



Date: Thursday, August 20, 2026 4:46:06 PM

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IRB_00044244Created: 8/17/2010 1:10 PMIRB_00044244

PI: Hilary Coon Ph.D.Submitted: 3/22/2011

1. Contacts and Title

Title: Utah Suicide Mortality Research Study (USMRS)

1. Study Introduction

1. Responsible Investigator:
Hilary Coon

Email	Training	Col Date
hilary.coon@utah.edu	12/3/2024 SMG	8/19/2026

a. Position of the Investigator:

- ☒ Faculty or Non-Academic Equivalent
- ☐ Student
- ☐ Staff
- ☐ Resident/Fellow
- ☐ Other

2. Contact Persons for the Responsible Investigator:

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Eric Monson	eric.monson@hsc.utah.edu	11/4/2024 MG
Emily Sullivan	Emily.Sullivan@hsc.utah.edu	2/26/2024 MG
Jennifer West	jennifer.a.west@utah.edu	4/7/2025 SMCG

3. Guests of the Responsible Investigator:

Last Name	First Name	E-Mail
There are no items to display		

4. What type of application is being submitted?
New Study Application (or Amendment/Continuing Review)

5. Title Of Study:
Utah Suicide Mortality Research Study (USMRS)

6. Study Purposes and Objectives:

NOTE: This IRB was originally developed for a single grant/study. The updated version is now more inclusive, encompassing the Utah Suicide Mortality Research Study (USMRS). Though methods described are now more comprehensive, the overall goal has not changed: to understand risk of or resilience to suicide mortality thereby help save lives and further the public health objectives of the State of Utah.

This IRB describes general work to build and utilize the data resources of the Utah Suicide Mortality Research Study (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 (inclusive of the data resource and individual researchers and staff) has grown and evolved through a unique and ongoing collaboration with the Utah Department of Health and Human Services (UDHHS), particularly through foundational data from Utah deaths investigated by the Utah Office of the Medical Examiner (OME). This data enables access to valuable information on individuals who have died by suicide in Utah.

This USMRS aims to Continue to build upon a secure Suicide Death Data repository that links OME-derived autopsy and biosample data (including genetic data) from Utah deaths to the UPDB to allow comprehensive studies of factors relating to suicide risk and resilience.

1) Conduct basic comparisons of aggregated data from suicide deaths to data from non-suicide deaths and to data from matched living controls.

2) Ascertainment and description of defined subtypes using demographics, clinical factors, exposures, familial risks, and/or genetic risks to define a more specific group at high risk or a group that is resilient. Compare this subset to: data from other non-subtype suicide deaths; data from non-suicide deaths with and without the subtype characteristics; and data from matched controls with and without the subtype characteristics.

3) Ascertainment, characterization, and analyses of suicide deaths in extended families determined to be at high risk of suicide death using existing familial risk software within the UPDB. This study design is particularly powerful for the discovery of genetic variations leading to risk.

The USMRS provides critical resources to assess factors associated with suicide risk/resilience as fully as possible.

7. Is this a multi-site study, where more than one site needs IRB approval?

☐ Yes ☒ No

8. Background and Introduction:

Over 48,000 individuals die by suicide in the US every year (<https://afsp.org/suicide-statistics/>; Curtin et al., 2023). Suicide rates are high in Utah, where suicide was the second leading cause of death for persons aged 10-44 in 2023 (https://ibis.utah.gov/ibisph-view/indicator/complete_profile/SuicDth.html). Prediction and prevention is a public health priority, but suicide rates continue to rise, and identification of risk factors remains difficult (Belsher et al., 2019). A 50-year meta-analysis of the demographic, diagnostic, and sociological risk factors for suicide shows that prediction is only slightly better than chance (Franklin et al., 2017). Studies using multiple types of data (demographic, clinical, genealogical, biological, exposure, geographic) could greatly enhance our ability to predict those at risk of death and to understand resilience.

A key element available to USMRS that is missing in many other studies of suicide mortality is the permission to study genetic data. Evidence supporting genetic risk for suicide comes from several sources. Risk of suicidal behavior to relatives is increased approximately five fold (Kim et al., 2005; Baldessarini & Hennen, 2004; Brent et al., 2002). Adoption studies show increased risk of suicide for biological relatives of suicidal probands, but no increased risk caused for adopting relatives (Wender et al., 1986; Brent & Mann, 2005). Twin studies provide an estimate of the variation in suicide risk due to genetic factors (heritability). Suicide and suicidal behavior is more concordant among MZ as compared to DZ twin pairs (Pederson & Fiske, 2010; Althoff et al., 2009; Roy & Segal, 2001). Recent estimates aggregating available studies from large data resources indicate that heritability of completed suicide is approximately 45-50% (Pederson & Fiske, 2010; Althoff et al., 2009; McGirr et al., 2009; McGuffin et al., 2001; Fu et al., 2002), even after accounting for other risk factors, such as psychiatric history, traumatic life events, and socio-economic status (SES) factors. Genetic factors therefore provide a key element for discovery.

Importantly, previous studies of suicide outcomes that include genetics have primarily focused on *suicidal behaviors* due to availability of data and to maximize statistical power. The rate of suicidal behaviors is relatively common (4.3% per year) compared to suicide death (0.01-0.02% per year; Hedegaard et al., 2018). While genetic studies of risk of suicide attempts have resulted in some promising findings (Galfalvy et al., 2015; Stein et al., 2017; Erlangsen et al., 2018; Strawbridge et al., 2019; Mullins et al., 2022; Docherty et al., 2023), replication has proven challenging, likely due to heterogeneity and variation in phenotype definition. But also, the lack of ability to study mortality is important. Estimates indicate <10% of those who attempt will die by suicide (Owens et al., 2002;; Carroll et al., 2014; Liu et al., 2020), and only about half of individuals who die by suicide had evidence of a prior attempt (Belsher et al., 2019). These facts highlight that studies focusing on suicide attempts provide a poor proxy for understanding suicide mortality. For individuals with evident suicidality, accurate prediction to discern who will go on to die by suicide is still

beyond reach. And for the ~50% of suicide deaths with no prior evident suicidality, prediction and prevention is even more elusive.

To truly understand risk of suicide death and to implement highly effective interventions that provide appropriate, targeted services to those most likely to die, we must understand the risks specifically associated with suicide deaths. While other large data resources exist for the study of suicide behaviors in living individuals, the Utah Suicide Mortality Research Study (USMRS) has permissions to study comprehensive data from suicide deaths

Our knowledge of subsets of individuals at high risk also continues to evolve. Current work gives important insights into familial risks (Coon et al., 2022; Bakian et al., 2023); youth suicide (Keeshin et al., 2018); trauma exposure and suicide risk (Campbell et al., 2024; Byrne et al., 2022); suicide and neurodiversity (Kirby et al., 2019; Kirby et al., 2025); suicide risk and psychiatric disorders (Monson et al., 2021; Kaufman et al., 2024), chronic pain associated with suicide (Dibiasi et al., 2024; Han et al., 2026) suicide risks when suicide occurred without prior warning (Coon et al., 2025a; Coon et al., 2025b); demographic differences (Tharp et al., 2024), contributions of specific genetic variants (Dibiasi et al., 2025; Das et al., 2024; Han et al., 2024; William et al., 2021; DiBlasi et al., 2021; Coon et al., 2020), and contributions of environmental exposures (Bakian et al., 2015; Lamichhane et al., 2026).

To enhance and complement work noted above, the USMRS has permission not only for use of comprehensive statewide genetic data derived from individuals who died by suicide blood samples collected and owned by the OME, but also for use of data derived from other biosamples, as follows. The OME collects hair providing the opportunity to study presence of toxins, drugs of use or abuse, and/or hormones such as cortisol. The OME collection of skin biopsies allows future studies of data describing characteristics of cells from resulting fibroblast cultures. These cellular studies can include: using fibroblast cells to create induced pluripotent stem cells (iPSCs) that can be differentiated into neurons; experiments using electrophysiology and calcium imaging to identify functional defects; rescue experiments in cells in which mutated genes are re-expressed in neurons to determine if functional defects can be rescued; and drug screening in cells to identify potential new therapeutics. The USMRS also has permission to study data from non-suicide deaths processed by the OME where there is autopsy data and archived blood spots dating back to 2005. These deaths will provide an important Utah-population-based comparison group to clarify differences between deaths from suicide vs. deaths from other causes. Analysis of data from these other biosamples will continue to complement ongoing discoveries of genetic variation in subsets suicide deaths, taking into account demographics, clinical characteristics, and familial risks, and exposures.

In summary, the USMRS engages in work to understand suicide risk/resilience on a comprehensive data resource, and also focuses on compliant, transparent, and respectful stewardship of an important resource for both current and future work. Suicide deaths accrue slowly over time. After decades of work, USMRS permissions for use of comprehensive data from Utah suicide deaths has just begun to result in understanding that can have the potential to change clinical care and public policy. Current discovery becomes a springboard for additional studies and perhaps targeted interventions. The data resource can provide a way to address risk/resilience using techniques that are emerging or yet to be developed.

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2. Study Location and Sponsors

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Submitted: 3/22/2011

Title: Utah Suicide Mortality Research Study (USMRS)

2. Study Location and Sponsors

1. Add all locations applying for approval of research via the University of Utah IRB or Human Research Protection Program (HRPP).

Click the appropriate button(s) below to add locations:

Site Name	Investigators Name	Covered Entity	Sub Sites
View University of Utah	Hilary Coon	No Yes	

2. Will a Central IRB (CIRB) or Single IRB (SIRB) model be used for review of this study for the sites listed in this application?

☐ Yes ☒ No

3. Indicate the source(s) of funding obtained or applied for to support this study.

Sponsor	Sponsor Type	Sponsor Contact Information	Prime Sponsor	Prime Sponsor Type	OrgID
View NIH NATIONAL INSTITUTE OF MENTAL HEALTH	Federal Government				10172

4. Does this study have functions assigned to a Contract Research Organization (CRO)?

☐ Yes ☒ No

5. Does this study involve use of the Utah Resource for Genetic and Epidemiologic Research (RGE)?
Examples: Utah Population Database (UPDB), Utah Cancer Registry (UCR), All Payers Claims Database (APCD), etc.

☒ Yes ☐ No

Addition of a Site

1. Site Name:
University of Utah
2. Site Principal Investigator
☒ Mark if Same as Responsible Investigator (syncs with investigator on the first page)
Hilary Coon

Email	Training	Col Date
hilary.coon@utah.edu	12/3/2024 SMG	8/19/2026

a. Position of the Site Principal Investigator
Faculty or Non-Academic Equivalent

b. Will the Site PI consent participants? ☐ Yes ☒ No

3. Site Contact Persons, if different from the Site PI:
☒ Mark if Same as Contacts for Responsible Investigator (syncs with contacts on the first page)

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Sally Zuspan	sally.zuspan@hsc.utah.edu	9/8/2024 MCG	☐	9/11/2025

5. Site Guests:

Name	Email	Training
There are no items to display		

6. Select HIPAA coverage for this study:

Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)

Study procedures will be conducted outside a HIPAA Covered Entity at this site (HIPAA Privacy Rule does not apply)

7. Select the study procedures that will be conducted at this site:

Data analysis

8. Select the University of Utah department responsible for this research:

PSYCHIATRY

9. Add any additional sites that are part of this performance group

There are no items to display

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IRB Smart Form

PI: Hilary Coon Ph.D.

Submitted: 3/22/2011

Title: Utah Suicide Mortality Research Study (USMRS)

Sponsor Information

- a. Are you receiving award or contract management for the sponsored funds through the University of Utah Office of Sponsored Projects?

☒ Yes ☐ No

If yes, select the associated OSP Proposal ID/DSS through eAward to link it to the ERICA system.

You must have a fully approved Proposal ID/DSS number through eProposal which will show up in eAward after OSP has integrated the ID. To access the eAward application, use the instructions on the OSP website.

Link to a Proposal ID/DSS through eAward

Proposal ID/DSS: 10076557

PI: Coon,Hilary H

Sponsor: NIH NATIONAL INSTITUTE OF MENTAL HEALTH

Prime Sponsor:

Department:

Short Title: COON_R01MH122412RENEWAL_MAR25

Sponsor Award Number:

Type: Federal Government

Award Start Date: 12/1/2025

Award End Date: 11/30/2030

Prime Sponsor Type:

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IRB_00044244 3. Participants

PI: Hilary Coon Ph.D.

Submitted: 3/22/2011

Title: Utah Suicide Mortality Research Study (USMRS)

3. Participants

1. Ages of Participants:

Less than 7 years old	(Parental permission form needed)
7 to 17 years old	(Parental permission and assent form needed)
18 and older	(Consent form needed)

2. Specific age range of participants (e.g., 7-12 years old, 60+, etc.):

All ages

3. Indicate any vulnerable participant groups (other than children) included:

None

If "Other", please specify:

If "None" and no children are involved, answer the following question.

Has the participant selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?

☐ Yes ☒ No

4. Number of participants to be included and/or enrolled in this entire study, across all study locations: 9 million people: 25,000 suicide deaths, ~35,000 non-suicide comparison deaths, and the remaining are controls.

At Utah prior to October 2019: ~20,000 cases, 1.5 million controls with ICD9/ICD10 data, and 9 million persons overall to accommodate selection for each of the risk factors that will be analyzed for the study

5. Characteristics of Participants/Inclusion Criteria:

Cases (suicide deaths) are defined as: 1) Manner of death = Suicide from death certificates (UPDB Vital Records accessed back to 1904); 2) Any other death not included in (1) where manner of death was determined by the Utah OME as suicide or likely suicide.

Comparison non-suicide deaths: deaths investigated by the Utah OME where final manner of death is determined as being other than suicide.

Controls: UPDB staff match data records from 10:1 with individuals within UPDB living at the time of the suicide death and matching for sex and birth year (at-risk sampling); these controls are for all primary studies. For studies within selected subsets, matching to control records may require other/additional constraints above and beyond birth year and sex.

Additional characteristics for matching: Aggregated de-identified characteristics from other approved UU studies may be linked within the UPDB to provide additional inclusion characteristics for studies of suicide risk within defined subsets. At this time, these approved studies are:

- IRB_00133374 Identification of subgroups at high risk for suicide using electronic health records;
- IRB_00144804, environmental exposures as risk of suicide mortality;
- IRB_00082991, Genetic and salivary neuroendocrine markers in youth treated for traumatic experiences;
- IRB_00049521 Chronic Obstructive Pulmonary Disease (COPD);
- IRB_00057455 Developmental disorders.

- IRB_00006824 Gastric Bypass

6. Participant Exclusion Criteria:

There will be no exclusions of Utah suicide death with one exception, that is the OME provides next-of-kin the opportunity to opt a deceased relative out of the study. If this occurs, all OME-derived data from the suicide or non-suicide death will be excluded from USMRS studies.

7. Is a substantial percentage of the participant population anticipated to be non-English speaking?

☐ Yes ☒ No

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- Vulnerable Populations

PI: Hilary Coon Ph.D.**Submitted:** 3/22/2011**Title:** Utah Suicide Mortality Research Study
(USMRS)

Vulnerable Populations

Justification Requirements for the Inclusion of Vulnerable Populations

1. * How does the nature of the research require or justify using the proposed subject population:

USMRS studies include studies of suicide risk/resilience across the lifespan. In an effort to avoid bias and be as inclusive as possible in understanding and preventing suicide risk, we include all suicide deaths in our study

2. * Would it be possible to conduct the study with other, less vulnerable subjects?

☐ Yes ☒ No

If yes, justify the inclusion of vulnerable subjects:

3. * Is this population being included primarily for the convenience of the researcher?

☐ Yes ☒ No

If yes, explain:

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4. Study Information

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Title: Utah Suicide Mortality Research Study
(USMRS)

4. Study Information

1. Design of Study (select all that apply):

☒ **Non-Experimental and/or Descriptive Research Design:**

Secondary/Archival Data Analysis or Retrospective Chart Review
Survey/Questionnaire Research

☐ **Experimental and/or Interventional Research Design:**

There are no items to display

☒ **Development of a research resource (repositories, databases, etc.)**

There are no items to display

☒ **Other**

If Other, describe:

Genetic pedigree study; genetic case-control study

2. Does your study involve the use of any placebo?

☐ Yes ☒ No

3. Length of entire study, from initiation through closeout:

until 6/30/2031

4. How will participants be recruited or identified for inclusion in the study?

a. Select all methods that will be used:

Other

This study involves records and analyses of data derived from biosamples
Data from suicide deaths and non-suicide deaths are permissioned for analyses through ongoing collaboration with the Utah OME.
Additional data on suicide deaths may also be linked through approved protocols: IRB_00133374, IRB_00082991, IRB_00049521, IRB_00006824, IRB_00057455, and IRB_00144804; de-identified records from these studies on these individuals are then studied by the research team.
Matched controls living at the time of the suicide death are identified by PPR staff as necessary via the Utah Population Database.

b. Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):

Identification of suicide death cohort: 1) Suicide deaths as determined from death certificates back to 1904 through UPDB Vital Records access; 2) Any additional deaths not in (1) processed by the Utah OME where manner of death is determined to be suicide or likely suicide.

Identification of non-suicide death cohort: deaths processed by the Utah OME where final determination of manner of death is other than suicide.

Identification of control cohorts: UPDB staff match data records from 10:1 individuals within UPDB living at the time of the suicide death and matching for sex and birth year (at-risk sampling); these controls are for all primary studies. For studies within selected subsets, matching to control records may require other/additional constraints above and beyond birth year and sex.

Additional de-identified data to define subset cohorts: The participants in IRB_00133374, IRB_00082991, IRB_00049521, IRB_00006824, IRB_00057455, IRB_00006824, and IRB_00144804 may also be linked to suicide deaths, non-suicide deaths, and controls.

5. How will consent be obtained?

Waiver or Alteration of Informed Consent

6. Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.

- a. Autopsy information from the OME from their master electronic database on suicide deaths and non-suicide deaths is sent to the UPDB via secure, encrypted FTP transfer to the highly secure servers of the UPDB for record linking (data are not yet sent to the study team). Suicide death cases from this transfer are supplemented by additional data records from suicide deaths determined from death certificates back to 1904 when postmortem samples were not collected by the OME.
- b. Within the UPDB, staff not associated with the study match data records from 10:1 individuals within UPDB living at the time of the suicide death and matching for sex and birth year (at-risk sampling). These primary study controls may be supplemented by controls for specific analyses of selected at-risk or resilient subsets (e.g., controls with and without specific diagnoses of interest; controls with and without specific exposures of interest).
- c. UPDB staff link information (see table below for data fields) to all suicide and non-suicide deaths and controls. Suicide deaths and non-suicide deaths aged 90 and over at death will be assigned an age at death of >90; matching controls aged >90 at matching will be assigned an age of >90. UPDB staff will manage the linking to clinical data using the Master Subject Index to link to the UHSC EDW and the Master Linkage File to link to the IH EDW. Diagnostic data will be de-identified as follows: for each ICD code, month and year of the first and last times it was assigned and total N of times it was assigned will be given. We have previously requested and have been approved for all diagnostic codes (2016 amendment) because there is evidence to suggest that risk factors associated with suicide span both mental and physical health. Studies of all codes on cases and family members will provide opportunity to potentially identify novel co-occurring risk factors. Cluster analysis techniques will be used to identify and aggregate significant co-occurring conditions. Aggregation to preserve anonymity will follow current APCD guidelines that incorporate demographics and diagnostic frequency. We request approval to abstract additional EHR-based chart-review elements from UHSC EDW and Intermountain Health EDW related to behavioral health screening, suicide risk assessment, safety planning, physical health assessment and related clinical interventions. We also request data related to whether other suicide-focused assessment or management approaches were documented, and whether EHR-based screens, questionnaires, clinical decision-support tools, or other structured tools were used. Data collection will be limited to the minimum necessary to meet the study objectives and will follow approved procedures.
- d. We request to receive un-aggregated month and year of approved diagnoses, procedures, and medication data from the EHR in the 2 years preceding the suicide death for the suicide and in that same time window for controls matched to the suicide. This detail will still not give exact encounter dates, so will preserve anonymity of cases, but will allow us to test risk prediction models that require knowledge of ordering of longitudinal events leading up to the suicide death. We additionally request a yes/no flag and service type (e.g., emergency department) to be set by the UPDB for codes that occur within one week of the suicide death. Please note: this does not require us to know the actual suicide date, only that certain codes are a result of the attempt (e.g., cardiac arrest, respiratory failure) and not a pre-existing condition. Service type (e.g., emergency department) allows additional evidence that a code was likely due to the final death event and not pre-existing risk. We will then have the option of deleting these codes in risk modeling.
- e. Identifiers from all data from steps 1-4 will be removed by UPDB staff and a resulting limited use dataset will be securely transferred to the study team. This dataset will be stored in the Protected Environment of the Center for High Performance Computing (CHPC-PE) or in another secure location meeting approval of the Utah Department of Health and Human Services (UDHHS).
- f. Additional data will be obtained from OME the (see OME data table below). This includes demographic and medical data from the OME death investigation and also biospecimen-derived data. Biospecimen data are from routine postmortem OME biosamples, and may include genotyping, genetic sequence data, mass spec data of exposures from hair, cellular characteristics from biopsy cells. Biosample-derived data from the OME will be

stored on a secure encrypted server approved by DHHS and will be linked to data from steps 1-4 through an anonymous numeric identifier assigned by the OME.

- g. To facilitate data harmonization, security, compliance, and control data experts at the UU Data Coordinating Center (DCC) will access and manage the master dataset on the secure encrypted server approved by DHHS.
- h. Each specific USMRS analysis requesting to access data under this IRB goes through the USMRS process described in the Data Monitoring section of this protocol summary. Members of the DCC will provide individuals approved to access the data from each specific USMRS approved analysis.
- i. All study IDs (cases and controls) from this are IRB will be shared with IRB 00133374 and IRB_00144804).
- j. At the end of the study all OME data will be returned or destroyed as per the DSA

DATA TABLE FOR DATA LINKED FROM THE UPDB:

UPDB Data Source	Data Elements to be Accessed	Scientific Justification for Access
Demographic Data	Sex, Race, Ethnicity, Marital Status, Education Level, Industry/Occupation Codes, Year of Birth, Year of Death, Age at Death, Birth Month/Year, Death Month/Year	Demographic data is necessary in comparing subjects to matched controls and in determining familial risk patterns. Average age at death from all causes (excluding suicide cases) within each family will be used as indicator of serious chronic disease.
Geographic Groupings	UDHHS Small Health Statistical Area, County (>20,000), US Census Block, Zip Code	Geographic location will be used as a basis for environmental exposure.
Family Relationship Information	High risk extended pedigrees	We will analyze families with excess suicides.
Birth Certificate Details	Age of parents, Geocodes, details of birth of child of female suicides (for studies of peri-/post-partum depression), including risks and complications with the pregnancy, congenital malformations or anomalies of the child as they appear on the birth certificate either in text, ICD9 codes or check boxes	We are studying early life stressors and later life health outcomes; exposures associated with place of birth could be important to this work. Stressors/exposures will be compared to de-identified matched controls. For the parent study, control cases and their families are chosen from the 9 million records in the UPDB, matched for age at death, sex, and birth year. For the peri-/post-natal risk study, control selection will be similar, but matching will instead be on sex, birth year, and age at delivery of the child.

Death Certificate Details	Primary and secondary causes of death, Geocodes	Identifying suicides from death certificates is key to this study. Causes of death will help define familial risks of co-occurring conditions. Also, Drs. Bakian, VanDerslice, and Zhang are studying acute environmental exposure as a risk mechanism in suicide. Exposures will be compared between de-identified cases and matched controls. In addition to death. Finally, death of a child of a female suicide case within 1 year of delivery is needed as it is an important risk factor for peri-/post-partum suicide.
Fetal Death Certificate	Primary and secondary causes of death; month and year of death	We are investigating risks of peri- /post-partum depression in the female cases in our study. To make this analysis more complete, we will request fetal death records, as miscarriage may be a significant trigger for post-partum depression. Data requested includes: risks and complications with the pregnancy, congenital malformations or anomalies of the child as they appear on the birth certificate either in text, ICD9 codes or check boxes
Driver License Division	Height/Weight (BMI)	We request BMI from driver's licenses to more accurately characterize longitudinal BMI as a risk factor
Health Facility Data (Inpatient, Ambulatory surgery, Emergency Department)	For selected ids representing suicides, relatives of suicides, controls, and relatives of controls, all codes will be provided. Diagnosis/Procedure age, Diagnosis/Procedure month/year Taxonomy/specialty codes of the provider associated with each encounter for a diagnosis and procedure (no other provider information requested)	all codes will provide opportunity to potentially identify novel co-occurring risk factors (see item 3 in the text above). Cluster analysis techniques will be used to identify and aggregate significant co-occurring conditions. Taxonomy/specialty codes designating type of provider will be used to identify patterns of service access
UUHSC / IHC	For selected ids representing suicides, relatives of suicides,	all codes will provide opportunity to potentially identify novel co-occurring

	controls, and relatives of controls, all codes will be provided. Diagnosis age, Diagnosis month/year. EHR-based chart-review elements related to behavioral health screening, suicide risk assessment, safety planning, physical health assessment and related clinical interventions.	risk factors (see item 3 in the text above). Cluster analysis techniques will be used to identify and aggregate significant co-occurring conditions.
US Census Data for Utah	Sibship size, SES (as indexed by the maximum achieved occupation code), number of offspring, marital history, geographical location as basis for environmental exposure	For older cases in the cohort, these factors will be approximated using census data
Prescription medication data	Prescription data will be linked to cases within the UPDB; only limited use data will be released to the study team for analysis	Prescription data will provide: 1) a second data point to validate of ICD9/ICD10 diagnosis; 2) data to study characteristics of individuals who were prescribed selected classes of medications died by suicide.
All Payer Claims Database (APCD)	All ICD9/10 Diagnosis/Procedure age, Diagnosis/Procedure month/year Prescription (medication prescribed and filled) data will be linked to cases within the UPDB; only limited use data will be released to the study team for analysis Taxonomy/specialty codes of the provider associated with each encounter for a diagnosis and procedure (no other provider information requested)	APCD data will provide more comprehensive diagnosis/procedure and medication information. Uses will again be for: 1) a second data point to validate of ICD9/ICD10 diagnosis; 2) data to study characteristics of individuals who were prescribed selected classes of medications who died by suicide. Taxonomy/specialty codes designating type of provider will be used to identify patterns of service access

OME Data Table from death investigation and from routine autopsy biosamples

Type of data	Data elements	Scientific justification
Basic demographics at time of death	Sex; age at death, reported race and ethnicity, state, county, zip code of residence, birth year, death year; education; occupation; veteran status; height; weight	Cross-validation with UPDB-derived demographics from death certificates; enable complete case-control comparisons when deaths do not link to UPDB

Death characteristics	Final manner of death, drug-related death, immediate and secondary causes of death, weapon type, injury description, motor vehicle	Cross-validation with UPDB-derived death characteristics; enable complete studies of causes of death when deaths do not link to UPDB
Drug/substance-related data	Tobacco, drugs found at scene of death	Complements drug/substance data from UPDB because these data are from the OME death investigation; increases knowledge of these aspects as risk/resilience factors
Identifying data for UPDB linking	Name, birth date, death date, Utah state file number, OME ID	Sent to UPDB for linking purposes
Biosample derived data	Data derived from routine autopsy biosamples (e.g., genotyping, genetic sequence data, toxicology data, cell characteristics)	Determine underlying mechanistic biological vulnerabilities leading to risk/resilience

7. Are all procedures for research purposes only (non-standard or non-standard of care procedures)?

☒ Yes ☐ No

If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):

8. Is there a safety monitoring plan for this study?

☐ Yes ☒ No

9. Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.

Methods now match recent ongoing and newly funded work. Study designs adhere to overall goals (discovery of factors leading to suicide risk/resilience); data elements are restricted to those approved in this protocol. Methods use state-of-the-art software and techniques, updated as necessary to accommodate new innovations.

Data. Sources of records data (demographics, clinical data, genealogical data, exposure data, and other contextual data) are noted in the study information section above.

Processing of genomic microarray data: Genome-wide microarray platforms generate data on genetic and/or epigenetic variation across the genome. Data will be processed using validated software and established analytic pipelines appropriate to the platform. Standard quality control procedures will be applied to identify and remove poorly performing samples or markers and to address potential technical artifacts. When relevant to the study design, genetic ancestry will be estimated using appropriate publicly available reference datasets, and genome-wide data may be used to assess relatedness among participants to inform study design and statistical analyses.

Processing of genomic sequence data: Whole genome sequencing (WGS) data will be processed using validated, state-of-the-art bioinformatics pipelines for sequence alignment, joint variant calling, and analysis. Raw sequencing data will be stored in approved locations with controlled access, allowing for reanalysis as methods and reference data are updated. Sequence reads will be aligned to the current human reference genome assembly using widely accepted algorithms with the advice of the Utah Center for Genetic Discovery (UCGD). Rigorous quality control procedures will be applied at multiple stages, including assessment of sequencing error rates, duplicate reads, mapping quality, coverage metrics, variant call distributions, concordance with public databases, and transition/transversion ratios. Sample identity and contamination will be evaluated using validated computational tools. Additional quality checks will be performed during downstream statistical analyses to ensure data integrity. All

genomic data processing will comply with institutional policies and applicable regulatory standards to protect participant confidentiality and ensure scientific validity.

Other genomic data resources: To support interpretation of genomic findings, we will integrate other multi-omic data resources. These may include databases of evolutionary conservation, transcription factor binding and histone modifications, gene expression and expression quantitative trait loci (eQTLs), microRNA annotations, chromatin accessibility, and three-dimensional genome architecture (e.g., chromatin interaction data) or other genomic features. These resources are widely used in genomic research and will be used solely for annotation and functional interpretation of study findings. If datasets are not publicly available, appropriate permissions to access data will be acquired.

Other biosample-derived data: Small pilot studies have been conducted using additional biospecimen-derived data. These include exploratory analyses of molecular analytes from hair samples and laboratory-based studies using cultured cells. In some cases, cells may be reprogrammed and differentiated into relevant cell types to evaluate functional effects of genetic variation and to explore potential therapeutic strategies. These activities are resource-intensive and therefore conducted selectively. At present, this work is limited in scope. If these analyses become a primary focus of the study, additional details will be submitted to the IRB for review and approval as appropriate.

Other non USMRS comparison data: Other control data may be obtained from controlled-access research resources or publicly available datasets. Access to these data is typically subject to a formal application process, ethical review, and approval by the owner. Any use of such external control datasets in this study will occur only after all required institutional approvals, data use agreements, and governance requirements have been obtained, and analyses will be conducted in accordance with the terms and conditions of the data provider.

Approvals to use data. Each researcher seeking to use USMRS data for analysis must follow the regulations outlined in the Data Management section of this IRB protocol summary.

Methods overview

USMRS uses a combination of large-scale genomic, epidemiologic, and integrative analytic methods to better understand risk and resilience factors associated with suicide. Across studies, standard statistical safeguards are used, including correction for multiple testing, sensitivity analyses, and replication where possible. Collectively, these methods reflect a comprehensive framework to better characterize the complex contributors to suicide risk.

Hypothesis-driven ascertainment and analysis of subtypes: Hypothesis-driven analyses of clinically, demographically or genetically defined subgroups of interest. Subtypes will be identified using appropriate diagnostic, clinical, familial, genetic or other relevant information, followed by descriptive and contextual characterization (e.g., age, sex, and other relevant variables). Analyses include genomic, epidemiologic, and integrative analytical methods. Comparative analyses may be conducted between defined subgroups and appropriate comparison groups (e.g., other deaths and/or living individuals/controls) to examine factors associated with suicide risk or resilience. Appropriate statistical models will be used, adjusting for relevant covariates such as age, sex, and other relevant factors. Stratified analyses (e.g., by age or sex) may be performed to evaluate potential moderating effects. To evaluate co-occurring diagnoses, medications or procedures, standardized, hierarchical groupings of diagnostic, medication or procedural codes may be used to systematically assess patterns across clinical conditions. More detailed categories may be examined when warranted. In addition, we recognize that factors contributing to suicide risk extend beyond traditional mental health diagnoses. Therefore, we will examine subgroups of cases defined by clinical, behavioral, environmental, or genetic characteristics. These subgroups may include, for example, indicators of physiological stress dysregulation, altered brain function, trauma exposure, or other environmental factors. Additional subgroups may be explored as supported by emerging evidence. Analyses may incorporate additional data elements, such as, geographic or spatial factors, and other demographic and contextual variables, as funding and study aims evolve.

Data-driven ascertainment and analysis of subtypes: In addition to hypothesis-driven approaches, data-driven analytic methods will be used to identify meaningful subgroups and to model clinically relevant outcomes. These approaches may include predictive modeling and time-to-event analyses, as well as machine learning and statistical modeling techniques designed to identify patterns and predictors that distinguish groups while minimizing overfitting and enhancing interpretability. Predictive modeling approaches may be used to estimate the probability of binary or continuous outcomes, while survival analysis methods (e.g., Cox proportional hazards models, parametric survival models) may be used to evaluate time-to-event outcomes while appropriately accounting for censoring. Additional examples include penalized regression methods, ensemble learning approaches (e.g., decision tree-based models), and Bayesian modeling frameworks. Model performance, calibration, discrimination, and stability will be evaluated using internal cross-validation procedures, in which data are repeatedly partitioned into training and test sets to assess reproducibility and robustness of findings. Subgroups identified through data-driven approaches will be prioritized based on model stability, consistency of predictors across analytic methods, and statistically meaningful differences in relevant outcomes compared to appropriate comparison groups.

Assessing underlying genetic vulnerabilities with PGS: We will conduct additional analyses to evaluate whether underlying genetic risk factors, as measured using polygenic scores (PGS), correspond with documented clinical findings and/or suggest additional indicators of risk or resilience. Polygenic scores provide an estimate of an

individual's inherited genetic susceptibility for health-related traits or conditions. These scores are calculated using results from previously published genome-wide association studies (GWAS), which identify genetic variants associated with specific psychiatric, medical, or behavioral outcomes. For this study, summary findings (e.g., effect size estimates) from relevant, publicly available GWAS will be applied to genotype/genomic data from cases. Selection of GWAS sources will be conducted carefully to ensure that the traits are well-defined and that study populations are reasonably comparable with respect to factors such as genetic ancestry, age, and sex. Polygenic scores will be computed using established and widely accepted analytic software. Because different computational approaches rely on different statistical assumptions, we will use multiple validated methods to confirm that findings are consistent and not dependent on a single analytic approach.

Assessing underlying genetic vulnerabilities with WGS: Most recent genetic research has focused on identifying common genetic variants associated with complex health outcomes through large-scale genomic studies. However, as with many multifactorial conditions, vulnerability to suicide is likely influenced by a combination of both common and less common (rare) genetic variation. Because commonly studied variants explain only a portion of inherited risk, additional analyses are needed to examine the potential contribution of rare genetic differences. To address this, we will conduct further genomic analyses designed to identify rare and common genetic variation that may contribute to risk or resilience. Rare variants are of particular interest because they may provide insights into biological mechanisms that could inform future clinical understanding. This work will incorporate functional annotation, gene-based testing, and integration with gene expression and other omics datasets to prioritize biologically relevant pathways. Single-variant and gene-based analyses will be used to evaluate less common genetic variation. Within defined subgroups, additional genomic sequencing will be conducted in cases and comparison groups to identify genetic variation that may be associated with risk or resilience.

Genome-wide association analyses: Genome-wide association studies (GWAS) will be performed using standardized methods (e.g. those developed by the Psychiatric Genomics Consortium) to study suicide risk and resilience. In which genetic variants across the genome are tested for association with suicide attempt or suicide death in case-control designs. These analyses include rigorous quality control procedures, adjustment for ancestry, and meta-analysis across cohorts to increase statistical power. Aggregate genetic liability will also be evaluated using polygenic scores (PGS), which summarize the cumulative effect of many genetic variants.

SNP-based heritability estimation and genetic correlation analyses to assess shared genetic influences between suicide outcomes and related traits will also be conducted. In accordance with current UDHHS Data Sharing Agreement regulations, all GWAS, even when performed for consortium studies, will be performed within Utah secure computing environments by individuals who have met the requirements outlined in the Data Monitoring section of this IRB protocol.

Derived data e.g., summary statistics from GWAS and several complementary statistical methods are used to test for example (1) how much the traits share genetic causes (2) which specific genetic regions and genes are shared (3) whether the relationship looks causal (4) whether other health or behavioral traits. In accordance with current UDHHS Data Sharing Agreement regulations, all derived data, even when performed for consortium studies, will be performed within Utah secure computing environments by individuals who have met the requirements outlined in the Data Monitoring section of this IRB protocol.

Familial risks: Using UPDB de-identified multi-generational family data allow several types of familial comparisons to study suicide risk and resilience.

(1) Familial aggregation - disease incidence within a family can be compared to population-based rates adjusting for appropriate confounders (e.g., age, sex, and family structure). Co-aggregation of conditions will also be assessed to evaluate whether related conditions cluster within families (e.g., psychiatric and medical comorbidities).

(2) Epidemiological measures of risk - to determine whether conditions are overrepresented in specific pedigrees measures of relative risks (e.g. standardized incidence ratios (SIRs), familial standardized incidence ratios (FSIRs) will be computed.

(3) Risk by degree of relatedness - Disease risk will be compared among first-, second-, and more distant-degree relatives of affected individuals. This will allow for the assessment of whether risk declines with decreasing genetic relatedness. Spousal vs. biological relatives will also be compared to assess shared environment versus biologically related individuals (shared genetics) to help distinguish environmental and genetic influences.

(4) Comparing affected vs. unaffected relatives - health characteristics, comorbidities, or exposures between affected individuals and their unaffected relatives will be compared.

(5) Cross-generational analyses - We will examine transmission patterns across generations (e.g., parent-child, grandparent-grandchild). This will allow for the assessment of relevant patterns such as condition onset age shifts across generations.

(6) Genomic familial analyses - In families with multiple affected members, genomic regions shared more frequently than expected by chance will be identified. Statistical methods designed for pedigree-based analyses are used to evaluate excess sharing of inherited genomic segments, with significance assessed through simulation-based approaches to generate appropriate null distributions.

Ongoing work may include linkage of newly identified cases to genealogical data to identify additional familial risks.

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- Request for Waiver of Consent

PI: Hilary
Coon Ph.D.

Submitted: 3/22/2011

Title: Utah Suicide Mortality Research Study
(USMRS)

Request for Waiver or Alteration of Consent

* Requested Waivers

Date Created	Type of Request	Purpose of Waiver Request
View 12/11/2012	Waiver of Informed Consent	Suicide deaths and non-suicide comparison deaths cannot be contacted for consent. Acquiring direct permission to link to other data to discover aspects of risk / resilience is therefore not possible. In addition, to determine significance of aspects of risk/resilience , aggregated data from records of family members and matched controls must be studied from the ~9,000,000 records in the UPDB. Matching is done within the UPDB. All data for this study are made into limited use datasets prior to analysis.

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IRB Smart Form

PI: Hilary Coon Ph.D.

Submitted: 3/22/2011

Title: Utah Suicide Mortality Research Study (USMRS)

Request for Waiver or Alteration of Consent

1. Purpose of the Waiver Request:

Suicide deaths and non-suicide comparison deaths cannot be contacted for consent. Acquiring direct permission to link to other data to discover aspects of risk / resilience is therefore not possible.

In addition, to determine significance of aspects of risk/resilience, aggregated data from records of family members and matched controls must be studied from the ~9,000,000 records in the UPDB. Matching is done within the UPDB. All data for this study are made into limited use datasets prior to analysis.

2. Type of Request:

Waiver of Informed Consent

3. List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc.).

Identifying information needed by the UPDB to link suicide deaths and non-suicide comparison deaths to health, demographic, environmental, and genealogical data includes: name, birth date, death date, location at time of death, and the State Death Certificate number. These identifying elements will ONLY be transferred directly from the Office of the Medical Examiner to the UPDB. This information will ONLY be used by the UPDB for linking, and will not be transferred to the research personnel on this project. The research personnel will receive: data fields from the OME autopsy approved by the UDHHS, numeric identifier assigned by the OME to link to biosample data, and other approved UPDB data. The researchers will be given only a limited dataset.

4. Explain why the research could not be practicably conducted without using identifiable information. Examples of such explanation could include the following:

Identifying information is only needed by the UPDB to link suicide deaths and non-suicide comparison deaths to health, demographic, and biosample data for risk analysis. Without use of identifying information by UPDB staff, linking of cases to other data would not be possible. This linking is essential for the primary aims of this study, which include characterization of high-risk subgroups and development of risk models by the analysis team. This analysis work depends upon health data, membership in high-risk families, and genetic risk. Once data are linked to cases, then linking identifiers stripped to form a limited use data set.

5. Explain why the research could not practicably be conducted without the waiver or alteration. For example, complete the following sentence "If I had to obtain consent, the research could not be conducted because...":

Permission cannot be obtained from the suicide deaths, or from non-suicide comparison deaths. Contacting family members or matched controls for permission would be extremely intrusive and not logistically feasible. We will not know the identity of individuals and are not requesting any contact with these families or with matched controls, and will use all data with the utmost caution to prevent revealing the identity of any family member.

6. Explain why the research and privacy risk of the research are no more than *minimal*:

There will be no subject contact. Identifying information used for linking ONLY will be transferred from the OME to the UPDB and will not be used for

analysis.

7. Describe the measures you will take to ensure the waiver or alteration will not adversely affect the rights and welfare of the *subjects*:

Any publication involving suicide deaths, non-suicide comparison deaths, diagnoses, and/or pedigree structure will be disguised to protect the identity of subjects. No attempt will be made to discover the identity of deaths or of family members.

8. Explain how you will, if applicable and appropriate, provide the subjects with additional pertinent information *after* they have participated in the study, or indicate "*Not applicable*":

Not applicable.

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5. Data Monitoring

PI: Hilary Coon Ph.D.

Submitted: 3/22/2011

Title: Utah Suicide Mortality Research Study (USMRS)

5. Data Monitoring Plan

- 1. Privacy Protections:** Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **What precautions will be used to ensure subject privacy is protected?**

Select all that apply:

The research intervention is conducted in a private place

The collection of information about participants is limited to the amount necessary to achieve the aims of the research, so that no unneeded information is being collected

Other or additional details (specify):

All data use is done under the stipulations of the attached fully executed Data Sharing Agreement with the Utah Department of Health and Human Services (UDHHS). The Utah Suicide Mortality Research Study has implemented the following specific internal expectations below regarding its access and use of Data.

1. Each USMRS researcher will sign a Memorandum of Understanding (attached to this protocol) setting forth expectations to ensure the responsible conduct of research.
 2. Formally proposed uses of Data (defined as uses that are expected to result in public facing scientific analysis that contribute to generalizable knowledge) by USMRS researchers will undergo a rigorous internal review including involvement of USMRS leadership, members of the University's Office of Research Integrity and Compliance who are familiar with this Agreement, community representatives and those with lived experience, and OME. Reviews will ensure alignment with UDHHS priorities and will assess regulatory, scientific, ethical, and privacy issues.
 3. Each person who will be the lead for the analysis or who will be accessing the data or will be involved in analysis or will be engaged in viewing detailed results will be listed in this IRB.
 4. Approval of plans for a specific public facing project will be followed by completion of an internal USMRS Data Use Agreement (DUA) that will be approved and tracked by the University's Office of Research Integrity and Compliance.
 6. Approved specific project analyses will only be allowed within computing environments approved by the UDHHS.
 7. Results of each completed specific project must be reviewed by the USMRS and by UDHHS representatives and UDHHS Privacy Officers. Reviews will ensure scientific rigor, compliance with ethical standards, alignment with UDHHS priorities, and anonymity of research results to ensure any subjects of Data cannot be re-identified.
 8. Results of intended publication will be reviewed by UDHHS's privacy team for review of privacy issues and confidentiality precautions.
 9. With the completion of each specific project, the research team's access to Data will be removed and study details and protocols securely archived.
 10. The University will undertake best efforts to secure and maintain a National Institutes of Health Certificate of Confidentiality covering research activities facilitated by this Agreement. USMRS activities related to this Agreement currently operate under a Certificate of Confidentiality.
 11. Protocols governing research efforts facilitated by this Agreement will be reviewed annually by Institutional Review Boards (IRBs) at the University, UDHHS, and Intermountain Health
- External sharing of all original and derived data will only be done adhering to current local institutional and state regulatory requirements, as stipulated in the current UDHHS Data Sharing Agreement.

- 2. Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. **What precautions will be used to maintain the confidentiality of identifiable information?**

Select all that apply:

Storing research data on password protected computers or in locked cabinets or offices

All data that will be transferred or transported outside of the institution will be encrypted

Other or additional details (specify):

Other or additional details (specify):

Any publication involving printed drawings of pedigree structure and suicide/psychiatric disorder status will be disguised as recommended by the UPDB, and as practiced previously by our research group in our autism pedigree studies. All rare diagnoses and other groupings of small size, and all data concerning ages > 90 years will be

aggregated to protect identify. All publications will first be reviewed by the RGE and a representative from UDHHS Privacy team.

Only limited use data will be available to the study team.

Locally, data are stored on the secure computer system approved by the UDHHS (currently: CHPC Protected Environment, and in a completely de-identified state on the HIPAA-compliant UBox). UBox was developed for use by University of Utah faculty and staff. It is HIPAA-compliant, and is among the select number of platforms for sensitive data storage. Level of access is controlled by the study PI, who will restrict access to only those approved on the IRB. In addition, study team must access UBox from approved University of Utah devices that have been encrypted using accepted encryption algorithms. Box is encrypted using AES 256bit for data at rest and TLS 1.2 for data in motion. Backups are encrypted using this same methodology and stored in the cloud. The UofU has also negotiated in the Business Associate Agreement with Box that backups are not stored in any datacenter outside the United States. Note: For this study, only HIPAA Safe Harbor de-identified data will be stored on UBox while limited use data and all genetic data will be stored on the CHPC PE

3. Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?

☐ Yes ☒ No

If yes, describe the recording/images and what will become of them after creation (e.g., shown at scientific meetings, stored in the medical/research record, transcribed, erased, etc.):

4. How will study data and documentation be monitored throughout the study?

Select all that apply:

Periodic review and confirmation of participant eligibility

Periodic review of the transfer/transcription of data from the original source to the research record

Other additional details (specify):

5. Who will be the primary monitor of the study data and documentation?

Select all that apply:

Principal Investigator

Data (and safety) Monitoring Board or Committee

Other or additional details (specify):

Other or additional details (specify):

Data on CHPC PE is monitored continuously by safeguards set up by CHPC management and will be managed by the DCC team. UBox use (fully de-identified data only) will be via encrypted approved UU devices. Access will be controlled by the study PI; only IRB-approved study team members will be allowed access. Use of UBox will be accompanied by the following additional security aspects:

1) Periodic (at least annual) external audit whereby the study PI provides access to UPDB Data Security Officer to ensure personnel who have been given access to the UBox folders all are IRB-approved for the study.

2) Additional audit by the UPDB Data Security Officer triggered by any IRB amendment that results in addition or removal of study staff.

6. How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?

At least twice a year and after data is updated. Additional auditing may be done by the UPDB Data Security Officer triggered by any IRB amendment that results in addition or removal of study staff.

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6. Risks and Benefits

PI: Hilary Coon Ph.D.

Submitted: 3/22/2011

Title: Utah Suicide Mortality Research Study
(USMRS)

6. Risks and Benefits

1. Describe the reasonable foreseeable risks or discomforts to the participants:

The primary risk is breach of confidentiality and privacy. However, we feel that efforts are in place to avoid such events. Specifically only limited-use data will be studied. Biosample derived data will only be studied from individuals who died by suicide and non-suicide comparison deaths, not on living individuals. There will be no procedures performed on subjects. There will be no direct contact with any living controls or family members.

2. Describe the potential benefits to society AND to participants (do not include compensation):

In this study, we hope to begin to identify specific demographic, clinical, familial, environmental, and genetic risk/resilience factors associated with suicide mortality. This discovery has already begun. Knowledge of risks can change clinical care, reduce stigma, and enhance the ability to engage in effective prevention and intervention, thereby saving lives.

3. Are there any costs to the participants from participation in research?

☐ Yes ☒ No

If yes, specify:

4. Is there any compensation to the participants?

☐ Yes ☒ No

a. If yes, answer the following:

Specify overall amount:

b. Specify when participants will be paid (e.g. at each visit, at end of study, etc.):

c. If applicable, please specify payment by visit or other time interval (e.g. \$10 per visit, etc.):

d. If applicable, explain plan for prorating payments if participant does not complete the study:

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7. HIPAA & the Covered Entity

PI: Hilary
Coon Ph.D.

Submitted: 3/22/2011

Title: Utah Suicide Mortality Research Study
(USMRS)

7. HIPAA and the Covered Entity

1. Does this study involve Protected Health Information (PHI) or de-identified health information?

☒ Yes ☐ No

a. Select the method(s) of authorization that will be used:

Select the method of de-identification: Safe Harbor De-Identification

b. Will PHI be disclosed outside the Covered Entity?

☐ Yes ☒ No**Does this study involve any of the following:**

2. The investigational use of a drug?

☐ Yes ☒ No*Mark yes, for an expanded access application.*

3. The investigational use of a medical device or humanitarian use device?

☐ Yes ☒ No*Mark yes, for an expanded access application.*

4. The investigational use of a dietary supplement, food, or cosmetic?

☐ Yes ☒ No

5. Is this an investigator-initiated drug or device trial lead by the Principal Investigator?

☐ Yes ☒ No*All investigator-initiated drug or device trials are required to have a full research protocol attached to the Documents and Attachments page.*

6. Will this study involve the use of an imaging modality from the department of Radiology?

☐ Yes ☒ No

7. Exposure to radioisotopes or ionizing radiation?

☐ Yes ☒ No

8. **Genetic testing and/or analysis of genetic data?**
☒ Yes ☐ No
9. **Creating or sending data and/or samples to a repository to be saved for future research uses?**
☒ Yes ☐ No
10. **Are you:**
- Collecting samples of blood, organs or tissues from participants for research purposes;
 - Introducing Recombinant or Synthetic Nucleic Acids (e.g. viral vectors, oligonucleotides) or cells containing recombinant nucleic acids (e.g. CAR-T) into participants; OR
 - Introducing other biological materials (e.g. bacteria, viruses) into participants.
- ☐ Yes ☒ No
11. **Does this study involve any of the following?**
- Cancer Patients
 - Cancer Hypothesis
 - Cancer risk reduction
 - Cancer prevention
- ☐ Yes ☒ No
12. **Any component of the Clinical and Translational Science Institute (CTSI)?**
☒ Yes ☐ No
The Clinical Research Unit (CRU)?
☐ Yes ☒ No

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- Request for Waiver of Authorization

PI: Hilary
Coon Ph.D.

Submitted: 3/22/2011

Title: Utah Suicide Mortality Research
Study (USMRS)

Request for Waiver or Alteration of Authorization

Request for Waiver of Authorization for **Recruitment Only**

This option must only be used if you are reviewing PHI in order to identify eligible participants BEFORE approaching them to obtain consent and authorization. All other waiver requests must be entered below.

Other Requests for Waivers of Authorization:

- *Click "Add" below to add a new waiver request to this application.*
- *Click the waiver name link to edit a waiver that has already been created.*
- *To delete a waiver request, contact the IRB.*

Date Created	Type of Request	Purpose of Waiver Request
View 12/11/2012	Waiver of Authorization	We cannot obtain authorization from suicide deaths or comparison non-suicide deaths. Family members are only included in the study to identify aggregated estimates of familial risk of suicide mortality and other co-morbid risks, and to define familial clustering of suicides. Only limited-use phenotypic information is used on any subjects. No attempts will be made to contact living relatives. Next-of-kin are provided with the opportunity to opt out a deceased relative from the study. Opt out is provided on the Utah Office of the Medical Examiner website and relatives are notified of the opportunity to opt out of this and other OME studies. If a deceased individual is opted out by next-of-kin, to preserve anonymity of the opted out case, honest data brokers not affiliated with the study at the OME will provide the anonymous ID associated with that case to the study team for removal of data. To determine significance of the risk of co-occurring conditions/demographic characteristics/geocoded clustering, data from matched controls must be studied from within the ~9,000,000 records in the UPDB. Matching is done within the UPDB. All data are made into limited use data sets prior to analysis.

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IRB Smart Form

PI: Hilary Coon Ph.D.

Submitted: 3/22/2011

Title: Utah Suicide Mortality Research Study (USMRS)

Request for Waiver or Alteration of Authorization

1. Purpose of the Waiver Request:

We cannot obtain authorization from suicide deaths or comparison non-suicide deaths. Family members are only included in the study to identify aggregated estimates of familial risk of suicide mortality and other co-morbid risks, and to define familial clustering of suicides. Only limited-use phenotypic information is used on any subjects. No attempts will be made to contact living relatives. Next-of-kin are provided with the opportunity to opt out a deceased relative from the study. Opt out is provided on the Utah Office of the Medical Examiner website and relatives are notified of the opportunity to opt out of this and other OME studies. If a deceased individual is opted out by next-of-kin, to preserve anonymity of the opted out case, honest data brokers not affiliated with the study at the OME will provide the anonymous ID associated with that case to the study team for removal of data.

To determine significance of the risk of co-occurring conditions/demographic characteristics/geocoded clustering, data from matched controls must be studied from within the ~9,000,000 records in the UPDB. Matching is done within the UPDB. All data are made into limited use data sets prior to analysis.

2. Type of Request:

Waiver of Authorization

3. List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc).

Identifying information is needed by the UPDB to link data from suicide deaths and non-suicide comparison deaths to other approved UPDB data. Identifying information will ONLY be transferred directly from the Office of the Medical Examiner to the UPDB. This information, including State Death Certificate number and names, will ONLY be used by the UPDB for linking, and will not be transferred to the research personnel on this project. The research personnel will receive limited use data as detailed elsewhere in this protocol summary Data will be linked to bio-specimen-derived data received by the study team using an anonymous numeric identifier assigned by the OME.

4. Explain why the *PHI* to be used or disclosed is the minimum necessary to accomplish the research objectives:

PHI will only be exchanged between the Office of the Medical Examiner (OME) and the UPDB. This information is necessary to link data from suicide deaths and non-suicide deaths to other approved UPDB data. PHI will be used as necessary by the UPDB to match data from controls within the UPDB, but matching identifiers will then be stripped and will not be used by study investigators.

5. Explain why the research could not practicably be conducted without the waiver of authorization. For example, complete the following sentence: "If I had to obtain authorization, the research could not be conducted because..."

Suicide deaths or non-suicide deaths cannot be contacted for consent. Contact of family members of all suicide and non-suicide deaths would be prohibitive, and would be needlessly intrusive for these families.

6. Describe your plan to protect the identifiers from improper use and disclosure, and indicate where the *PHI* will be stored and who will have access:

Identifiers will only be accessible to the OME. They will be securely transferred to the UPDB to be used for linkage and not accessed by the study team.

- 7. The identifiers must be destroyed at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. Describe how and when you will destroy the identifiers, or justify their retention:**

The research personnel will never have access to identifiers used for linking. The OME has the right to retain access. The UPDB will destroy identifiers at the end of the project.

- 8. Describe the measures you will take to ensure the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research approved by the IRB:**

Because the research personnel will never have the identifiers, they will not be able to disclose them to any other entity. The study team will also undertake best efforts to maintain the current National Institutes of Health Certificate of Confidentiality that covers the USMRS research activities.

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- Safe Harbor De-Identification Agreement

PI: Hilary
Coon Ph.D.Submitted:
3/22/2011Title: Utah Suicide Mortality Research
Study (USMRS)

Safe Harbor De-Identification

1. This declaration applies to the following part(s) of this study:

- A. ☐ All of the information used or disclosed in this study.
The information received or
- B. ☐ collected from these sources:
The information shared with
- C. ☒ or disclosed to these NIMH groups:

2. As the principal investigator for this study, I declare the following:

1. To the best of my knowledge, the information could not be used (alone or with other information) to identify an individual who is a subject of the information, and
2. None of the following types of information, regarding subjects or relatives, employers, or household members of subjects, are used or disclosed in the part of this study indicated above:
 - a. Names;
 - b. All geographic identifiers except state or the first three digits of a zip code (however, all data from the following 17 3-digit zips are combined together under "000": 036, 059, 063, 102, 203, 556, 692, 790, 821, 823, 830, 831, 878, 879, 884, 890, and 893)
 - c. The month and day (the year can be kept) from all dates directly related to an individual, including birth date, admission date, discharge date, date of death. Ages over 89 are combined in a single category of "Age 90 and older."
 - d. Telephone numbers;
 - e. Fax numbers;
 - f. Electronic mail addresses;
 - g. Social security numbers;
 - h. Medical record numbers;
 - i. Health plan beneficiary numbers;
 - j. Account numbers;
 - k. Certificate/license numbers;
 - l. Vehicle identifiers and serial numbers, including license plate numbers;
 - m. Device identifiers and serial numbers;
 - n. Web Universal Resource Locators (URLs);
 - o. Internet Protocol (IP) address numbers;

- p. Biometric identifiers, including finger and voice prints;
- q. Full face photographic images and any comparable images; and,
- r. Any other unique identifying number, characteristic, or code, except as permitted for re-identification.

3. If I assign a code or other means of record identification to allow de-identified information to be re-identified,

- 1. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual, and
- 2. I will not use or disclose the code or other means of record identification for any purpose other than re-identification, and I will not disclose the mechanism for re-identification.

4. Before I allow a code to be used to re-identify this information,

- 1. If the purpose of the re-identification is within the scope of the original protocol, I will obtain approval of an amendment from the IRB and comply with the requirements of HIPAA; or
- 2. If the purpose of the re-identification is outside the scope of the original protocol, I will submit a full New Study Application, obtain IRB approval, and comply with the requirements of HIPAA.

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- Genetic Research

PI: Hilary Coon Ph.D.

Submitted: 3/22/2011

Title: Utah Suicide Mortality Research Study (USMRS)

Genetic Research

1. Describe the risks to participants in regard to genetic testing, including applicable risks to privacy and confidentiality, as well as psychological and social risks.

The primary risk is breach of confidentiality and privacy. However, we feel that efforts are in place to avoid such events. Specifically only limited-use data will be studied. Biosample derived data will only studied from individuals who died by suicide and non-suicide comparison deaths, not on living individuals. There will be no procedures performed on subjects. There will be no direct contact with any living controls or family members.

2. Describe the privacy protections in place for participants in regard to genetic testing. This includes how family member privacy will be protected.

All data use is done under the stipulations of the attached fully executed Data Sharing Agreement with the Utah Department of Health and Human Services (UDHHS). The Utah Suicide Mortality Research Study has implemented the following specific internal expectations below regarding its access and use of Data.

1. Each USMRS researcher will sign a Memorandum of Understanding (attached to this protocol) setting forth expectations to ensure the responsible conduct of research.
 2. Formally proposed uses of Data (defined as uses that are expected to result in public facing scientific analysis that contribute to generalizable knowledge) by USMRS researchers will undergo a rigorous internal review including involvement of USMRS leadership, members of the University's Office of Research Integrity and Compliance who are familiar with this Agreement, community representatives and those with lived experience, and OME. Reviews will ensure alignment with UDHHS priorities and will assess regulatory, scientific, ethical, and privacy issues.
 3. Each person who will be the lead for the analysis or who will be accessing the data or will be involved in analysis or will be engaged in viewing detailed results will be listed in this IRB.
 4. Approval of plans for a specific public facing project will be followed by completion of an internal USMRS Data Use Agreement (DUA) that will be approved and tracked by the University's Office of Research Integrity and Compliance.
 6. Approved specific project analyses will only be allowed within computing environments approved by the UDHHS.
 7. Results of each completed specific project must be reviewed by the USMRS and by UDHHS representatives and UDHHS Privacy Officers. Reviews will ensure scientific rigor, compliance with ethical standards, alignment with UDHHS priorities, and anonymity of research results to ensure any subjects of Data cannot be re-identified.
 8. Results of intended publication will be reviewed by UDHHS's privacy team for review of privacy issues and confidentiality precautions.
 9. With the completion of each specific project, the research team's access to Data will be removed and study details and protocols securely archived.
 10. The University will undertake best efforts to secure and maintain a National Institutes of Health Certificate of Confidentiality covering research activities facilitated by this Agreement. USMRS activities related to this Agreement currently operate under a Certificate of Confidentiality.
 11. Protocols governing research efforts facilitated by this Agreement will be reviewed annually by Institutional Review Boards (IRBs) at the University, UDHHS, and Intermountain Health
- External sharing of all original and derived data will only be done adhering to current local institutional and state regulatory requirements, as stipulated in the current UDHHS Data Sharing Agreement.

3. Are you performing whole genome or whole exome sequencing?

☒ Yes ☐ No

4. Describe the confidentiality protections in place for participants' genetic information. Discuss if and how data will be shared and protected outside the local study team.

Any publication involving printed drawings of pedigree structure and suicide/psychiatric disorder status will be disguised as recommended by the UPDB, and as practiced previously by our research group in our autism pedigree studies. All rare diagnoses and other groupings of small size, and all data concerning ages > 90 years will be aggregated to protect identify. All publications will first be reviewed by the RGE and a representative from UDHHS Privacy team.

Only limited use data will be available to the study team.

Locally, data are stored on the secure computer system approved by the UDHHS (currently: CHPC Protected Environment, and in a completely de-identified state on the HIPAA-compliant UBox). UBox was developed for use by University of Utah faculty and staff. It is HIPAA-compliant, and is among the select number of platforms for sensitive data storage. Level of access is controlled by the study PI, who will restrict access to only those approved on the IRB. In addition, study team must access UBox from approved University of Utah devices that have been encrypted using

accepted encryption algorithms. Box is encrypted using AES 256bit for data at rest and TLS 1.2 for data in motion. Backups are encrypted using this same methodology and stored in the cloud. The UofU has also negotiated in the Business Associate Agreement with Box that backups are not stored in any datacenter outside the United States. Note: For this study, only HIPAA Safe Harbor de-identified data will be stored on UBox while limited use data and all genetic data will be stored on the CHPC PE

5. **Will incidental findings relevant to individuals or families be communicated to the participants?**

☐ Yes ☒ No

If yes, answer the questions below:

- a. **Describe the process for determining which incidental findings will be returned to the participants. Describe the information and expert consultation that will be used to make this determination.**
- b. **Indicate the process that will be used to return information about incidental finding to participants:**
There are no items to display
If Other, describe and justify the process that will be used:

6. **Will genetic information or samples be submitted to a national or international database because of this research?**

☒ Yes
☐ No

Indicate all databases with which the genetic information will be shared.

Database Short Name

Name

There are no items to display

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- Data & Tissue Banking

PI: Hilary Coon Ph.D.

Submitted: 3/22/2011

Title: Utah Suicide Mortality Research Study
(USMRS)

Data & Tissue Banking

1. Select the items that will be banked:

Biological samples

Data

List all the specific, participant information (identifiable and non-identifiable) that will be contributed to the repository (e.g., name, date of birth, phone number, age, gender, diagnosis, treatment status, outcome, date of collection, etc.):

Data will only be shared via NIH with restrictions wherein requestors are added to this IRB, achieve University of Utah Affiliate status, analyses are done on DHHS approved servers, and all data requests, approvals, and oversight occurs as described in item 7 below.

Data elements will include: anonymous numeric identifier, age at death, sex, aggregated yes/no status for depression, anxiety, schizophrenia, bipolar disorder, race reported by medical examiner, year of birth; and genetic data (if creation of genetic data was funded by NIH).

Data that are generated using NIH funding are required to be shared. A fully de-identified ID will be associated with data, the NIMH Global Unique Identifier (GUID). The GUIDs will be created using Protected Health Information by staff within the UPDB using cryptographic hashing (please see <https://nda.nih.gov/nda/using-the-nda-guid>). The original Personally Identifying Information (PII) used to create the GUIDs will not subsequently be used for any other purpose, and will not be sent to the local study team, or to the NIMH. The one-way hashing process that creates the GUIDs cannot be reversed into the original PII, and again, the original PII is not used for any study purpose, not given to the investigator team, and not given to the NIMH. The resulting de-identified GUIDs can, however, be compared within and across studies to determine if there are duplications. This cross-study checking using the anonymized GUIDs is a requirement by the NIMH. If there are duplications, the duplication is noted so that those using the data are aware of duplicated data. There is no attempt to determine the actual identity of any duplicated participants.

GUIDs will be created and assigned to data from Utah suicide deaths where data creation is supported by NIMH funding. This data funded by the NIMH will be stored at the NIMH Data Archive, which is a U.S. based secure archive with AES-256 encryption. Data in the NDA will only be shared with controlled access and any results will be subject to local institutional and DHHS review as explained in item 7 below.

Type(s) of samples to be collected:

DNA aliquots from suicide deaths were shared previously with NIH repositories (new state regulations require that all biosamples and derivatives remain in the custody of the Utah OME).

2. What type(s) of future research will be allowed on the data/samples?

Samples are stored in secure lab space approved by UDHHS (USMRS Biosample Laboratory) and data are generated on them on behalf of the Utah OME to comply with current University of Utah Suicide Mortality Research Study (USMRS) and the Utah OME / UDHHS regulations. While previously DNA aliquots from suicide deaths were sent to the NIMH Repository and Genomics Resource (NRGR; now at Coriell), new state regulations now require that all biosamples and derivatives remain the custody of the Utah OME. Samples are associated with fully de-identified IDs (GUIDs, see item 1 above).

In accordance with the UDHHS Data Sharing Agreement, the contract between the UU (USMRS) and the Utah OME/UDHHS, and a data sharing agreement with the NIMH (also attached to this protocol), use of biosamples and sharing of data will occur with controlled access. This protocol of controlled access will apply to those requesting access either through the NIMH or via other scientific consortia or as individual collaborators. Controlled access will include: requirement of the recipient IRB and other institutional and state permissions; requirement of recipient USMRS and UU collaboration; use of data limited to the study of suicide; and use of data limited to not-for-profit organizations.

3. Who manages the repository and where will the data/samples be stored?

Utah Suicide Mortality Research Study Biosample Laboratory on behalf of the Utah State Office of the Medical Examiner (OME)

NOTE: samples from this project were previously at the NIMH Repository and Genomics Resource (NRGR, Coriell).

4. Indicate whether the data/samples in the repository will be identifiable directly or through a code/link.

a. Select one of the following options:

OPTION 3: All data/samples will be de-identified to all individuals who have responsibilities to manage or oversee the repository. No link or code will be accessible to or maintained by the repository.

c. If you selected OPTION 2 or 3 above, describe the process for de-identifying the data/samples:

Who will de-identify the data/samples?

Samples stored on behalf of the Utah OME will only be associated with the fully de-identified ID generated by the UPDB (GUIDs, see item 1 above) and a numeric ID generated by the Office of the Medical Examiner and by their anonymous CCTS LABID number.

When will the data/sample be de-identified?

After linking data elements, linking identifiers and all PII used to create the GUIDs (see item 1 above) are not retained for analysis. All remaining study data will be limited use (month and year are included to allow longitudinal study of events, and genetic data are now determined to be potentially identifiable). All other data elements are de-identified.

NOTE: previously, for all samples and data at the NIMH repositories, aggregated demographic and clinical data was completely de-identified; genetic data is now determined to be potentially identifiable. All data was tracked by the anonymous GUID (see item 1 above).

5. Describe the procedures for participants to withdraw their data/samples from the repository. If participants will not be able to withdraw their samples, please provide an explanation:

Subjects are deceased and will therefore not be able to withdraw their samples themselves. Control and family data is de-identified records only data. There is an option to opt out a deceased participant on the Utah OME website. If a deceased participant is opted out by a family member, a Utah OME staff member unaffiliated with the study will notify the study of the anonymous ID associated with that participant so that data can be deleted.

6. Will future research results or findings be communicated to the participants?

☐ Yes ☒ No

7. Describe the procedures for other researchers to obtain data/samples from the repository for use in future research.

Researchers requesting access must first receive permission through the official NIMH approval process, through a consortium, or from the USMRS leadership directly if they are an individual external collaborator.

Next, unless otherwise explicitly approved by the UDHHS, all shared use will require the recipient to: 1) demonstrate approved IRB status for the proposed work; 2) notify USMRS of intended data use and obtain internal USMRS data use agreement permissions; 3) obtain UU affiliate status; 4) conduct all research on UDHHS approved computer servers; and 5) secure all appropriate reviews (e.g., RGE, Utah OME, UDHHS Privacy) prior to release of public results.

NOTE: Previously, use of samples and data in the NIMH repositories occurred through an application/approval process governed by the NIH. Use of additional detailed pedigree structure data not in the repository by investigators requesting repository access only occurred in the past with the explicit approval of the RGE.

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8. Resources and Responsibilities

PI: Hilary
Coon Ph.D.

Submitted: 3/22/2011

Title: Utah Suicide Mortality Research Study
(USMRS)

8. Resources and Responsibilities

1. * State and justify the qualifications of the study staff:

IRB Leads: will oversee scientific and administrative aspects of this project with the assistance of the Advisory Group of the USMRS. These duties will also include ensuring that annual review and approval occurs for an IRB with the Utah Department of Health and Human Services and Intermountain Health.

Names: Drs. Coon, Monson and DiBlasi

Office of the Medical Examiner (OME) Partners: will manage secure transfer of Office of the Medical Examiner (OME) autopsy data to UPDB staff and receive a copy of relevant data back from UPDB. They will manage the secure transfer of biosample data to UDHHS-approved computer servers for USMRS analysis. They will help with study design and review and interpretation of results. They will also provide tracking of opt-out requests and notification to USMRS of need for resulting data exclusion.

Names: Dr. Staley, Dr. Amaro and Mr. Callor (external investigator)

USMRS Program Manager: Will assist with study coordination, data permissions and transfer, coordination among collaborators and community stakeholders, negotiations of contracts and agreements, planning of retreats and local presentations, and coordination of data management issues.

Names: Ms. Emily Sullivan

Content, Methodological, Analytical and Clinical expertise: Will provide support for study design, methods, data generation, data analysis for case-control studies, analyses within specific subpopulations, and studies incorporating familial, genetic, or data science methods, as well as interpretation of findings and preparation of manuscripts, reports or grant proposals.

Names: Drs. Camp, Monson, DiBlasi, Keeshin, Bakian, Kaufman, Kirby, Jawish, Mickey, Williams, Han, Pugh, Pettine, Kious, Shabalin, Scholand, Docherty, VanDerslice, Yue, Zhang, Koppelmans, Han, Marth, Quinlan, Deatley, Guo, Jasperson, Goldstein, Hollingshaus, Stephens, Tay, Tharp and Laurel Haitt, Danli Chen, Theodore Baende, Elliott Ferris, Lisa Baird, Nicholas, Hill

University of Utah Data Coordinating Center (DCC) partners: The DCC team will support the USMRS by providing overall data management.

Names: Drs. Cook, Meeks and Telford, and Sally Jo Zuspan, John Brumett, Andrea Lundrigan and Jonathan Zadra

Trainees: Will participate in analyses of risk/resilience subtypes under the supervision of USRMS investigators.

Names: Alexander Adelman, Heather Cummins, Andrew Del Colle, Erina Horikawa, Dirga Lamichhane, Behzad Sorouri Khorashad, and Sam Webster

UPDB Partners: Will work with data linking, high-risk pedigree identification, and other specialized analysis software tools developed for UPDB data and resources.

Names: Zhe (David) Yu and Myke Madsen

IH Partners: Will oversee linking of IH clinical data done by an IH 'honest broker' using the IH Linkage ID provided by the UPDB.

Names: Dr. Crockett, Dr. Giles, Adam Heisey, Mark Olsen and Tressa Price

External collaborators: Will assist with studies of data done on secure Utah servers that may include external de-identified data from other centers with suicide outcomes.

Names: Drs. Mullins, Colbert, Das, Johnston

2. * Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:

Communication will be ongoing by phone and email. Meetings will occur regarding specific grants and analyses in conjunction with the study. These meetings are project-dependent, but happen at least bi-weekly with relevant subsets of investigators. Drafts of grants and papers are circulated among all study personnel for review.

3. *** Describe the facilities where the research activities will be performed (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.).**

Research activities will be conducted across a comprehensive network of clinical, research, data, and administrative facilities at the University of Utah (UU), Intermountain Health and The Utah State Office of the Medical Examiner (OME). Investigators are housed in offices located within Research Park and across the University of Utah Health Sciences and main campuses, with access to standard office, computing, and laboratory equipment. Additional institutional support is provided through university-wide resources (UPDB, CTSI, UCGD, CHPC, OVPR, DCC).

Primary research sites include the University of Utah School of Medicine and the Department of Psychiatry, which maintain dedicated clinical, research, and administrative space across the Huntsman Mental Health Institute (HMHI). These locations provide offices, research support infrastructure, and access to interdisciplinary faculty, trainees, and administrative personnel.

The Utah State Office of the Medical Examiner (OME) provides access to the Utah Medical Examiner Database (UMED), including autopsy and biospecimen data that are permissioned for analysis through the Utah Suicide Mortality Research Study (USMRS). The OME also provides office and collaborative space for research personnel.

Staff and resources from the Utah Population Database (UPDB), The Utah Center for Genomic Discovery (UCGD), The Utah Clinical & Translational Science Institute (CTSI), The Utah Data Coordinating Center (DCC), University of Utah Center for High Performance Computing (CHPC), Office of the Vice President for Research (OVPR) are also utilized for this work.

Data storage, management, and analysis are conducted using secure computing infrastructure approved by DHHS. The master USMRS database will be housed on approved protected servers and managed by approved personnel with controlled backup and recovery systems.

Biospecimens are processed and stored within approved facilities operating under appropriate agreements with the OME. USMRS Laboratory facilities are fully equipped to support biospecimen processing, storage, and tissue culture, and all equipment undergoes routine maintenance and calibration.

DNA extraction and quality assessment are performed by a designated laboratory using validated protocols, with sample metrics recorded in a secure laboratory information management system.

Specimens, including extracted DNA and select tissue samples, are stored in secure, access-controlled laboratories in monitored freezers equipped with continuous temperature tracking and automated alarm systems. All biospecimens are labeled with coded numeric identifiers to maintain confidentiality. Biospecimens not immediately required for research remain under the custody of the OME until needed, in accordance with established protocols.

4. *** Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.**

NA

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Documents and Attachments

PI: Hilary
Coon Ph.D.

Submitted: 3/22/2011

Title: Utah Suicide Mortality Research Study
(USMRS)

Documents and Attachments

If any of your documents (such as investigational brochures, sponsor protocols, advertisements, etc.) are not available in an electronic format, please scan and save them as PDF files or contact our office for assistance.

Naming Documents: Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.

Examples:

Consent Document Control Group 04/14/05

Consent Document Treatment Group 4/14/05

Sponsor Protocol 04/14/05 Version 2

Assent Document(Highlighted Changes)

[Apple/Macintosh Users:MS Word documents must have a .doc file extension. See ERICA home page for instructions.](#)

Print View: IRB Draft Protocol Summary

eProtocol Summary:

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

Parental Permission Documents:

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

Assent Documents:

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

VA Consent Documents:

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

Surveys, Questionnaires, Interview Scripts, etc.:

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

Full Protocol (company protocol, sponsor protocol, investigator-initiated protocol, etc.):

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

Investigational Brochure (IB) for Investigational Drug or Drug/Device Package Insert:

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

Grant Application:

The Federal Government is a direct or indirect sponsor of your research. You are required to provide a copy of the grant proposal, grant award, or sub-award.

By submitting to the IRB, you are confirming the grant and the study protocol are consistent (Design, Study Population, Study Objectives and Goals, Test Interventions and Procedures, etc.)

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

Literature Cited/References:

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

Principal Investigator's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
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Faculty Sponsor's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

Other Stamped Documents:

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

Other Documents:

Name	Version	Date Created	Date Modified	Date Approved
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There are no items to display

IRB_00044244**Created:** 8/17/2010 1:10 PM**IRB_00044244**

Ancillary Applications

PI: Hilary Coon Ph.D.**Submitted:** 3/22/2011**Title:** Utah Suicide Mortality Research Study
(USMRS)

Ancillary Application

This page should be used for submitting human research applications to the following ancillary committees:

Resource for Genetic and Epidemiologic Research (RGE) for access to the Utah Population Database (UPDB) and Utah Cancer Registry (UCR)

Phone: 801-581-6351

Website: <https://rge.utah.edu/>

Radiological Drug Research Committee Human Use Subcommittee (RDRC-HUS)

Phone: 801-581-6141

HUS Website: <https://rso.utah.edu/committees/hus-rsc.php>RDRC Website: <https://rso.utah.edu/committees/rdrc.php>

Institutional Biosafety Committee (IBC)

Phone: 801-581-6590

Website: <https://ibc.utah.edu>

ID	Name	Status
 RGE_00000283	Genetic risk factors in suicide and depression	RGE Approved

IRB_00044244**Created:** 8/17/2010 1:10 PM**IRB_00044244**

Finish

PI: Hilary Coon Ph.D.**Submitted:** 3/22/2011**Title:** Utah Suicide Mortality Research Study (USMRS)

Finish Instructions

Finish Instructions

1. To view errors, select the "Validate" option at the top-left of the page. If you have errors on your application, you won't be able to submit it to the IRB.
2. Selecting the Finish button will NOT submit the application to the IRB.
You MUST select the "Submit" option on the workspace once you've selected the "Finish" button.
3. If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.