

**US Army Medical Research and Development Command
Regulatory Review Requirements
Regulatory Review Submission Template for Funded Projects**

Purpose: The information below is required for requesting regulatory review by the United States Army Medical Research and Development Command Office of Research Protections (USAMRDC ORP). All Department of Defense (DoD)/USAMRDC supported research involving animals, humans, cadavers, human data, or human specimens must be reviewed for compliance with Federal and DoD regulatory requirements and approved by the ORP. Additional information will be required for individual protocol submissions.

Instructions: Please complete the template and submit with proposal documents to ORP electronic mailboxes. Animal research should be submitted to the ACURO mailbox usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil, human or cadaver research submitted to the HRPO mailbox usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil, and both types of research to both ACURO and HRPO boxes.

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 #)

Program Management Office:

Other PMO:

Fiscal Year:

Program Management Office Contact:

(Examples: COR/STM/PM/SO)

PMO Prefix

PMO First Name

PMO Last Name

PMO Email Address

PMO Telephone

Award Administration Contact:

(Examples: Contract/Grant Specialist)

Award Admin Prefix

Award Admin First Name

Award Admin Last Name

Award Admin Email Address

Award Admin Telephone

SECTION II: PROPOSAL INFORMATION

Proposal Title:

Period of Performance *(if known)*:

to

POP Start Date

POP End Date

Proposal Investigator Information:

Proposal Investigator Prefix

Proposal Investigator First Name

Proposal Investigator Last Name

Proposal Investigator Email Address

Proposal Investigator Telephone

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

Proposal Investigator institution:

PI street address line 1:

PI street address line 2:

Proposal Investigator city:

Proposal Investigator state:

Proposal Investigator zip code:

Proposal Investigator country:

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

No

Yes (If yes, please describe below)

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

Estimated ACURO Start *(if known):*
(Example: Animal research will start right away)

Estimated HRPO Start *(if known):*
(Example: Human Subject research projected in year 2)

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: ORP CHECKLIST

Please indicate Yes or No, and provide additional notes to ORP
(Indicate Animal &/or Human Use, as applicable)

<u>ACURO</u>	<u>Yes</u>	<u>No</u>	<u>Notes to ACURO</u>
Animals used?			
ACURO appendix provided?			
IACUC approval?			
Animal protocol provided?			

<u>Human Cell Line Use</u>	<u>Yes</u>	<u>No</u>	<u>Notes to HRPO (cell line use)</u>
Research involves cell lines?			
Commercially available (for purchase) cell lines used?			
Non commercially available (not for purchase) cell lines used?			
Commercially available human embryonic cell lines used?			
Cell lines of unknown source used?			
Optional verification documentation (e.g. Claim of Exemption or letter)?			

<u>Human Anatomical Substance Use</u>	<u>Yes</u>	<u>No</u>	<u>Notes to HRPO (anatom. substance use)</u>
Human anatomical substances or data used? HRPO submission form on use of data/specimen form provided? IRB letter or institutional letter provided?			

<u>Human Subjects</u>	<u>Yes</u>	<u>No</u>	<u>Notes to HRPO (human subject use)</u>
1) Human subjects used? a) Human use exempt study? b) Local IRB approval provided? c) Detailed human subject protocol provided? d) Informed consent documents provided? 2) Proposal includes clinical trial(s)? a) FDA regulated? b) Planned emergency research with trauma patients?			

<u>Cadaver Use</u>	<u>Yes</u>	<u>No</u>	<u>Notes to HRPO (cadaver use)</u>
Cadaver use? ORP cadaver checklist provided?			

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

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

<u>Environment</u>	<u>Yes</u>	<u>No</u>	<u>Notes to Safety and Environment</u>
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 7)			

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