Research Other Transactions Agreement

AGREEMENT BETWEEN

U.S. Army Medical Research and Development Command (USAMRDC)

And

TBD

Address:

Concerning:

SUPPORT OF THE CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS RECONSTRUCTIVE TRANSPLANT RESEARCH PROGRAM CLINICAL NETWORK AWARD

Agreement Number:

Effective Date:

Authority: 10 U.S.C. § 4001, as amended

This Agreement is entered into between the United States of America, hereinafter called the Government, represented by the U.S. Army Medical Research and Development Command (USAMRDC), U.S. Army Medical Research Acquisition Activity (USAMRAA), and the TBD

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RESEARCH OTHER TRANSACTIONS AGREEMENT

Article 1. PREAMBLE

1.1 The Reconstructive Transplant Research Program (RTRP) seeks to promote a major multi-institutional network of vascularized composite allotransplantation (VCA) Centers and associated collaborators for the purpose of standardizing clinical protocols and clinical practice guidelines (CPGs) for face and hand transplantation and assessing those protocols in multi-institutional clinical trials. It is the intent of the RTRP to bring together investigators from as many VCA Centers for both face and hand transplantation as possible to establish a consensus in the field of reconstructive transplantation for these protocols and CPGs. The RTRP recognizes that such a consensus is a necessary first step to advancing face and hand transplantation from experimental status to that of a viable choice with the potential for reimbursement under health insurance policies.

1.1.1 The RTRP intends to allocate up to $13M to support the RTRP Clinical Network over 6 years, subject to availability of funding. This effort will be executed through a two-phase approach in the form of a single award to the Clinical Network Coordinating Center, hereby referred to as the Coordinating Center. The Coordinating Center will serve as the Clinical Network information and planning nexus, providing administrative, operational, and data management support services to implement Clinical Network activities in a timely manner. The period of performance for Phase 1 is 2 years, with maximum funding of $3M in RTRP funding for total costs to the Coordinating Center. The Coordinating Center will manage funding to the Network Sites as subawards and for other key collaborators. RTRP funding for the Phase 2 is contingent on successful completion of Phase 1 objectives and on available funding. The period of performance for Phase 2 is 4 years, with maximum funding of $10M in RTRP funding for total costs to the Coordinating Center.

1.2 This Agreement is an Other Transactions Agreement as authorized by 10 USC 4001 It comprises the basic terms and conditions under which the Awardee (Coordinating Center) will accomplish the objectives of this Agreement.

1.3 The applicable provisions of this Agreement will be incorporated by the Coordinating Center with network sites.

1.4 In consideration of the foregoing, the Government and the Coordinating Center agree to the mutual covenants and promises contained in this Agreement.

Article 2. DEFINITIONS

When used in this Agreement, the following terms, whether used in the singular or plural, shall have the meanings set forth herein.

2.1 "Agreement" means this Research Other Transactions Agreement (rOTA).

2.2 "Agreements Officer" (AO) means the person identified by the Government in this Agreement authorized to (1) obligate the Government under this Agreement, and (2)

modify this Agreement.

2.3 "Agreements Officer Technical Representative" (AOTR) means the person designated by USAMRAA to be responsible for managing the scientific and technical aspects of this agreement and assisting with agreement administration.

2.4 "Agreements Specialist" means the person identified by the Government to assist the Agreements Officer.

2.5 "Base Agreement" means the agreement between the Government and the Coordinating Center that serves as the baseline agreement. The Base Agreement flows down applicable terms and conditions from this Other Transactions Agreement.

2.6 "Cash Contribution" means the Coordinating Center and/or the Clinical Trial performers (or Awardees' lower tier subawards) financial resources expended to perform a Clinical Trial. The cash contribution may be derived from the Clinical Network or Network Sites funds or outside sources or from nonfederal contract or grant revenues or from profit or fee on a federal procurement contract. A site's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Network Site will be spent on performance of the Statement of Work (SOW) of a Phase I or Phase II specific tasks identified within the SOW or the Coordinating Center or of a Phase II Clinical Trial. Prior IR&D funds will not be considered as cash or In-Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on the Coordinating Center or Network Site's cost sharing portion. Cash contributions include the funds a Coordinating Center or Network Site will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward efforts expended on the SOW of a Clinical Trial, and restocking the parts and material consumed.

Cash is the preferred form of resource sharing because of the level of commitment it represents and the ease of valuation. Cash contributions can include costs like direct labor, including benefit expenses and direct overhead; materials expenses; and Independent Research and Development (IR&D) costs. IR&D is acceptable as resource-sharing only for OTs, even though it may be reimbursed by the Government through other awards. It is standard business practice for all for-profit firms to recover their research and development costs through prices charged to their customers. Under Federal procurement contracts, the Federal Government allows some of its larger performers to recover these IR&D costs or independent research investments by allowing a pro-rated spread of these costs across the performer's federal business base.

2.7 "Clinical Network Coordinating Center" means the INSERT AWARDEE. Referred to hereafter as the Coordinating Center

2.8 "Clinical Network Sites" means the sites that are responsible for working collaboratively with the Coordinating Center and with other Network Sites to meet the objectives of the Clinical Network. Referred to as Network Sites.

2.9 "Cure Notice" means written notification provided to the Parties concerning the terms

and or conditions of this Agreement not being met prior to the Government taking action, as set forth in Article 13.

2.10 "Effective Date" means the date first written above and on which this Agreement is signed and executed by the Coordinating Center and the U.S. Army Medical Research Acquisition Activity (USAMRAA).

2.11 "Government" means the United States of America herein represented by the USAMRDC, USAMRAA, and CDMRP (Congressionally Directed Medical Research Programs).

2.12 "Government Fiscal Year" (FY) means the period commencing on October 1 and ending September 30 of the following calendar year.

2.13 "Independent Research and Development (IR&D)" means cost relative to projects falling within the four following areas: (a) basic research, (b) applied research, (c) development, and (d) system and other concept formulation studies. The term does not include the cost of effort sponsored by a grant or required in the performance of a contract. IR&D effort shall not include technical effort expended in developing and preparing technical data specifically to support submitting a bid and proposal.

2.14 "In Kind Contribution" includes equipment, facilities, materials, intellectual property, and other similar items in the possession of performers but not charged as a direct cost to the program. In-kind assets are more difficult to value and are generally less desirable than cash assets but can often be of great use to the program. When considering the value of physical items such as equipment or facilities, AOs will generally consider the depreciated value (unless the item is fully depreciated) or a reasonable usage cost. In determining a reasonable usage cost, the Government team should consider the original cost of the asset, total estimated remaining useful life at the time of negotiations, the effect of any increased maintenance charges or decreased efficiency due to age, and the amount of depreciation previously charged to procurement contracts and sub contracts.

2.15 "Party" means the Government and the Clinical Network Coordinating Center

2.16 "Parties" means the Government and the Clinical Network Coordinating Center, collectively.

2.17 "Pre-Award Costs" are those costs that directly support the SOW approved by the AO that are incurred before the signing of the agreement or a subsequent modification(s) to incorporate clinical trials in order to meet the agreed to schedule. Documentation for Pre-award Costs must be provided in a written request by the Clinical Network Coordinating Center and approved in writing by the AO prior to the costs being incurred.

2.18 "Research Other Transactions Agreement" (rOTA) means this Other Transactions Agreement entered into by the Clinical Network Coordinating Center and the Government.

2.19 "Subawardee" means any supplier, distributor, vendor, or firm that furnishes supplies or services to or for the Clinical Network Coordinating Center.

2.20 “Subject Invention” means any Invention Made in the performance of work under this Agreement. Such Inventions may be made by employees or contractors or others working on behalf of Clinical Network Coordinating Center, the Government, or any combination thereof. "Invention" and "Made" have the meanings set forth in Title 15 U.S.C. Section 3703(7) and (8).

2.21 “USAMRAA” means U.S. Army Medical Research Acquisition Activity. USAMRAA is the contracting organization in USAMRDC. USAMRAA is the authorized representative of the Department of the Army to contract and administer this Agreement.

2.22 “USAMRDC” means the U.S. Army Medical Research and Development Command.

Article 3. RESPONSIBILITIES

3.1 Government Responsibilities. The Government will provide periodic briefings and ongoing guidance.

3.1.1. The Government may:

- Provide strategic and/or technical guidance

- Provide full or partial funding

- Share expertise and facilities

- Participate as the Government Sponsor in arranged meetings including membership/ recruiting events, program reviews, audio/video tele-conferences, and other industry related events.

3.1.2. The Government shall:

- Provide oversight through the RTRP Clinical Network Steering Committee

  • The RTRP Clinical Network Steering Committee will consist of the RTRP Programmatic Panel, program staff, and other key subject matter experts and USAMRDC personnel; ad hoc members may be included as needed. This committee will provide oversight of all aspects of the Clinical Network, as well as guidance for the Coordinating Center at critical junctures, to include establishment of the Clinical Network, scientific review of the clinical trial applications in both face and hand transplantation, etc.

  • In Progress Reviews: The Network Director and Network Site PIs are required to present progress updates to the RTRP Clinical Network Steering Committee at annual IPR meetings, which will be hosted by the RTRP. It is anticipated that these meetings will be held in person toward the end of each performance year; however, alternative arrangements will be made (e.g., teleconference or other media platform) should in-person meetings be restricted or otherwise infeasible.

- Provide technical oversight of Phase 1 and Phase 2;

- Assess efficiency and effectiveness of Clinical Network Coordinating Center activities.

3.1.3 Additional Government Participation. The Parties agree that the other Services and other organizations within the U. S. Government may participate in the collaborative activities under this Agreement to the extent permitted by applicable laws and regulations.

3.2 Clinical Network Coordinating Center (Coordinating Center) Responsibilities

3.2.1 Develop and maintain the Clinical Network organizational structure. Work with the RTRP Clinical Network Steering Committee to invite VCA Centers and other collaborators into the Clinical Network as subawards to serve as Network Sites. Network Sites will not be included as subawards in the application itself; rather, they will be added once the Coordinating Center has been selected.

3.2.2 Under leadership of the Network Director, provide day-to-day management of the Clinical Network and ensure that the Clinical Network adheres to the planned timeline and milestones for overall study execution in both Phases 1 and 2.

3.2.3 Establish and manage procedures to ensure that all Network Sites receive RTRP funding for the phase(s) in which they participate.

3.2.4 Facilitate the necessary agreements (e.g., regulatory, intellectual and material property, Cooperative Research and Development Agreements [CRADAs]) between all participating Network Sites to ensure seamless collaboration so that the Clinical Network functions as a cohesive unit rather than a collection of different sites.

3.2.5 Develop and manage a communications plan and real-time communications with Network Site members, the RTRP Clinical Network Steering Committee, and other key collaborators.

3.2.6 Establish and manage an intellectual and material property plan for all institutions participating in the Clinical Network.

3.2.7 Manage real or potential conflicts of interest.

3.2.8 Facilitate a collaborative research environment for the development of standardized protocols and CPGs for VCA, as well as for the development of clinical trials (one for face transplantation and one for hand transplantation), and coordinate schedules and maintain timelines for achieving objectives, etc.

- For example, this might be done through the establishment of a multi-institutional working group for each protocol and CPG to be standardized and/or clinical trial protocol to be written.

- Ensure that the appropriate expertise is included in the efforts to develop each protocol, CPG, and clinical trial (e.g., scientific, medical, human subjects protection, regulatory).

3.2.9 Establish a fair and equitable process through which each protocol and CPG is developed, reviewed, revised, and ultimately finalized as standard.

3.2.10 Establish and maintain procedures for ensuring compliance with FDA requirements for investigational agents, devices, and procedures, as applicable.

3.2.11 Provide a Clinical Research Manager who will facilitate the regulatory approvals for each clinical trial protocol and will interact with the Clinical Research Coordinators at each Network Site to coordinate patient accrual and study activities across sites.

3.2.12 Establish and manage procedures to obtain approval for and maintain compliance of protocols with a single unified IRB of record for the Clinical Network and with OHRO.

3.2.13 Develop and manage a comprehensive data collection and data management plan that addresses the needs of all Network Sites in terms of access to data, data security, and data integrity measures.

3.2.14 Develop and manage quality assurance and quality control mechanisms for clinical trial monitoring.

- Registration, tracking, and reporting of participant accrual.

- Timely medical review, rapid reporting, communication of adverse events, and management/coordination among all Network Sites.

- Interim evaluation and consideration of measures of outcome.

3.2.15 Ensure the standardized collection, cataloging, storage, and use of specimens, imaging products, and other data as appropriate for the clinical trials.

3.2.16 Ensure that the clinical trials are initiated (i.e., open for enrollment) within 2 months of the start of Phase 2.

3.2.17 Develop and manage procedures for timely publication of major outcomes and other public dissemination of data and study results.

3.2.18 During Phase 1, coordinate and facilitate at least two internal Clinical Network review meetings for all Clinical Network key investigators to facilitate face-to-face discussions and evaluate progress toward objectives. These meetings should be open to and coordinated with the RTRP Clinical Network Steering Committee and are recommended at approximately months 6 and 18 of the award.

3.2.19 During Phase 2, coordinate regularly scheduled meetings (via teleconference or other media platform) to facilitate discussion of clinical trial progress among Network Sites (e.g., recruitment efforts, enrollment, patient listings, transplants, rejection episodes or other adverse events, successes, challenges). These meetings should be open to the RTRP management team.

3.2.20 Coordinate the preparation of briefings for and attend annual In Progress Review (IPR) meetings. IPR meetings will be hosted by the RTRP and, when possible, will occur in person in the National Capital Region, but may alternatively occur via teleconference or other media platform.

3.2.21 Maintain regular communications with the RTRP management team, to include the CDMRP Science Officer, Agreements Officer Technical Representative (AOTR), USAMRAA Agreements Officer, and other USAMRDC personnel.

3.3 Network Site Responsibilities. Network Sites will be invited into the Clinical Network after the Coordinating Center is awarded. The Network Sites are to serve as equal partners in the Clinical Network and are responsible for working collaboratively with the Coordinating Center and with other Network Sites to meet the objectives of the Clinical Network. No single Network Site, including the Network Site associated with the Coordinating Center, if applicable, is to have authority over the other Network Sites or to have the final determination or veto power of the protocols and CPGs being developed.

Key responsibilities of Network Sites are to:

3.3.1 Work with the Coordinating Center to complete all agreements (e.g., regulatory, intellectual and material property, CRADAs) as necessary to participate in the Clinical Network.

3.3.2 Participate and work collaboratively to develop standardized protocols, CPGs, and clinical trials for face and/or hand transplantation.

3.3.3 Comply with the Coordinating Center's communication plan (e.g., participate in scheduled meetings).

3.3.4 Participate in procedures developed by the Coordinating Center for resolution of intellectual and material property issues among organizations in the Clinical Network.

3.3.5 Implement procedures established by the Coordinating Center for ensuring compliance with FDA, IRB, and OHRO requirements, as applicable.

3.3.6 Comply with the quality assurance and quality control procedures established by the Coordinating Center, including participation in an onsite monitoring program to be managed by the Coordinating Center.

3.3.7 Implement the Coordinating Center's management plan for collection, cataloging, storage, and use of specimens, imaging products, and other clinical data.

3.3.8 Share available research resources with other members of the Clinical Network.

3.3.9 During Phase 2, participate as a clinical site for enrollment in at least one clinical trial (if a VCA Center).

- Provide a Clinical Research Coordinator, who will interact with the Clinical Research Coordinators of other Network Sites and the Coordinating Center's Clinical Research Manager to ensure regulatory approvals for the standardized protocols and CPGs and to coordinate patient accrual and study activities across sites.
- Participate in procedures developed by the Coordinating Center for timely publication of Clinical Network outcomes and other public dissemination of data and study results, as applicable.
- Support the Clinical Network's collaborative effort by participating in internal

Clinical Network review meetings during Phase 1 and regularly scheduled teleconferences during Phase 2, as specified by the Coordinating Center. These meetings are intended to facilitate discussion across Network Sites and evaluate progress of protocol/CPG development (Phase 1) and clinical trial execution (Phase 2).

• Assist with preparation of briefings for, and attend, annual IPR meetings.

Article 4. REPORTS

4.1. The Coordinating Center in accordance with this Agreement shall maintain records of the research and development activities performed and funds expended by the Coordinating Center as well as activities and funds expended by Network Sites. All the records shall include the results of studies, analyses, tests and other investigations.

4.2 The Coordinating Center shall submit the following through Phase I and Phase II:

4.2.1. Quarterly and Annual Reports

4.2.1.1 Technical Status Report. Quarterly and annual (if effort is for more than one year). The technical status report shall detail technical progress to date and report on all problems, technical issues or major developments during the reporting period. The AO may specify additional reporting requirements. Quarterly reports are due no later than 30 days after the end of the project quarter and annual reports are due no later than 30 days after the end of the project year.

- Technical reports will provide a concise and factual discussion of the significant accomplishments and progress made during the reporting period. Each of the topics described below shall be addressed for the effort performed:

- A comparison of actual accomplishments with the goals and objectives established for the period;

- Reasons why established goals and objectives were not met, if appropriate;

- Other pertinent information including, and when appropriate, analysis and explanation of cost variances;

- A cumulative chronological list of written publications in technical journals, papers, or other presentations at meetings, conferences, seminars, etc. regarding the Coordinating Center activities. All reports will identify resubmissions to publications, information, and/or notification of status of publication submissions; and

- New discoveries, inventions, or patent disclosures, and specific applications stemming from the Clinical Trial provided that such disclosures shall not compromise IP rights of the Government, Coordinating Center, or Clinical Sites.

Additional guidance is provided at
https://mrdc.amedd.army.mil/index.cfm/resources/researcher_resources/reporting/technical

4.2.1.2. Business Status Report. The business status report shall provide summarized details of the resource status for Coordinating Center operations, including the status of the contributions by all participants. This report will include a quarterly accounting of current expenditures. Any major deviations from the agreed to project plan shall be explained with a discussion of proposed actions to address the deviations. The format of this report is expected to follow the SF425 with supplemental information, but the format is subject to negotiation.

4.2.2 Final Reports

4.2.2.1 Final Technical Report (FTR) - A Draft FTR shall be submitted to the AOTR within 120 calendar days of the completion of the period of performance. This report will provide a comprehensive cumulative and substantive summary of the progress and significant accomplishments achieved during the total period of the effort. Each of the topics described above shall be addressed as appropriate for the effort performed. The AOTR shall provide written comments on the Draft FTR to the Coordinating Center within thirty (30) calendar days of receipt of the report. The FTR shall be submitted within fourteen calendar days of receipt of the AOTR comments on the Draft FTR. If the FTR is acceptable, as submitted, the AOTR will forward his/her approval within thirty (30) calendar days to the Coordinating Center.

Additional guidance is provided at:
https://mrdc.amedd.army.mil/index.cfm/resources/researcher_resources/reporting/technical

4.2.2.2. Final Business Status Report

- The final business status report shall provide summarized details of the resource status for Coordinating Center operations, including the status of the contributions by all participants. This report will include a final accounting of current expenditures. Any major deviations from the agreed to project plan shall be explained with a discussion of proposed actions to address the deviations. The format of this report is expected to follow the SF425 with supplemental information, but the format is subject to negotiation.

4.3 The Coordinating Center shall submit the following reports specific to Phase II Clinical Trials:

4.3.1. Quarterly and Annual Reports

4.3.1.1 Technical Status Report. Quarterly and annual (if effort is for more than one year). The technical status report shall detail technical progress to date and report on all problems, technical issues or major developments during the reporting period. The AO may specify additional reporting requirements. Quarterly reports are due no later than 30 days after the end of the project quarter and annual reports are due no later than 30 days after the end of the project year.

- Technical reports will provide a concise and factual discussion of the significant accomplishments and progress made during the reporting period. Each of the topics described below shall be addressed for the effort performed:

- A comparison of actual accomplishments with the goals and objectives established for

the period;

- Reasons why established goals and objectives were not met, if appropriate;

- Other pertinent information including, and when appropriate, analysis and explanation of cost variances;

- A cumulative chronological list of written publications in technical journals, papers, or other presentations at meetings, conferences, seminars, etc. regarding the Coordinating Center activities. All reports will identify resubmissions to publications, information, and/or notification of status of publication submissions; and

- New discoveries, inventions, or patent disclosures, and specific applications stemming from the Clinical Trial effort provided that such disclosures shall not compromise IP rights of the Government, Coordinating Center, or Clinical Sites.

Additional guidance is provided at
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4.3.2 Final Reports

4.3.2.1 Final Technical Report (FTR) - A Draft FTR shall be submitted to the AOTR within 120 calendar days of the completion of the period of performance. This report will provide a comprehensive cumulative and substantive summary of the progress and significant accomplishments achieved during the total period of the effort. Each of the topics described above shall be addressed as appropriate for the effort performed. The AOTR shall provide written comments on the Draft FTR to the Coordinating Center within thirty (30) calendar days of receipt of the report. The FTR shall be submitted within fourteen calendar days of receipt of the AOTR comments on the Draft FTR. If the FTR is acceptable, as submitted, the AOTR will forward his/her approval within thirty (30) calendar days to the Coordinating Center.

Additional guidance is provided at:
https://mrdc.amedd.army.mil/index.cfm/resources/researcher_resources/reporting/technical

4.3.2.2. Final Business Status Report

- The final business status report shall provide summarized details of the resource status for Clinical Trial, including the status of the contributions by all participants. This report will include a final accounting of current expenditures. Any major deviations from the agreed to project plan shall be explained with a discussion of proposed actions to address the deviations. The format of this report is expected to follow the SF425 with supplemental information, but the format is subject to negotiation.

Additional guidance is provided at:
https://mrdc.amedd.army.mil/index.cfm/resources/researcher_resources/reporting/technical

4.4 Flow down. The Coordinating Center through shall include this Article, suitably modified, to identify all parties, in all Clinical Trials or subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

Article 5: OBLIGATION AND PAYMENT

5.1 Obligation- The Government's liability to make payments to the Coordinating Center is limited to only those funds obligated under this Agreement or by modification to the Agreement. The Government may incrementally fund this Agreement.

5.2 Payments- Payments for Phase II Clinical Trials will be expenditure or milestone based on the terms provided once the trials are identified. Payments for the Coordinating Center may be expenditure based.

5.2.1 In addition to any other financial reports provided or required, the Coordinating Center shall notify the USAMRAA AO immediately if any resource share contribution is not made as required.

5.2.2 Prior to the submission of invoices by the Coordinating Center, the Coordinating Center shall have and maintain an established accounting system which complies with Generally Accepted Accounting Principles and with the requirements of this Agreement and shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for all funding. The Parties recognize that as a conduit, the Coordinating Center does not incur nor does it allocate any indirect costs of its own to the Network Sites cost directly incurred pursuant to this Agreement. Consistent with this, an acceptable accounting system will be one in which all cash receipts and disbursements are controlled and documented properly.

5.2.3 The Coordinating Center shall document the accomplishments of each milestone by submitting or otherwise providing a Milestone Report. The Coordinating Center shall submit one (1) copy of all invoices to the AOTR for payment approval. After written verification of the accomplishment of the milestone by the AOTR, and approval by the AO, the invoices will be forwarded to the payment office within fifteen (15) calendar days of receipt of the invoices at USAMRDC.

5.2.4 Address of Payee: (INSERT NAME AND ADDRESS OF PAYEE)

5.2.5 Payments will be made by the Defense Finance and Accounting Services office, as indicated below, within 30 (thirty) calendar days of an accepted invoice in Wide Area Workflow (WAWF). Wide Area Workflow (WAWF) is a secure web-based system for electronic invoicing, receipt and acceptance. The WAWF application enables electronic form submission of invoices, government inspection, and acceptance documents in order to support

DoD's goal of moving to a paperless acquisition process. Authorized DoD users are notified of pending actions by e-mail and are presented with a collection of documents required to process the contracting or financial action. It uses Public Key Infrastructure (PKI) to electronically bind the digital signature to provide non-refutable proof that the user (electronically) signed the document with the contents. Benefits include online access and full spectrum view of document status, minimized re-keying and improving data accuracy, eliminating unmatched disbursements and making all documentation required for payment easily accessible.

The Coordinating Center is required to utilize the Wide Area Workflow system when processing invoices and receiving reports under this Agreement. The Coordinating Center shall (i) ensure an Electronic Business Point of Contact is designated in System for Award Management at http://www.sam.gov and (ii) register to use WAWF–RA at the https://wawf.eb.mil site, within ten (10) calendar days after award of this Agreement. Step by Step procedures to register are available at the https://wawf.eb.mil site. The Coordinating Center is directed to use the "2-in-1" format when processing invoices. The Coordinating Center should submit a copy of the AOR approval of the milestone, as well as a copy of the milestone report, with each invoice.

a. For the Issue By DoDAAC, enter XXXXXX.

b. For the Admin DoDAAC, enter XXXXXX.

c. For the Service Acceptor AOR fields, enter the Service Acceptor AOR DoDAAC.

d. Leave the Inspect by DoDAAC, Ship From Code DoDAAC, Service Approver, and LPO DoDAAC fields blank unless otherwise directed by the AO.

e. The following guidance is provided for invoicing processed under this Agreement through WAWF:

- The AOTR identified in Article IV, "Agreement Administration" shall continue to formally inspect and accept the outcomes/milestones. To the maximum extent practicable, the AOTR shall review the outcome(s)/milestone report(s) and either: 1) provide a written notice of rejection to the Coordinating Center which includes feedback regarding deficiencies requiring correction, or 2) written notice of acceptance to the USMARAA AO and Agreements Specialist.

- Acceptance within the WAWF system shall be performed by the AOTR upon receipt of a confirmation email, or other form of transmittal, from the AOTR.

- The Coordinating Center shall send an email notice to the AOTR and upload the AOTR approval as an attachment upon submission of an invoice in WAWF (this can be done from within WAWF).

- Payments shall be made by DFAS-(INSERT APPROPRIATE DFAS OFFICE).

5. Payee Information: As identified at Central Contractor Registration.

- Cage Code:
- DUNS:
- TIN:

6. Government funds shall be maintained in an interest-bearing account prior to disbursement to Network Sites. This account shall not be in U. S. Treasury Notes. Any interest earned shall be remitted annually to the USAMRAA AO, or designee. Interest payments shall be made payable to the U. S. Treasury. Interest amounts less than $250 per year may be retained by the Coordinating Center for administrative expenses.

7. Limitation of Funds: In no case shall the Government's financial liability exceed the amount obligated under this Agreement.

8. Payments shall be made in the amounts set forth in each Clinical Trial, provided the AOTR has verified the accomplishment of the milestone. It is recognized that the quarterly accounting of current expenditures reported in the "Business Status Report" is not necessarily intended or required to match the milestone until submission of the Final Report; however, milestones shall be revised during the course of the program to reflect current and revised projected expenditures.

9. Financial Records and Reports: The Coordinating Center and Network Sites shall maintain adequate records to account for all funding under this Agreement and shall maintain adequate records to account for Coordinating Center and Network Sites funding provided under this Agreement. Upon completion or termination of this Agreement, whichever occurs earlier, the Coordinating Center shall furnish to the AO, Agreements Specialist, and AOTR a copy of the Final Report required by Article 4. The Coordinating Center's and Network Site's relevant financial records are subject to examination or audit on behalf of USAMRDC by the Government for a period not to exceed three (3) years after expiration of the term of this Agreement. The AO or designee shall have direct access to sufficient records and information of the Coordinating Center and Network Sites, to ensure full accountability for all funding under this Agreement. Such audit, examination, or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party.

Article 6. ADMINISTRATION

6.1. Administrative Responsibilities. The following administrative provisions apply to this Agreement.

6.1.1. Administrative Matters. Administrative matters under this Agreement shall be referred to the following representative:

Government

U.S. Army Medical Research Acquisition Activity:

Agreements Officer:

Telephone:

Email:

Agreements Specialist: Asha Phillips
Telephone:
E-Mail:

Coordinating Center

Title: Name:

Telephone: E-Mail:

Additional Authorized Personnel:

6.2 Management of Clinical Trials. Performance of the work on Clinical Trials is subject to the technical direction of the AOTR designated by the Agreements Officer.

6.2.1 For the purposes of this clause, technical direction includes the following:

- Direction which shifts work emphasis between work areas or tasks, requires pursuit of certain lines of inquiry, fills in details or otherwise serves to accomplish the objectives described in the statement of work;

- Guidelines that assist in the interpretation of drawings, specifications or technical portions of work description.

- Review and, where required, approval of technical reports, drawings, specifications, or technical information to be delivered under the Clinical Trial.

6.2.2 The AOTR shall monitor the Clinical Trial with respect to compliance with the technical requirements.

6.2.3 Technical direction must be within the general scope of work stated in the approval of the Clinical Trial. Technical direction may not be used to:

- Assign additional work under the Clinical Trial;

- Increase or decrease the estimated Clinical Trial cost, or the time required for the research and development period of performance;

- Change any of the terms, conditions or specifications of the Clinical Trial;

- Accept non-conforming work.

6.2.4 As such, no verbal or written request, notice, authorization, direction or order received by the Coordinating Center or Network Site(s) shall be binding upon the Government, or serve as the basis for a change in cost or any other provision of the agreement, unless issued (or confirmed) in writing by the USAMRAA Agreements Officer.

The Coordinating Center or Network Site(s) shall immediately notify the Agreements Specialist whenever a verbal or written change notification has been received from anyone other than the USAMRAA, which would affect any of the terms, conditions, cost, schedules, etc., and the Coordinating Center and Network Site are to perform no work or make any changes in response to any such notification or make any claim on the Government unless the Agreements Specialist directs the Coordinating Center or Network Site, on behalf of the AO, in writing, to implement such change notification.

6.3 Modifications- As a result of meetings, annual reviews, or at any time during the term of the Agreement, progress or results may indicate that a change in the Agreement would be beneficial to program objectives. Recommendations for modifications, including justifications to support any changes to the Agreement, will be documented and submitted by the Coordinating Center to the AOTR and the Agreements Specialist, with a copy to the AO. This documentation will detail the technical, chronological, and financial impact of the proposed modification to the research program. The Coordinating Center shall approve any Agreement modification.

6.3.1 The AOTR shall be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement.

6.3.2 For minor or administrative Agreement modifications (e.g., changes in the paying office or appropriation data, changes to Government or Coordinating Center personnel identified in the Agreement, etc.) no signature is required by the Coordinating Center.

6.4 Pre-Award Costs- Pre-Award costs supporting a Clinical Trial may be recognized as acceptable costs only after receiving written AO approval for the costs and only if they are determined to be reasonable, allocable, and allowable. To obtain approval of Pre-Award Costs, the Coordinating Center must submit their request in writing to the Government. Each request must contain the costs that the Coordinating Center intends to incur prior to approval of a Clinical Trial, why the effort must be started before award and sufficient cost detail for technical and cost review

6.5 Subaward Approval. Subawards that are proposed and agreed to during negotiations for a Clinical Trial are considered as having AO approval. Modifications to approved Subawards and/or new Subawards, during Phase I or Phase II, that will significantly impact the teaming arrangement and/or technical approach proposed and accepted require AO approval prior to

being executed.

6.6 Incremental Funding. The Government's share for full performance of the Clinical Trials under this Agreement shall be determined once a Clinical Trial is identified. In no event is the Government obligated to reimburse the recipient for expenditures in excess of the total funds allotted by the Government for a Clinical Trial, regardless of anything to the contrary in any Termination clause herein. The Government anticipates that from time-to-time additional amounts will be allotted to Clinical Trials under this Agreement by unilateral modification by the Government, until the total Government's share for full performance under the Clinical Trial is fully funded.

To minimize interruption of effort due to lack of funds, the Coordinating Center shall notify the Government in writing (electronic format acceptable) whenever the amount of funds expended under a Clinical Trial, when added to anticipated costs in the next 60 calendar days, will exceed 75% of the amount allotted under the Clinical Trial by the Government plus the Coordinating Center's and Network Sites' corresponding share. The Coordinating Center and Network Sites are not obligated to continue performance or otherwise incur costs in excess of (1) the amount then allotted to the Clinical Trial or, (2) if the Clinical Trial is a cost-sharing agreement, the Coordinating Center or Network Sites corresponding share, until the AO notifies the Coordinating Center in writing that the amount allotted by the Government has been increased and specifies an increased amount, which shall then constitute the total amount allotted by the Government. When and to the extent that the amount allotted by the Government to this Clinical Trial is increased, any costs the Coordinating Center incurs before the increase that are in excess of (1) the amount previously allotted by the Government or, (2) if this is a cost-sharing agreement, the amount previously allotted by the Government to the Coordinating Center's corresponding share, shall be allowable to the extent they would have been allowable if incurred afterward, unless the AO directs that the increase is solely to cover specific expenses.

6.7 Program Income

6.7.1. Program income as used in this award is gross income that you earn that is directly generated by a supported activity or earned as a result of this award; or a subrecipient earns as a result of a subaward you make under this award.

6.7.1.1 Includes, but is not limited to, income earned under this award from:

- Fees for services performed;

- The use or rental of real or personal property acquired under any Federal award and currently administered under this award;

- The sale of commodities or items fabricated under this award; and

- License fees and royalties on patents and copyrights;

- Payments of principal and interest on loans made with Federal award funds.

6.7.1.2 Does not include for purposes of this award any:

- Interest earned on advance payments,

- Proceeds from the sale of real property, equipment or supplies, which is addressed;

- Rebates, credits, discounts, and interest earned on any of them; and

- Governmental revenues, including any taxes, special assessments, levies, fines and similar revenues you raise.

6.7.2 Encouragement to earn program income. You are encouraged to earn program income under this award when doing so does not interfere with the project or program the award supports.

6.7.3 Costs of generating program income. You may deduct costs incidental to the generation of program income from the amount that you use in accordance with Section 6.7.5 of this Article, as long as those costs are not charged to this award (which includes their being counted toward any cost sharing or matching you are required to provide).

6.7.4 License fees and royalties. You have no obligations to the Federal Government with respect to program income earned under this award from license fees and royalties for patents or patent applications, copyrights, trademarks, or inventions developed or produced under the award.

6.7.5 Use of program income- You must use any program income that you earn during the period of performance under this award to increase the amount of the award (the sum of the Federal share and any resource sharing or matching you are required to provide), thereby increasing the amount budgeted for the project or program. The program income must be used for the purposes and under the terms and conditions of the award. Your use of the additional funding is subject to the terms and conditions of this award, including:

a. Your use of balances of program income before you request additional funds from us and;

b. Allowability of costs for which the funds may be used.

3. You must report on each Business Status Report that you submit in accordance with Article 4 the program income that you earn and any that you use during the reporting period.

6.7.6 The requirements concerning disposition of program income in Section 6.7.5 of this Article apply only to program income you or your subrecipients earn during the period of performance. There are no requirements under this award applicable to program income you or your subrecipients earn after the end of the period of performance.

6.8 Title and Disposition of Property

6.8.1 Title to Property

No significant items of property are expected to be acquired under this Agreement. Title to each item of property acquired under this Agreement with an acquisition value of $5,000 or less shall vest in the Coordinating Center upon acquisition with no further obligation of the Parties unless otherwise determined by the AO. Should any item of property with an acquisition value greater

than $5,000 be required, the Coordinating Center shall obtain prior written approval of the AO. Title to this property shall also vest in the Coordinating Center upon acquisition. The Coordinating Center shall be responsible for the maintenance, repair, protection, and preservation of all property at its own expense.

6.8.2 Disposition of Property

At the completion of the term of this Agreement, items of property with an acquisition value greater than $5,000 shall be disposed of in the following manner:

1. Purchased by the Coordinating Center at an agreed-upon price, the price to represent fair market value, with the proceeds of the sale being returned to USAMRAA; or

2. Transferred to a Government research facility with title and ownership being transferred to the Government; or

3. Donated to a mutually agreed University or technical learning center for research purposes; or

4. Any other USAMRAA -approved disposition procedure.

6.8.3 Flow Down- The Coordinating Center shall include this Article, suitably modified, to identify all parties, in all subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

6.9 Award Transfers. The Coordinating Center cannot be transferred to another organization.

6.10. Personnel Changes. A change the Coordinating Center PI may be allowed at the discretion of the USAMRAA Agreements Officer. Changes in PI's Clinical Trials may be allowed at the discretion of the USAMRAA Agreements Officer.

Article 7. PROPRIETARY INFORMATION

7.1. Definitions for Article 7.

7.1.1. "Disclosing Party" means the Coordinating Center, a Network Site, or the Government which discloses Confidential Information as contemplated by the subsequent paragraphs.

7.1.2. "Receiving Party" means the Coordinating Center, a Network Site, or the Government which receives Confidential Information disclosed by a Disclosing Party.

7.1.3. "Proprietary Information" means information and materials of a Disclosing Party which are designated as Proprietary Information or as a Trade Secret or subject to export control in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or

legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information that are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Proprietary Information or a Trade Secret or be subject to export control if such Disclosing Party, within thirty (30) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information and indicating that it is proprietary or a Trade Secret or subject to export control. Any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Article.

7.1.4. "Trade Secret" means all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if,

7.1.4.1 The owner thereof has taken reasonable measures to keep such information secret; and

7.1.4.2 The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

7.2 Exchange of Information. The Government may from time to time disclose Government Proprietary Information to the Coordinating Center and Network Sites in connection with the Phase I and Phase II, a Coordinating Center or Network Site may from time to time disclose Trade Secrets to the Government or to other Network Site(s) in connection with the performance of Phase I or Phase II. Neither the Government nor the Coordinating Center or the Network Sites shall be obligated to transfer Proprietary Information or Trade Secrets independently developed to any Party to this Agreement.

7.3. Confidentiality and Authorized Disclosure. The Receiving Party agrees, to the extent permitted by law, that Proprietary Information and Trade Secrets shall remain the property of the Disclosing Party (no one shall disclose such information unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Proprietary Information and Trade Secrets shall not be disclosed, divulged, or otherwise communicated by the Receiving Party to third parties (including without limitation, other Network Sites) or used by the Receiving Party for any purposes other than in connection with the Clinical Trials and the licenses granted in Articles 9 and 10; provided that the terms "Proprietary Information "and "Trade Secrets" shall exclude materials or information that:

7.3.1. Are received or become available without restriction to the Receiving Party under separate agreement;

7.3.2. Are not identified with a suitable notice or legend per Paragraph 8.1.3 herein;

7.3.3. Are in possession of the Receiving Party at the time of disclosure thereof as demonstrated by prior written records;

7.3.4. Are or later become part of the public domain through no fault of the Receiving Party;

7.3.5. Are received by the Receiving Party from a third Party having no obligation of confidentiality to the Disclosing Party that made the disclosure;

7.3.6. Are developed independently by the Receiving Party without use of Proprietary Information or Trade Secrets as evidenced by written records;

7.3.7. Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

7.4. Return of Proprietary Information. Upon request by the Coordinating Center or Network Site that made a disclosure of Proprietary Information or Trade Secrets to the Government or another Network Site, the Coordinating Center, or the Government shall promptly return all copies and other tangible manifestations of the Trade Secrets or Proprietary Information disclosed. Upon request by the Coordinating Center, the Government, or Network Site shall promptly return all copies and other tangible manifestations of the Proprietary Information disclosed by the Government. As used in this section, tangible manifestations include human readable media as well as magnetic and digital storage media.

7.5. Term. The obligations of the Receiving Party under this Article shall continue for a period of five (5) years after the expiration or termination of this Agreement; provided, however, that in the case of a Network Site that withdraws, or is deemed to have withdrawn, pursuant to Article 14 Termination, the Receiving Party's obligations with respect to such Network Sites' Trade Secrets or Proprietary Information shall continue only for a period of five (5) years after the effective date of such Network Site's withdrawal.

7.6. Flow down. The Coordinating Center shall include this Article, suitably modified, to identify all parties, in all subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

Article 8. RIGHTS IN TECHNICAL DATA

8. The Parties agree that in consideration for Government funding, the Coordinating Center intends to reduce to practical application items, components and processes developed under this Agreement.

8.1 With respect to Data developed or generated under this Agreement related to the program, the Government shall receive Government Purpose Rights, Government Purpose Rights are defined as Rights to use, duplicate, or disclose Data, in whole or in part and in any manner, for Government purposes only, and to have or permit others to do so for Government purposes only.

8.2 March-In Rights- In the event the Government chooses to exercise its March-in Rights, as defined in Article 9.9 , the Coordinating Center agrees, upon written request from the Government, to deliver at no additional cost to the Government, all Data necessary to achieve practical application within sixty (60) calendar days from the date of the written request. The Government shall retain Unlimited Rights to this delivered Data. Unlimited Rights are defined as the rights to use, duplicate, release, or disclose, Data in whole or in part, in any manner and for any purposes whatsoever, and to have or permit others to do so.

8.2.1 To facilitate any potential deliveries, the Coordinating Center agrees to retain and maintain in good condition until (INSERT NUMBER OF YEARS) after completion or termination of this Agreement, all Data necessary to achieve practical application of any subject invention. An invention is defined as any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

8.3 Marking of Data- Any Data delivered under this Agreement shall be marked with the following legend:

> Use, duplication, or disclosure is subject to the restrictions as stated in Agreement HT9425-XX-3-XXXX between the Government and the Coordinating Center.

8. 4 Flow down. The Coordinating Center shall include this Article, suitably modified, to identify all parties, in all subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

Article 9. PATENT RIGHTS

9.1 Allocation of Principal Rights

9.1.1 Unless the Coordinating Center shall have notified USAMRAA, in accordance with subparagraph 9.1.2 below, that the Coordinating Center does not intend to retain title, the Coordinating Center shall retain the entire right, title, and interest throughout the world to each subject invention consistent with the provisions of this Article.

9.1.2 With respect to any subject invention in which the Coordinating Center retains title, USAMRDC shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the subject invention throughout the world.

9.2 Invention Disclosure, Election of Title, and Filing of Patent Application

9.2.1 The Coordinating Center shall disclose each subject invention to USAMRDC within four (4) months after the inventor discloses it in writing to their organization personnel responsible for patent matters. The disclosure to USAMRDC shall be in the form of a written report and shall identify the Agreement and circumstances under which the invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Invention. The disclosure shall also identify any publication, sale, or public use of the invention and whether a manuscript describing the invention has been submitted and/or accepted for publication at the time of disclosure.

9.2.2 If the Coordinating Center determines that it does not intend to retain title to any such Invention, the Coordinating Center shall notify USAMRDC, in writing, within eight (8) months of disclosure to USAMRDC. However, in any case where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by USAMRDC to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

9.2.3 The Coordinating Center shall file its initial patent application on a subject invention to which it elects to retain title within one (1) year after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. The Coordinating Center may elect to file patent applications in additional countries (including the European Patent Office and the Patent Cooperation Treaty) within either ten (10) months of the corresponding initial patent application or six (6) months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

9.2.4 The Coordinating Center shall notify USAMRDC of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

9.2.5 Requests for extension of the time for disclosure election, and filing under Article VII, may be granted at USAMRDC's after considering the circumstances of the Coordinating Center and the overall effect of the extension.

9.2.6 The Coordinating Center shall submit to USAMRDC annual listings of subject inventions. At the completion of the Agreement, the Coordinating Center shall submit a comprehensive listing of all subject inventions identified during the course of the Agreement and the current status of each.

9.3 Conditions When the Government May Obtain Title

9.3.1 Upon USAMRDC's written request, the Coordinating Center shall convey title to any subject invention to USAMRDC under any of the following conditions:

9.3.1.1 If the Coordinating Center fails to disclose or elects not to retain title to

the subject invention within the times specified in Section 9.2 B of this Article; however, USAMRDC may only request title within sixty (60) calendar days after learning of the failure of the Coordinating Center to disclose or elect within the specified times;

9.3.1.2 In those countries in which the Coordinating Center fails to file patent applications within the times specified in section 9.2 of this Article; however, if the Coordinating Center has filed a patent application in a country after the times specified in section 9.2 of this Article, but prior to its receipt of the written request by USAMRDC, the Coordinating Center shall continue to retain title in that country; or

9.3.1.3 In any country in which the Coordinating Center decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a subject invention.

9.4. Minimum Rights to the Coordinating Center and Protection of the Coordinating Center's Right to File

9.4.1 The Coordinating Center shall retain a nonexclusive, royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the Coordinating Center fails to disclose the subject invention within the times specified in section 9.2 of this Article. The Coordinating Center's license extends to its domestic (including Canada) subsidiaries and affiliates, if any, and includes the right to grant licenses of the same scope to the extent that the Coordinating Center was legally obligated to do so at the time the Agreement was awarded. The license is transferable only with the approval of USAMRDC, except when transferred to the successor of that part of the business to which the subject invention pertains. USAMRDC approval for license transfer shall not be unreasonably withheld.

9.4.2 The Coordinating Center's domestic license may be revoked or modified by USAMRDC to the extent necessary to achieve expeditious practical application of the Subject Invention pursuant to an application for an exclusive license submitted consistent with appropriate provisions at 37 C.F.R. Part 404. This license shall not be revoked in that field of use or the geographical areas in which the Coordinating Center has achieved practical application and continues to make the benefits of the subject invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of USAMRDC to the extent the Coordinating Center, its licensees, or the subsidiaries or affiliates have failed to achieve practical application in that foreign country.

9.4.3 Before revocation or modification of the license, USAMRDC shall furnish the Coordinating Center a written notice of its intention to revoke or modify the license, and the Coordinating Center shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

9.5 Action to Protect the Government's Interest

9.5.1 The Coordinating Center agrees to execute or to have executed and promptly

deliver to the USAMRDC all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions to which the Coordinating Center elects to retain title, and (ii) convey title to USAMRDC when requested under paragraph C of this Article and to enable the Government to obtain patent protection throughout the world in that subject invention.

9.5.2 The Coordinating Center agrees to require by written agreement with its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Coordinating Center each subject invention made under this Agreement in order that the Coordinating Center can comply with the disclosure provisions of paragraph B of this Article. The Coordinating Center shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U. S. or foreign statutory bars.

9.5.3 The Coordinating Center shall include, within the specification of any United States patent application and any patent issuing thereon covering a subject invention, the following statement:

This invention was made with Government support under Agreement No. HT9425-XX-3-XXXX, awarded by USAMRDC. The Government has certain rights in the invention.

9.6 Flow down. The Coordinating Center shall include this Article, suitably modified, to identify all parties, in all Clinical Trials or subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

9.7 Reporting on Utilization of Subject Inventions

9.7.1 The Coordinating Center agrees to submit, during the term of the Agreement, an annual report on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the Coordinating Center or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Coordinating Center, and such other data and information as the agency may reasonably specify. The Coordinating Center also agrees to provide additional reports as may be requested by USAMRDC in connection with any march-in proceedings undertaken by USAMRDC in accordance with Section 9.8 of this Article. USAMRDC agrees it shall not disclose such information to persons outside the Government without permission of the Coordinating Center, unless required by law.

9.7.2. All required reporting shall be accomplished, to the extent possible, using the i-Edison reporting website: https://s-edison.info.nih.gov/iEdison/. To the extent any such reporting cannot be carried out by use of i-Edison, reports and communications shall be submitted to the Agreements Officer.

Preference for American Industry- Notwithstanding any other provision of this clause, the Coordinating Center agrees that it shall not grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any product embodying the subject invention or produced through the use of the subject invention shall be manufactured substantially in the United States. However, in individual cases, the requirements for such an agreement may be waived by USAMRDC upon a showing by the Coordinating Center that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

9.8 March-in Rights - The Coordinating Center agrees that, with respect to any subject invention in which it has retained title, USAMRDC has the right to require the Coordinating Center, an assignee, or exclusive licensee of a subject invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the Coordinating Center, assignee, or exclusive licensee refuses such a request, USAMRDC has the right to grant such a license itself if USAMRDC determines that:

9.8.1 Such action is necessary because the Coordinating Center or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the subject invention:

9.8.2 Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the Coordinating Center, assignee, or their licensees;

9.8.3 Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by the Coordinating Center, assignee, or licensees; or

9.8.4 Such action is necessary because the agreement required by paragraph (H) of this Article has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such Agreement.

Article 10. FOREIGN INVOLVEMENT

10.1 Foreign Involvement Disclosure: The Coordinating Center shall provide a list of all positions and scientific appointments, both domestic and foreign, held by senior/key personnel that are relevant to the Agreement, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary). The Coordinating Center shall notify the AO for any changes in status.

10.2 Technology must be consistent with the U.S. export laws, regulations and policies (e.g., the International Traffic in Arms Regulation at chapter I, subchapter M, title 22 of the CFR (22 CFR parts 120 through 130), the DoD Industrial Security Regulation in DoD 5220.22-R, 3 and the Department of Commerce Export Regulation at chapter VII, subchapter C, title 15 of the CFR (15 CFR parts 730 through 774), as applicable.

10.3 Flow down. The Coordinating Center shall include this Article, suitably modified, to identify all parties, in all Clinical Trials or subawards. This Article shall, in turn, be included

in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

Article 11. PUBLICATION AND ACADEMIC RIGHTS

11.1. Use of Information. Subject to the provisions of Paragraph 11.3, the Coordinating Center and the Network Sites (and their employees) and the Government (and its employees) shall have the right to publish or otherwise disclose information and/or data developed by the Government, the Coordinating Center and/or Network Sites under a Clinical Trial or Subaward. The Coordinating Center and Network Sites (and their employees) and the Government (and its employees) shall include an appropriate acknowledgement of the sponsorship of the Clinical Trial and or Subaward by the Government, the Coordinating Center and/or other Network Sites in such publication or disclosure. The Parties shall have the right to use, disclose, and exploit any such data and information in accordance with the rights held by them pursuant to this Agreement. Notwithstanding the above, it is the intention of the Parties that no Proprietary Information or proprietary information shall be disclosed through this process.

11.2. Oral and Visual Information. If oral or visual presentation of information from a Clinical Trial or subaward program is made to an external organization, then the Coordinating Center must notify the AOTR in writing 30 days in advance identifying the organization to which the presentation is to be made, the benefit of the presentation to the program, and any associated risks with presenting the information to the external group and any costs to the Government that will be incurred. All oral or visual presentation of information shall have appropriate disclaimers.

11.3. Publication or Public Disclosure of Information.

11.3.1. Clearance of Technical Information for Public Release.

11.3.1.1. Disclosure of unclassified Clinical Trials shall be in accordance with the applicable Distribution Statement.

11.3.1.2. Approval of the Agreements Officer is not required prior to the release of information received in the performance of a Clinical Trials or developed pursuant to a Subaward if a Clinical Trial or Subaward is awarded to a college, university or laboratory and the research work is performed on campus,

11.3.1.3. Parties to this Agreement are responsible for assuring that an acknowledgment of Government support will appear in any publication of any material based on or developed under this Agreement, a Clinical Trial, or a Subaward, in the following terms:

. 11.3.1.3.1 “Effort sponsored by the Government under Other Transactions Number HT9425-XX-3-XXXX;

11.3.1.3.1 The U.S. Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation

thereon."

11.3.1.4. Parties to this Agreement, a Clinical Trial or a Subaward, are responsible for assuring that every publication of material based on or developed contains the following disclaimer:

"The views and conclusions contained herein are those of the authors and should not be interpreted as necessarily representing the official policies or endorsements, either expressed or implied, of the U.S. Government."

11.4. Notices. To avoid disclosure of Proprietary Information or Trade Secrets belonging to the Coordinating Center, a Network Site and/or the Government and the loss of patent rights as a result of premature public disclosure of patentable information, the Party that is proposing to publish or disclose such information, agrees to provide notice to both the Party to whom such

Proprietary Information or Trade Secrets belongs and the Agreements Officer at least thirty (30) calendar days prior to any submission for publication or disclosure, together with any and all materials intended for publication or disclosure relating to technical reports, data, or information developed by the Government, the Coordinating Center and/or the Network Sites during the term of and pursuant to this Agreement.

11.5. Filing of Patent Applications. During the course of any such ninety (90) calendar day period, the Party to whom such Proprietary Information or Trade Secrets belongs and/or Government shall provide notice to the AO whether it desires that a patent application be filed on any invention disclosed in such materials. In the event that the Party to whom such Proprietary Information or Trade Secrets belongs and/or Government desires that such a patent application be filed, the Party proposing to publish or disclose such materials agrees to withhold publication and disclosure of such materials until the occurrence of the first of the following:

11.5.1. Filing of a patent application covering such invention, or

11.5.2. Written agreement, from the AO and Party to whom such Proprietary Information or Trade Secrets belongs, that no patentable invention is disclosed in such materials.

Further, during the course of any such ninety (90) calendar day period, any Party who believes that any of its Proprietary Information or Trade Secrets have been included in the proposed publication or disclosure shall provide notice to the Party proposing to publish or disclose such materials of the extent of the Proprietary Information or Trade Secrets that should be removed from such proposed publication or disclosure. The Party proposing the publication or disclosure of such materials agrees to remove all such Proprietary Information or Trade Secrets from the proposed publication or disclosure.

11.6. Flow down. The Coordinating Center shall include this Article, suitably modified, to identify all parties, in all Clinical Trials or subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

Article 12. OTHER TRANSACTION TERM AND TERMINATION

12.1 Term of this Agreement- The Agreement commences upon the date of the last signature hereon. Phase I is planned for a 2-year duration and Phase 2 is planned for 4 years, to follow Phase 1 upon successful completion of Phase 1 and subject to availability of funds. If all funds are expended prior to the completion of Phase 1 and Phase 2, the Parties have no obligation to continue performance and may elect to cease development at that point. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for periods of time other than specified herein, shall be given effect, notwithstanding this Article.

12.2 Termination Provisions- Subject to a reasonable determination that the program will not produce beneficial results commensurate with the expenditure of resources, either Party may terminate this Agreement by written notice to the other Party, provided that such written notice is preceded by consultation between the Parties. In the event of a termination of the Agreement, it is agreed that disposition of Data developed under this Agreement, shall be in accordance with the provisions set forth in Article 8, Data Rights. The Government and the Coordinating Center will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article 18, Disputes. The Government has no obligation to pay the Coordinating Center beyond the last completed and paid milestone if the Coordinating Center decides to terminate.

12.3 Extending the Term- The Parties may extend by mutual written agreement the term of this Agreement if funding availability and research opportunities reasonably warrant. Any extension shall be formalized through modification of the Agreement by the Agreements Officer ("AO") and the Coordinating Center.

12.4 Renewal. The Government and the Coordinating Center may meet to consider a renewal of the term of this Agreement. Subject to the requisite Government approvals and regulations, if the Parties so agree to such a renewal, they shall enter into an appropriate amendment of this Agreement reflecting the terms to be in effect during the renewal period.

Article 13. CLINICAL TRIAL TERMS AND TERMINATION

13.1 Term. The term of the Clinical Trial will be as stated in the terms and conditions of each individual Research Project Award.

13.2 Termination. Any Clinical Trial awarded pursuant to this Agreement may be terminated in whole or in part, upon prior consultation by the Parties and the expiration of thirty (30) calendar days following written notice to the Government, the Clinical Network and Clinical Site performing the Clinical Trial, as set forth below:

13.2.1 By the AO, should insufficient funds be available to accomplish the goals or intent of the Clinical Trial or for other convenience to the Government. Such termination will be effective immediately upon written notice notwithstanding any prior notice requirement of this Agreement. In any event, thirty (30) calendar days prior written notice will be provided to the maximum extent practicable;

13.2.1 By the Parties, based on an agreement by the Government and Coordinating Center that the Clinical Trial will not produce beneficial results commensurate with the expenditure of resources;

13.2.2 By the AO, with the consent of the other Parties. In this case the Parties shall agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

13.2.3 By the Coordinating Center, upon sending the AO a written notification, setting forth the reasons for such termination, the effective date and, in the case of partial termination, the portion to be terminated. The notice shall also include the total costs incurred or committed to date as well as projected costs for closeout. The Coordinating Center must provide such notice at least sixty (60) calendar days prior to the effective date of the termination. No costs shall be incurred beyond those listed in the termination notice, unless otherwise agreed to by the Agreements Officer. Upon receipt of the termination notice, the AO in consultation with the AOTR, will determine the appropriate path forward, which may include a full or partial transfer of tasks to another Network Site, full or partial termination of the Clinical Trial, or other mutual agreement between the Parties. If the AO determines, in the case of partial termination, that the reduced or modified portion of the Clinical Trial will not accomplish the purposes for which the Clinical Trial was awarded, the AO may terminate the Clinical Trial in its entirety.

13.3 Close-out Procedures. If this Agreement and/or any Clinical Trial issued pursuant to this Agreement are completed or terminated, the following closeout procedures apply.

13.3.1 Definitions

13.3.1.1 "Close-out" – is the process by which the Government determines that all applicable administrative actions and all required work have been completed by the Coordinating Center and the Government.

13.3.1.2 "Date of Completion" – is the date on which all work is completed or the date on the Clinical Trial or an amendment thereto on which the period of performance ends.

13.3.1.3 "Disallowed costs" – are those charges to the Clinical Trial that the Government or its representative determines to be unallowable, in accordance with the terms and conditions stated in this Agreement.

13.3.2 Upon request, the Government shall make prompt payments to the Coordinating Center for allowable reimbursable costs under the Clinical Trial being closed out.

13.3.3 The Government shall obtain from the Coordinating Center within ninety (90) calendar days after the date of completion of the Clinical Trial all financial, performance, and other reports required as the condition of the Clinical Trial. The Government may grant extensions when requested by the Coordinating Center.

13.3.4 When authorized by the Clinical Trial, the Government shall make a settlement for any upward or downward adjustments to the Government's share of costs, not to exceed the Government's obligated cost share amount,

after these reports are received.

13.3.5 Quick close-out procedures similar to FAR 42.708 shall be followed when possible.

13.3.6 The Coordinating Center and Network Sites shall account for any property received from the Government.

Article 14. STOP WORK ORDERS

14.1 After consultation between the Agreements Officer and the Coordinating Center, the Coordinating Center may, at any time, in accordance with its Manual of Operations or other governing agreement, by written order to the Network Site(s), require the Network Site(s) to stop all, or any part, of the work called for under any Clinical Trial for a period of 90 days after the written order is delivered to the Network Site(s), and for any further period to which the Parties may agree. The order shall be specifically identified as a stop-work order issued under this Article. Upon receipt of the order, the Network Site(s) shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of 90 days after a stop- work is delivered to the Network Site(s), or within any extension of that period to which the Parties shall have agreed, the Coordinating Center shall either:

14.1.1. Cancel the stop-work order; or

14.1.2. Terminate the work covered by the Clinical Trial.

14.2. If a stop work order issued under this clause is canceled, the Network Site(s) shall resume work. The Government through the Coordinating Center shall make an equitable adjustment in the delivery schedule or Clinical Trial estimated cost/price, or both, and the Government's share of the Clinical Trial shall be modified, in writing, accordingly, if—

14.2.1. The stop-work order results in an increase in the time required for, or in the Network Site's cost properly allocable to, the performance of any part of the Clinical Trial; and

14.2.2. The Network Site(s) asserts its right to the adjustment within 30 days after the end of the period of work stoppage; provided that, if the Government decides the facts justify the action, the Government through the Coordinating Center may receive and act upon a proposal submitted at any time before final payment under the Clinical Trial.

14.3. If a stop work order is not canceled and the work covered by the Clinical Trial is terminated the Coordinating Center shall work with the Network Site(s) to negotiate an equitable reimbursement.

14.4. Flow down. The Coordinating Center shall include this Article, suitably modified, to identify all parties, in all Clinical Trials or subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where

flow-down of rights and obligations is required.

ARTICLE 15. RESOURCE SHARING

15.1. The resource sharing requirement is intended to highlight the dual focus of the authority this Agreement is issued under and show commitment on the part of the performing team to pursue and/or commercialize the technology in the future. The Government and the Coordinating Center agree that the Coordinating Center's resource share should equal (TBD)% of the resources provided by the Government. While tracking is required for Phase I and Phase II operations, the resource share shall be tracked at the overall Agreement level, and will include all resources provided through Phase I and Phase II operations. Throughout the period of performance of the Agreement, the Coordinating Center, the AO, the Agreements Specialist, and the AOTR will actively monitor resource sharing. The Coordinating Center will be given the opportunity to become compliant with this term should they be found non- compliant. Failure to comply may result in termination.

15.1.1 It is anticipated that each Clinical Trial should include a significant resource share, which will be included in the specific Clinical Trial budgets. Examples of what might be considered a significant extent or significant contribution include, but may not be limited to supplying new key technologies or products, accomplishing a significant amount of the effort, or in some other way causing a material reduction in the cost or schedule or increase in the performance.

15.2. Resource Sharing Arrangement Adjustment. If a Clinical Trial or Coordinating Center efforts are performed under budget or the Clinical Trial performer or Coordinating Center does not expect to contribute its specified share, the Government will review the share ratio to determine whether the Government's share is still equitable or whether the Government's share should be revised based upon the circumstances. Costs will be evaluated based upon the terms and conditions contained in the Clinical Trial approval.

15.3. Resource Sharing Liability. The Clinical Trial performer's liability to fund the Clinical Trial shall be limited to the total Clinical Trial performer's share value identified in the Government approval unless modified at a later date. In no case shall the Government's financial liability exceed the amount obligated. The Government is not obligated to reimburse the Clinical Trial Performer for costs incurred in excess of the total amount obligated by the Government under the Agreement.

15.4. Flow down. The Coordinating Center shall include this Article, suitably modified, to identify all parties, in all Clinical Trials or subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

ARTICLE 16. REPRESENTATIONS AND WARRANTIES

16.1. Representations and Warranties of All Parties. Each Party to this Agreement represents and warrants to the other Parties that:

16.1.1. It is a validly existing legal or Government entity;

16.1.2. It is free to enter into this Agreement;

16.1.3. In so doing, it will not violate any other agreement to which it is a Party; and

16.1.4. It has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.

16.2. Limitations. Except as expressly provided herein, neither the Coordinating Center nor the Government makes any warranty, express or implied, either in fact or by operation of law, by statute or otherwise, relating to (a) any research conducted under this Agreement or (b) any invention conceived and/or reduced to practice under this Agreement or (c) any other intellectual property developed under this Agreement, and each one specifically disclaims any implied warranty of merchantability or warranty of fitness for a particular purpose.

16.3 Flow down. The Coordinating Center shall include this Article, suitably modified, to identify all parties, in all Clinical Trials or subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The Government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

Article 17. LIABILITY OF THE PARTIES

17.1. Waiver of Liability. With regard to the activities undertaken pursuant to this Agreement, no Party shall make any claim against another Party, another Party's employees, another Party's related entities (e.g., contractors, Subawardees, etc.) or employees of another Party's related entities for any injury to or death of its own employees or employees of its related entities, or for damage to or loss of its own property or that of its related entities, whether such injury, death, damage, or loss arises through negligence or otherwise, except in the case of willful misconduct.

17.2. Damages. To the extent that a risk of damage or loss is not dealt with expressly in this Agreement, the Parties liability to the other Parties arising out of this Agreement whether or not arising as a result of an alleged breach of this Agreement, shall be limited to direct damages only, and shall not include any consequential, punitive, special and incidental damages, claims for lost profits, or other indirect or consequential damages.

17.3. Extension of Waiver of Liability. The Coordinating Center agrees to extend the waiver of liability as set forth above to subawards by requiring them, by contract or otherwise, to agree to waive all claims against any and all Parties to this Agreement or sub-tier award.

17.4. Applicability. Notwithstanding the other provisions of this article, this waiver of liability shall not be applicable to:

17.4.1. Claims between the Parties regarding a material breach or non-payment of funds,

17.4.2. Claims for damage caused by willful misconduct,

17.4.3. IP claims.

17.5. Limitation of Liability. In no case shall the Government's or the Coordinating Center's financial liability exceed the amount obligated by the Government or committed as a Cash Contribution or In-kind Contribution by the Coordinating Center. Nothing in this Article shall be construed to create the basis of a claim or suit where none would otherwise exist.

17.6. Flow down. The Coordinating Center shall include this Article, suitably modified, to identify all parties, in all subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

Article 18. DISPUTE RESOLUTION

18.1. Dispute Resolution Process. The Parties recognize that disputes relating to their rights and obligations hereunder may arise from time to time during the term of this Agreement or during performance of a Clinical Trial awarded under this Agreement. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement and any Clinical Trial in an expeditious manner by mutual cooperation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article if and when a dispute arises under this Agreement, or any Clinical Trial awarded pursuant to this Agreement.

18.1.1. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than three (3) months prior to the notification made under this article constitute the basis for relief under this article unless the Senior Contracting Official (SCO), in the interest of justice waives this requirement.

18.1.2. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through their respective AO or the Coordinating Center representative as the case may be) in writing documenting the relevant facts, identifying unresolved issues, specifying the clarification or remedy sought, and documenting the rationale as to why the clarification/remedy is appropriate. Within ten (10) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a decision by the SCO. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The SCO will conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such position. Any such decision is final and binding, unless a Party shall, within thirty (30) calendar days request further review as provided by this article.

18.1.3. If requested within thirty (30) calendar days of the SCO's decision, further review will be conducted by the Head of the Contracting Activity (HCA) and the Coordinating Center Director. If the HCA and the Consortium Director reach a mutually agreeable resolution, that decision is final subject to modification of the agreement pursuant to Article 6 to reflect the dispute resolution decision. In the absence of a decision within sixty (60) calendar days of referral to the HCA and Consortium Director (or such other period as agreed to by the parties), the parties may, but are not required to, agree to explore and establish an Alternate Disputes Resolution procedure to resolve the dispute. This agreement provides no other process or procedure for dispute resolution. Nothing in this agreement waives or should be construed as a waiver of the sovereign immunity of either party.

18.2. Flow down. The Coordinating Center shall include this Article, suitably modified, to identify all parties, in all Clinical Trials or subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

Article 19. GENERAL PROVISIONS

19.1. Fees. Fees/ Profits are not allowable costs under this Agreement.

19.2. Regulatory Affairs. Development and production of medical products and processes may be regulated by the U.S. Food and Drug Administration (FDA) and Research involving FDA-regulated medical products in animal (non- clinical) or human (clinical) studies is regulated by other laws, directives, and regulations. Clinical Trials under this Agreement that involve work in support of or related to FDA approval of drugs, biologics, or medical devices will specify:

(a) which party is the sponsor and/or applicant to FDA,

(b) ensure Government access to all regulatory communications and meetings regarding the Clinical Trial, and (c) ensure Government access to regulatory rights (including but not limited to sponsorship or holdership of a regulatory application and/or rights of reference thereto) in the event of the Coordinating Center or Network Site's product development abandonment or failure. Efforts conducted under this rOTA shall be done ethically and in accordance with all applicable laws, directives, and regulations.

19.3. Parties Bound. This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their respective successors, assigns, and legal representatives. Nothing herein shall be construed to give any Network Site rights as a Party to or third-Party beneficiary of this Agreement. Rights or obligations of Network Sites referenced herein shall be provided for by agreements between and among the Coordinating Center and Network Sites.

19.4. Assignment.

19.4.1. This Agreement may not be assigned or transferred by any of the Parties hereto

without the prior written consent of the other Parties; provided, however, that the Coordinating Center or a Network Site may assign its rights and delegate its obligations (i) to any affiliate of the Coordinating Center or such Network Site (although, in the event of any such assignment and delegation, the assigning Party shall remain primarily liable for its obligations hereunder) and (ii) to a purchaser of all or substantially all of the business of the Coordinating Center or such Network Site to which this Agreement relates by merger, sale of assets, or otherwise.

19.5. Affiliates. The Parties hereto acknowledge that some Parties will carry out certain activities required or permitted pursuant to this Agreement through their affiliates. The Parties hereby represent and warrant that this Agreement shall be binding on their affiliates in accordance with this Agreement as if such affiliates were Parties to this Agreement. In the event that any Party to this Agreement is acquired by another company, the technology and programs of the acquiring company in existence at the time of such transactions shall not be subject to the Agreement.

19.6. Civil Rights Act. This Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to the nondiscrimination in federally assisted programs.

19.7. Entire Agreement. This Agreement constitutes the entire and only agreement between the Parties relating to the subject matter hereof, and all prior negotiations, representations, agreements, and understandings are superseded hereby.

19.8. Further Assurances. At any time or from time to time, the Parties shall, at the request of the Coordinating Center or the Government:

19.8.1. Deliver to the Coordinating Center, the Government, or Network Sites such records, data, or other documents consistent with the provisions of this Agreement;

19.8.2. Execute, and deliver, or cause to be delivered, all such assignments, consents, documents, or further instruments of transfer or license; and

19.8.3. Take or cause to be taken all such other actions, as any Party may reasonably deem necessary or desirable in order for the Party to obtain the full benefits of this Agreement and the transactions contemplated hereby.

19.9. Right to Develop Independently. Although it is the intent of the Parties to utilize this Agreement in the Government's award of its R&D activities in the Field, nothing will impair any Party's right to independently acquire, license, develop or have developed, utilize or otherwise exploit similar information and technology performing the same or similar functions as the information and technology which is the subject of the technical objectives or any other relevant Planning, Program and Budgeting System document.

19.10. Radioactive Materials. Network Sites shall assure compliance with the provisions of Title 10 CFR 21. This regulation establishes procedures and requirements for implementation of Section 206 of the Energy Reorganization Act of 1974.

19.11. Recombinant DNA. By signing the award or accepting funds under the award, you assure that all work involving the use of recombinant DNA will be in compliance with guidance

provided at https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/

19.12. Environmental Liability. The Network Sites are responsible for achieving compliance with all environmental laws applicable to the work performed under this Agreement, including but not limited to any licenses and permit applications required under Federal, State, or local laws or regulations. The Network Site shall not name the United States, the Department of Army (DA), or any other Government agency, instrumentality or employee as an owner, operator or in any other capacity on any license or permit application required under environmental laws unless written consent is first obtained from an authorized agent of the Federal agency or instrumentality to be named.

19.13. Prohibition of Use of Human Cadavers.

Research, development, testing and evaluation (RDT&E), education or training activities involving human cadaveric specimens under a Clinical Trial shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012

(https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview).

The USAMRDC Office of Research Protections (ORP) is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this policy.

Approval must be obtained from the USAMRDC ORP. Network Sites must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. ORP will issue written approvals to begin under separate notification to the Network Sites, a copy of which shall be provided to the appointed AOTR. Written approval to proceed from the USAMRDC ORP is also required for any subaward that will use funds from a Clinical Trial to conduct RDT&E, education or training involving human cadaveric specimens.

The Network Site must promptly report problems related to the conduct of the activity involving cadavers or the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers to the appointed SOTR who informs USAMRDC ORP.

The Network Site must maintain complete records of the activity.

The USAMRDC or designees must be permitted to observe the activity upon request and/or audit activity records to ensure compliance with the approved protocol or applicable regulatory requirements.

Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

19.14. Prohibition of Use of Human Subjects.

Research under this Agreement or Clinical Trial involving the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data, cannot begin until the USAMRDC's ORP provides authorization that the research may proceed. The USAMRDC ORP will issue written approval to begin research under separate notification to the

Network Site, a copy of which shall be provided to the appointed AOTR. Written approval to proceed from the USAMRDC ORP is also required for any Network Site (or lower tier subawards) that will use funds from this award to conduct research involving human subjects.

The USAMRDC ORP conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRDC as a part of their responsibility to protect human subjects in research.

Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

The Coordinating Center is required to adhere to the following reporting requirements:

Submission of substantive modifications to the protocol, continuing review documentation, and the final report as outlined in the USAMRDC ORP approval memorandum.

Unanticipated problems involving risks to subjects or others, subject deaths related to participation in the research, clinical holds (voluntary or involuntary), and suspension or termination of this research by the IRB, the institution, the Sponsor, or regulatory agencies, must be promptly reported to the USAMRDC ORP.

Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to the USAMRDC ORP HRPO.

The knowledge of any pending compliance inspection/visits by the FDA, ORP, or other government agency concerning this clinical investigation or research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies, and any instances of serious or continuing noncompliance with regulatory requirements that relate to this clinical investigation or research, must be reported immediately to the USAMRDC ORP.

Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

DoD requirements for human subject's research, including 32 CFR Part 219, DoD Instruction 3216.02, and USAMRDC ORP Human Research Protection Office submission instructions can be accessed at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

19.15. Notices. Any notice or other communication required or permitted under this Agreement shall be in writing and (a) personally delivered, (b) mailed, postage prepaid, first class, certified mail, return receipt requested, (c) sent, shipping prepaid, return receipt requested by national overnight courier service, or (d) sent by electronic mail to the appropriate Party or Parties at the addresses as set forth herein, or at such other addresses as may be given from time to time in accordance with the terms of this notice provision. Any notice or other communication given by personal delivery or electronic mail shall be deemed given on the date personally or electronically delivered; any notice or other communication given by mail shall be deemed given five (5) calendar days after the date deposited in the United States mail; and any notice or other communication given by national overnight courier service shall be deemed given on the next business day after being sent.

19.16. Waiver. No waiver of any rights shall be effective unless assented to in writing by the Party to be charged, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

19.17. Section Headings. The headings of the several sections of this Agreement are intended for convenience of reference only and are not intended to be a part of, or to affect the meaning or interpretation of this Agreement.

19.18. Severability. In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision; provided that no such severability shall be effective if the result of such action materially changes the economic benefit of this Agreement to the Parties.

19.19. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. The Coordinating Center shall receive a copy of this executed Agreement and modifications thereto with the Agreements Officer retaining the originals.

19.20. Public Announcements. Any written announcements, press releases, or similar publicity (collectively, "Announcements") with respect to the execution of this Agreement shall be agreed upon by the Government, the Coordinating Center, and the affected Network Site or Members in advance of such Announcement. Each Party agrees to provide to each other Party a copy of any proposed public Announcements relating to this Agreement as soon as reasonably practicable under the circumstances prior to its scheduled release. Each Party shall have the right to expeditiously review and recommend changes to any Announcement regarding this Agreement. Except as otherwise required by law, the Party whose Announcement has been reviewed shall consider in good faith the removal of any information any reviewing Party reasonably deems to be inappropriate for disclosure. In proposing, reviewing, and considering comments on Announcements, the interests of all Parties shall be taken into consideration, with the overall goal being the furtherance of the objectives of this Agreement and the harmonization of the interests of all Parties. Public release of information related to this Agreement and individual Clinical Trials will follow the procedure set forth in Article 12– Publication and Academic Rights. Nothing herein will prohibit or constrain the Government from exercising its statutory and regulatory requirements to the full extent thereof.

19.21. Force Majeure. No failure or omission by the Coordinating Center or the Network Sites in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond the control of the Parties, including, but not limited to, the following: acts of God; acts or omissions of any Government; any rules, regulations or orders issued by any Government authority or by any officer, department, agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; and invasion and provided that such failure or omission resulting from one of the above causes is cured as soon as is practicable after the occurrence of one or more of the above mentioned causes.

19.22. Order of Precedence. In the event of any inconsistency between the terms of this Agreement and the terms of any Clinical Trial made pursuant to this Agreement, the

inconsistency shall be resolved by giving precedence in the following order: (1) the Clinical Trial approval and the applicable Statements of Work, drawings, and specifications, (2) this Agreement.

19.23. Excluded Statutes. The Parties understand and agree that this Agreement as well as any Clinical Trials awarded pursuant to this Agreement ARE NOT subject to the Competition in Contracting Act, the Contract Disputes Act, and the GAO Procurement Protest System.

19.24. Code of Conduct. No employee, officer, or agent of any Party to this Agreement shall participate in the selection, award, or administration of a contract supported by Federal funds if a real or apparent conflict of interest would be involved. Such a conflict would arise when the employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the Parties indicated herein, has a financial or other interest in the firm selected for an award. The officers, employees, and agents of the recipient shall neither solicit nor accept gratuities, favors, or anything of monetary value from contractors, or Parties to subagreements. However, recipients may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. The standards of conduct shall provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the recipient.

19.25. Flow down. The Coordinating Center shall include this Article, suitably modified, to identify all parties, in all Clinical Trials or subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

Article 20. REFERENCES

For reference only and NOT incorporated into this Agreement.

1. DoD Directive 7045-14

2. AR 40-32, The Care and Use of Laboratory Animals in DoD Programs

3. DoD Instruction 3216.01, Use of Animals in DoD Programs

4. Title 32 Code of Federal Regulations Part 219, Protection of Human Subjects

5. 21CFR Parts 50 and 56, Institutional Review Board, Part 312, Investigation of New Drug Applications, Part 812, Investigational Device Exemption

6. 45 CFR 160-164, Public Welfare

7. DoD Directive 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research

8. AR 70-25, Use of Volunteers as Subjects of Research