SECRETARY OF THE ARMY
WASHINGTON

05 NOV 2019

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation, Education, or Training

1. References:

a. Revised Uniform Anatomical Gift Act (UAGA), drafted by National Conference of Commissioners of Uniform State Laws, 2006.

b. Laws or regulations applicable to states and U.S. territories that govern the use and/or transportation of cadavers.

2. The Army is committed to the dignified and respectful treatment of human cadavers used in Research, Development, Testing and Evaluation (RDT&E), education, and/or training activities. The procurement, inventory, use, storage, security, transportation, and disposition of cadavers used for RDT&E, education, or training activities, conducted or supported by the Army, must be implemented safely, respectfully, and in compliance with legal, public health, and ethical standards.

3. All Army organizations supporting or conducting RDT&E, education, or training activities involving cadavers will comply with the requirements of the enclosed policy. The proponent for this policy is the Commanding General (CG), U.S. Army Medical Research and Development Command (USAMRDC), Fort Detrick, Maryland. Requests for revisions and exceptions to this policy will be submitted for approval to the CG, USAMRDC.

4. Point of contact for this policy is the Director, Headquarters USAMRDC Office of Research Protections (FCMR-RP), 504 Scott St, Fort Detrick, MD 21702, 301-619-7802 (DSN: 343), usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil.

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DISTRIBUTION:
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SUBJECT: Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation, Education, or Training

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Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation (RDT&E), Education, or Training

1. References:

a. Revised Uniform Anatomical Gift Act (UAGA), drafted by National Conference of Commissioners of Uniform State Laws, 2006.

b. Laws or regulations applicable to states and U.S. territories that govern the use and/or transportation of cadavers.

2. Applicability and Scope: The enclosed policy applies to all uses of human cadavers in Department of the Army (DA)-conducted or supported Research, Development, Test, Evaluation (RDT&E), education, or training activities. This policy does not apply to other therapeutic uses of cadavers (e.g., for organ donation, tissue transplantation, or other medical therapy) that are regulated by the U.S. Food and Drug Administration and subject to other federal laws and regulations.

3. Purpose: The Army is committed to the ethical use of human cadavers in RDT&E, education, or training. This policy establishes the requirements that must be met for DA organizations to conduct or support activities involving the use of human cadavers in RDT&E, education, or training.

4. Proponent: The proponent of this policy is the Commanding General (CG), U.S. Army Medical Research and Development Command (USAMRDC). The Action Office for this policy is the Headquarters (HQ) USAMRDC Office of Research Protections (ORP).

5. Definitions:

a. The term "cadaver" means a deceased person or portion thereof, and is synonymous with the terms "human cadaver" and "post-mortem human subject" or "PMHS." The term includes organs, tissue, eyes, bones, arteries or other specimens obtained from an individual upon or after death. The term "cadaver" does not include portions of an individual person, such as organs, tissue or blood, that were removed while the individual was alive (for example, if a living person donated tissue for use in future research protocols, that tissue is not considered a "cadaver" under this policy, regardless of whether the donor is living or deceased at the time of tissue use).

b. The term "DA-conducted" means DA personnel are the primary personnel performing the RDT&E, education or training activities. The DA-conducted activity can occur at a DA or non-DA location.

c. The term "DA-supported" means the DA is providing at least some of the resources for the activity. Resources may include but are not limited to funding, facilities, equipment or personnel. In these situations the RDT&E, education, or training activities are primarily performed by non-DA personnel.

d. The term “sensitive uses” of cadavers means RDT&E, education, or training activities that involve exposing cadavers to impacts, blasts, ballistics testing, crash testing and other destructive forces.

6. Responsibilities:

a. CG, Army Futures Command (AFC).

(1) Informs the Deputy Under Secretary of the Army; Vice Chief of Staff of the Army; Chief of Public Affairs (CPA); and Chief of Legislative Liaison (CLL); The Surgeon General (TSG); and other affected HQDA Principal Officials of planned sensitive uses of cadavers in DA-conducted or DA-supported RDT&E, education, or training in advance of their implementation.

(2) Informs Army leaders of major problems related to the use of cadavers in DA-conducted or DA-supported RDT&E, education, or training, as appropriate. Major problems may include issues related to the procurement, use and/or disposition of cadavers.

(3) Distributes the annual summary of cadaver use in DA-conducted and DA-supported RDT&E education, or training to TSG, CPA and CLL.

b. CG, USAMRDC.

(1) May approve exceptions or waivers to this policy consistent with the controlling laws and regulations.

(2) Forwards notifications received from HQ USAMRDC ORP of proposed sensitive uses of cadavers to CG, AFC in accordance with (IAW) this policy.

(3) Reviews and approves DA-conducted or DA-supported RDT&E, education or training activities involving sensitive uses of cadavers.

(4) Notifies CG, AFC regarding problems related to the procurement, inventory, use, storage, transfer, transportation and disposition of cadavers IAW this policy.

(5) Submits annual summary of activities covered by this policy to CG, AFC.

c. Director, HQ USAMRDC ORP.

(1) Reviews and recommends approval of DA-conducted or DA-supported RDT&E, education or training activities involving sensitive uses of cadavers to CG, USAMRDC.

(2) Notifies CG, USAMRDC of proposed sensitive uses of cadavers using the Strategic Communication (STRATCOM) Summary Outline provided in Appendix A.

(3) Notifies CG, USAMRDC of problems related to the procurement, inventory, use, storage, transfer, transportation and disposition of cadavers IAW this policy;

(4) Ensures that DA organizations that conduct RDT&E, education or training involving cadavers implement the applicable requirements outlined in this policy.

(5) Implements a program of active compliance oversight of DA-conducted and/or DA-supported RDT&E, education or training that involves sensitive use of cadavers. Annually, HQ USAMRDC will conduct a minimum of two intra- or post-completion audits of DA-conducted or DA-supported RDT&E, education, or training activities that involve the sensitive use of cadavers to assess adherence to approved research and/or testing plans. Provides audit results to CG, USAMRDC, DA, and civilian organizations audited.

d. Commanders/Directors/Heads of DA Organizations conducting or supporting RDT&E, education, or training activities involving the use of cadavers.

(1) Ensure that the organization has policies and processes as required under Paragraph 7.a. of this policy.

(2) Approve all RDT&E, education, or training activities involving cadavers prior to implementation.

(3) Ensure that activities involving sensitive uses of cadavers comply with the requirements described in Paragraphs 7.c. and 7.d. and are submitted to HQ USAMRDC ORP for review and approval.

(4) Notify HQ USAMRDC ORP if there are problems related to the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers IAW this policy that occur during the conduct of DA-conducted or DA-supported RDT&E, education, or training activities using the format provided in Appendix B.

e. Principal Investigators, Test Directors, Instructors, and other individuals responsible for a DA-conducted or DA-supported RDT&E, education or training activity covered by this policy.

(1) Design, obtain review and approval of, and conduct activities IAW their approved plans and this policy.

(2) Report problems encountered in the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers used for RDT&E, education, or training to the DA organization supporting the activity.

7. Policy: The procurement, inventory, use, storage, security, transportation, and disposition of cadavers used for RDT&E, education, or training must be conducted safely, respectfully, and in compliance with legal, public health, and ethical standards.

a. Required institutional policies. All DA organizations conducting RDT&E, education, or training activities involving cadavers must have policies and procedures governing cadaver use that adhere to this Army policy and applicable federal and state laws and regulations. These policies and procedures must address, at a minimum, the following:

(1) Allowable cadaver use. Policies must specify the scope of DA-conducted or DA-supported RDT&E, education, or training cadaver use permitted at or by the organization. The process for obtaining organizational review and approval of each activity involving the use of cadavers must be described.

(2) Procurement. Cadavers must be properly and legally procured. Suppliers must be licensed/certified if and as required by applicable law. The point of contact for acquisition and receipt of cadavers must be identified.

(3) Transportation and transfer. Transportation of cadavers must comply with applicable state and local laws and regulations. Organizations must ensure that cadavers are properly packaged and labeled prior to and during transport.

(4) Security. Cadavers must be stored in a secure location. Access to cadavers must be limited to only authorized personnel.

(5) Storage. Cadaver storage must be appropriate (e.g., temperature-controlled environment, suitable containment apparatus). Facilities and storage conditions must meet all applicable laws and regulations.

(6) Record-keeping. Inventories of cadavers and their location, movement, and use must be tracked from the time of arrival at the DA organization until their final disposition, including during transfer between investigators and other institutions. Records related to the activity (e.g., approved protocol, test plan, or other governing document; financial transactions; and approval documents) must be maintained for six years after conclusion of the activity and may be subject to audit.

(7) Disposition. Disposal of cadavers must be in a manner consistent with donor intent and legal requirements. Legal and regulatory requirements related to the handling of hazardous chemicals and biohazardous waste must be met, if and as applicable.

b. No procurement activities involving cadavers, whether DA-conducted or DA-supported, may occur in states that have not enacted laws at least as stringent as the UAGA.

c. Review and approval of activities involving cadavers. The Commander/Director, or Head of a DA organization conducting or supporting RDT&E, education, or training activities involving cadavers, or his/her designee, must review and approve all activities IAW this policy prior to implementation. Approval may only be granted if the following criteria are satisfied:

(1) The use of human cadavers is necessary. Cadavers will not be used if alternative models (e.g., manikins, simulators, etc.) are available and sufficient for the intended purpose. The benefits of the activity must be significant enough to justify the use of cadavers.

(2) Use of the cadavers is consistent with donor intent. To assist in determination of donor intent, and ensuring use is consistent with donor intent, the

Principal Investigator (PI), Test Director, or Instructor (or other individual responsible for the conduct of the RDT&E, education, or training) will provide copies of relevant sample cadaver donation form(s) and any supplemental information provided to donors (e.g., brochures). The donation forms will be evaluated to determine if donors would have had a reasonable expectation that their bodies could be used for activities consistent with the contemplated use. If it is clear that a donor prohibited the contemplated use, then the donor's cadaver will not be used.

(3) Protocols, test plans, programs of instruction or other governing documents describing the intended RDT&E, education, or training activity must include activity-specific procedures for the treatment, storage and disposition of cadavers. For example, the documents should describe provisions for transportation of cadavers to the activity site; security of cadavers and if/how access to cadavers is limited to only those personnel with a need for access; and provisions for security related to the activity (e.g., limited access to the activity location).

(4) Cadavers are properly and legally procured. Suppliers are licensed/certified if and as required by applicable law.

(5) Cadavers are tested for at least Hepatitis B and HIV and any other communicable diseases as required by state law and institutional policy. The PI, Test Director, Instructor or other responsible individual will provide relevant information about the results of testing for communicable diseases to the DA organization's Commander/Director or Head. The documentation must indicate whether tests were positive for any cadaver, and if so, for what diseases. The use of cadavers that test positive for a communicable disease is not expressly prohibited; cadavers harboring a communicable disease may or may not be appropriate for the intended activity. All personnel who may come in contact with a cadaver that tested positive for a communicable disease must be made aware of the positive test result and any necessary precautions to prevent disease transmission. If the PI, Test Director or Instructor believes that testing is impossible or unnecessary for a given protocol, a justification must be provided.

d. Additional requirements for approval of sensitive uses of cadavers in RDT&E, education, or training. Exposures of cadavers to impacts, blasts, ballistics testing, crash testing and other destructive activities are distinct from more conventional RDT&E, education, or training uses. The need to honor donors' wishes for use(s) of donated bodies, and the often high-profile nature of such projects, necessitate additional criteria for approval. All DA-conducted or supported RDT&E, education, or training activities

that involve sensitive uses of cadavers must be reviewed and approved by the HQ USAMRDC ORP prior to implementation.

(1) Research protocols, test plans, or programs of instruction accompanied by a one-page STRATCOM (see Appendix A) summary must be submitted to the Director, HQ USAMRDC ORP at least sixty (60) days in advance of the proposed start date of the activity involving sensitive uses of cadavers. The HQ USAMRDC ORP will review the submitted materials and provide a written approval within forty-five (45) days if it is determined that the requirements outlined in Paragraph 7.c (1-5) and the following additional requirements have been met:

(a) To be considered acceptable, the donation forms will be evaluated to determine if donors would have had a reasonable expectation that their bodies could be used for military testing or research that involves sensitive uses. If it is clear that a donor prohibited the contemplated use, then the donor's cadaver will not be used. The donor language may describe only applicable specific sensitive uses or may be generic. An example of acceptable generic donor consent language is:

"I understand that my body may be used for education, research, or the advancement of medical science and healthcare. In some cases such research and/or testing may involve exposures to destructive forces, e.g., impacts, crashes, ballistic injuries, blasts. Examples of how the gift might be used include medical education and training, forensic pathology, vehicle safety or the development of protective equipment (e.g., military, law enforcement, sports)."

(b) The RDT&E, education, or training should be designed so as to minimize the potential for psychological harm to participating staff and other personnel due to the nature of the work with human cadavers (e.g., limiting access to and visibility of the RDT&E, appropriate training of personnel and ensuring proper and respectful disposition of cadaver remains at the activities' conclusion).

(c) The PI, Test Director or Instructor must inform personnel who will be involved in the RDT&E, education, or training activities of the intended cadaver use(s). The PI should consider concerns or objections of the personnel, if any, involved in the work and exclude personnel without prejudice from the activity where appropriate.

(d) Referrals for mental health care should be available if personnel seek such care because of their involvement in the RDT&E, education or training.

(2) After HQ USAMRDC ORP recommends approval of the activity to the CG, USAMRDC, the HQ USAMRDC ORP will forward the STRATCOM summary prepared by the DA organization conducting or supporting the activity to the CG, USAMRDC for further notification to CG, AFC. The CG, USAMRDC may approve the activity fifteen (15) days after submission of the STRATCOM to the CG, AFC unless objections are received from senior leaders during the staffing period.

e. The organizations performing the DA-supported activities must follow all applicable laws, regulations, and institutional policies/procedures related to cadaver procurement, inventory, use, storage, security, transfer, transportation, record-keeping and disposition of cadavers. To ensure compliance, the HQ USAMRDC ORP and the DA organization supporting the activity may review copies of relevant laboratory/ institution policies and/or conduct on-site assessments.

f. The organizations performing the DA-conducted or supported RDT&E, education, or training activity must adhere to the approved protocol, test plan, programs of instruction or other governing documents. The Commander/Director/Head granting approval, the HQ USAMRDC ORP, or designees, must be permitted to observe the activity and/or audit activity records to ensure compliance with the approved protocol or applicable regulatory requirements.

g. Problems related to the conduct of RDT&E, education, or training involving the use of cadavers must be reported promptly to the Commander/Director/Head of the DA organization conducting or supporting the activity. These may include, but are not limited to, problems involving the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers. Examples of problems include but are not limited to: loss of confidentiality of cadaveric donors, breach of security, significant deviation from the approved protocol, failure to comply with state laws and/or institutional policies, and public relations issues. The Commander/Director/Head must report to the Director, HQ USAMRDC ORP (See Appendix B), and should consult with the Public Affairs, legal office, and/or next higher Command level, as appropriate. The HQ USAMRDC ORP will report the problem to the CG, USAMRDC and CG, AFC.

h. Reporting.

(1) DA organizations conducting or supporting RDT&E, education, or training activities regulated by this policy must provide an annual summary of all activities conducted or supported during the calendar year to Director, HQ USAMRDC ORP (see Appendix C). Annual reports will be submitted to the Director, HQ USAMRDC ORP by 30 January of the following calendar year and include: title of the RDT&E, education or

training activity; date the activity was conducted; identification of the DA organization's responsible individual (e.g., Principal Investigator or individual primarily responsible for providing support); a brief description of the use(s) of cadavers in the activity; and a brief description of the DA organization's involvement in the activity.

(2) The Director, HQ USAMRDC ORP will prepare an annual summary of information reported by DA organizations that conduct or support RDT&E, education or training. This report will be submitted to the CG, USAMRDC and CG, AFC.

8. Waivers. The DA organization supporting or conducting an activity involving cadavers may request a waiver of this policy or a portion thereof. The request must include a written justification for the waiver and explanation of expected activity outcomes. All waiver requests must be endorsed by the supporting or conducting DA organization's senior legal officer and Commander/Director or Head. Endorsed waiver requests will be forwarded through the DA organization's higher headquarters to the CG, USAMRDC.

9. Requests for revisions and exceptions to this policy will be submitted for approval to the CG, USAMRDC.

10. Point of contact for this policy is the Director, HQ USAMRDC ORP (FCMR-RP), 504 Scott St, Fort Detrick, MD 21702, 301-619-7802 (DSN: 343), usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil.

APPENDIX A
STRATEGIC COMMUNICATION SUMMARY

MEMORANDUM FOR Director, Headquarters, U.S. Army Medical Research and Development Command, Office of Research Protections, 504 Scott St, Fort Detrick, MD 21702

SUBJECT: Strategic Communication Summary – Upcoming Department of Army (DA)-supported or conducted RDT&E, education or training (specify one) activity that will involve exposing human cadavers to impacts, blasts, ballistics testing, crash testing and other destructive forces

1. Purpose: The purpose of this memorandum is to inform the U.S. Army leadership of an upcoming Department of Army (DA) supported or conducted RDT&E, education or training (specify which one) activity that will involve the sensitive use of human cadavers.

2. Background.

a. Briefly describe mission of the DA organization conducting or supporting the RDT&E, education or training activity that will involve the sensitive use of human cadavers.

b. Briefly describe the DA program and nature of support RDT&E, education or training activity that will involve the sensitive use of human cadavers.

(1) What

(2) Who

(3) When

(4) Where

4. Talking Points (3-5 overall key messages about the RDT&E, education or training activity).

5. Questions and Answers (state anticipated questions you may receive from media or external audiences and provide answers).

6. Points of contact (communication, PI, etc.).

APPENDIX B
PROBLEM REPORT

MEMORANDUM FOR Director, Headquarters, U.S. Army Medical Research and Development Command, Office of Research Protections, 504 Scott St, Fort Detrick, MD 21702

SUBJECT: Problem Report – Use of cadavers in Department of Army (DA) supported or conducted RDT&E, education or training (specify which one) activity

1. Purpose: The purpose of this memorandum is to inform the Director, HQ, USAMRDC ORP of a problem related to the conduct of approved RDT&E, education or training (specify which one) involving human cadavers. This problem may include, but is not limited to, the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers.

2. Background.

a. Provide information about the DA program and nature of the supported RDT&E, education or training activity that experienced the problem. Include factual details about the program or specific activity such as title, assigned log number, location of the program or activity and local point of contact.

b. Describe the problem. Include the chronology of events, pertinent facts contributing to the problem, and the current status of the RDT&E, education or training activity (e.g., the activity is on hold, ongoing or completed).

c. Explain the actions taken as a result of the problem. Include a description of actions taken to address, correct, or resolve the problem, and any future actions that will be taken to prevent the problem from recurring.

3. Points of contact (communication, PI, etc.).

APPENDIX C

ANNUAL SUMMARY REPORT
Army Supported or Conducted Activity Involving Cadavers

In accordance with the Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation (RDT&E), Education, or Training, annual summary reports of Department of the Army-conducted and/or supported activities involving cadavers must be submitted to the Headquarters, US Army Medical Research and Development Command, Office of Research Protections at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil. Summary reports for a calendar year must be sent no later than 30 January of the following calendar year.

Name of Army Institution:
Name and Contact Information of Individual Providing Report:
Date of Report:

Date Activity was Approved	Date(s) Activity was Conducted	Project Title	Brief Description of the Cadaver Use(s) in the Activity	Type, Number, and Source of Specimens Used	Local Point of Contact for the Activity	Nature of Involvement in the Activity (select all applicable)
						☐ Conducting ☐ Supporting: ☐ Training ☐ Graduate Medical Education ☐ RDT&E
						☐ Conducting ☐ Supporting: ☐ Training ☐ Graduate Medical Education ☐ RDT&E
						☐ Conducting ☐ Supporting: ☐ Training ☐ Graduate Medical Education ☐ RDT&E