



DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
503 ROBERT GRANT AVENUE
SILVER SPRING, MD 20910-7500

REPLY TO
ATTENTION OF

MCMR-UWZ-C

3 January 2013

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: WRAIR Policy 13-01, Use of Human Cadavers for Research, Development, Test and Evaluation, Education, or Training

1. References:

- a. Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation, Education, or Training (dated 20 April 2012).
- b. Revised Uniform Anatomical Gift Act (UAGA), drafted by National Conference of Commissioners of Uniform State Laws, 2006.

2. History: This is the first version of this Walter Reed Army Institute of Research (WRAIR) policy. This version of the policy will remain in effect until amended or rescinded.

3. Purpose: The WRAIR 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 WRAIR and its detachments, must be implemented safely, respectfully, and in compliance with legal, public health, and ethical standards. This policy establishes the requirements that must be met for WRAIR staff to conduct or support activities involving the use of human cadavers in RDT&E, education, or training.

4. Applicability and Scope: The enclosed policy applies to all uses of human cadavers at the WRAIR and/or its detachments, in which WRAIR conducts or supports 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 (FDA) and subject to other federal laws and regulations.

5. Definitions:

- a. "Cadaver": 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. "Cadaver Use Panel": An ad hoc panel chosen by the WRAIR Commander to review the sensitive uses of cadavers. This panel is charged with reviewing the request prior to approval and determining compliance with requirements in this policy and the Army cadaver policy. Minimally, this panel will contain members from SESC, HSPB, and USAMRMC ORP.

c. "Conducted": WRAIR personnel are the primary personnel performing the RDT&E, education or training activities. The WRAIR-conducted activity can occur at a WRAIR or non-WRAIR location.

d. "Supported": the WRAIR 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-WRAIR personnel.

e. "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. The WRAIR Commander (or his/her designee):

(1) Ensures that WRAIR will conduct RDT&E, education or training involving cadavers as outlined in this policy. Implements a program of active compliance oversight of WRAIR conducted/supported RDT&E, education or training that involves sensitive use of cadavers. Annually, sends a report to the U.S. Army Medical Research and Materiel

(2) Command (USAMRMC) Office of Research Protections (ORP) with regard to cadaver uses. To assist in this compliance activity, the HSPB/SESC will be responsible for requesting information on an annual basis from the Science Branches/Detachments and compiling this information for the Commander. Science Branch Directors/Detachment Commanders are responsible for capturing and sending this information to the HSPB/SESC by prescribed deadlines.

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

(4) Ensures that activities involving sensitive uses of cadavers comply with the requirements set forth in this policy and are submitted to USAMRMC ORP for prospective review and approval.

(5) Notifies HQ USAMRMC 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 WRAIR conducted or supported RDT&E, education, or training activities. (See Appendix D for report format.)

b. Branch Directors:

(1) Review and endorse all RDT&E activities involving the use of human cadavers for their respective Branch.

(2) Ensure that all Branch protocol submissions for activities involving human cadavers possess the scientific merit to justify their use and that no alternative models are available and sufficient for the intended purpose.

(3) Ensure that all Branch personnel involved with activities performing and/or supporting human cadaver RDT&E comply with this policy.

(4) Ensure that an appropriate Principal Investigator (PI), or Instructor (or other individual responsible for the conduct of the RDT&E, education, or training) with the appropriate knowledge and experience has been assigned to perform the functions, as determined by the WRAIR Commander.

(5) For sensitive use, ensure that study personnel fully understand that their personal involvement with activities associated with human cadaver research. Objections to participation should be discussed with the supervisor of the activity and efforts should be made to ensure that the PI considers concerns or objections of the personnel involved in the work and he/she excludes personnel without prejudice from the activity, where appropriate. (See Appendix G- Participation Form)

(6) Ensure that all contracts, grants, collaborative agreements, etc. involving the use of human cadavers shall comply with Office of Research Technology Applications (ORTA) and Resources Management (RM) requirements.

(7) Science Branch Directors/Detachment Commanders are responsible for capturing and sending information on cadaveric uses to the HSPB/SESC by prescribed deadlines.

c. Principal Investigators, Instructors, and other individuals responsible for a WRAIR-conducted/supported RDT&E, education or training activity covered by this policy:

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(1) Begin with a verbal concept discussion with Human Subjects Protection Branch (HSPB) or Science Education and Strategic Communication (SESC).

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

(3) Complete Appendix A, Request for Use of Human Cadavers for Medical Research/Education/Training, obtain required signatures, and forward a copy of the completed form to the HSPB or SESC for review and approval prior to implementation. (For education/training uses, please contact SESC; for research uses, please contact HSPB.)

(4) If a sensitive use, complete Appendices B & C.

(5) Maintain all documentation in support of the ethical use of human cadavers and provide information to Branch Directors with regard to status of these projects.

(6) Report problems encountered in the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers used for RDT&E, education, or training to the WRAIR Commander, and the HSPB or SESC. Note that the forms provided in Appendix D of this policy must be used for reporting.

(7) Responsible for all aspects of the research project, including the coordination of and documentation of procurement, inventory, use, storage, security, transportation, and disposition of cadavers. This includes the development and maintenance of SOPs for these activities.

(8) Read the current Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation (RDT&E), Education or Training published by the Secretary of the Army.

(9) Provide annual project status updates to the HSPB/SESC (see Appendix F).

(10) Retain records for 6 years following the close-out of the project.

d. The HSPB/SESC will:

(1) Forward RDT&E, education or training activities involving the sensitive use of cadavers to the HQ USAMRMC ORP for review and approval.

(2) Review records concerning state and local laws regarding the use of human cadavers, and consult with the HQ USAMRMC legal representative on questions related to whether and how legal requirements are met. Research will only be forwarded for

approval to the Commander, WRAIR if state and local laws regarding human cadavers are being followed.

- (3) Serve on the Cadaver Use Panel, as needed.
- (4) Assist in verifying that the proposed use of the cadaver is consistent with the donor's intent based on review of donation forms/process.
- (5) Verify all required documents (e.g., communicable testing certification, willed donor documents) are provided with the protocol packet.
- (6) Maintain files and a record of all RDT&E, education and training activities involving the use of cadavers and provide an annual report to the WRAIR Commander at the end of each calendar year.
- (7) For Sensitive Uses, ensure the protocol or Request for Use of Human Cadavers for Medical Education/Training addresses the likelihood of psychological harm to research staff and other personnel due to the nature of the work with human cadavers in the activity, and assure that procedures are in place to minimize the possibility of such harm.
- (8) Assure that all applicable documents are present and provide documentation to the Investigator that the RDT&E, education or training activity is approved.
- (9) Prepare WRAIR Commander approval letter for implementation of cadaver activity.
- (10) Ensure the annual summary of all activities conducted or supported during the calendar year is reported to the Director, HQ USAMRMC ORP by 30 January of the following year as outlined in Section 6.a.(5).

8. 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. Requirements:

- (1) Allowable cadaver use. The use of cadavers will be reviewed on a case-by-case basis. The process for obtaining review and approval of each activity involving the use of cadavers is described below.
- (2) Procurement. Cadavers must be properly and legally procured. Suppliers must be licensed/certified if and as required by applicable law. The Individual PIs will serve as point of contact for acquisition and receipt of cadavers. This includes verifying

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licensure of the contracting organization/vendor for this procurement, when appropriate per state law of local country requirements. (If clarification is needed as to state requirements, the USAMRMC Judge Advocate Office should be contacted prior to procurement. If clarification is needed, please coordinate with local partners and/or the U.S. Embassy.)

Note: Laws or regulations applicable to states and U.S. territories that govern the use and/or transportation of cadavers must also be met.

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

(3) Transportation and transfer. Transportation of cadavers must comply with applicable state and local laws and regulations. WRAIR staff must ensure that cadavers are properly packaged and labeled prior to and during transport. This includes verifying licensure of the contracting organization/vendor for this procurement, when appropriate per state law of local country requirements. (If clarification is needed as to state requirements, the USAMRMC Judge Advocate Office should be contacted prior to procurement. If clarification is needed as to in-country requirements, please coordinate with local partner organizations and/or the U.S. Embassy.)

(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 WRAIR or its detachments 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 by the WRAIR PI (or WRAIR point of contact) 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. Review and endorsement by the Branch Directors. The Branch Director will evaluate the proposed project and will provide endorsement by signing the request form if or when 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) The PI or personnel from within the branch who will conduct the activity have the appropriate training, knowledge, and experience, as determined by the Branch Director and Commander, WRAIR (for sensitive uses).

(3) The terms of applicable contracts, grants, collaborative agreements, etc. involving the use of human cadavers complies with ORTA and RM requirements.

c. Review and approval of activities by the cadaver use panel. The panel will review the request and the endorsement by the Branch Director. Representatives will document their review and will forward the review findings to the Commander, WRAIR with a recommendation for approval (or approval contingent on approval by the USAMRMC ORP for all 'sensitive uses' of cadavers) if or when the following criteria are satisfied:

(1) Procedures for the procurement, transportation and transfer, security, storage, record-keeping and disposition of cadavers must be provided either in the Request for Use of Human Cadavers for Medical Research/Education/Training (Appendix A) or Human Cadaver (Sensitive Use) Protocol Template (Appendix B) or as stand-alone documents (e.g., SOPs). The procedures must be compliant with section 8a of this policy. Note: that SOPs will need to be generated on a project basis by the department/branch/detachment.

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

(4) 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, Instructor or other responsible individual will provide relevant information about the results of testing for communicable diseases along with the Request for Use of Human Cadavers for Medical Research/Education/Training (Appendix A) or Human Cadaver

(Sensitive Use) Protocol Template (Appendix B). 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 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 USAMRMC ORP prior to implementation. Activities that meet the definition of 'sensitive uses' of cadavers and that have been found to be compliant with this policy's sections 8b and 8c will be forwarded to the USAMRMC ORP for approval prior to implementation. The USAMRMC ORP will evaluate the proposed activity and will approve the project if or when the following criteria are satisfied:

(1) 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)."

(2) 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).

(3) For sensitive uses, the PI 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.

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

(5) After USAMRMC ORP approves the activity, USAMRMC ORP will forward the STRATCOM summary prepared by WRAIR to the Commanding General (CG), USAMRMC for further notification to TSG. The WRAIR may implement the activity fifteen (15) days after USAMRMC ORP approval and submission to the CG, USAMRMC unless objections are communicated to the USAMRMC ORP, WRAIR Commander or PI/Instructor.

e. The WRAIR Commander (or his/her designee), USAMRMC 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.

f. Problems related to the conduct of RDT&E, education, or training involving the use of cadavers must be reported promptly to the Commander. 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 (or his/her designee) must report to the Director, USAMRMC ORP, and should consult with the Public Affairs, and/or MRMC legal office, as appropriate. The USAMRMC ORP will report the problem to the CG, USAMRMC and TSG.

g. Reporting: The WRAIR must provide an annual summary of all activities conducted or supported during the calendar year to Director, USAMRMC ORP (see Appendix E). Annual reports will be submitted to the Director, USAMRMC 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.

9. Waivers: WRAIR Personnel 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 Commander, WRAIR and USAMRMC Judy Advocate Office. Endorsed waiver requests will be forwarded to the CG, USAMRMC for review/approval.

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10. Points of contact for this policy are the Director, Human Subjects Protection Branch, at (301) 319-9940, and the Director, Science Education and Strategic Communication.

Signature on file at HSPB

Distribution A & B

RALPH L. ERICKSON
COL, MC
Commanding

ENCLS

Appendix A- Request for Use of Human Cadavers for Medical Research, Education, or Training Activity

Appendix B- Sensitive Uses Protocol Template

Appendix C- Strategic Communication Summary for Sensitive Uses of Cadavers

Appendix D- Problem Report – Use of cadavers in WRAIR supported (or conducted) RDT&E, education, or training activity

Appendix E- Annual Summary Report for WRAIR Supported or Conducted Activities Involving Cadavers

Appendix F- Annual Report Format for Cadaver Use

Appendix G- Information Form

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APPENDIX A: Request for Use of Human Cadavers for Medical Research/Education/Training

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Date

MEMORANDUM THRU Director, Human Subjects Protection Branch, Walter Reed Army Institute of Research (WRAIR), 503 Robert Grant Ave., Silver Spring, MD 20910

Director, Science Education and Strategic Communication, Walter Reed Army Institute of Research (WRAIR), 503 Robert Grant Ave., Silver Spring, MD 20910

FOR Director, Headquarters, U.S. Army Medical Research and Materiel Command, Office of Research Protections, 504 Scott St, Fort Detrick, MD 21702 (ATTN: Dr. Sarah Donahue)

SUBJECT: Request for Use of Human Cadavers for Medical Research/Education/Training

1. Title of Project:

2. Name of Requestor/Principal Investigator:

Include: Department, Organization, Telephone/Cell#, Email Address:

3. Purpose of Request:

Background/Significance:

Objective/Hypothesis:

4. No. of Cadavers:

Duration of Use:

Cadaver Delivery Date:

Proposed Procedure/Training Lab Date:

Cadaver Disposition Date:

5. Military Relevance: (And, Medical Relevance, if Training/Education):

6. Source of Cadavers: (Specify from Where The Cadavers/Specimens Will Be Obtained)

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7. Study Design/Methods:

8. References/Bibliography

9. Describe Method of Transportation (This can be described provided SOPs or explicitly detailed in section. This is also the case for following sections: storage, security and disposition methods)

10. Describe Storage

11. Describe Security

12. Describe Disposition

13. Point of Contact:

Signature Block of PI

Signature Block of Branch Director or Overseas Commander

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APPENDIX B: Human Cadaver (Sensitive Use) Protocol Template
(If Sensitive use: full protocol is needed)

PROTOCOL TITLE:

PROTOCOL NUMBER: XX-XXX

PERSONNEL INVOLVED:

A. PRINCIPAL INVESTIGATOR:

B. ASSOCIATE INVESTIGATOR(S):

1.

2.

3.

LOCATION OF STUDY:

DURATION OF STUDY:

A. Expected Start Date:

B. Expected Completion Date:

RESEARCH PLAN:

A. PURPOSE:

B. HYPOTHESIS:

BACKGROUND:

MILITARY RELEVANCE:

MEDICAL RELEVANCE:

DESIGN:

REVIEW OF LITERATURE:

A. Date of Search:

B. Period Searched:

C. Sources Searched:

D. Key Words of Search

E. Results of Search:

CADAVER PROTECTION AND OTHER ISSUES

A. Procurement of the Cadavers: *Cadaveric specimens will be obtained from an authorized vendor and in accordance with state and local laws. The suppliers or vendors will be informed in writing of the intended use of the cadavers. Any restrictions requested by the donor on the use of the cadaver will be honored. Documentation that the cadavers have been tested for HIV, Hepatitis B or other communicable diseases will be included with the protocol. Applicable portions of the state law concerning procurement, storage or disposition of the cadavers will be provided with the protocol.*

B. Storage of the Cadavers: *The cadaveric specimens will be handled with dignity at all times during the research and during transportation to and from the Morgue and kept secure in the Morgue when not being used for the research study. The cadavers will be appropriately stored and refrigerated at XX when not being used, and transported to the research work area with dignity. This may also be described in SOPs, which are to be provided as appendices to this document.*

C. Method of Transportation: *Describe how the cadavers will be transported to and from the site where the activity will be conducted. This may also be described in SOPs, which are to be provided as appendices to this document.*

D. Disposition of the Cadavers: *Describe if cadavers will be returned, stored, gifted, etc. This may also be described in SOPs, which are to be provided as appendices to this document.*

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E. Benefits:

F. Risks:

G. Information for Research Staff: *Research staff members will be given a document describing the research to be conducted on cadaveric specimens. Supervisors should work with research staff to ensure they understand their roles and responsibilities prior to assisting with this cadaveric study.*

H. Confidentiality and Security: *Describe how the confidentiality of cadaveric donors will be maintained, the procedures that will be used to ensure security of the cadavers/specimens:*

DATA ANALYSIS: *Consult with statistician as needed.*

CASE REPORTING FORM/DATA COLLECTION SHEET (if any):

REFERENCES:

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APPENDIX C
STRATEGIC COMMUNICATION SUMMARY

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Date

MEMORANDUM THRU Director, Human Subjects Protection Branch, Walter Reed Army Institute of Research (WRAIR), 503 Robert Grant Ave., Silver Spring, MD 20910

Director, Science Education and Strategic Communication, Walter Reed Army Institute of Research (WRAIR), 503 Robert Grant Ave., Silver Spring, MD 20910

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

SUBJECT: Strategic Communication Summary for Sensitive Uses of Cadavers—Upcoming WRAIR 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 Walter Reed Army Institute of Research 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

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

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

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

Signature Block of PI

Signature Block of Branch Director or Overseas Commander

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APPENDIX D
PROBLEM REPORT

MEMORANDUM FOR Director, Headquarters, U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), 504 Scott St, Fort Detrick, MD 21702

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

1. Purpose: The purpose of this memorandum is to inform the Director, USAMRMC 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 WRAIR 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.).

Signature Block of PI

Signature of Director/Overseas Commander

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APPENDIX E

**ANNUAL SUMMARY REPORT
WRAIR 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 Materiel Command, Office of Research Protections at HRPO@amedd.army.mil. Summary reports for a calendar year must be sent no later than 30 January of the following calendar year.

Organization Submitting Report: Walter Reed Army Institute of Research Report Date: _____
Name of Person Providing Report: _____ Email of Person Providing Report: _____

Date(s) Activity was Conducted	Title of the Activity	Brief Description of the Cadaver Use(s) in the Activity	Local Point of Contact for the Activity	Nature of Involvement in the Activity
1				<input type="checkbox"/> Conducting <input type="checkbox"/> Supporting:
2				<input type="checkbox"/> Conducting <input type="checkbox"/> Supporting:
3				<input type="checkbox"/> Conducting <input type="checkbox"/> Supporting:
4				<input type="checkbox"/> Conducting <input type="checkbox"/> Supporting:
5				<input type="checkbox"/> Conducting <input type="checkbox"/> Supporting:
6				<input type="checkbox"/> Conducting <input type="checkbox"/> Supporting:
7				<input type="checkbox"/> Conducting <input type="checkbox"/> Supporting:
8				<input type="checkbox"/> Conducting <input type="checkbox"/> Supporting:
9				<input type="checkbox"/> Conducting <input type="checkbox"/> Supporting:
10				<input type="checkbox"/> Conducting <input type="checkbox"/> Supporting:
11				<input type="checkbox"/> Conducting <input type="checkbox"/> Supporting:
12				<input type="checkbox"/> Conducting <input type="checkbox"/> Supporting:

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SUBJECT: WRAIR Policy 13-01, Use of Human Cadavers for Research, Development, Test and Evaluation, Education, or Training

APPENDIX F- ANNUAL REPORT FOR CADAVER USE
For The Period XX XXX XX to XX XXX XX

PROTOCOL #: C-XX **DATE OF APPROVAL: XX XXX XX**

TITLE OF PROTOCOL:

PRINCIPAL INVESTIGATOR:

OBJECTIVE/HYPOTHESIS:

PROTOCOL STATUS:

- Active (experiments, data gathering ongoing)
- Closed (experiments complete; data analysis ongoing)
- Terminated (study has been terminated prior to completion of research)

NUMBER OF CADAVERS/CADAVERIC PARTS (Type) USED TO DATE:

CHANGES TO THE PROTOCOL:

PROBLEMS: This problem may include, but is not limited to, the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers.

SUMMARY OF RESULTS TO DATE:

PROJECT PERSONNEL LISTING:

MCMR-UWZ-C

SUBJECT: WRAIR Policy 13-01, Use of Human Cadavers for Research, Development, Test and Evaluation, Education, or Training

NAME	DATE

ABSTRACTS/PRESENTATIONS/PUBLICATIONS:

CERTIFICATION OF THE PRINCIPAL INVESTIGATOR: I understand the requirements of applicable research regulations, and the WRAIR policies for conducting research. I further certify that all personnel associated with this project will continue to conduct the project in full compliance with the aforementioned requirements

Principal Investigator Signature

Date

MCMR-UWZ-C

SUBJECT: WRAIR Policy 13-01, Use of Human Cadavers for Research, Development, Test and Evaluation, Education, or Training

APPENDIX G
INFORMATION FORM

Protocol Title and Date: _____

I have read and understand the protocol referenced above and will comply with the provisions of the protocol and the WRAIR Cadaver Use Policy 12-31. I understand that the research to be performed involves the use of human cadavers and that the following conditions of this research apply to my individual participation:

1. I have been informed of the planned activities that will involve the use of human cadavers and have let my supervisor know of any concerns or objections I have based on this information
2. I understand that the cadavers that I may come in contact with as part of this research have been tested for at least HIV and Hepatitis B and potentially other communicable diseases, and I have been informed of results of any cadavers/specimens testing positive.
3. Mental health care will be made available in the event that I wish to seek it; seeking care will bring neither prejudice nor reprisal.
4. I am personally committed to the respectful use of human cadavers, consistent with the donor's intent and operational SOP(s), without deviation.
5. I shall report all problems as they relate to the respectful use of human cadavers. Problems may include but are not limited to the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers.

I certify that I understand my rights and will comply with donor's intent, this protocol, and the WRAIR Policy for Use of Human Cadavers for Research, Development, Test, and Evaluation (RDT&E).

Print Name

Signature

Date