

**US Army Medical Research and Development Command EGS Record Creation for
Safety/Environment and Regulatory Review Requirements
Submission Template for Funded Projects and non-EGS managed OTA Projects**

This form must be completed by the funding agency

Purpose: This form allows the creation of an EGS record in order to facilitate Safety/Environmental review and DOD human and animal research regulatory compliance review and approval. For projects under an Other Transaction Agreement (OTA) please follow the OTA-specific guidance. For all others, please follow the OHARO-specific guidance.

OHARO: The Office of Human and Animal Research Oversight Office of Human Research Oversight (OHARO OHRO) and Animal Care and Use Review Office (OHARO ACURO) now uses the U.S. Army Medical Research and Development Command's Electronic Grants System (EGS) as its review platform for all research that requires OHARO OHRO or ACURO approval. Please complete all applicable sections of the attached OHARO Proposal Submission Form to enable creation of a record in the EGS. An individual who oversees/is familiar with the funding of the research must complete the form, e.g., the COR, Program Manager, Science Officer.

OTA: The collection of the information requested in this form is required for the generation of an EGS record. This will facilitate the initiation request for Safety/Environment review, as well as OHARO review of human and/or animal studies as applicable.

Instructions:

OHARO: Please complete the template and submit with proposal documents to the OHARO electronic mailboxes. Animal research should be submitted to the ACURO mailbox (usarmy.detrick.medcom-usamrmc.other.acuro@health.mil), human or cadaver research submitted to the OHRO mailbox (usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil) and projects with both types of research to both ACURO and OHRO boxes.

OTA: Please complete the form and submit it together with the required documents to either MTSC Analyst Sally Robey, sarah.v.robey.ctr@health.mil, or Program Lead Sara Langdon, sara.b.langdon.civ@health.mil. For OTAs with human and/or animal use, please submit to the MTSC analyst and requests will be subsequently forwarded to OHARO.

SECTION I: PROGRAM AND AWARD INFORMATION

System Log Number: *(if applicable)*

(Examples: DTRA ROB Number (e.g., CB-2019-##); OTA Base Agreement Number (e.g. 2018-833); MCS Proposal Log Number; etc...)

Award Number:

(Examples: MRDC Contract Number; MIPR/FAD # (e.g., HDTRA 1828370 funded through W15QKN-16-9-1002, OTA Agreement #)

MTEC Solicitation ID(MTEC Only):

Program Management Office:

Other PMO:

Fiscal Year:

Program:

Assigned COR/GOR/SOTR Contact:

COR/GOR/SOTR Prefix

COR/GOR/SOTR First Name

COR/GOR/SOTR Last Name

COR/GOR/SOTR Email Address

COR/GOR/SOTR Telephone

Assigned PM/SO/STM Contact:

PM/SO/STM Prefix

PM/SO/STM First Name

PM/SO/STM Last Name

PM/SO/STM Email Address

PM/SO/STM Telephone

Assigned CS/GS Contact:

CS/GS Prefix

CS/GS First Name

CS/GS Last Name

CS/GS Email Address

CS/GS Telephone

SECTION II: PROPOSAL INFORMATION

Proposal Title:

Period of Performance *(if known)*:

to

POP Start Date

POP End Date

Proposal Principal Investigator (PI) Information:

Proposal PI Prefix

Proposal PI First Name

Proposal PI Last Name

Proposal PI Email Address

Proposal PI Telephone

Proposal PI Degree(s) *if known* **or Suffix**

Proposal PI Institution:

Proposal PI Street Address Line 1:

Proposal PI Street Address Line 2:

Proposal PI City:

Proposal PI State:

Proposal PI Zip Code:

Proposal PI Country:

Is this project linked to a prior or on-going DOD/USAMRDC Award(s), if known?

No

Yes (If yes, please describe below)

OHRO/ACURO Log Number <i>(if known)</i>	System Proposal/ Log Number <i>(if known)</i>	Award Number	Active (Y/N)	Funding Activity/Program Office

SECTION III: DoD/USAMRDC Proposal Documentation for Submission

(please check all documents submitted)

Documents **required at the time of submission:**

Proposal

Statement of Work (SOW)

Documentation of scientific merit ***when available:***

Award/funding documentation

Statement of scientific merit

SECTION IV: OHARO CHECKLIST

Please indicate Yes or No, and provide additional notes to OHARO

(Indicate Animal &/or Human Use, as applicable)

ACURO	Yes	No	Notes to ACURO
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Animals used?

Select Animal Species

Rodents (mouse/rat/hamster)	Non-Human Primates
Pigs	Rabbits
Dogs	Service animals
Cats	Marine mammals
Other	

* Please specify in note to ACURO

Will any DOD-funded animal studies be performed at a site outside the US?

**If yes, please provide details in note to ACURO*

Estimated ACURO Start (if known):

(Example: Animal Research will start right away)

Human Anatomical Substances	Yes	No	Note to OHRO
<p>Does the project involve any of the following:</p> <p>1. Collecting human specimens prospectively for research purposes</p> <p>2. Human cell lines that cannot be purchased from a vendor</p> <ul style="list-style-type: none"> Note: this includes human cell lines that may be published or otherwise freely available, but are not commercially available <p>3. Commercially available human anatomical substances (non-pooled)</p> <ul style="list-style-type: none"> E.g., tissue samples, PBMCs, primary cells, blood, saliva, etc. from a single donor <p>4. Creation of new patient-derived xenograft (PDX) models from human tissue samples</p> <p>5. Using human specimens obtained through</p> <ul style="list-style-type: none"> Clinical trials or research studies, including existing publicly available specimen banks Collaboration with other investigators or institutions Established institutional clinical repositories, biobanks, or tumor banks Medical facility clinical departments/services (e.g., excess or discarded surgical materials obtained from clinical laboratories, including pathology, or clinical care areas, such as operating suites) <p>6. Cadavers or post-mortem human specimens</p> <p>7. Unique or regulated sample types, e.g., human embryonic stem cell lines</p> <ul style="list-style-type: none"> Exception: use of HEK293 cells does NOT require OHRO review 			

Human Data - Secondary Use	Yes	No	Note to OHRO
<p>Does the project involve secondary use of human data?</p> <p>Examples may include:</p> <ul style="list-style-type: none"> Data obtained from clinical trials or other research studies not performed under this DOD award Established data repositories or publicly available datasets <ul style="list-style-type: none"> E.g., The Cancer Genome Atlas [TCGA], ORIEN, published clinical trial results, publicly available sequencing databases, etc. Data obtained from medical records 			

Human Subjects	Yes	No	Note to OHRO
<p>1. Does the project involve interaction/ intervention with human subjects?</p> <p>2. Does the project involve a clinical trial?</p> <p> a. Is it FDA regulated?</p> <p> b. Will any clinical trial sites be located outside the US?</p>			

Other/Special Topics	Yes	No	Note to OHRO
<p>Does the project involve:</p> <p>1. Situations requiring additional levels of OHRO and DOD review and/or additional coordination not listed above. Special topics may include:</p> <ul style="list-style-type: none"> Planned emergency research involving Exception from Informed Consent (EFIC) Large scale genomic data from DOD-affiliated personnel Fetal tissue research (not including embryonic cell lines) Sensitive use of human cadavers <p><i>*If yes, promptly notify OHRO Director/Deputy Director & plan for additional time for review</i></p>			

<p>Estimated OHRO Start (if known):</p> <p>(Example: Estimated Start of first OHRO Protocol, Human Subject Research projected in year 2)</p>

SECTION V: SAFETY AND ENVIRONMENT *(for MRDC Extramural research ONLY)*

Please indicate Yes or No, and provide additional notes where applicable

Environment	Yes	No	Notes to Safety and Environment
Involves army provided infectious agents?			
Involves use of biological select agents or toxins (BSAT)?			
Involves use of specific chemical agents?			
Involves pesticides outside of established lab?			
Potential likelihood of significant negative effects on public health, safety or environment?			
Biological select agents and toxins (BSAT)			
Chemical Agents List (See page 9)			

SECTION VI: INFORMATION OF THE PERSON WHO COMPLETED THE FORM

First Name:

Last Name:

Email Address:

Phone Number:

Office:

Title:

Chemical Agents

Schedule 1 Chemical Agents
Sarin
Soman
Tabun
VX
Ricin
Sulfur mustards
Lewisites
Nitrogen mustards
Saxitoxin

Schedule 2 Chemical Agents
Amiton
PFIB
3-Quinuclidinyl benzilate

Schedule 3 Chemical Agents
Phosgene
Cyanogen chloride
Hydrogen cyanide
Chloropicrin