UNFUNDED AGREEMENT
DATA USE AGREEMENT QUESTIONNAIRE

Providing the following information will assist the Sponsored Programs Administration (SPA) to review and negotiate data use agreement requests with less interference and more efficiency and effectiveness. **NOTE:** Not providing a reply to all questions, even if "No" or "N/A", may cause additional inquiry from SPA.

UMB Principal Investigator

Name	Rosemary Kozar
Study Team Contact Name and Email Address	Chavi Rehani crehani@som.umaryland.edu

Collaborator

Please enter the name and email address of the POC. This is the person responsible for reviewing & executing the DUA and may differ from the Principal Investigator (PI).

PI Name	
*Point of Contact - Name and Email Address	
Physical Address	

Is UMB: ☒ Data Recipient ☐ Data Provider ☐ Both

Owner of Data: ☐ UMB ☒ Collaborator ☐ Other *If other*: _____

DUA Project Description / Justification for Use

This section should provide sufficient information such that each party understands the project that the Recipient will perform using the Data. Examples of information include: Objectives, purpose of the Recipient's work, or a general description of the actions to be performed by the Recipient using the Data and possibly the anticipated results.

If a Justification For Use has been submitted to the Data Provider, do not complete this section and upload it into KR.

Objective of the study is to determine in a prospective multicenter observational study the incidence and associated mortality of injured patients presenting with early trauma-induced coagulopathy.

Source & Type of Data (check all that apply):

(For information on data types: https://thefdp.org/wp-content/uploads/human_subject_data_classification_tool.pdf)

☒ De-identified ☐ Limited Data Set ☐ Personal Health Information (PHI) ☐ Personally Identifiable Information (PII)

☐ Other; *please explain*: _____

Description of Data

This section should provide sufficient information such that each party understands the information that will be transmitted under this Agreement. Examples of information include: Whether the data is obtained from human subjects and, if so, the number of subjects or a description of the population included in the data; if the data is from animal subjects, the species of animal the data was obtained using; if not from human or animal subjects, a description of the data and/or experiments included. Name of the study that the data was obtained under if there is a particular study that needs to be acknowledged/cited as the source of the data.

Data will be collected from injured patients requiring admission to a trauma center or death at any time after hospital arrival between the ages of 18-89. The number of patients this will be depends on the trauma center volume for the designated time of the study. Data includes basic demographics, prehospital data, injury and outcome data. The study name is "A multi-center study on early trauma-induced coagulopathy: Defining clinical and biochemical profiles."

If UMB is the Data Provider, are there data management / disposition requirements for the Data Recipient? ☐ Yes ☒ No

If Yes, please explain:

UMB is the Data recipient

Third Party Permitted / Will any other entity access the data? ☐ Yes ☒ No
If Yes, provide name: _____

Will the data be combined with data from any other sources? ☐ Yes ☒ No

Transmission Method: ☒ Electronically ☐ Mail ☐ Repository ☐ Data Coordinating Center

Data transferred across international borders? ☐ Yes ☒ No

Does the data involve personal data of a citizen or resident living in the European Economic Area or the European Union?
☐ Yes ☒ No

Cost associated with data transfer: ☐ Yes ☒ No

Proposed Duration of the Agreement/Length of time for use of Data: seven years

Related Sponsored Funding

Complete if there is any sponsored funding associated with the referenced data.

Funding Source: ☐ Sponsored ☐ UMB Internal Funds
If Sponsored, enter KR award info: _____
UMB Project ID#: _____
eUMB# (if applicable): _____

Intellectual Property

Do you anticipate new intellectual property (patents/copyrights) will be developed using the data? ☐ Yes ☒ No
Is there a reasonable possibility of commercial utility? ☐ Yes ☒ No

Publishing

Will any publications result from this data transfer? ☒ Yes ☐ No
If Yes, will this be a joint publication? ☒ Yes ☐ No

Confidential Information

Other than the data described, will Confidential Information be transferred between parties?
UMB Confidential Information? ☐ Yes ☒ No
External Entity's Confidential Information? ☐ Yes ☒ No

If Yes, please explain:

Regulatory Compliance

*(**NOTE**: **SKIP** this section, if the following is accurate & up-to-date in Kuali Research)*

Does the data for this Agreement involve:

Human Subjects? ☒ Yes ☐ No
If yes, IRB protocol #: ~~HRP-519 for UMI~~
Status of IRB review: ☒ Approved ☐ Pending
Primary IRB: ☐ UMB ☐ Collaborator ☒ Both
If the primary IRB is outside UMB, provide the collaborator's protocol reference #: _____

Use of Vertebrate Animals: ☐ Yes ☒ No
If yes, IACUC Protocol # _____
IACUC location: _____
Status of IACUC review: ☐ Approved ☐ Pending