CRADA COVER SHEET

Action: New Agreement
Agreement Type: Master CRADA

[NOTE: This Cover Sheet is for internal management purposes only. It is not part of the Agreement & neither party is bound to anything contained in it]

Title: Master Cooperative Research and Development Agreement among US Army Medical Command, Leonard Wood Institute, and Phelps County Regional Medical Center

Effective Date:	1/13/2017	**Expiration Date:**	1/12/2027
MRMC Control No:	MC-17-0131	**DA Control No:**	
MTF:	GLWACH – General Leonard Wood Army Community Hospital	**Lab Field:**	
Concurrence obtained from appropriate IRB and AHRPO (if needed):			N/A
Concurrence obtained from US Trade Rep (if "YES" then concurrence must be attached):			N/A
Keywords:	Traumatic brain injury	mTBI	neurotrauma

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	Office Symbol:	MCMR-RPC	**DTIC Source Code:**	427365
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Lab's Legal Counsel:	Commander, US Army Medical Research and Materiel Command ATTN: MCMR-JA (Technology Transfer Legal Staff) 810 Schreider Street, Fort Detrick, MD 21702-5012 **Phone:** 301-619-2065; **FAX:** 301-619-5034			
	Legal Reviewer:	Mr. Robert Charles		

Partner's Technical POC:	Mr. Kent Thomas			
	Executive Director, Leonard Wood Institute			
	197 Replacement Ave.			
	Ft. Leonard Wood	MO		65473
	Entity Status:	Non-profit	**DTIC Source Code:**	
	Phone:	573-329-8502	**FAX:**	
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	DoD Status:	Traditional (Collaboration with DoD in the past 3 years)		
Partner's Technical POC:	Mr. Barry White			
	Phelps County Regional Medical Center			
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	Rolla	MO		65401
	Entity Status:	Educational	**DTIC Source Code:**	
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CRADA COVER SHEET

	Email Address:	bsw3006@gmail.com		
	DoD Status:	Non-Traditional (No collaboration with DoD in the past 3 years)		

Summary:

This 3-party master CRADA is designed to encompass multiple projects related to mTBI through the Acute Effects of Neurotrauma Consortium (AENC), a collaboration that includes multiple universities in the Ft. Leonard Wood area for which Phelps County Regional Medical Center (PCRMC) provides administrative support. This master CRADA may also encompass projects related to other topic areas or involving other consortia supported by PCRMC.

MASTER COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
AMONG
CLINICAL AND TRANSLATIONAL RESEARCH PROGRAM OFFICE
U.S. ARMY MEDICAL COMMAND
AND
LEONARD WOOD INSTITUTE
197 Replacement Avenue
Ft. Leonard Wood, MO 65473
AND
PHELPS COUNTY REGIONAL MEDICAL CENTER
1000 West 10th Street
Rolla, MO 65401

The Clinical and Translational Research Program Office, U.S. Army Medical Command (hereinafter "Federal Laboratory"), Leonard Wood Institute (hereinafter “LWI”), and Phelps Country Regional Medical Center (hereinafter "Collaborating Party") enter into this Master Cooperative Research and Development Agreement (CRADA) No. _____ for performing the medical Research, Development, Testing, and/or Evaluation (RDTE) work described in the Statement of Work (SOW) attached hereto as an Appendix, and agree as follows:

Article 1
General

1.1. Authority. This Master CRADA is entered into pursuant to the Stevenson-Wydler Technology Innovation Act of 1980 as amended by the Federal Technology Transfer Act (Title 15, United States Code (U.S.C.) §§3701 et seq.), which permits directors of Federal laboratories to enter into cooperative research and development agreements and intellectual property licenses for intellectual property owned by or assigned to the United States Government. This is not a procurement contract, grant, or cooperative agreement as those terms are used in 31 U.S.C. §§6303, 6304, and 6305.

1.2. Entire Agreement. This Master CRADA includes the attached SOW (Appendix) and together they constitute a single, entire document hereinafter referred to as the "Agreement."

1.3. Purpose. The purpose of this Agreement is to expedite the transfer of federal technology from the Federal Laboratory to the private sector (represented by the Collaborating Party) through the sharing of resources and information towards the successful completion of the RDTE project (the "Study"). The medical objective of the Study is described in the SOW.

1.4. Statement of Work. The RDTE project, which is described in the SOW, will be conducted under a clinical research protocol which has been reviewed by the appropriate Institutional Review Board in accordance with Army Regulation 40-38, Clinical Investigation. The SOW incorporates all of the terms and provisions of these Articles by reference. In cases of apparent conflict between the terms and provisions of the SOW and these Articles, the terms and provisions of the Articles shall control. In the case of a Master CRADA, the SOW will be independent of any other SOW executed under the Master CRADA.

1.5. Consideration. The Federal Laboratory, LWI, and the Collaborating Party agree that they are entering into this Agreement for the mutual benefit of each Party. The Federal Laboratory, LWI, and the Collaborating Party will cooperate in support of the clinical investigation protocol specified in the SOW. The RDTE project entered into under this Agreement will benefit the Federal Laboratory by providing valuable research experience for the Principal Investigator and medical residents involved and by providing valuable access to new drugs and medical devices for the medical treatment of Army patients. In addition, patients involved in the RDTE project may benefit directly from the medical treatment received and all medical patients will potentially benefit from the knowledge gained as a result of the RDTE project. LWI will benefit by developing technologies and services that meet Army or DoD capability requirements and that help to sustain Ft. Leonard Wood, key components of LWI’s mission as a nonprofit research center. The Collaborating Party will also benefit from promoting research collaboration among participating members of local research consortia for which the Collaborating Party provides administration and leadership and serves as the legal entity.

1.6. Principal Investigator. The RDTE project conducted under the SOW will be supervised by a Principal Investigator named therein. The Principal Investigator may be changed for good cause by written notification to the other Party(ies).
1.7. LWI Representative. The person signing this Agreement on behalf of LWI represents that he or she has the authority to bind LWI to the terms of this Agreement and the execution and

delivery of this Agreement does not contravene any material provision of, or constitute a material default under, any material agreement binding on LWI or any valid order of any court, any regulatory agency, or other body having authority to which LWI is subject.

1.8. Collaborating Party Representative. The person signing this Agreement on behalf of the Collaborating Party represents that he or she has the authority to bind the Collaborating Party to the terms of this Agreement and the execution and delivery of this Agreement does not contravene any material provision of, or constitute a material default under, any material agreement binding on the Collaborating Party or any valid order of any court, any regulatory agency, or other body having authority to which the Collaborating Party is subject.

Article 2
Definitions

2.1. "Agreement" refers to the entire CRADA including the SOW.

2.2. "Adverse Drug Experience" means an adverse event as defined under 21 C.F.R. §310.305, Records and Reports Concerning Adverse Drug Experience, and other applicable Federal Regulations.

2.3. "Background inventions" mean inventions other than subject inventions.

2.4. "Clinical Brochure" means a document containing all the relevant information about a drug, including animal screening, preclinical toxicology, and detailed pharmaceutical data. Also included, if available, is a summary of current knowledge about pharmacology, mechanism of action, and a full description of the clinical toxicities.

2.5. "Collaborating Party" means the person(s), intermediary(ies), or entity(ies), including healthcare facilities providing administrative support and leadership for research consortia facilitating a research project pursuant to this Agreement.

2.6. "Computer software" or "software" means computer programs, source code, source code listings, object code listings, designs, details, algorithms, processes, flow charts, formulae, and related

material that would enable the software to be reproduced, recreated, or recompiled. Computer software does not include computer databases or computer software documentation.

2.7. "FDA" means the Food and Drug Administration, Department of Health and Human Services.

2.8. "Federal Laboratory" means the Clinical and Translational Research Program Office, U.S. Army Medical Command, Fort Sam Houston, TX (formerly the Clinical Investigation Regulatory Office, Ft. Detrick, MD), which has been designated by the Secretary of Army as a Federal laboratory.

2.9. "Government" means the United States of America and the agencies thereof.

2.10. "Government purpose" means any activity in which the Government is a Party, including cooperative agreements with international or multinational defense organizations, or sales or transfers by the Government to foreign governments or international organizations, and competitive procurements. Government purpose does not include for commercial purposes.

2.11. "Invention" means any invention or discovery which is or may be patentable or otherwise protected under Title 35 of the United States Code or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. §§2321 et seq.).

2.12. "Made" when used in conjunction with any invention means the conception or first actual reduction to practice of such invention.

2.13. "Party" or "Parties" refers to the Federal Laboratory, LWI, the Intermediary, or the Collaborating Party or all (in singular or plural usage as indicated by the context).

2.14. "Principal Investigator" means an individual who actually conducts a clinical investigation (i.e. under whose immediate direction a drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the Principal Investigator is the responsible leader of the team. "Subinvestigator" includes any other individual member of that team (21 C.F.R. §312.3).

2.15. "Proprietary information" means information which embodies trade secrets or which is confidential technical, business, or financial information provided that such information:

a. is not generally known, or is not available from other sources without obligations concerning its confidentiality;

b. has not been made available by the owners to others without obligation concerning its confidentiality;

c. is not described in an issued patent or a published copyrighted work or is not otherwise available to the public without obligation concerning its confidentiality;

d. can be withheld from disclosure under 15 U.S.C. §3710a(c)(7)(A)&(B) and the Freedom of Information Act, 5 U.S.C. §552 et seq; and

e. is identified as such by labels or markings designating the information as proprietary.

2.16. "Raw Data" means the primary quantitative and empirical data first collected by the intramural and extramural investigators from experiments and clinical trials conducted under the scope of this Agreement.

2.17. "Subject data" means any technical data first produced in the performance of work under this Agreement.

2.18. "Subject invention" means any invention conceived or first actually reduced to practice in the performance of work under this Agreement.

2.19. "Technical data" means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation and databases). The term does not include computer software or data incidental to the administration of this Agreement, such as financial or management information.

2.20. "Master CRADA" means an agreement incorporating Articles 1 - 27, which forms the basis for repetitive cooperative research and development agreements among the same parties upon the subsequent execution of a SOW.

Article 3

Cooperative Research

3.1. Review of Work. Periodic conferences may be held among the Parties for the purpose of reviewing the progress of the cooperative effort. It is understood that the nature of this cooperative effort is such that completion within the period of performance specified or within the resources allotted cannot be guaranteed. Accordingly, it is agreed that all cooperative research and development activities performed by all Parties are to be performed on a best efforts basis.

3.2. Changes. If at any time the Principal Investigator, a Collaborating Party, or the Federal Laboratory determines that the research data dictates a substantial change in the direction of the work, he or she shall promptly notify the Parties, and the Parties shall make a good faith effort to agree to any necessary changes to the SOW consistent with the basic scope of research.

3.3. Assignment of Personnel. If the SOW contemplates the assignment of one Party's personnel to the other Party's facilities, then the employees shall remain employees of the assigning Party and will not be considered as employees of the other Party for any purpose, including but not limited to any requirements to provide workers' compensation, payment of salary or other benefits, or withholding of taxes. Assigned personnel will observe the other Party's security, safety, health, and environmental facility regulations. Assigned personnel can be denied access or removed by the other Party from its facilities at its discretion. LWI personnel assigned to a Federal Laboratory will work under the direction of the Principal Investigator only. That direction will be limited to matters within the scope of the actual research and will not extend to any matters that are normally encompassed by the employer-employee relationship. For example, LWI is responsible for determining the working hours of its assigned personnel.

Article 4
Reports

4.1. Progress Reports. As provided in the SOW, the Parties will prepare and exchange written reports, in a timely manner, on the progress of their work, results obtained, problems encountered, and recommendations for further research and development. To the

extent reasonable, further detail concerning the contents of the reports shall be provided upon request, if necessary for the other Party to fully understand the results achieved. At a minimum, the Principal Investigator will submit annual progress reports to the Parties.

4.2. Final Report. As provided in the SOW, the Parties will prepare and exchange a final report at the completion of the cooperative effort performed under this Agreement, on the progress of their work, results obtained, problems encountered, and recommendations for further research and development. To the extent reasonable, further detail concerning the contents of the report(s) shall be provided upon request if necessary for the other Party to fully understand the results achieved.

4.3. Adverse Drug Experiences, Annual Reports, Other Investigational New Drug Data. The Principal Investigator will provide the Parties with copies of all adverse drug experience reports. The Principal Investigator shall establish and maintain records and make reports to the FDA for the following Adverse Drug Experiences: (1) all serious, unexpected adverse drug experiences, (2) any significant increase in the frequency of serious unexpected adverse drug experiences, and (3) any significant increase in the frequency of therapeutic failure.

Article 5
Transfer of Funds

5.1. Payment Schedule. The payment schedule, described in the SOW, is subject to modification by mutual consent of all Parties in the event unforeseen circumstances arise which delay initiation of this project, including delays due to insufficient volunteer enrollment, actions from responsible review or regulatory authorities, lack of equipment, malfunctions, or insufficient support personnel. In the event of cancellation or termination of a research project, the Collaborating Party shall not be responsible for payments beyond such cancellation or termination date except for payments which have accrued prior to said date and as yet remain unpaid. The U.S. Government shall not reimburse the Collaborating Party for its expenditures prior to cancellation or termination of the research project.

5.2. Federal Laboratory. The Federal Laboratory shall not provide any Federal funds directly to LWI or to the Collaborating Party. The Federal Laboratory shall contribute equipment,

material and services toward the cooperative research and development effort as set forth in the SOW.

5.3. Collaborating Party. The Collaborating Party shall transfer funds and other resources to the Federal Laboratory and to LWI for the performance of research and development as set forth in the SOW.

5.4 LWI. LWI shall use funds transferred from the Collaborating Party to provide personnel, supplies, travel, and/or material support for the performance of research and development at the Federal Laboratory as set forth in the SOW.

5.5. Salaries and Travel. Unless otherwise provided in the SOW, each Party shall provide financial support to its respective personnel in the performance of this Agreement, including salary, reimbursement for travel, and other expenses as appropriate.

5.6. Accounting Records. The Federal Laboratory, LWI, and the Collaborating Party shall each maintain separate and distinct current accounts, records, and other evidence supporting all its expenditures under this Agreement. The accounts and records of the Federal Laboratory which are relevant to the conduct of this project shall be available for reasonable inspection and copying by the Collaborating Party or its authorized representative.

Article 6
Personal and Real Property

6.1. Personal Property. Any tangible personal property provided by a Party during the performance of this Agreement shall remain the personal property of the Party providing it, unless otherwise agreed in the SOW. Property provided by a Party to another Party may only be used for the performance of the cooperative effort under this Agreement, unless otherwise agreed in the SOW. Government property may be repaired or modified by the Collaborating Party at its expense only after obtaining the written approval of the Federal Laboratory. Any repair or modification of the property shall not affect the title of the Government. The Federal Laboratory makes no warranty, express or implied, with respect to property contributed or loaned by it. Upon completion of the cooperative effort performed under this Agreement, each Party shall immediately account for the property in its possession and return, at its expense, all property belonging to the other Party in the condition in which it was received, normal wear and tear excepted. Any disposal of property

shall be in accordance with applicable Federal, State, and local environmental laws and regulations.

6.2. Real Property. Any real property made available for use by a Party to another Party for the performance of this Agreement shall remain the property of the Party providing it. Any use of such property shall be in accordance with all applicable Federal, State, and local laws and regulations to include environmental laws and regulations.

Article 7
Patents

7.1. Disclosure. Each Party shall promptly disclose in writing to the other Party subject inventions made by its employees or subcontractors in sufficient detail to enable someone with skill in the art to make and use the inventions.

7.2. Federal Laboratory Inventions. The Federal Laboratory, on behalf of the Government, shall retain title to each subject invention made solely by its employees. The Federal Laboratory may file patent applications on these subject inventions at its own expense. The Federal Laboratory grants to the Collaborating Party a royalty-free, nonexclusive, irrevocable license to practice or have practiced worldwide by or on behalf of the Collaborating Party subject inventions covered by any resultant patents. Such nonexclusive license(s) shall be evidenced by a confirmatory document prepared by the Federal Laboratory in a form satisfactory to the Collaborating Party.

7.3. Collaborating Party Inventions. The Collaborating Party shall retain title to each subject invention made solely by its employees. The Collaborating Party may file patent applications on these subject inventions at its own expense. The Collaborating Party grants to the Government a royalty-free, nonexclusive, irrevocable license to practice or have practiced worldwide by or on behalf of the Government for Government purposes subject inventions covered by any resultant patents. Such nonexclusive license(s) shall be evidenced by a confirmatory license agreement prepared by the Collaborating Party in a form satisfactory to the Federal Laboratory. If the Collaborating Party transfers or releases the rights to employee inventions provided for by this paragraph, such transfer or release shall be subject to the Government purpose license granted to the Government.

7.4. Joint Inventions. Title to subject inventions made jointly by employees of the Federal Laboratory and the Collaborating Party shall be held jointly by the Government and the Collaborating Party. The Collaborating Party shall have the initial option to file patent applications on joint subject inventions at its own expense.

7.5. Filing of Patent Applications. The Party having the right to retain title and/or file patent applications on a specific subject invention may elect to file patent applications thereon provided it so advises the other Party within 120 days from the date of the report of the subject invention. In the event that the Party, having the right to file patent applications, fails to advise the other Party, within 120 days of the report of the subject invention, of its intent to file patent applications (and in which countries it intends to file), then the other Party may elect (but is not required) to file patent applications on such subject invention in those countries instead. If the other Party elects to file patent applications, the Party initially having the right to file patent applications on the subject invention agrees to assign to the other Party its rights, title, and interest in such subject invention in those countries in which the other Party elects to file, subject to the retention by the assigning Party of a royalty-free, nonexclusive, irrevocable license to practice or have practiced worldwide by or on behalf of that Party the subject invention covered by any resultant patents. The Party filing an application shall provide a copy thereof to the other Party. NOTE: Any patent application filed on any invention made under this Agreement shall include in the patent specification thereof the statement: "This invention was made in the performance of a Cooperative Research and Development Agreement with the Department of the Army. The invention may be manufactured and used by or for the Government of the United States for all government purposes without the payment of any royalty."

7.6. Patent Expenses and Cooperation. The expenses attendant to the filing of patent applications as specified above shall be borne by the Party filing the patent application. Each Party shall provide the other Party with copies of patent applications it files in the U.S. Patent and Trademark Office or any foreign patent offices, along with the power to inspect and make copies of all documents retained in the official patent application file by the applicable patent office. The Party filing the patent application shall have the right to control the prosecution of the application. The Parties agree to cooperate with each other in the preparing and prosecution of patent applications.

7.7. Maintenance Fees. The fees payable to a patent office in order to maintain the patent's enforcement will be paid by the Party owning the patent. If that Party decides not to pay the maintenance fees, it shall promptly notify the other Party, who may pay the maintenance fees if it desires to maintain the enforcement of the patent.

7.8. Exclusive Licensing of Government Inventions. The Federal Laboratory, on behalf of the U.S. Government, agrees to grant, at the Collaborating Party's option, a limited-term, exclusive license in each Government invention (Federal Laboratory made and jointly made) subject to the reservation of a royalty-free, nonexclusive, paid-up license to practice and have practiced worldwide the subject invention by and on behalf of the U.S. Government for government purposes. The Federal Laboratory agrees to enter into negotiations with the Collaborating Party, as requested, for the exclusive licensing of Government inventions for any field of use at a fair and reasonable royalty rate to be negotiated in good faith. The Collaborating Party shall exercise the option to obtain an exclusive license by giving written notice thereof to the Federal Laboratory within three months after disclosure of the invention. The royalty rate and other terms and conditions of the license shall be set forth in a separate license agreement and shall be negotiated promptly after notice is given.

7.9. Assignment and Transfer. The Collaborating Party agrees that any nonexclusive license granted to the Collaborating Party by the Government pursuant to this Article may not be assigned, sublicensed, or otherwise disposed of except to a corporate affiliate of the Collaborating Party or to the successor of the Collaborating Party or its corporate affiliate. Exclusive licenses granted to the Collaborating Party pursuant to paragraph 7.8 may be sublicensed by the Collaborating Party.

7.10. Background Inventions. The Parties grant each other, to the extent that each has the authority to do so, expressed or implied, royalty-free, nonexclusive licenses to practice or have practiced on their behalf, background inventions necessary for the performance of work under this Agreement. However, this Agreement does not grant any implied licenses for practicing background inventions in the performance of work not being conducted under this Agreement.

7.11. Commercialization of Subject Inventions. The Collaborating Party agrees that with respect to any subject invention in which it has acquired title or an exclusive license under this Agreement, the Government has the right to require the

Collaborating Party or an assignee or exclusive licensee of the subject invention to grant a nonexclusive license in any field of use to a responsible applicant or applicants upon terms that are reasonable under the circumstances, and if the Collaborating Party, assignee, or exclusive licensee refuses such request the Government has the right to grant such a license itself, if the Government determines that one or more of the following conditions exist:

7.11.1. Practical Application. Such action is necessary because the Collaborating Party, assignee, or licensee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention. Practical application means to manufacture in the case of a composition or product; to practice in the case of a process or method; or to operate in the case of a machine or system; and, in each case, under conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

7.11.2. Health or Safety. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the Collaborating Party, assignee, or licensee.

7.11.3. Public Use. Such action is necessary to meet requirements for public use specified by Federal regulation and such requirements are not reasonably satisfied by the Collaborating Party, assignee, or licensee.

7.12. Other Inventions. Inventions which are developed by aParty before or after the term of this Agreement remain the sole property of that Party.

Article 8
Copyrights

8.1. Works Created by Collaborating Party. Ownership to copyrights for original works of authorship created solely by employees of the Collaborating Party or for hire by the Collaborating Party in the course of performance of work under this Agreement are retained by the Collaborating Party. The Collaborating Party shall mark any such works with a copyright notice showing the Collaborating Party as an owner and shall have the option to register the copyright at the Collaborating Party’s expense. The Collaborating Party grants to the

Government a royalty-free, nonexclusive, irrevocable license to use, modify, prepare derivative works, reproduce, distribute, perform, and display worldwide such copyrighted works by or on behalf of the Government for Government purposes. The Collaborator will mark prominently each such copyrighted work with the words: "This work was created in the performance of a Cooperative Research and Development Agreement with the Department of the Army. The Government of the United States has a royalty-free government purpose license to use, duplicate or disclose the work, in whole or in part and in any manner, and to have or permit others to do so, for government purposes."

8.2. Joint Works. Ownership of copyrights for joint works prepared by employees of (or for hire by) the Federal Laboratory and the Collaborating Party in the course of performance of work under this Agreement are retained solely by the Collaborating Party. The Collaborating Party, however, grants to the Government a royalty-free, nonexclusive, irrevocable license to use, modify, prepare derivative works, reproduce, distribute, perform, and display worldwide such copyrighted works by or on behalf of the Government for Government purposes.

8.3. Software. The Party creating software in the course of the performance of work under this Agreement will provide the other Party with the source code, object code, and minimum support documentation needed by a competent user to use the software.

Article 9
Trademarks

9.1. Trademark Use. The Parties recognize that the Collaborating Party may seek to obtain trademark protection for goods developed under this Agreement which it subsequently commercially markets. The Parties agree that the Government may indicate on any similar goods produced by or for the Government that the goods are a Government version of the goods protected by the trademark. The Government shall also have the right to use the trademark in print or communications media.

9.2. Qualifying Notice. Prior to the use of the trademark by the Government, the Parties will negotiate any reasonable qualifying language that must accompany the trademark.

Article 10

Proprietary and Protected Information

10.1. Exchange of Data. The Parties agree to exchange all subject data produced in the course of the performance of this Agreement. All information or data exchanged among the Parties in the course of, or in contemplation of, this Agreement may be used and disseminated without restriction by the Parties for any purpose unless the data or information is proprietary or otherwise protected as provided in paragraph 10.2 or Article 8.

10.2. Proprietary and Protected Information.

10.2.1. Form. Proprietary or protected information may be disclosed to another Party orally, electronically, visually, in writing, or in any other tangible or intangible form. If it is initially disclosed in a nonfixed media, then the Party disclosing the data must furnish the other Party with the information in a fixed media with appropriate marking within ten days of its initial disclosure. Failure to furnish the fixed media within ten days or to prominently mark the information as proprietary or otherwise protected will not automatically result in the loss of the information's protected status, but will excuse any Party's unauthorized disclosure or use of the information caused by the failure to meet the ten-day suspense to properly mark the information.

10.2.2. Collaborating Party Background Information. The Collaborating Party shall place a proprietary legend on all proprietary information that it furnishes to the Federal Laboratory or to LWI under this Agreement which was produced or obtained prior to this Agreement or during the term of this Agreement, but not in the course of the performance of this Agreement. The legend shall prominently and explicitly identify which material is proprietary and which material is not proprietary. Any such marked proprietary information furnished by the Collaborating Party to the Federal Laboratory or to LWI under this Agreement, or in contemplation of this Agreement, shall be used by the Federal Laboratory or by LWI only for the purpose of carrying out this Agreement and for Government administrative and oversight purposes. Such marked proprietary information, as long as it maintains its proprietary status, shall not be disclosed or otherwise made available outside the Government without the consent of the Collaborating Party or of LWI.

10.2.3. Federal Laboratory Background Information. The Federal Laboratory shall place a nondisclosure legend on all protected

information it produced or obtained prior to this Agreement or during the term of this Agreement, but not in the course of the performance of this Agreement, that it furnishes to the Collaborating Party or to LWI under this Agreement and that it asserts is protected. The legend shall prominently and explicitly identify which material is protected and which material is not protected. Any such marked protected information furnished by the Federal Laboratory to the Collaborating Party or to LWI under this Agreement, or in contemplation of this Agreement, shall be used by the Collaborating Party or by LWI only for the purpose of carrying out this Agreement. Such marked protected information, as long as it maintains its protected status, shall not be disclosed or otherwise made available to anyone other than the Collaborating Party or LWI without the consent of the Federal Laboratory.

10.2.4. Subject Data. Subject data produced by employees of a Party or jointly by employees of the Parties may be designated as protected material by that Party if such information would be proprietary information if obtained from a non-Federal Party. Unless a lesser period of time is set forth in the SOW, the Federal Laboratory will provide appropriate protection against dissemination of such information, including exemption from 5 U.S.C. Chapter 5, Subchapter II, for five years after the data is developed, unless the information loses its protected status earlier. The Federal Laboratory shall have the right to use subject data for government purposes. The Collaborating Party may use subject data for any purpose. Protected subject data must contain a prominent legend stating: (1) it is protected, (2) the rights to use of the Parties, and (3) the date the protected status is due to expire.

10.2.5. Other Proprietary or Protected Information. Proprietary or protected information other than subject data or background information that is furnished by the Collaborating Party to the Federal Laboratory under this Agreement and which is marked proprietary or protected shall be used by the Federal Laboratory only for the purpose of carrying out this Agreement and for Government administrative and oversight purposes. Such marked proprietary or protected information, as long as it maintains its proprietary or protected status, shall not be disclosed or otherwise made available outside the Government without the consent of the Collaborating Party. Proprietary or protected information other than subject data or background information that is furnished by the Federal Laboratory to the Collaborating Party or to LWI under this Agreement and which is marked proprietary or protected shall be used by the

Collaborating Party or by LWI only for the purpose of carrying out this Agreement. Such marked proprietary or protected information, as long as it maintains its proprietary or protected status, shall not be disclosed or otherwise made available to anyone other than the Collaborating Party or LWI without the consent of the Federal Laboratory.

10.2.6. FDA Documents. If this Agreement involves a product regulated by the FDA, then the Collaborating Party, LWI, or the Federal Laboratory, as appropriate, may file any required documentation with the FDA. In addition, the Parties authorize and consent to allow each other or its contractor or agent access to, or to cross-reference, any documents filed with the FDA related to the product.

10.2.7. Standard of Care. Each Party is obligated to use reasonable care in the protection of proprietary and protected information.

Article 11
Prepublication Review

11.1. Publication. The Parties anticipate that their employees may wish to publish technical developments and/or research findings made under this Agreement. Each Party shall submit to the other Party prior to publication or other public disclosure, any proposed publication or disclosure pertaining to work under this Agreement. The other Party shall provide a written response within 30 days either objecting or not objecting to the proposed publication or public disclosure. The proposed publication or public disclosure shall not be deemed objectionable unless the proposed publication contains proprietary information, protected information, or material that would create potential statutory bars to the filing of U.S. or corresponding foreign patent applications, or for any other reasonable basis.

11.2. Protection of Proprietary Rights. If requested in writing by any Party, the Collaborating Party, LWI, the Principal Investigator, and/or the Federal Laboratory shall withhold such submission for publication an additional 60 days to allow for filing a patent application or taking such measures as the requester deems appropriate to establish and preserve its proprietary rights in the information in the manuscript or disclosure.

Article 12
Export Control

12.1. Compliance. The Parties understand that information and technology resulting from the performance of this Agreement may be subject to export control laws and regulations, and each Party is responsible for its own compliance with such laws and regulations. Nothing in this Agreement waives any such statutory or regulatory requirement.

Article 13
U.S. Competitiveness

13.1. Manufacture. The Parties agree that a purpose of this Agreement is to provide substantial benefit to the U.S. economy. To the extent feasible, the Parties agree to exercise reasonable efforts to manufacture substantially in the United States, products embodying intellectual property developed under this Agreement.

Article 14
Liability

14.1. **NO WARRANTY. EXCEPT AS SPECIFICALLY STATED ELSEWHERE IN THIS AGREEMENT OR THE SOW, THE PARTIES MAKE NO EXPRESS OR IMPLIED WARRANTY AS TO THE CONDITIONS OF THE RESEARCH, INVENTIONS, OR TECHNICAL DATA, OR PRODUCTS EXCHANGED, MADE, OR DEVELOPED UNDER THIS AGREEMENT, OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE, TECHNICAL FEASIBILITY, OR FREEDOM FROM INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF THE RESEARCH, INVENTIONS, TECHNICAL DATA, OR PRODUCTS. NO PARTY SHALL BE LIABLE FOR LOST PROFITS, LOST SAVINGS, SPECIAL, CONSEQUENTIAL, INCIDENTAL, OR OTHER INDIRECT DAMAGES, EVEN IF SUCH PARTY IS MADE AWARE OF THE POSSIBILITY THEREOF.**

14.2. Products Liability. To the extent not specifically prohibited by applicable State or local law, the Collaborating Party and LWI agree to indemnify and hold harmless the Government for any loss, claim, damage, expense, or liability of any kind occurring as a result of the making, using, or selling of a product, process, or service by or on behalf of the Collaborating Party or LWI, its assignees and licensees, which was derived from work performed under this Agreement. In respect to this provision, the Government shall not be considered an assignee or licensee of the Collaborating Party or to LWI as a result of reserved Government rights under this

Agreement. The Government's liability for losses, claims, damages, or expenses of the Collaborating Party or of LWI occurring as a result of the making or using of a product, process, or service by or on behalf of the Government shall be governed by the provisions of the Federal Tort Claims Act.

14.3. Parties' Employees. To the extent not specifically prohibited by applicable State or local law, the Collaborating Party and LWI shall indemnify and hold harmless the Government for any loss, claim, damage, expense, or liability of any kind involving an employee or independent contractor of the Collaborating Party or LWI arising in connection with the performance of work under this Agreement, except to the extent that such loss, claim, damage, or liability arises from the negligence of the Federal Laboratory or its employees. The Government's liability for the loss of property, personal injury or death, or otherwise arising out of any negligent act or omission of its employees in connection with the performance of work under this Agreement shall be governed by the Federal Tort Claims Act.

14.4. Notice and Assistance. The indemnification provisions of this Article shall apply only if the Party upon which the claim or lawsuit is asserted gives the other Party prompt notice of the claim or lawsuit and allows that Party to participate in the defense/adjudication of the claim or lawsuit as is permitted by applicable laws and Government regulations.

Article 15
Force Majeure

15.1. Force Majeure Events. No Party shall be liable for any unforeseen event beyond its reasonable control not caused by the fault or negligence of such Party, which causes such Party to be unable to perform its obligations under this Agreement and which it has been unable to overcome by the exercise of due diligence. Such unforeseen events include, but are not limited to, fire, storm, flood, earthquake or other natural catastrophes, accidents, acts of civil disturbance or disobedience, war, rebellion, insurrection, labor strikes or disputes, compliance with any laws, requirements, rules, regulations, or orders of any governmental authority or instrumentality thereof, sabotage, invasion, quarantine, and embargoes.

15.2. Best Efforts. The excused Party shall use its best efforts to resume performance as quickly as possible and shall

suspend performance for only such period as is reasonably necessary as a result of the force majeure event.

Article 16
Severability

16.1. Contrary to Law. Any provision of this Agreement, to include the SOW, that is prohibited by applicable law is void, but the remaining provisions shall survive.

Article 17
Termination

17.1. Mutual Consent. The Parties may elect to terminate this Agreement, or portions thereof, at any time by mutual consent.

17.2. Unilateral Action. Any Party may unilaterally terminate this Agreement at any time by giving the other Party written notice, not less than 30 days prior to the desired termination date.

17.3. Termination Costs. Unless otherwise specifically provided in this Agreement, each Party shall be responsible for all of the costs for which it bears responsibility under this Agreement which have been incurred through the effective date of termination. Each Party shall be solely responsible for any costs it incurs after the effective date of termination.

17.4. Continuing Obligations. In the event of termination, the Parties shall specify the disposition of all property, patents, and other results of work accomplished or in progress under this Agreement, when such disposition is not otherwise specified in this Agreement. All obligations under this Agreement to safeguard proprietary and other protected information and relating to rights in intellectual property or technical data shall survive any termination of this Agreement. The termination of this Agreement shall not affect the rights and obligations of the Parties accrued prior to the effective date of termination.

Article 18
Disputes

18.1. Resolution Procedures. The Parties recognize that disputes arising under this Agreement are best resolved at the working level. All Parties are encouraged to be imaginative in designing mechanisms and procedures to resolve disputes at the lowest level possible as soon as practicable. The Parties agree to use their best efforts to resolve any dispute amongst themselves. Any dispute arising under this Agreement which is not disposed of by agreement of the Parties at the working level shall be submitted jointly to the signatories of this Agreement or their successors or their designees for resolution. Although the Parties may agree to use alternate disputes resolution (ADR) techniques to resolve disputes, nothing in this Agreement precludes any Party from pursuing resolution of a dispute using other legal review available by law.

18.2. ADR Process and Costs. If the Parties decide by mutual consent on an appropriate ADR method (to include the choice of mediator, judge, or panel members), they shall bear the costs of the ADR process equally.

18.3. Obligations. Pending the resolution of a dispute pursuant to this Article, the Parties agree to diligently continue performing all obligations in accordance with the SOW.

Article 19
Modifications

19.1. Modifications. If any Party desires to modify this Agreement, the Parties, upon reasonable notice of the proposed modification by the Party desiring the change, shall confer in good faith to determine the desirability of such modification. Any resulting modification shall not be effective until a written amendment is signed by the duly authorized representatives of the Parties. Any material modification of this Agreement is subject to the authority of the Assistant Secretary of the Army (Research, Development, and Acquisition) to disapprove or require modification within 30 days of the date it is presented to the Assistant Secretary.

Article 20
Interpretation

20.1. Entire Agreement. This Agreement includes Articles 1 - 27 and the SOW (Appendix). Together, they constitute the entire agreement among the Parties with respect to the subject matter

hereof and all prior representations or agreements relating hereto have been merged into the documents and are superseded in totality by this Agreement.

20.2. Precedence. In the event of a conflict between the terms and provisions of the SOW and the terms and provisions in the Articles, the terms and provisions in the Articles shall control.

Article 21
Notices

21.1. Notices. All notices, pertaining to or required by this Agreement, shall be in writing and shall be delivered by hand or sent by certified mail, return receipt requested, express mail, or private delivery service addressed as specified below. Any Party may change such address by written notice given to the other Parties in the manner set forth.

Mailing Address of Federal Laboratory:

Clinical and Translational Research Program Office
U.S. Army Medical Command
2748 Worth Road
Ft. Sam Houston, TX 78234-6000

Mailing Address of LWI:

Leonard Wood Institute
197 Replacement Ave.
Fort Leonard Wood, MO 65473

Mailing Address of Collaborating Party:

Phelps County Regional Medical Center
1000 West 10th Street
Rolla, MO 65401

21.2 Waiver. None of the provisions of this Agreement shall be considered waived by any Party unless such waiver is given in writing to the other Parties. The failure of a Party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any right of any Party hereto.

Article 22
Nonassignment

22.1. Nonassignment. This Agreement may not be assigned or otherwise transferred by any Party without the prior written consent of the other Parties.

Article 23
Officials Not To Benefit

23.1. Officials Not to Benefit. No member of Congress shall be admitted to any share or part of this Agreement, or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this Agreement if made with a corporation for its general benefit.

Article 24
Endorsements

24.1. No Endorsements. By entering into this Agreement, the Federal Laboratory does not directly or indirectly endorse any product or service provided by the Collaborating Party, LWI, their successors, assignees, or licensees. The Collaborating Party or LWI shall not in any way imply this Agreement is an endorsement by the Government of any such product or service.

24.2. Use of Name. The Collaborating Party or LWI may use, refer to, and disseminate reprints of scientific, medical, and other published articles which disclose the name of the Federal Laboratory consistent with U.S. copyright laws, provided such use does not constitute, or imply, an endorsement of any commercial product or service by the U.S. Government. The Collaborating Party and LWI shall take every step possible to ensure that references to the articles are accurate, and shall explicitly state that any such reference does not claim, infer, or imply an endorsement or recommendation of the product or service by Government investigators, the Federal Laboratory, or the U.S. Government. The Collaborating Party and LWI shall not use the name of the Principal Investigator or the Federal Laboratory in any advertising, packaging, or promotional material in connection with a product or service. The Principal

Investigator and the Federal Laboratory shall not use the name of the Collaborating Party or LWI in any publication or presentation regarding the Study except with the written permission of the Collaborating Party or LWI or as may be required by law.

Article 25
Governing Law

25.1. The construction, validity, performance, and effect of this Agreement for all purposes shall be governed by the laws applicable to the Government of the United States.

Article 26
Duration of Agreement

26.1. Effective Date. This Agreement will be effective upon the date that the last Party signs this Agreement.

26.2. Duration. It is mutually recognized by the Parties that the objectives to be attained by this Agreement cannot be rigidly defined in advance and that projected milestones are subject to adjustment by mutual agreement of the Parties. Notwithstanding, this Agreement will not extend beyond the latest period of either ten years following the date of the last signature to this Agreement or the latest period of time stated in a SOW executed under this Agreement.

26.3. Continuing Obligations. All obligations under this Agreement to safeguard proprietary and other protected information and relating to publication, liability, rights in intellectual property or technical data existing at the termination or expiration of this Agreement shall survive the termination/expiration of this Agreement.

Article 27
HIPAA Compliance
Privacy of Protected Health Information

27.1. *Definitions.* As used in this clause:
Individual has the same meaning as the term “individual” in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

Privacy Rule means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

Protected Health Information has the same meaning as the term "protected health information" in 45 CFR 164.501, limited to the information created or received by the Collaborating Party or LWI from or on behalf of the Government.

Required by Law has the same meaning as the term "required by law" in 45 CFR 164.501.

Secretary means the Secretary of the Department of Health and Human Services or his/her designee.

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in 45 CFR 160.103 and 164.501.

27.1.1. The Collaborating Party and LWI agree to not use or further disclose Protected Health Information other than as permitted or required by the Agreement or as Required by Law.

27.1.2. The Collaborating Party and LWI agree to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.

27.1.3. The Collaborating Party and LWI agree to mitigate, to the extent practicable, any harmful effect that is known to the Collaborating Party or LWI of a use or disclosure of Protected Health Information by the Collaborating Party or LWI in violation of the requirements of this Agreement.

27.1.4. The Collaborating Party and LWI agree to report to the Government any use or disclosure of the Protected Health Information not provided for by this Agreement.

27.1.5. The Collaborating Party and LWI agree to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by the Collaborating Party or LWI on behalf of the Government agrees to the same restrictions and conditions that apply through this Agreement to the Collaborating Party or LWI with respect to such information.

27.1.6. The Collaborating Party and LWI agree to provide access, at the request of the Government, and in the time and manner designated by the Government to Protected Health Information in a Designated Record Set, to the Government or, as directed by the Government, to an Individual in order to meet the requirements under 45 CFR 164.524.

27.1.7. The Collaborating Party and LWI agree to make any amendment(s) to Protected Health Information in a Designated Record Set that the Government directs or agrees to pursuant to 45 CFR 164.526 at the request of the Government or an Individual, and in the time and manner designated by the Government.

27.1.8. The Collaborating Party and LWI agree to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by the Collaborating Party or LWI on behalf of, the Government, available to the Government, or at the request of the Government to the Secretary, in a time and manner designated by the Government or the Secretary, for purposes of the Secretary determining the Government's compliance with the Privacy Rule.

27.1.9. The Collaborating Party and LWI agree to document such disclosures of Protected Health Information and information related to such disclosures as would be required for the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

27.1.10. The Collaborating Party and LWI agree to provide to the Government or an Individual, in time and manner designated by the Government, information collected in accordance with this Clause of the Agreement, to permit the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

27.2. General Use and Disclosure Provisions.

27.2.1. Except as otherwise limited in this Agreement, the Collaborating Party or LWI may use or disclose Protected Health Information on behalf of, or to provide services to, the Government for the following purposes, if such use or disclosure of Protected Health Information would not violate the Privacy Rule or the Department of Defense Health Information Privacy Regulation if done by the Government to carry out the purposes

of this Cooperative Research and Development Agreement as stated in the Statement of Work.

27.3. Specific Use and Disclosure Provisions.

27.3.1. Except as otherwise limited in this Agreement, the Collaborating Party or LWI may use Protected Health Information for the proper management and administration of the Collaborating Party or to carry out the legal responsibilities of the Collaborating Party.

27.3.2. Except as otherwise limited in this Agreement, the Collaborating Party or LWI may disclose Protected Health Information for the proper management and administration of the Collaborating Party, provided that disclosures are required by law, or the Collaborating Party or LWI obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Collaborating Party or LWI of any instances of which it is aware in which the confidentiality of the information has been breached.

27.3.3. Except as otherwise limited in this Agreement, the Collaborating Party or LWI may use Protected Health Information to provide Data Aggregation services to the Government as permitted by 45 CFR 164.504(e)(2)(i)(B).

27.3.4. Collaborating Party or LWI may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j)(1).

27.4. Obligations of the Government. Provisions for the Government to Inform the Collaborating Party or LWI of Privacy Practices and Restrictions.

27.4.1. Upon request, the Government shall provide the Collaborating Party or LWI with the notice of privacy practices that the Government produces in accordance with 45 CFR 164.520, as well as any changes to such notice.

27.4.2. The Government shall provide the Collaborating Party or LWI with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect the Collaborating Party's or LWI’s permitted or required uses and disclosures.

27.4.3. The Government shall notify the Collaborating Party or LWI of any restriction to the use or disclosure of Protected Health Information that the Government has agreed to in accordance with 45 CFR 164.522.

27.5. Permissible Requests by the Government.

27.5.1. The Government shall not request the Collaborating Party or LWI to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by the Government, except for providing Data Aggregation services to the Government and for management and administrative activities of the Collaborating Party or LWI as otherwise permitted by this clause.

27.6. Termination.

27.6.1. A breach by the Collaborating Party or LWI of this clause, may subject the Collaborating Party or LWI to termination under any applicable default or termination provision of this Agreement.

27.7. Effect of Termination.

27.7.1. If this Agreement has records management requirements, the records subject to the Clause should be handled in accordance with the records management requirements. If this Agreement does not have records management requirements, the records should be handled in accordance with paragraphs (2) and (3) below.

27.7.2. If this Agreement does not have records management requirements, except as provided in paragraph (3) of this section, upon termination of this Agreement, for any reason, the Collaborating Party or LWI shall return or destroy all Protected Health Information received from the Government, or created or received by the Collaborating Party or LWI on behalf of the Government. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of the Collaborating Party or LWI. The Collaborating Party and LWI shall retain no copies of the Protected Health Information.

27.7.3. If this Agreement does not have records management provisions and the Collaborating Party or LWI determines that returning or destroying the Protected Health Information is

infeasible, the Collaborating Party or LWI shall provide to the Government notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Government and the Collaborating Party or LWI that return or destruction of Protected Health Information is infeasible, the Collaborating Party or LWI shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as the Collaborating Party or LWI maintains such Protected Health Information.

27.8. Miscellaneous.

27.8.1. Regulatory References. A reference in this Clause to a section in the Privacy Rule means the section as in effect or as amended, and for which compliance is required.

27.8.2. Survival. The respective rights and obligations of Business Associate under the “Effect of Termination” provision of this Clause shall survive the termination of this Agreement.

27.8.3. Interpretation. Any ambiguity in this Clause shall be resolved in favor of a meaning that permits the Government to comply with the Privacy Rule.

Signatures appear on the following page

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as follows:

For the U.S. Government (Federal Laboratory):

BY: _____ DATE: 13 January 2017

Jay Bucci, MD, PhD, RAC, CIP
Lieutenant Colonel, Medical Corps
Director, Clinical and Translational Research Program Office
U.S. Army Medical Command
2748 Worth Road
Ft. Sam Houston, TX 78234-6000
Tel: (210) 808-0156

For Leonard Wood Institute (LWI):

BY: _____ DATE: 5 JAN 2017

Kent Thomas
Executive Director
Leonard Wood Institute
197 Replacement Ave.
Fort Leonard Wood, MO 65473
Tel: (573) 329-8502

For Phelps County Regional Medical Center (Collaborating Party):

BY: _____ DATE: 1/5/2017

Edward Clayton
Chief Executive Officer
Phelps County Regional Medical Center
1000 West 10th Street
Rolla, MO 65401
Tel: (573) 458-7901