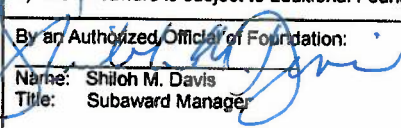
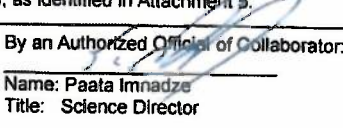


International Subaward Agreement ("Subaward")

Institution/Organization ("Foundation") Name: The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Address: 6720-A Rockledge Drive, Suite 100 Bethesda, MD 20817		Institution/Organization ("Collaborator") Name: L. Sakvarelidze National Center for Disease Control and Public Health Address: 9 M. Asatiani St. Tbilisi 0177, Georgia EIN: N/A DUNS: 683525574	
Prime Award No.: FA8650-10-2-6131		Issuance Date: 8/13/2010 CFDA No.: 12.800	
Awarding Agency: US AIR FORCE RESEARCH LABORATORY		Prime Award Period of Performance: 8/13/2010 – 3/31/2015	
Subaward Agreement No.: 2472		HJF Cost Center Code: 306318-02.04-63420	
Purchase Order No.: 815245		Subaward Period of Performance: 4/15/2014 – 3/31/2015	
Subaward Period of Performance: 4/15/2014 – 3/31/2015		Effective Date: 4/15/2014 Amount Funded: \$20,000	
Project Title: Collaboration to Enhance MDR-TB Surveillance using the Xpert™ MTB/RIF Assay and Color Test in Diverse Settings			
Advance Payments [Check here if applicable: ☐ See Attachment 8]			
1) Foundation hereby awards a cost reimbursable Subaward, as described above, to Collaborator. The statement of work and budget for this Subaward are (check one): ☐ as specified in Collaborator's proposal dated ____; or ☒ as shown in Attachment 6. In its performance of Subaward work, Collaborator shall be an independent entity and not an employee or agent of Foundation. The Collaborator will bear primary responsibility for the conduct of the research described in the statement of work and will exercise sound judgment within the limits of the Subaward terms and conditions. 2) Collaborator understands and agrees that this Subaward is funded only for the period referenced above and that future funding is subject to the availability of funds and satisfactory progress on the project. The maximum obligation of the Foundation for support of this Subaward will not exceed the amount funded. Collaborator shall submit invoices on a monthly basis and Foundation shall reimburse Collaborator not more often than monthly for allowable costs. Costs must be expressed in U.S. Dollars (US\$) using the applicable exchange rate at the time the invoice is submitted. Monthly invoices shall be submitted no later than twenty-five (25) days after the month-end and must include the following information: invoice date, Collaborator's Name and address, HJF PO number, HJF agreement number, HJF cost center code, period of performance of the Subaward, period covered by the invoice, current and cumulative cost listed by budget line item as presented in Collaborator's budget (e.g. personnel, travel, supplies, animal costs, participant costs, equipment costs listed by equipment, other direct costs with details, etc.), and certification as to truth and accuracy of the invoice (<i>A model invoice is provided as Attachment 7</i>). Invoices shall be submitted to AP-docs@hjf.org by e-mail. The subject line of the e-mail must include the PO number. Invoices that do not follow the above requirements will be rejected. Questions concerning invoice receipt or payments should be directed to the appropriate party's Financial Contact, as shown in Attachment 3. All payments by the Foundation will be in U.S. Dollars. Payments shall be considered provisional and subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Collaborator. A final statement of cumulative costs incurred marked 'final' shall be submitted to Foundation's Financial Contact no later than thirty (30) days after the Subaward end date or termination date to allow sufficient time for Foundation to prepare close-out reports for the Awarding Agency. The final statement of cumulative costs shall constitute Collaborator's final financial report. 3) The Collaborator shall not conduct ANY research under this Subaward involving human subjects, human anatomical substances, or laboratory animals until the Collaborator has received written approval from the Foundation to begin such research. Written approval will be issued to Collaborator and Collaborator's Principal Investigator by separate letter from the Foundation. Failure to comply with this provision may result in the withholding of funds or termination of the Subaward. 4) Matters concerning the technical performance of this Subaward should be directed to the appropriate party's Principal Investigator or Project Director, as shown in Attachment 3. Technical reports are required in accordance with Attachment 4, "Subaward Reporting Requirements." Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, should be directed to the appropriate party's Administrative Contact, as shown in Attachment 3. Any such changes made to this Subaward require the written approval of each party's Authorized Official, as shown in Attachment 3. No-cost extensions require the written approval of the Foundation. Requests for a no-cost extension should be addressed to and received by the Foundation Administrative Contact, as shown in Attachment 3, not less than thirty days prior to the desired effective date of the requested change. The Collaborator shall obtain written approval from the Foundation Administrative Contact prior to: (1) replacement of the Collaborator PI or any key personnel, (2) absence of the Collaborator PI or key personnel from the project during any continuous period of three months or more, and (3) reduction of Collaborator PI or key personnel effort devoted to the project by twenty-five percent or more. The only method this Subaward may be modified is by a formal, written modification signed by each party's Authorized Official, as shown in Attachment 3. No other communications, whether oral or in writing, are valid to change the terms and conditions of this Subaward. 5) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law. 6) Either party may terminate this Subaward with thirty (30) days written notice to the appropriate party's Administrative Contact, as shown in Attachment 3. Foundation shall pay Collaborator for termination costs as allowable under OMB Circular A-21 or A-122, as applicable. 7) The Subaward is subject to the terms and conditions of the Prime Award and other special terms and conditions, as identified in Attachment 2. By signing below Collaborator makes the certifications and assurances shown in Attachments 1 and 2. Where necessary to make incorporated provisions applicable to this Subaward, references to the "Government," the "Grantor," or words of similar import shall mean the "Foundation"; references to the "Grantee," the "Awardee," the "Recipient" or words of similar import shall mean the "Collaborator"; and references to "Grants Officer" shall mean the "Foundation Authorized Official." 8) The Subaward is subject to additional Foundation terms and conditions, as identified in Attachment 5.			
By an Authorized Official of Foundation:  Name: Shiloh M. Davis Title: Subaward Manager		By an Authorized Official of Collaborator:  Name: Paata Imnadze Title: Science Director	
Date: 10/28/2014		Date: 10.10.14	

Attachment 1 Certifications and Assurances

A. By signing the Subaward Agreement, the authorized official of COLLABORATOR certifies, to the best of his/her knowledge and belief, that:

Certification Regarding Lobbying

1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the Collaborator, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, or the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Collaborator shall complete and submit Standard Form - LLL, "Disclosure of Lobbying Activities," to the Foundation.

3) The Collaborator shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U. S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters

Collaborator certifies by signing this Subaward Agreement that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.

OMB Circular A-133 Assurance

Collaborator assures Foundation that it complies with OMB Circular A-133 and that it will notify FOUNDATION of completion of required audits and of any adverse findings that impact this subaward.

Attachment 2

Subaward Agreement

Agency-Specific Certifications/Assurances

1. By signing this Subaward, the Collaborator's Authorized Official provides certifications and assurances that it will comply with applicable provisions of the following National policies on:
 - a. Prohibiting discrimination:
 - i. On the basis of race, color, or national origin, in Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d, et seq.), as implemented by DoD regulations at 32 CFR part 195;
 - ii. On the basis of age, in the Age Discrimination Act of 1975 (42 U.S.C. 6101, et seq.) as implemented by Department of Health and Human Services regulations at 45 CFR part 90;
 - iii. On the basis of handicap, in Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), as implemented by Department of Justice regulations at 28 CFR part 41 and DoD regulations at 32 CFR part 56;
 - iv. On the basis of sex and blindness, in Title IX of the Educational Amendments of 1972 (20 U.S.C. 1681, et seq.)
 - b. The Clean Air Act (42 U.S.C. 7401, et seq.) and Clean Water Act (33 U.S.C. 1251, et seq.), as implemented by Executive Order 11738 (3 CFR, 1971-1975 Comp/ p. 799).
 - c. For humans, the Common Federal Policy for the Protection of Human Subjects, codified by the Department of Health and Human Services at 45 CFR part 46 and implemented by the DoD at 32 CFR part 219.
 - d. For animals, Rules on animal acquisition, transport, care, handling, and use in:
 - i. 9 CFR part 1-4, Department of Agriculture rules that implement the Laboratory Animal Welfare Act of 1966 (7 U.S.C. 2131-2156); and
 - ii. The "Guide for the Care and Use of Laboratory Animals," National Institutes of Health Publication No. 86-23.

General terms and conditions:

1. The restrictions on the expenditure of federal funds in appropriations acts to the extent those restrictions are pertinent to this Subaward.
2. This agreement will be administered in accordance with, and Collaborator shall comply with the applicable requirements of DoD 3210.6-R, the Department of Defense Grant and Agreement Regulations (DoDGARs) (13 Apr 98).
3. The provisions in Appendix A to DoDGARs Part 32 apply to this Subaward.
4. The Collaborator's property system shall meet the standards as set forth in DoDGARs 32.30 through 32.37.
5. Collaborator shall report deviations from budget and program plans and shall request prior approvals for budget and program plan revisions for all situations listed in DoDGARs 32.25(c)(1) through 32.25(c)(9), 32.25(d)(3), and 32.25(i).
6. To the extent practicable, Collaborator shall use the technical information resources of the Defense Technical Information Center (DTIC) and other Government or private facilities to investigate recent and on-going research and avoid needless duplication of scientific and engineering effort.
7. Travel supported by U.S. Government funds under this agreement shall use U.S.-flag air carriers (air carriers holding certificates under 49 U.S.C. 41102) for international air transportation of people and property to the extent that such service is available, in accordance with the International Air Transportation Fair Competitive Practices Act of 1974 (49 U.S.C. 40118) and the interpretative guidelines issued by the Comptroller General of the United States in the March 31, 1981, amendment to Comptroller General Decision B138942. (See General Services Administration amendment to the Federal Travel Regulations, Federal Register (Vol. 63, No. 219, 63417-63421.)

Special terms and conditions:

1. **Inventions**

The clause entitled Patent Rights (Small Business Firms and Nonprofit Organizations), 37 CFR 40114(a), is hereby incorporated by reference and is modified as follows: replace the word "contractor" with "Collaborator;" replace the words "agency," "Federal Agency," and "funding Federal Agency" with "Government;" replace the word "contract" with "Subaward;" delete paragraphs (g)(2), (g)(3), and the words "to be performed by a small business firm or domestic nonprofit organization" from paragraph (g)(1). With respect to paragraph (l), Communications, the Government point of contact on matters relating to this clause will be the servicing Staff Judge Advocate's office. The Collaborator shall document invention reporting in annual performance reports and shall file an Invention (Patent) Report on the DD Form 882, Report of Inventions and Subcontracts, within 60 days of completion or termination of this Subaward. The Collaborator shall submit the original and one copy to the Foundation Administrative Contact, who will present it to the servicing Staff Judge Advocate's Office.

2. Copyrights

Collaborator grants to Foundation an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward Agreement, solely for the purpose of and only to the extent required to meet Foundation's obligations to the Federal Government under its Prime Award.

3. Data Rights

All rights and title to data, as defined in 48 CFR 27.401, generated under this Subaward shall vest in the Collaborator. Collaborator grants to Foundation the right to use data created in the performance of this Subaward Agreement, solely for the purpose of and only to the extent required to meet Foundation's obligations to the Federal Government under its Prime Award. Collaborator grants to the U.S. Government a royalty free, world-wide, nonexclusive, irrevocable license to use, modify, reproduce, release, perform, display, or disclose any data for Government purposes. The Collaborator is responsible for affixing appropriate markings indicating rights on all data delivered under this Subaward. The Foundation and the Government will have unlimited rights in all data delivered without markings.

4. Collaborator Monitoring

Collaborator understands and agrees that the Foundation is obligated to ensure that funds administered by the Foundation to Collaborator are utilized in compliance with all pertinent Government regulations as well as generally accepted auditing standards. Accordingly, from time to time, the Foundation may audit Collaborator's use of funds under this Agreement, either directly or through designated external auditors. At the request of the Foundation, the Collaborator shall promptly and fully produce all data, financial records, and information relating to the Project to the Foundation and its representatives during normal business hours, and shall assist them in promptly resolving any questions and in performing audits or monitoring performance of the Project. Collaborator agrees to cooperate with the representatives of the Foundation who visit the Collaborator. The Foundation's auditing activities under this section may involve requests by mail, phone, facsimile, or in person for data, financial records, and information relating to the project or program.

Attachment 3 Subaward Contacts

Foundation Contacts	Collaborator Contacts
Administrative Contact Name: Richard Franetzki Sr. Subaward Specialist Address: The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. 6720-A Rockledge Drive, Suite 500 Bethesda, MD 20817 Telephone: 240-694-2122 Fax: 240-694-3111 Email: osp_subaward@hjf.org RFranetzki@hjf.org	Administrative Contact Name: Neli Chakvetadze Scientific Secretary Address: L.Sakvarelidze National Center for Disease Control and Public Health(NCDC) 9 M.Asatiani str, Tbilisi 0177, Georgia Telephone: +995 32 239 89 46 Fax: +995 32 243 30 59 Email: science@ncdc.ge
Principal Investigator or Project Director Name: Artthtur W. Hapner Address: The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. 6720-A Rockledge Drive, Suite 500 Bethesda, MD 20817 Telephone: 240-694-2000 Fax: 240-694-3100 Email: Ahapner@hjf.org	Principal Investigator or Project Director Name: Ekaterine Zangaladze, MD,PhD Address: L.Sakvarelidze National Center for Disease Control and Public Health(NCDC) 9 M.Asatiani str, Tbilisi 0177, Georgia Telephone: +995 32 239 89 46 Fax: +995 32 243 30 59 Email: zangaladze@yahoo.com
Financial Contact Name: Monica D. Buhl Accounts Payable Manager Address: The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. 6720-A Rockledge Drive, Suite 700 Bethesda, MD 20817 Telephone: 240-694-2219 Fax: 240-694-3137 Email: APDept@hjf.org	Financial Contact Name: Tariel Chanturidze Deputy Director Address: L.Sakvarelidze National Center for Disease Control and Public Health(NCDC) 9 M.Asatiani str, Tbilisi 0177, Georgia Telephone: +995 32 231 17 54 Fax: +995 32 243 30 59 Email: t.chanturidze@ncdc.ge
Authorized Official Name: Shiloh M. Davis Subaward Manager Address: The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. 6720-A Rockledge Drive, Suite 500 Bethesda, MD 20817 Telephone: 240-694-2253 Fax: 240-6943111 Email: osp_subawards@hjf.org	Authorized Official Name: Paata Imnadze Science Director Address: L.Sakvarelidze National Center for Disease Control and Public Health(NCDC) 9 M.Asatiani str, Tbilisi 0177, Georgia Telephone: +995 32 231 17 54 Fax: +995 32 243 30 59 Email: pimnadze@ncdc.ge

Attachment 4 Subaward Reporting Requirements

- A. Collaborator shall submit interim reports (e.g., monthly, quarterly, and/or annual) summarizing the research findings with respect to the approved Statement of Work in accordance with the schedule below. A copy of the report(s) shall be submitted to the Foundation's Principal Investigator and the Foundation Administrative Contact listed on Attachment 3.

<u>Report Type</u>	<u>Period Covered</u>	<u>Report due on</u>
*Interim Report	4/15/2014 – 9/30/2014	10/30/2014
Annual Report	4/15/2014 – 3/31/2015	04/15/2015

- B. In lieu of the last interim report due, Collaborator shall submit a final report summarizing the entire research effort, including all data and findings from interim reports, no later than 30 days after the end date of the Period of Performance. The final report will provide a complete reporting of the research findings and shall include a bibliography of all publications and meeting abstracts resulting from the research. A copy of the report shall be submitted to the Foundation's Principal Investigator and the Foundation Administrative Contact listed on Attachment 3.

- C. Special Reporting Requirement. Collaborator shall submit special reports as required by the Prime Award and as detailed below. A copy of this report shall be submitted to the Foundation's Principal Investigator and the Foundation Administrative Contact listed on Attachment 3.

The report(s) should be provided as per the following schedule:

<u>Period Covered</u>	<u>Report due on</u>
N/A	

D. Additional Reporting Requirements

1. In accordance with 37 CFR 401.14, Collaborator shall notify Foundation's Administrative Contact, as stated in Attachment 3, within two months after Collaborator's inventor discloses invention(s) in writing to Collaborator personnel responsible for patent matters. A Final Patent Report shall be submitted to the Foundation Administrative Contact identified in Attachment 3 within sixty (60) days of the termination date of this Subaward. A negative report is required if there were no inventions under this Subaward.
2. All reporting shall be in English and in U.S. dollars (\$US).

- E. Payments will be withheld if the required reports are not submitted when due.

- F. The reporting requirements listed above supersede any reporting requirements listed in the Prime Award.

- G. Although there is no page limitation for the reports, each report shall be of sufficient length to provide a thorough description of the accomplishments with respect to the approved Statement of Work.

- H. All reports shall have the following elements in this order: front cover, table of contents, introduction, body, key research accomplishments, reportable outcomes, conclusions, references, and appendices.

Front Cover: To include: project title; type of report, principal investigator name, period of time report covers, name and address of recipient organization; HJF subaward number, date of report.

Table Of Contents

Introduction: Narrative that briefly describes the subject, purpose, and scope of the research.

Body: This section of the report shall describe the research accomplishments associated with each task outlined in the approved Statement of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Appended publications and/or presentations may be substituted for detailed descriptions but must be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Recommended changes or future work to better address the research topic may also be included.

Key Research Accomplishments: Bulleted list of key research accomplishments emanating from this research.

Reportable Outcomes: Provide a list of reportable outcomes that have resulted from this research to include (if applicable): manuscripts, abstracts, presentations; patents and licenses applied for and/or issued; degrees obtained that are supported by this award; development of cell lines, tissue or serum repositories; informatics such as databases and animal models, etc.

Conclusions: Summarize the results to include the importance and/or implications of the completed research and, when necessary, recommend changes on future work to better address the problem.

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

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

PROGRESS REPORT
(Monthly, Quarterly, Annual, or Final report)

I. Cover Page

Date of the report: _____

Subawardee's Name _____

Subaward Number: _____

Foundation's Principal Investigator/Project Director: _____

Project Title: _____

Purpose: (check one)

☐ Annual

☐ Quarterly

☐ Monthly

☐ Final

Period covered by this report: from _____ to _____

II. Table of Contents

III. Introduction

IV. Body

V. Key Research Accomplishments:

VI. Reportable Outcomes:

VII. Conclusions:

VIII. References:

VIII. Appendices:

(Refer to the enclosed details for information to be covered under III – VIII)

Attachment 5

Additional Foundation Terms and Conditions

1. **Dispute Resolution.** In the event any controversy, claim, dispute, difference, or misunderstanding (a "Dispute") arises out of or relates to this Subaward, the Collaborator and the Foundation will attempt in good faith to amicably resolve such Dispute. If the parties are unable to resolve the Dispute, each party will prepare a written position statement summarizing the unresolved issues and such party's proposed resolution. These position statements will be delivered to the designated senior officers of each party, who will then attempt to resolve the Dispute. If after thirty days the parties continue to be unable to resolve the Dispute, either party may initiate arbitration in accordance with the **Arbitration** provision below, except that in the case of Disputes affecting ownership of intellectual property, involving proprietary information, or by which either party seeks to obtain from the other monetary damages in excess of One Million U.S. Dollars (US\$1,000,000), which are excluded from arbitration, either party, in lieu of proceeding with arbitration may commence an action in a court of competent jurisdiction. Collaborator agrees that the Maryland courts sitting in Montgomery County, Maryland and the appropriate appellate courts therefrom shall have jurisdiction to resolve Disputes excluded from arbitration. All Disputes shall be resolved using the English language and any monetary award shall be in U.S. Dollars.
2. **Arbitration.** Unless excluded under the **Dispute Resolution** provision above, the parties agree to submit to binding arbitration all Disputes between them arising out of or related to the Subaward. Within thirty (30) days after either party has notified the other in writing that it is submitting a Dispute to arbitration, one arbitrator shall be selected under the then current Rules of Arbitration of the International Chamber of Commerce ("ICC") pertaining to arbitration of commercial disputes ("Rules"). The arbitration shall be conducted in accordance with the Rules, except the ICC shall not have the authority to make any award for damages excluded in the Subaward. The place of arbitration shall be Montgomery County, Maryland, United States of America. The arbitration shall be by written decision and shall be final and binding and enforceable by any court of competent jurisdiction.
3. **Governing Law.** This Subaward shall be governed by the laws of the State of Maryland, United States of America, exclusive of the choice of law rules thereof, but giving due regard to U.S. Federal laws and regulations governing the interpretation of Federal grants and contracts.
4. **Language and Standards.** All reports, correspondence, drawings, notices, markings, and other communications shall be in the English language. In the event that a translation of this Agreement is prepared and signed by the parties, this English language version shall be the official version and shall govern if there is a conflict between this English language version and the translation.
5. **Foreign Corrupt Practices Act.** It is the Foundation's policy to conduct its business in strict compliance with all laws, rules, and regulations applicable to such business in all countries in which it operates and to require all the Foundation's collaborators to avoid any activities that would involve or potentially involve the Foundation in any unlawful practice. The Collaborator agrees to comply with this policy. If any question exists as to the propriety of any proposed transaction, the matter should be referred to the Foundation's General Counsel prior to entering into the transaction. The Collaborator understands and acknowledges that the Foundation is subject to the U.S. Foreign Corrupt Practices Act ("FCPA"). The Collaborator hereby represents, warrants, and covenants to the Foundation that it understands the Foundation's obligations under the FCPA and that neither it nor any of its employees, representatives, agents, or advisors have made nor will make, directly or indirectly, any solicitation, request, offer, payment, promise to pay, or authorization of any of the foregoing that is in violation of the FCPA.
6. **Export Control.** Collaborator understands and acknowledges that the Foundation is subject to various national security and export control laws and regulations that prohibit or restrict the export or diversion of certain controlled information and materials. Thus, in the performance of this subaward, the Collaborator agrees that it will comply with all applicable U.S. laws, regulations, Executive Orders and U.S. Department of Defense policies concerning the use, handling, and dissemination of controlled information and materials. Nothing in this subaward shall be construed to permit any dissemination of controlled information or materials in violation thereof.
7. **Insurance.** All work to be performed under this Subaward will be performed entirely at the Collaborator's risk. In addition to any insurance coverages expressly required under this Subaward, the Collaborator shall secure and maintain in full force and effect during the term of this Subaward (and following termination to cover any claims arising from this Subaward) commercially reasonable insurance coverages (or self-insurance retention) in such amounts and subject to such limitations as appropriate for the work performed hereunder. Such insurance policies shall name the Foundation as an additional insured with respect to work performed under this Subaward. It should be expressly understood, however, that the coverages required under this section shall not in any way limit the liability of Collaborator. Collaborator agrees to furnish evidence of Collaborator's insurance coverages at the Foundation's request.
8. **Limitation of Foundation Liability.** IN NO EVENT WILL FOUNDATION BE LIABLE FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL, OR INCIDENTAL DAMAGES ARISING OUT OF OR RELATING TO THIS SUBAWARD EVEN IF FOUNDATION HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.
9. **Indemnification.** Collaborator agrees to indemnify, defend, and hold the Foundation, its officers, directors, employees, and agents harmless from and against any and all losses, liabilities, demands, suits, judgments, claims, and expenses (including, without limitation, personal injuries, property damage, and reasonable attorney's fees), to the extent that such losses, liabilities, demands, suits, judgments, claims, and expenses arise out of or result from the negligent or intentional acts or omissions of Collaborator, or of its officers, directors, employees or agents, in performing its obligations under this Subaward.
10. **Publications.** It is understood that the research to be performed under the Subaward statement of work is part of a collaborative research project with other institutions and that Collaborator's Project Director will be free to publish the results of his or her part of the research in collaboration with other investigators at other sites in this study. The Collaborator agrees to submit a copy of any manuscript and/or abstract to the Foundation Administrative Contact for review and comment thirty (30) days prior to its submission for publication. Collaborator agrees to give the review comments serious consideration prior to publishing. In the

event Foundation notifies Collaborator that it intends to seek patent protection for material contained in a proposed publication, the time within which Foundation shall provide Collaborator its revisions and/or deletions to a proposed publication shall be extended by an additional ninety (90) days.

In all publications, Collaborator shall acknowledge the support of the Awarding Agency, in accordance with the terms of the Prime Award, and the Foundation, as appropriate. Following publication, one copy of published papers shall be submitted to the Foundation.

11. **Use of Name.** Neither party to this Subaward shall use the name of the other party in any publicity or advertising without the advance written approval of the other party.
12. **Confidentiality.** In the performance of this Subaward, both parties may find it necessary to disclose information that the disclosing party deems to be proprietary and confidential ("Confidential Information"). All such information shall be reduced to writing and marked "Confidential" and, if disclosed orally, shall be reduced to writing and marked "Confidential" within thirty (30) days of disclosure. For purposes of this clause, "reduced to writing" includes documentary (paper) and machine readable (electronic) formats. Except as otherwise provided in this Subaward, for a period of five (5) years after the date of such disclosure, the receiving party shall maintain the confidentiality of such Confidential Information and shall use it solely for the purposes of this Subaward. The receiving party shall use the same degree of care as it uses to protect its own confidential and proprietary information of a similar nature, but no less than a reasonable degree of care.

The following types of information shall not be considered Confidential Information:

- A. Information which is or becomes publicly known through no fault of the receiving party;
- B. Information learned from a third party entitled to disclose it;
- C. Information already known to or at any time developed by a party independent of any disclosure by the other party; or
- D. Information a party is obligated to produce or disclose pursuant to an order of a court of competent jurisdiction or a facially valid administrative, Congressional, or other subpoena, provided that the party is subject to the order or the subpoena.

The limitations on disclosure and use of Confidential Information shall survive the expiration or termination of this subaward.

13. **HIPAA Privacy.** Collaborator shall comply with the applicable provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), any applicable regulations such as DoD 6025.18-R and DoD 8580.02-R, as amended, and with the following provisions applicable to the disclosure of Protected Health Information to the Collaborator under this Subaward.

A. It is likely that the source of the Protected Health Information disclosed to Collaborator will be the U.S. Government. (In the event that the source of, or the entity responsible for the protection of, Protected Health Information is the Foundation, the following provision is amended by substituting the word "Foundation" for the word "Government.")

(i) Definitions. As used in this clause:

"Government" means the United States Government.

"Individual" has the same meaning as the term "individual" in 45 CFR 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

"Electronic Protected Health Information" has the same meaning as the term "protected health information" in 45 CFR 160.103,

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

"Protected Health Information" has the same meaning as the term "protected health information" in 45 CFR 160.103, limited to the information created or received by the Collaborator from or on behalf of the Government.

"Required by Law" has the same meaning as the term "required by law" in 45 CFR 164.103.

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

"Security Rule" means the Health Insurance Reform: Security Standards at 45 CFR part 160, 162, and part 164, subpart C.

Terms used in this provision, but not otherwise defined in this Subaward, shall have the same meaning as those terms in 45 CFR 160.103, 160.502, 164.103, 164.304 and 164.501.

(ii) The Collaborator agrees not to use or further disclose Protected Health Information other than as permitted or required by the Subaward or as Required by Law.

(iii) The Collaborator agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Subaward.

(iv) The Collaborator agrees to use administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of electronic protected health information that it creates, receives, maintains, or transmits in the execution of this Subaward.

(v) The Collaborator agrees to mitigate, to the extent practicable, any harmful effect that is known to the Collaborator of a use or disclosure of Protected Health Information by the Collaborator in violation of the requirements of this Subaward. If applicable, these mitigation actions will include as a minimum those listed in the TMA Breach Notification Standard Operating Procedure (SOP), which is available at: <http://www.tricare.mil/tmaprivacy/breach.cfm>.

(vi) The Collaborator agrees to report to the Government any security incident involving protected health information of which it becomes aware.

(vii) The Collaborator agrees to report to the Government any use or disclosure of the Protected Health Information not provided for by this Subaward.

(viii) The Collaborator agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by the Collaborator on behalf of the Government, agrees to the same restrictions and conditions that apply through this Subaward to the Collaborator with respect to such information.

(ix) The Collaborator agrees to ensure that any agent, including a subcontractor, to whom it provides electronic Protected Health Information, agrees to implement reasonable and appropriate safeguards to protect it.

(x) To the extent applicable, the Collaborator agrees to provide access, at the request of the Government and in the time and manner designated by the Government, to Protected Health Information in a Designated Record Set, to the Government or, as directed by the Government, to an Individual in order to meet the requirements under 45 CFR 164.524.

(xi) To the extent applicable, the Collaborator agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Government directs or agrees to pursuant to 45 CFR 164.526 at the request of the Government or an Individual, and in the time and manner designated by the Government.

(xii) The Collaborator agrees to make its internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by the Collaborator on behalf of the Government, available to the Government, or at the request of the Government to the Secretary, in a time and manner reasonably designated by the Government or the Secretary, for purposes of the Secretary determining the Government's compliance with the Privacy Rule.

(xiii) The Collaborator agrees to document any such disclosures of Protected Health Information and information related to such disclosures as would be required for the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

(xiv) The Collaborator agrees to provide to the Government or an Individual, in the time and manner designated by the Government, information collected in accordance with this Subaward, to permit the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

B. General Use and Disclosure Provisions

Except as otherwise limited in this Subaward, the Collaborator may use or disclose Protected Health Information on behalf of, or to provide services to, the Foundation and the Government for the purposes set forth in the statement of work, if such use of Protected Health Information would not violate the HIPAA Privacy Rule, the HIPAA Security Rule, or DoD 6025.18-R or DoD 8580.02-R if done by the Government.

C. Specific Use and Disclosure Provisions

(i) Except as otherwise limited in this Subaward, the Collaborator may use Protected Health Information for the proper management and administration of the Collaborator or to carry out the legal responsibilities of the Collaborator.

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

(iii) Except as otherwise limited in this Subaward, the Collaborator may use Protected Health Information to provide Data Aggregation services to the Government as permitted by 45 CFR 164.504(e)(2)(i)(B).

(iv) Collaborator may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j)(1).

D. Provisions to Inform the Collaborator of Privacy Practices and Restrictions

(i) Upon request the Government shall provide the Collaborator with the notice of privacy practices that the Government produces in accordance with 45 CFR 164.520, as well as any changes to such notice.

(ii) The Government may provide the Collaborator with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect the Collaborator's permitted or required uses and disclosures.

(iii) The Government may notify the Collaborator of any restriction to the use or disclosure of Protected Health Information that the Government has agreed to in accordance with 45 CFR 164.522.

E. Permissible Requests of the Collaborator

The Government shall not request the Collaborator to use or disclose Protected Health Information in any manner that would not be permissible under the HIPAA Privacy Rule, the HIPAA Security Rule, or any applicable Government regulations (including without limitation, DoD 6025.18-R and DoD 8580.02-R) if done by the Government, except for providing Data Aggregation services to the Government and for management and administrative activities of the Collaborator as otherwise permitted by this clause.

F. Termination

(i) Termination. A breach by the Collaborator of this clause may subject the Collaborator to termination of this Subaward.

(ii) Effect of Termination.

- (a) If this Subaward has any records management requirements, the records subject to this clause should be handled in accordance with the records management requirements. If this Subaward does not contain any records management requirements, the records should be handled in accordance with paragraphs (b) and (c) below
- (b) If this Subaward does not have records management requirements, except as provided in paragraph (c) of this section, upon termination of this Subaward, for any reason, the Collaborator shall return or destroy all Protected Health Information received from the Government, or created or received by the Collaborator on behalf of the Government. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of the Collaborator. The Collaborator shall retain no copies of the Protected Health Information.
- (c) If this Subaward does not have records management provisions and the Collaborator determines that returning or destroying the Protected Health Information is infeasible, the Collaborator shall provide to the Government notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Government and the Collaborator that return or destruction of Protected Health Information is infeasible, the Collaborator shall extend the protections of this Subaward to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as the Collaborator maintains such Protected Health Information.

G. Miscellaneous

(i) Regulatory References. A reference in this clause to a section in the Privacy Rule, the Security Rule, DoD 6025.18-R, or DoD 8580.02-R means the section as in effect or as amended, and for which compliance is required.

(ii) Survival. The respective rights and obligations of Collaborator under the "Effect of Termination" provision of this clause shall survive the termination of this Subaward.

(iii) Interpretation. Any ambiguity in this clause shall be resolved in favor of a meaning that permits the Government to comply with the Privacy Rule, the Security Rule, DoD 6025.18-R, and DoD 8580.02-R, as applicable .

14. **Survival.** The terms and conditions specified under this Attachment 5 shall survive the expiration or termination of this Subaward. In addition, all other Subaward terms and conditions that by their nature are intended to extend beyond the expiration or termination of this Subaward, shall also survive the expiration or termination of this Subaward.

Attachment 6 Statement of Work [SOW]

HJF PI Name:	Mr. Arthur Hapner (James Smith)
Contractor's Name:	National Center for Disease Control & Public Health Republic of Georgia (nCDC)
SOW Title:	Collaboration to Enhance MDR-TB Surveillance using the Xpert™ MTB/RIF Assay and Color Test in Diverse Settings
Date/Revision #	5-2-2014sd

I. INTRODUCTION/BACKGROUND:

The United States Air Force School of Aerospace Medicine (USAFSAM), Epidemiology Consult Service, manages the Multi-Drug Resistant Tuberculosis (MDR-TB) Surveillance Program. The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF) assists USAFSAM in the management and operation of this program through a Cooperative Agreement.

HJF is seeking to partner with the National Center for Disease Control & Public Health Republic of Georgia (nCDC) to enhance support and interactions with nCDC, Tbilisi Republic of Georgia. The purpose of this project is to determine methods and media to detect multi-drug resistant tuberculosis (MDR-TB) and extensively-drug resistant tuberculosis (XDR-TB). One laboratory technician and one coordinator will be needed to support this project at the nCDC laboratory in Tbilisi, Republic of Georgia.

SCOPE OF WORK

nCDC, to meet the objectives identified in the above mentioned study, will perform laboratory procedures for MDR-TB and XDR-TB testing using de-identified patient samples and approved study equipment.

II. TECHNICAL REQUIREMENTS:

The following tasks will be performed by the Subaward to meet the objectives listed above:

- a) Maintain a designated primary and alternate POC, in writing, to include telephone numbers and email addresses for each and provide this information to the HJF POC working at USAFSAM; communicate and provide up-dates as changes occur.
- b) One laboratory technician and one coordinator should be hired and ready to begin work by a mutually agreed upon date. The laboratory technician and coordinator will be qualified and capable in providing the following responsibilities:
 - i. Perform laboratory procedures for MDR-TB and XDR-TB testing using de-identified in-country patient samples and approved study equipment.
 - ii. Perform quality control procedures (QC) and equipment preventive maintenance to assure test performance, test methodologies, and equipment perform within the manufacturer's guidelines and performance specifications.
 - iii. Use considerable judgment to define and resolve problems and make recommendations.
 - iv. Maintains accurate records; tabulates and organizes data according to study guidelines.
 - v. Maintain an accurate inventory of study related supplies and equipment located at the nCDC lab.
 - vi. Study results, supply and equipment inventory will be recorded in approved databases. Information related to the databases will be provided once the databases are approved for use.
 - vii. Perform other duties as assigned.

III. **DELIVERABLES/SCHEDULE:**

The deliverables are listed as follows -

1. Interim (monthly) and final technical reports.
2. Hire lab technician and project coordinator
3. QC and maintenance logs upon request.
4. Perform testing of study samples.
5. Submit study testing data upon request.

IV. **APPLICABLE DOCUMENTS:**

Study Guidelines

Database parameters; information related to the databases will be provided once the databases are approved for use.

V. **PLACE OF PERFORMANCE:**

Tbilisi, Republic of Georgia

VI. **PERIOD OF PERFORMANCE:**

15 April 2014 to 31 March 2015

VII. **MONITORING THE PROGRESS:**

Subawardee agrees that satisfactory progress will be monitored during the life of the agreement as follows:

1. Communication and progress updates between the HJF POCs and Subawardee will occur regularly via teleconference and email correspondence, to occur at least monthly.
2. Formal monthly meetings will be scheduled to monitor progress, discuss information in interim reports, and agree to any changes to the statement of work that will be submitted as a modification to the agreement.
3. Prior to payment, the HJF POC will review invoices and technical reports for concordance with the statement of work.

The HJF POC(s) are:

James Smith
Program Manager/Site Lead
USAFSAM/PH
2510 5th Street
Wright Patterson AFB, OH 45433-7913
Phone: (937) 938-3301
e-mail: james.smith.219.ctr@us.af.mil

Joshua Cockerham
Customer Service/Supply Technician
USAFSAM/PHR
2510 5th Street
Wright Patterson AFB, OH 45433-7913
Phone: (937)938-3196
e-mail: joshua.cockerham.ctr@us.af.mil

VIII. **ACCEPTANCE CRITERIA:**

1. Complete and accurate documentation of effort and results in the interim and final technical reports.
2. Compliance with QC requirements.
3. Input study data in the approved database and submit to HJF POCs upon request
4. Perform testing of samples and adherence to Study Guidelines.

IX. **OTHER REQUIREMENTS:**

The project coordinator will work with both the nCDC (100 hours) and NCTLD (400 hours). Information gathered or obtained during the performance of this contract shall not be released to any party unless specifically authorized by HJF. Addresses, locations, and other program site information should be protected from public or private release at all times.

BUDGET AND JUSTIFICATION:

BUDGET - NCDC	
Personnel	
<u>Study/Project Coordinator</u>	
Hourly Rate = \$70	\$7,000
Total Hours = 100	
<u>Laboratory Technician</u>	
Hourly Rate = \$40	\$12,000
Total Hours = 300	
Customs Fees	\$1,000
TOTAL	\$20,000

Budget Justification

Salaries and Wages: One laboratory technician (300 hours x \$40/hr) and one project coordinator (100 hours x \$70/hr)

Custom Fees: Up to and not to exceed \$1,000.00 in support of customs fees imposed in order to expedite receipt of study related supplies and equipment.

Attachment 7

Invoice Template

Bill to:
Henry M. Jackson Foundation
for the Advancement of Military Medicine
6720-A Rockledge Drive
Bethesda, MD 20817

Invoice Date:
Invoice No:
Subawardee Name:
Subawardee PI Name:

Subaward Purchase Order No.
Subaward Agreement No:
HJF Cost Center Code No.:

Period of Performance of the Subaward:

Period of this Invoice (from to):

Invoice Total: _____ **(\$US)**

Expense Category				Current Costs	Cumulative Total	Budget Amount	Remaining Balance
Salary (See personnel details as per attached)							
Benefits							
Supplies							
Travel							
Equipment (Prior approval needed)							
Animal Costs							
Subject Participant Costs							
Other Costs (list other type of costs)							

Subtotal (\$US)

Indirect rate (@)

Indirect rate (expenses @ %)

Total with Indirect cost (\$US)

Explanation for any unusual or irregular expenses for the period covered by this invoice:

I certify that all payments requested are for appropriate purposes and in accordance with the subaward agreement.

Finance Manager - Name and Signature

Date

Information for Wire Transfer of Funds for Foreign Contractor

Name of Bank: National Bank of Georgia

Address of Bank: 2, Sanapiro St., 0114 Tbilisi, Georgia

Bank Phone No.: (995 32) 240 61 20

Bank Fax No.: (995 32) 240 65 77

Account No.: 021087992

Swift Code: BNLNGE22

Account Holder's Name: L.Sakvarelidze National Center for Disease Control & Public Health

Return completed form to: Office of Sponsored Programs or Office of Contracting
OSP Phone: (240) 694-4040 Contracting Phone: (240) 694-2270
OSP Fax: (240) 694-3111 Contracting Fax: (240) 694-3105