**US Army Medical Research and Development Command**

**Office of Human and Animal Research Oversight**

**Cadaver Use Submission Form**

PURPOSE: All Army supported research, development, testing and evaluation (RDT&E), education and training activities involving human cadavers require review and approval in accordance with the Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation, Education, or Training, 5 November 2019 (referred to herein as the ‘Army policy’). Activities involving human cadavers supported by the United States Army Medical Research and Development Command (USAMRDC) must be reviewed for compliance with the Army policy and approved by the Office of Human and Animal Research Oversight (OHARO). The Army policy can be located on the OHARO website: <https://mrdc.health.mil/index.cfm/collaborate/research_protections>. Note that the Army policy refers to the Office of Research Protections (ORP) as the proponent office for the policy; ORP is the former name of the OHARO.

INSTRUCTIONS:

1. Complete this submission form to provide key information and documents required by Army policy. The protocol, institutional policies, or other support documentation can be referenced when applicable in lieu of a full description within the submission form.
2. Submit all required documents to the electronic mailbox at 301-619-2165 or usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil. An incomplete submission will result in delay in review.
3. For questions regarding OHARO review requirements or assistance in completing this form, leave a message at 301-619-2165 or usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil and a staff member will contact you.

NOTE: You are reminded not to initiate Army-supported activities involving cadavers, to include post mortem biological specimens, until you receive approval from the OHARO.

**Principal Investigator or Project Lead:**

**Site(s) where cadaver use occurs:**

**Protocol/Test Plan/Project Title:**

**A. Proposal and Program Information**

1. Army organization supporting the activity (i.e. through provision of funds or other resources). Select all that apply:

[ ]  USAMRDC (e.g. Congressionally Directed Medical Research Program, Military Operational Medical Research Program)

[ ]  Combat Capabilities Development Command

[ ]  Other:

2. Proposal Number (if applicable):

3. Award Number (if applicable):

4. Associated statement of work task number (if applicable):

**B. Protocol/Test Plan/Project Information**

1. The use of cadavers involves (select all that apply):

[ ]  Research, Development, Testing and/or Evaluation

[ ]  Education

[ ]  Training

2. Type of specimens (e.g. frozen, un-embalmed heads):

3. Number of specimens:

4. Project synopsis:

**C. Cadaver Procurement Information**

1. Organization supplying cadavers (name and location):

2. Does the supplier obtain written authorization from donors for research and/or educational uses?

[ ]  Yes – Describe:

[ ]  No – Describe:

3. Describe any licensure requirements required in the state where the supplier operates, and confirm that the supplier has met those requirements:

**D. Institutional Review Information**

1. Identify the group(s) that provide institutional oversight for the project (e.g. Anatomical Use Committee, Institutional Biosafety Committee, or other):

**E. Army-Required Project Details**

1. Provide a written justification for the use of human cadavers in the project, including a description of why alternative models are either unavailable or insufficient for the intended purpose:

2. Describe the location/environment of the activities, or reference relevant support documents:

3. Describe plans for transporting, storing, physically securing, and dispositioning specimens, or reference relevant support documents:

4. Describe plans for keeping records of specimen procurement, use, and disposition, or reference relevant support documents:

5. Confirm that specimens will be tested for HIV and hepatitis B, at a minimum, or provide a justification for why testing is infeasible and/or unnecessary:

6. Describe biosafety procedures and use of personal protective equipment, or reference and provide relevant support documents:

7. Will any specimens that test positive for communicable diseases be used in the project?

[ ]  Yes – Describe how all personnel who may come in contact with cadavers are made aware of the positive test result and outline any necessary precautions that will be taken to prevent disease transmission:

[ ]  No

[ ]  N/A

**F. Additional Requirements for Sensitive Uses of Cadavers**

1. Does the project involve a “sensitive use” of cadavers, to include biological specimens or “coupons”? “Sensitive uses” means RDT&E, education, or training activities that involve exposing cadavers to impacts, blasts, ballistics testing, crash testing and other destructive forces.

[ ]  No – **Stop here and proceed to the next section.**

[ ]  Yes – Complete the remainder of this section.

2. Describe how the body donation form and, if applicable, supplemental material, provide information so donors would have had a reasonable expectation that their bodies could be used for the military testing or research planned in this activity:

3. Describe how the activity is designed to minimize the potential for psychological harm to participating staff and other personnel due to the nature of the work with human cadavers, or reference relevant support documents:

4. Confirm that the project lead will inform participating staff of the intended cadaver use, and, as recommended by Army policy, describe plans to consider concerns/objections of staff and exclude objecting staff from the activity without prejudice where appropriate:

5. Are referrals for mental health care available if personnel seek such care because of their involvement in the proposed cadaver activity?

[ ]  Yes – describe:

[ ]  No

**G. Support Documents** Please submit the following support documents along with this form. *Please note: documents to support items 1 – 3 below must be submitted before a project can be routed for review.*

1. Proposal/Award documents, which are required *to be submitted for non-USAMRDC supported projects:*

[ ]  Proposal

[ ]  Current Statement of Work

[ ]  Name and contact information for Program Manager:

2. Detailed description of how cadavers will be used:

[ ]  Full protocol, test plan, or program of instruction

3. Information about the source of cadavers:

[ ]  Supplier details (e.g. documentation of any required licenses, etc.)

[ ]  Supplier’s template body/specimen donation form(s)

[ ]  When applicable, any supplemental information provided to donors (e.g., brochures, FAQs)

4. Institutional review documents:

[ ]  Institutional approval memoranda, as applicable per local requirements. Please note that a memo from an Institutional Review Board Office stating that the project is “research not involving human subjects” is not sufficient documentation of institutional approval.

[ ]  Command approval memorandum if the project is DoD-conducted

[ ]  If no institutional body oversees cadaver use, provide written documentation from a department chair or comparable that the project team has met all local requirements to conduct the Army-supported cadaver project

[ ]  If available, scientific review or other independent assessment that the use of cadavers is necessary and justified

5. Standard Operating Procedures:

[ ]  Applicable Standard Operating Procedures that address requirements detailed in Army Policy if not otherwise addressed in the project description (e.g., specimen transportation, biosafety, etc.)

6. Additional requirements *for sensitive uses of cadavers only*:

[ ]  Applicable Standard Operating Procedures that address the Army’s requirements for sensitive uses of human cadavers if not otherwise addressed

[ ]  Draft Strategic Communication Summary