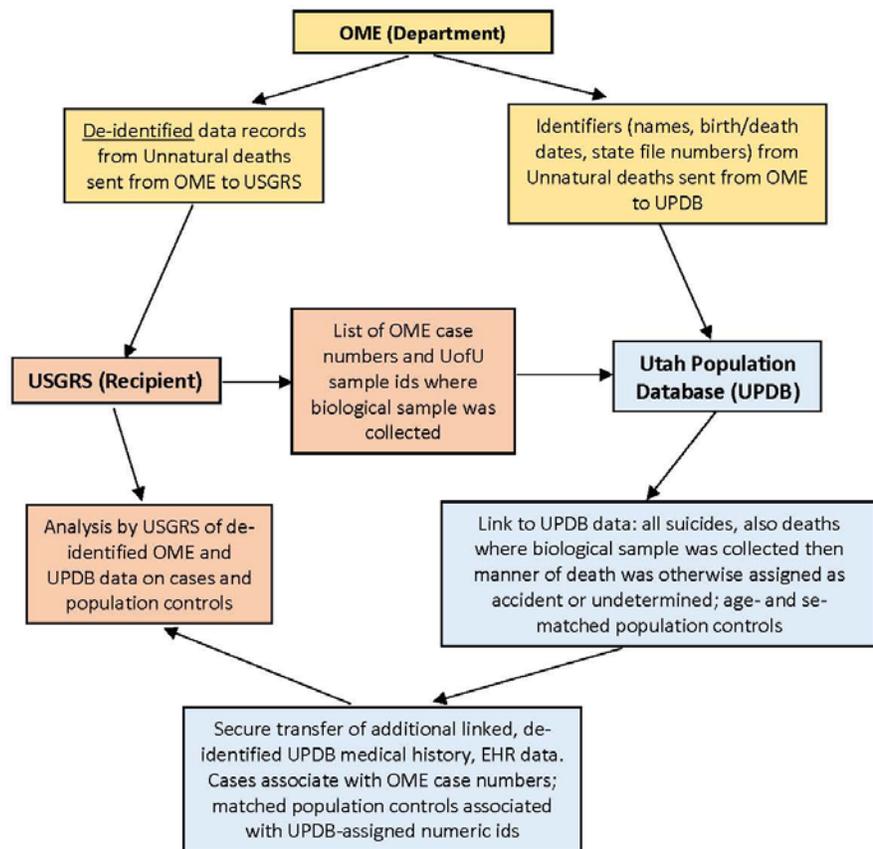
Data sharing will facilitate the study of risk factors for suicide death being conducted by a University of Utah research team. The protocol for this study is reviewed annually by Institutional Review Boards (IRBs) at the University of Utah (U of U), the Utah State Department of Health (UDOH), and Intermountain Health (IH).

Data flow for the study is depicted in the figure, and proceeds as follows. De-identified data from unnatural deaths will be sent by the OME Morgue Supervisor, Mr. William Brandon Callor (the Department) to the USGRS study team (Recipient).

Specific data fields that are transmitted are on the attached list. The OME case number is used as a numeric identifier for the data.

Transmission is done using secure ftp (SFTP) on an encrypted server with a temporary one-time login and password for the transmission. Separately, identifiers including name, birth date, death date, and state file number from unnatural deaths are sent via SFTP by Mr. Callor to the Utah Population Database (UPDB), which serves as an intermediary for secure data linking to additional data available within the UPDB for the Recipient. The USGRS study team (Recipient) also sends to the UPDB a list of OME case

ids and University of Utah anonymous numeric sample ids for all cases where a biological sample was collected. The UPDB then only links cases from the OME to additional UPDB data for: 1) all suicide deaths (regardless of successful biological sample collection), and 2) any additional deaths where a biological sample was collected when cause of death was pending, and which subsequently may have received a different manner of death determination (e.g., “undetermined” or “accident”). Within the secure UPDB environment, linking will occur to additional UPDB data. Identifiers allowing this linking (name, birth dates, etc.) are removed before the additional UPDB data are sent to the recipient. The UPDB also matches population controls by age and sex to cases, and sends de-identified UPDB data for



these controls to the USGRS (Recipient). UPDB data for cases and controls includes demographics, genealogical data, medical records, and health records. No identifiers for either cases or matched controls are sent from the UPDB to the Recipient. Cases are associated with OME case number. Population controls are associated with an anonymous numeric id assigned by the UPDB.

With the annually-reviewed approvals of the University of Utah IRB, the Utah Department of Health IRB, and the Intermountain Health IRB (IH supplies some of the Electronic Health Records used in the study), the USGRS research team (Recipient) will pursue studies to identify suicide risks. Examples of these studies include studies to identify genetic risk factors, studies of interactions between genetic and environmental risks, studies indicating spatial clustering of risk, and studies of risk prediction using electronic health records data. The study team anticipates that discovery of specific risk factors and high-risk subgroups may drive future more effective, targeted prevention efforts. All publications based on these data will be reviewed to ensure they do not contain any inadvertent breach of privacy or confidentiality by the University of Utah Resource for Genetic and Epidemiological Research (RGE) advisory board, which governs the use of UPDB data.

While advances have been made in risk prediction of suicide attempt, it is important to note that 1) more than half of individuals who die by suicide have no prior attempts, and 2) fewer than 10% of individuals who attempt suicide go on to die by suicide. Indeed, risk prediction for actual suicide death remains enormously challenging. The research partnership with the Utah State Office of the Medical Examiner hopes to address this urgent and growing health crisis.

1. AUTHORIZING STATUTE:

The Utah Office of the Medical Examiner is authorized to share data for research purposes via UCA 26-4-17(4), which states:

- (4) The medical examiner may provide a medical examiner record to a researcher who:
 - (a) has an advanced degree;
 - (b) (i) is affiliated with an accredited college or university, a hospital, or another system of care, including an emergency medical response or a local health agency; or
(ii) is part of a research firm contracted with an accredited college or university, a hospital, or another system of care;
 - (c) requests a medical examiner record for a research project or a quality improvement initiative that will have a public health benefit, as determined by the Department of Health; and
 - (d) provides to the medical examiner an approval from:
 - (i) the researcher's sponsoring organization; and
 - (ii) the Utah Department of Health Institutional Review Board.

2. DESCRIPTION OF DATA:

“Data” means all records and information created, received, maintained, or transmitted by the Department which is accessed or used by, or disclosed to, Recipient in connection with the purpose of this agreement.

“Data” means information about individuals, whether identifiable and non-identifiable, within the Department’s possession, custody, or control, and any data that the Department has disclosed to Recipient. The Department agrees to disclose the following data to the Recipient.

Data will be for deaths for the study described above, and will include the UMED data fields in the attached table. These represent data important for studies to identify risk factors and high-risk subgroups for suicide death. The highlighted fields are the identifiers which will be only used by the UPDB to link deaths to additional UPDB data. These fields are not sent to the Recipient.

3. PERMITTED USES AND DISCLOSURES:

- 3.1.** Recipient shall only access, use, or disclose data for research related to risk factors leading to suicide death. The Recipient may not use the data for any other purpose without prior approval of the Department.
- 3.2.** Recipient shall ensure any access to or use of the data is limited to authorized individuals within its organization who need to access or use the data in the performance of Recipient's duties under this Agreement.
- 3.3.** Unless specified otherwise, Recipient may not disclose or distribute any information from the data that identifies or may be used to identify an individual to any other organizations or persons. If the data does not include sufficient information to allow a person to identify the individual described in it or an organization that supplied the data, Recipient may not attempt to identify or contact an individual whose information is included in the data through linkage to other databases or through any other methods or process without the prior written approval by the Department.

4. METHOD OF DATA TRANSMISSION: All transmissions or exchange of data between parties shall be performed using a secure transfer method.

The Department agrees to send a flat data file annually. This file is classified as a restricted file and requires a secure data transfer protocol (SFTP). Data will be prepared by the Department (OME Morgue Supervisor). When the data are ready the staff member will notify the USGRS Recipient (for de-identified data) and the UPDB staff (for linking identifiers). The OME Morgue supervisor will transfer data using SFTP and one-time credentials for transfers. The USGRS Recipient server housing data is password protected and behind the University of Utah firewall. The UPDB server is a secure, encrypted drive that is managed by UPDB staff. After finding records of age- and sex-matched population controls to the cases, the UPDB will link cases and controls to demographic, diagnostic, and genealogical data as specified in approved IRB protocols (U of U, UDOH, and IH). These additional data will be stripped of linking identifiers and sent (again using SFTP) to the USGRS Recipient for analysis.

The Recipient agrees to maintain annual IRB approvals of this transfer process and the data elements to be transferred; if IRB approvals lapse, the Department may terminate data access. The Recipient will furthermore abide by all data safeguards outlined in this document.

5. SAFEGUARDING THE DATA:

- 5.1.** Recipient shall implement and maintain administrative, technical, and physical safeguards necessary to protect the confidentiality of the data and to prevent unauthorized use or access. Such safeguards include, as appropriate and without limitation: (i) securing Recipient's facilities, data centers, paper files, servers, back-up systems and computing equipment, including all mobile devices and other equipment with information storage capability; (ii) implementing network, device application, database and platform security; (iii) securing information transmission, storage and disposal; (iv) implementing authentication and access controls within media, applications, operating systems and equipment; (v) encrypting identifiable data stored on any mobile media and devices and computers/servers that allow remote access; (vi) encrypting identifiable data transmitted over public or wireless networks; (vii) strictly segregating identifiable data from information of other unauthorized customers so that Department data is not commingled with any other types of information where required; (viii) implementing appropriate personnel security and integrity procedures and practices; (ix) providing University of Utah required HIPAA training and additional Research Ethics and Compliance training through the online Biomedical Research Investigation and Good Clinical Practice CITI training courses (<https://about.citiprogram.org/en/homepage/>); and (x) any other measures reasonably necessary to prevent unauthorized use or access.

5.2. Recipient shall promptly report to the Department any unauthorized access, use, disclosure, modification, or destruction of the data or any interference with system operations in a system that involves data of which it becomes aware. Recipient agrees to take reasonable steps to mitigate any effects of such incident and limit any further use or disclosure of the data. Upon the Department's request, Recipient agrees to consult and cooperate with the Department regarding appropriate steps for remediation and any applicable reporting requirements.

6. **DATA OWNERSHIP:** The Department retains all ownership rights to the data. Recipient does not obtain any right, title, or interest in any data furnished by the Department. For purposes of the Agreement, data does not cease to be the Department's data solely because it was transferred or transmitted beyond the Department's immediate possession, control, or custody. The Department makes no representation or warranty, either expressed or implied, with respect to the accuracy of any data disclosed to Recipient.

7. **ACCESS TO BOOKS AND RECORDS REGARDING DATA:** Upon reasonable request by the Department, Recipient shall allow the Department to perform a review of the facilities, systems, books, records, agreements, policies and procedures relating to the access, use, or disclosure of data to determine Recipient's compliance with the Agreement. The Department may require Recipient to conduct a risk assessment that addresses administrative, technical, and physical risks, if reasonable and appropriate.

8. **TERM AND TERMINATION:** The Agreement is effective upon the signatures of all parties.

The term of the agreement is from July 1, 2020, to June 30, 2025. Either party may terminate the Agreement with or without cause upon thirty (30) days' prior written notice to the other party. The Department may terminate the Agreement at any time if deemed necessary because of a requirement of law or policy, upon determination by any party that there has been a breach of system integrity or security by Recipient, or by a failure of Recipient to comply with the Agreement.

9. **DISPOSITION OF DATA:** Upon termination of the Agreement, Recipient shall securely return or destroy all identifiable data, including any and all copies, compilations, or derivatives. If such return or destruction is not feasible, Recipient shall promptly notify the Department of the reasons for such in writing. Recipient shall extend the protections and limitations agreed to in the Agreement and shall limit further uses and disclosures to those purposes that make the return or destruction of the data infeasible. This provision shall survive termination of the Agreement.

10. INDEMNIFICATION:

10.1. If Recipient is a governmental entity, the parties mutually agree that each party assumes liability for the negligent and wrongful acts committed by its own agents, officials, or employees, regardless of the source of funding for the Agreement. Neither party waives any rights or defenses otherwise available under the Governmental Immunity Act.

10.2. If Recipient is a non-governmental entity, Recipient shall be fully liable for the actions of its agents, employees, officers, partners, and Subcontractors. Contractor shall fully indemnify, defend, and save harmless the Department and the State of Utah from all claims, losses, suits, actions, damages, and costs of every name and description arising out of Recipient's performance of the Agreement caused by any intentional act or negligence of Recipient, its agents, employees, or subcontractors, without limitation; provided, however, that Recipient shall not indemnify for that portion of any claim, loss, or damage arising hereunder due to the sole fault of the Department.

11. **NOTICE:** Any notice or other communications required or permitted to be given under this Agreement shall be sent to:

If to the Department:
Michael J. Staley, PhD
Office of the Medical Examiner

4451 South 2700 West
Taylorsville, Utah 84129
801-816-3850
mstaley@utah.gov

If to Recipient:

Hilary Coon, PhD
Department of Psychiatry/ Molecular Genetics Lab
20 South 2030 East/BPRB, Room 408
Salt Lake City, UT 84112
801-540-3817
hilary.coon@utah.edu

IN WITNESS WHEREOF, the parties have caused the Agreement to be signed and entered into by their authorized representative.



Signature

Dr. Hilary Coon

Title

August 3, 2020

Date

For Recipient:



Signature

Brent Brown, JD

Name

Director, Office of Sponsored Projects

Title

August 3, 2020

Date

For the Department:



Signature

Francesca Lanier

Name

Chief Privacy Officer,

10/01/2020

Date

Data Fields	Field Description	NOTES
ME Case Number	Medical examiner case number	
State File Number	State file number	
First Name	first name	ONLY FOR UPDB
Middle Name	middle name	ONLY FOR UPDB
Last Name	last name	ONLY FOR UPDB
Age In Years	Age of decedent in years	
Gender	Gender of decedent	
UMED_race	Race of decedent	
Overall race variable	collapsed race variable (White/Black/Asian/etc.)	
Residence Street Address 1	Residence Address1 of Decedent	
Residence Street Address 2	Residence Address2 of Decedent	
Residence City	Residence City of Decedent	
Residence Zip	Residence Zip code of Decedent	
Residence County	Residence County of Decedent	
Residence State	Residence State of Decedent	
Residence Country	Residence Country of Decedent if outside U.S.	
BirthMM	month of birth	
BirthYY	year of birth	
BirthDD	day of birth	ONLY FOR UPDB
DeathMM	month of death	
DeathYY	year of death	
DeathDD	day of death	ONLY FOR UPDB
COD	final Manner of Death (suicide/accident/undetermined/natural)	
Drug Related	Drugs related to manner of death	
Immediate Cause of Death	Immediate Cause of Death	
Additional Cause of Death 1	Additional Cause of Death 1	
Additional Cause of Death 2	Additional Cause of Death 2	
Underlying Cause of Death	Underlying Cause of Death	
Place of Death	Place of death	
Death Zip	Zip code for place of death	
Weapon Type	Type of weapon used	
Education	Education level of decedent	
Armed Forces	Veteran Status of decedent	
MVA	Motor vehicle involved (Driver, Passenger, Pedestrian)	
Rx 1	Current prescriptions for decedent	
Rx 2		
Rx 3		
Rx 4		

Rx 5		
Rx 6		
Rx 7		
Rx 8		
Rx 9		
Rx 10		
Rx 11		
Rx 12		
Histology	Histology was completed	
Underlying COD	Underlying COD Code	
Contrib COD 1	Contributing COD 1 Code	
Contrib COD 2	Contributing COD 2 Code	
Contrib COD 3	Contributing COD 3 Code	
Contrib COD 4	Contributing COD 4 Code	
Contrib COD 5	Contributing COD 5 Code	
Contrib COD 6	Contributing COD 6 Code	
Contrib COD 7	Contributing COD 7 Code	
Contrib COD 8	Contributing COD 8 Code	
Contrib COD 9	Contributing COD 9 Code	
Injury Description	Description of injuries to decedent	
Other Significant Conditions (Part II of D.C.)	Other significant conditions of the decedent	
Deceased Height Cm	Height of Decedent in Cm	
Deceased Height In	Height of Decedent in inches	
Deceased Weight Kg	Weight of Decedent in Kg	
Deceased Weight lbs	Weight of Decedent in pounds	
Tobacco	Smoking status of decedent	
Employment Status	Employment status of decedent	
ResCityFips		
ResCountyFips		
ResStateFips		
ResCountryFips		