

**A.** This award is made under the authority of 31 U.S.C. 6304 and 10 U.S.C. 2358. The recipient's statement of work on page \_\_\_ and the budget on page(s) \_\_\_ of the proposal dated \_\_\_\_\_ are incorporated herein by reference. **GOVERNMENT INTERACTION (NOV 2000) (USAMRAA).** The active participants in this award are the U.S. Army Medical Research and Materiel Command (USAMRMC) and its laboratories identified herein through the U.S. Army Medical Research Acquisition Activity (USAMRAA). The following USAMRMC Laboratory will be the focus of cooperative research conducted under this agreement:

**B. ACCEPTANCE OF AWARD:** The recipient is not required to countersign this assistance award. In case of disagreement, the recipient shall notify the Grants Officer and not assess the grant any costs until such disagreement(s) is resolved.

**C. TERMS AND CONDITIONS:** The recipient agrees to the General Terms and Conditions of the Federal Demonstration Partnership, Phase IV, dated October 1, 2002 and Department of Army - Agency Specific Requirements. Modifications to the General Terms and Conditions dated 1 October 2002 are modified as indicated below. If an article is not listed, there are no changes to that article.

#### **1. ARTICLE 6. PATENTS AND INVENTIONS**

a. The recipient shall use the Interagency Edison through the National Institutes of Health Commons (<http://www.iedison.gov>) for filing of Patent Application and Invention Disclosure. Negative reports are required and shall be submitted on a DD Form 882 to the Grants Officer. DD Form 882 can be located at <http://www.usamraa.army.mil/pages/Regulatory/MasterList.htm>.

b. Invention reports are due annually and at the end of the period of the award. Annual reports are due 30 days after the anniversary date of the award and final reports are due 30 days after the expiration of the award. The award will NOT be closed out until all invention reporting requirements are met.

#### **2. ARTICLE 8. REPORTING REQUIREMENTS**

##### RESEARCH TECHNICAL REPORTING

##### **Format Requirements for Annual/Final Reports**

a. Annual reports must provide a complete summary of the research accomplishments to date with respect to the **approved** Statement of Work. Journal articles **can be** substituted for detailed descriptions of specific aspects of the research, but the original articles **must** be attached to the report as an appendix and appropriately referenced in the text. The importance of the report to decisions relating to continued support of the research can not be over-emphasized. A report shall be submitted within 30 calendar days of the anniversary date of the award (a final report will be submitted upon completion of the research (last year of the award)).

b. A final report summarizing the entire research effort, citing data in the annual reports and appended publications shall be submitted at the end of the award performance period. The final report will provide a complete reporting of the research findings. Journal publications **can be** substituted for detailed descriptions of specific aspects of the research, but an original copy of each publication **must** be attached as an appendix and appropriately referenced in the text. All final reports must include a bibliography of all publications and meeting abstracts and a list of personnel (not salaries) receiving pay from the research effort.

c. Although there is no page limitation for the reports, each report shall be of sufficient length to provide a thorough description of the

accomplishments with respect to the approved Statement of Work. Submission of an original and two copies of the report are required. Reports shall be forwarded to:

Commander  
U.S. Army Medical Research and Materiel Command  
ATTN: MCMR-RMI-S  
504 Scott Street  
Fort Detrick, Maryland 21702-5012

d. All reports **shall** have the following elements in this order: front cover, Standard Form (SF 298), table of contents, introduction, body, key research accomplishments, reportable outcomes, conclusions, references, and appendices. Pages shall be consecutively numbered throughout the report. **DO NOT RENUMBER PAGES IN THE APPENDICES BUT DO INCLUDE THE APPENDICES IN THE PAGE COUNT IN BLOCK 15 ON THE SF 298.** Mark all pages of the report which contain proprietary or unpublished data that should be protected. **DO NOT USE THE WORD "CONFIDENTIAL" WHEN MARKING DOCUMENTS.** Indicate in your letter accompanying the report that the report contains proprietary or unpublished data, and that the distribution statement should indicate the limitations of the report.

FRONT COVER: Sample front cover provided at <https://mrmc.detrick.army.mil/rrptechrep.asp>. The Accession Document (AD) Number should remain blank.

STANDARD FORM 298: Sample SF 298 provided at <https://mrmc.detrick.army.mil/rrptechrep.asp>. The abstract in Block 13 **must** state the purpose, scope, major findings and be an **up-to-date** report of the progress in terms of results and significance. Subject terms are keywords that may have previously assigned to the proposal abstract or are keywords that may be significant to the research. The number of pages shall include all pages that have printed data (including the front cover, SF 298, table of contents, and all appendices). Please count pages carefully to ensure legibility and that there are no missing pages as this delays processing of reports. **Page numbers should be typed: please do not hand number pages.**

TABLE OF CONTENTS: Sample table of contents provided at <https://mrmc.detrick.army.mil/rrptechrep.asp>.

INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

BODY: This section of the report shall describe the research accomplishments associated with each task outlined in the **approved** Statement of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Appended publications and/or presentations **may** be substituted for detailed descriptions but **must** be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text may be embedded in the text or appended. Figures and graphs can also be referenced in the text and appended to a publication. Recommended changes or future work to better address the research topic may also be included, although changes to the original Statement of Work **must** be approved by the Grants Officer. This approval must be obtained prior to initiating any change to the original Statement of Work.

KEY RESEARCH ACCOMPLISHMENTS: Bulleted list of key research accomplishments emanating from this research.

REPORTABLE OUTCOMES: Provide a list of reportable outcomes that have resulted from this research to include:

manuscripts, abstracts, presentations; patents and licenses applied for and/or issued; degrees obtained that are supported by this award; development of cell lines, tissue or serum repositories; infomatics such as databases and animal models, etc.; funding applied for based on work supported by this award; employment or research opportunities applied for and/or received based on experience/training supported by this award.

CONCLUSIONS: Summarize the results to include the Importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the report.

REFERENCES: List all references pertinent to the report using a standard journal format (i.e. format used in *Science*, *Military Medicine*, etc.).

APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

BINDING: Because all reports are entered into the Department of Defense Technical Reports database collection and are microfiched, it is recommended that all reports be bound by stapling the pages together in the upper left hand corner. All original reports shall be legible and contain original photos/illustrations. Figures shall include figure legends and be clearly marked with figure numbers.

## TRAINING REPORTING REQUIREMENTS

### Annual Summary

An original and two copies of a 2-5 page annual summary, presenting a description of the training and research accomplishments to date, shall be submitted within 30 calendar days after the anniversary date of the award to:

Commander  
U.S. Army Medical Research and Materiel Command  
ATTN: MCMR-RMI-S  
504 Scott Street  
Fort Detrick, Maryland 21702-5012

The content of the report should address the training and research accomplishments associated with the tasks outlined in the **approved** Statement of Work. Any technical or unexpected difficulties encountered and/or any deviations from the original Statement of Work should be addressed. Journal articles **can be** substituted for detailed descriptions of specific aspects of the research/training, but the original articles **must** be attached to the report as an appendix and appropriately referenced in the text.

The report shall contain a cover, Standard Form (SF 298) and table of contents (refer to samples provided at <https://mrmc.detrick.army.mil/rrpotechrep.asp>).

The content **must** include:

- 1) a bulleted list of key accomplishments;
- 2) a list of reportable outcomes that have resulted from this award to include:

manuscripts, abstracts, presentations; patents and licenses applied for and/or issued; degrees obtained that are supported by this award; development of cell lines, tissue or serum repositories; infomatics such as databases and animal models, etc.; funding applied for based on work supported by this award; employment or research opportunities applied for and/or received based on experience/training supported by this award.

#### Manuscripts/Reprints, Abstracts

A copy of manuscripts or subsequent reprints resulting from the research shall be submitted to the USAMRMC. An extended abstract suitable for publication in the Proceedings of the Breast Cancer Research Program is required in relation to a DOD BCRP meeting planned during the term of this award. The extended abstract shall (1) identify the accomplishments since award and (2) follow instructions to be prepared by the USAMRMC and promulgated at a later date. The extended abstract style will be dependent on the discipline.

#### *SELECT ONE OF THE FOLLOWING "PAYMENTS" CLAUSES*

### **3. ARTICLE 10. PAYMENTS ADVANCE PAYMENTS AND INCREMENTAL FUNDING**

- a. Payments. Advance payments will be made to the recipient.
- b. Electronic Funds Transfer. All advance payments to the recipient will be made by electronic funds transfer (EFT). The recipient shall contact the Defense Finance and Accounting System (DFAS) named on the face page of this award to make arrangements for EFT. Failure to do so may result in nonpayment.
- c. It is estimated that the total cost to the Government for the full performance of this award shall be \$\_\_\_\_\_. There have been funds allotted for payment of allowable costs incurred in the performance of this award in the amount of \$\_\_\_\_\_. It is estimated that such funded amount shall be sufficient to cover allowable expenses until additional funds are provided for this award. Subject to the availability of funds, it is estimated that additional funds will be provided by modification in accordance with the following incremental schedule:

\$	On or about 200_
\$	On or about 200_
\$	On or about 200_

- d. Payments under this award will be made to the recipient in accordance with the schedule outlined below. If the recipient fails to perform, the Grants Officer shall notify DFAS in writing to withhold payments.

- e. Advance Payment Schedule:

Year One \$\_\_\_\_\_

<u>Amount</u>	<u>On or About</u>
\$ _____	Upon execution of this award
\$ _____	(Enter DAY/MONTH/YEAR)
\$ _____	(Enter DAY/MONTH/YEAR)
\$ _____	(Enter DAY/MONTH/YEAR)

Year Two \$ \_\_\_\_\_

<u>Amount</u>	<u>On or About</u>
\$ _____	(Enter DAY/MONTH/YEAR)

Year Three \$ \_\_\_\_\_

<u>Amount</u>	<u>On or About</u>
\$ _____	(Enter DAY/MONTH/YEAR)

Year Four \$ \_\_\_\_\_

<u>Amount</u>	<u>On or About</u>
\$ _____	(Enter DAY/MONTH/YEAR)

f. Interest Bearing Account. The recipient shall deposit all advance payments in an interest bearing account. Interest over the amount of \$250 per year shall be remitted annually to the Department of Health and Human Services, Payment Management System, P.O. Box 6021, Rockville, MD 20852. A copy of the transmittal letter stating the amount of interest remitted shall be sent to the U.S. Army Medical Research Acquisition Activity, ATTN: MCMR-AAA-\_\_\_, 820 Chandler Street, Fort Detrick, MD 21702-5014.

**ADVANCE PAYMENTS AND FULL FUNDING**

a. Payments. Advance payments will be made to the recipient.

b. Electronic Funds Transfer. All advanced payments to the recipient shall be made by electronic funds transfer (EFT). The recipient shall contact the Defense Finance and Accounting System (DFAS) named on the face page of this award to make arrangements for EFT. Failure to do so may result in nonpayment.

c. If the recipient fails to perform, the Grants Officer shall notify DFAS in writing to withhold payments.

d. Advance Payment Schedule

Year One \$ \_\_\_\_\_

Amount

On or About

\$ \_\_\_\_\_

Upon execution of this award

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

Year Two \$ \_\_\_\_\_

Amount

On or About

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

Year Three \$ \_\_\_\_\_

Amount

On or About

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

Year Four \$ \_\_\_\_\_

Amount

On or About

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

\$ \_\_\_\_\_

(Enter DAY/MONTH/YEAR)

e. Interest Bearing Account. The recipient shall deposit all advance payments in an interest bearing account. Interest over the amount of \$250 per year shall be remitted annually to the Department of Health and Human Services, Payment Management System, P.O. Box 6021, Rockville, MD 20852. A copy of the transmittal letter stating the amount of interest remitted shall be sent to the U.S. Army Medical Research Acquisition Activity, ATTN: MCMR-AAA-\_\_\_, 820 Chandler Street, Fort Detrick, MD 21702-5014.

**COST REIMBURSEMENT PAYMENTS AND INCREMENTAL FUNDING**

a. Payments. Payments under this award shall be made to the recipient on a cost reimbursement basis. The recipient shall submit one original Standard Form 270, Request for Advance or Reimbursement (form available at <http://www.usamraa.army.mil/pages/Regulatory/MasterList.htm>), monthly, but not less frequently than quarterly, to:

U.S. Army Medical Research Acquisition Activity  
ATTN: MCMR-AAA-\_\_\_  
820 Chandler Street  
Fort Detrick MD 21702-5014

No payment will be made if the recipient fails to submit the required form. Failure to invoice at least quarterly may result in delay of payment and may be cause for termination of the grant.

b. Electronic Funds Transfer. All payments to the recipient will be made by electronic funds transfer (EFT). The recipient shall contact the Defense Finance and Accounting System (DFAS) named on the face page of this award to make arrangements for EFT. Failure to do so may result in nonpayment.

c. It is estimated that the total cost to the Government for the full performance of this award shall be \$\_\_\_\_\_. There have been funds allotted for payment of allowable costs incurred in the performance of this award in the amount of \$\_\_\_\_\_. It is estimated that such funded amount shall be sufficient to cover allowable expenses until additional funds are provided for this award. Subject to the availability of funds, it is estimated that additional funds will be provided by modification in accordance with the following incremental schedule:

\$	On or about 200_
\$	On or about 200_
\$	On or about 200_

#### **COST REIMBURSEMENT PAYMENTS AND FULL FUNDING**

a. Payments. Payments under this award shall be made to the recipient on a cost reimbursement basis. The recipient shall submit one original Standard Form 270, Request for Advance or Reimbursement (form available at <http://www.usamraa.army.mil/pages/Regulatory/MasterList.htm>), monthly, but not less frequently than quarterly, to:

U.S. Army Medical Research Acquisition Activity  
ATTN: MCMR-AAA-\_\_\_\_  
820 Chandler Street  
Fort Detrick MD 21702-5014

No payment will be made if the recipient fails to submit the required form. Failure to invoice at least quarterly may result in delay of payment and may be cause for termination of the grant.

b. Electronic Funds Transfer. All payments to the recipient will be made by electronic funds transfer (EFT). The recipient shall contact the Defense Finance and Accounting System (DFAS) named on the face page of this award to make arrangements for EFT. Failure to do so may result in nonpayment.

#### **4. ARTICLE 12. USE OF HUMAN SUBJECTS**

a. The recipient or its subrecipients, are authorized to conduct research under this award involving humans as research subjects for the following protocols:

Protocols not identified are not approved.

b. Recipients and subrecipients are required to submit documentation of IRB review of protocols and consent forms from each of the funded institutions. Research at funded institutions may not begin until the U.S. Army Surgeon General's Human Subjects Research Review Board (HSRRB) approves the protocol and consent form for that site. Review by the HSRRB is separate

from, and in addition to, review by any other IRB. Recipients will be notified in writing of HSRRB approval or disapproval.

c. Recipients and subrecipients who enroll additional unfunded institutions are responsible to ensure that the institute conducts research in accordance with 45 CFR 46 and other applicable federal and state regulations. Prior to inclusion of any unfunded institution's participation under this award, the recipient is responsible to notify the Grants Officer.

d. Volunteer Registry Data Sheet (USAMRDC Form 60-R). In accordance with the "Use of Human Subjects" provision above, the Volunteer Registry Data Sheet, USAMRDC Form 60-R (form available at <http://www.usamraa.army.mil/pages/Regulatory/MasterList.htm>) is to be completed at the time the subject consents to participate and is entered into the study. The form shall be submitted to the Commander, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, MD 21702-5012 upon completion of the research project or upon expiration/termination of the award, whichever occurs first.

e. Unless the research has been ruled exempt from the requirements of the Federal Common Rule (32 CFR 219) by the HSRRB, the local IRB is required to conduct continuing review of the recipient's research at least annually, or more often if the local IRB deems it necessary, in accordance with the Federal Common Rule. Pursuant to Office for Human Research Protections guidance, recipients must submit the following to the local IRB for continuing review: a protocol summary and status report on the progress of the research, including (1) the number of subjects accrued; (2) a description of any adverse events or unanticipated problems involving risks to subjects or other and of any withdrawal of subjects from the research or complaints about the research; (3) a summary of any recent literature, findings obtained thus far, amendments or modifications to the research since the last review, reports on multi-center trials and any other relevant information, especially information about risks associated with the research; and (4) a copy of the current informed consent document. Recipients are required to submit all continuing review reports, and the final report approved by the local IRB, to the HSRRB within seven working days of each review. Submissions to the HSRRB should be sent to: Commander, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, MD 21702-5012. Submissions may also be faxed to: 301-619-7803 (ATTN: MCMR-RCQ-HR).

f. The recipient must submit any proposed modifications or amendments to the protocol or consent form to both the local IRB and the HSRRB for review and approval. A change of the Principal Investigator is considered to be a modification of the protocol. Research pursuant to such modifications or amendments may not be initiated without IRB and HSRRB approval except when necessary to eliminate apparent immediate hazards to the subject(s).

g. Single Project Assurance. The recipient's Single Project Assurance, dated \_\_\_\_\_, is incorporated by reference and is assigned number \_\_\_\_\_.

## **5. ARTICLE 13. USE OF LABORATORY ANIMALS**

a. The recipient or its subrecipients, are authorized to conduct research under this award involving animals as research subjects for the following protocols:

**Protocols not identified are not approved.**

b. ANIMAL WELFARE

(1) For those facilities that are required to do so by federal law, the recipient shall register its research facility with the Secretary of Agriculture in accordance with 7 U.S.C. 2136 and 9 CFR, Subchapter A, Part 2, Subpart C, and Section 2.30.

(2) The recipient shall acquire regulated animals only from dealers licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR, Subchapter A, Part 2, Subpart A, Sections 2.1 through 2.11, or from sources that are exempt from licensing under those sections.

(3) The recipient agrees that the care and use of animals will conform with the pertinent laws of the United States and regulations of the Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1 through 4), and that the research will adhere to the principles set forth in the Guide for Care and Use of Laboratory Animals, National Research Council, 1996.

(4) The Grants Officer may immediately suspend, in whole or in part, work and further payments under this award for failure to comply with the requirements of paragraphs (1) through (3) of this clause.

(a) The suspension will stay in effect until the recipient complies with the requirements.

(b) Failure to complete corrective action within the time specified by the Grants Officer may result in termination of this award and removal of the recipient's name from the list of facilities approved for funding.

(5) The recipient may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), for the region in which its research facility is located. The location of the appropriate APHIS regional office, as well as information concerning this program may be obtained by contacting the Senior Staff Officer, Animal Care Staff, USDA/APHIS, Animal Care, 4700 River Road, Unit 84, Riverdale, MD 20737-1234 (Phone number 301-734-4981 or email ace@usda.gov).

(6) The recipient shall include this clause, including this paragraph (6), in all subcontracts/subawards involving research of live vertebrate animals.

c. POST-AWARD OVERSIGHT OF THE USE OF LABORATORY ANIMALS

Post-award oversight of the use of laboratory animals shall be the responsibility of the recipient's Animal Care and Use Committee (ACUC). The Principal Investigator will notify the Grants Officer in writing of any significant changes to the proposed use of animals which was the basis for award. These changes must be approved by the recipient's ACUC and the USAMRMC. In addition, the ACUC shall immediately notify the Grants Officer of any violations of law, or regulation involving animal care, or of changes in the facility's accreditation status by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC)

d. Animal Use Reporting

(1) The recipient shall annually prepare and electronically submit the U.S. Army Medical Research and Materiel Command Animal Use Report detailing the use of animals in the research and development sponsored by the Army. The web site containing information for electronic submission of this

report may be found at  
<http://www.usamraa.army.mil/pages/Regulatory/MasterList.htm>.

(2) A letter with additional instructions concerning use of the electronic web site will be mailed at the end of the fiscal year. The reporting period shall be each Federal Fiscal Year, i.e., 01 October through 30 September, and the report shall be electronically received by the U. S. Army Medical Research and Materiel Command no later than 1 December of that year.

(3) For agreements with expiration dates prior to 30 September, instructions for submission of the final animal use report may be found at <http://www.usamraa.army.mil/pages/Regulatory/MasterList.htm>.

(4) The recipient shall also furnish a copy of the most recent USDA Inspection Report. This report can be submitted via fax or mail to:

Commander  
U.S. Army Medical Research & Materiel Command  
ATTN: MCMR-RCQ-AR  
504 Scott Street  
Fort Detrick MD 21702-5012  
FAX: (301) 619-4165

(5) The recipient is responsible for ensuring that a separate U.S. Army Medical Research and Materiel Command Animal Use Report and USDA Inspection Report be submitted for any subcontract/subaward facility.

## **5. ARTICLE 13. USE OF LABORATORY ANIMALS**

a. The recipient or its subrecipients, are authorized to conduct research under this award involving animals as research subjects for the following protocols:

### **Protocols not identified are not approved.**

#### **b. USE OF LABORATORY ANIMALS (OCONUS)**

All laws, customs, and practices of the country in which the research is to be conducted shall be complied with insofar as use of laboratory animals is concerned. In those instances where the local laws and regulations are in conflict with the laws and regulations of the United States and the Department of Agriculture, the more humane and stringent will be followed. The following U.S. standards and regulations for the protection, treatment, and use of animals should be adhered to where practicable: 7 U.S. Code 2131 et. seq. and 9 Code of Federal Regulations, Subchapter A, Parts 1 - 4, and that research will adhere to the principles set forth in the Guide for Care and Use of Laboratory Animals, National Research Council, 1996.

#### **c. POST-AWARD OVERSIGHT OF THE USE OF LABORATORY ANIMALS**

Post-award oversight of the use of laboratory animals shall be the responsibility of the recipient's Animal Care and Use Committee (ACUC). The Principal Investigator will notify the Grants Officer in writing of any significant changes to the proposed use of animals which was the basis for award. These changes must be approved by the recipient's ACUC and the USAMRMC. In addition, the ACUC shall immediately notify the Grants Officer of any violations of law or regulations involving animal care, or of changes in the facility's accreditation status by the Association for the Assessment and Accreditation of Laboratory Animal care, International (AAALAC).

d. ANIMAL USE REPORTING

(1) The recipient shall annually prepare and electronically submit the U.S. Army Medical Research and Materiel Command Animal Use Report detailing the use of animals in the research and development sponsored by the Army. The web site containing information for the electronic submission of this report may be found at <http://www.usamraa.army.mil/pages/Regulatory/MasterList.htm>.

(2) A letter with additional instructions concerning use of the electronic web site will be mailed at the end of the fiscal year. The reporting period shall be each Federal Fiscal Year, i.e., 01 October through 30 September, and the report shall be electronically received by the U. S. Army Medical Research and Materiel Command no later than 1 December of that year.

(3) For agreements with expiration dates prior to 30 September, instructions for submission of the final animal use report may be found at <http://www.usamraa.army.mil/pages/Regulatory/MasterList.htm>.

(4) The recipient is responsible for ensuring that a separate U.S. Army Medical Research and Materiel Command Animal Use Report be submitted for any subcontract facility.

**6. ARTICLE 14. USE OF HUMAN ANATOMICAL SUBSTANCES USE OF HUMAN ANATOMICAL SUBSTANCES**

a. The recipient, or its subrecipients, are authorized to conduct research under this award involving human anatomical substances for the following protocols:

**Protocols not identified are not approved.**

b. Any anatomical substance (organs, tissues, or tissue fluids) linked by identifiers to a particular person and used for research under this award shall be donated for the purpose of research or investigation. The donor shall be the person from whom the substance is removed or, in the event of death or legal disability of the person from whom the substance is removed, the next of kin or legal representative of such person. Donation shall be made by written consent and shall relinquish all ownership and/or rights to the substance. All human anatomical substances used in research under this award shall be lawfully acquired. It should be noted that a general autopsy consent form or a consent to perform surgery, in and of themselves, may not be adequate. If excised or autopsy tissue is to be used, the protocol shall include a copy of the consent form used to obtain the tissue.