Georgian Research and Development Foundation

Georgia Mini-Grant Program

AWARD AGREEMENT # 60211

PROJECT TITLE: INFLUENZA STUDY OF BACKYARD ANIMALS IN GEORGIA

GRANTEE INFORMATION:

Principal Investigator	Ann Machablishvili
Principal Organization	National Center for Disease Control and Public Health (NCDCPH)
Address	9 M. Asatiani Str. Tbilisi 0177, Georgia

GRDF REPRESENTATIVE

Nikoloz Burdiashvili

Program Manager

Georgian Research & Development Foundation (GRDF)

Tbilisi 0186, 7, Mindeli str. Phone: (995 32) 2 21 03 61 Fax: (995 32) 2 21 02 28 Email: niko@grdf.ge

AWARD FINANCIAL SUMMARY

Total Grant Ceiling (USD)	\$9,930
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Source Funding Information:

CRDF Global Agreement#	GRDF09, Mod08/60040,	CFDA #	12.351
	Annex P106235		
DTRA Agreement #	HDTRA1-11-1-0061	Authorization	10 U.S.C. 2358 as amended
Appropriation	AB: 9710134.34HQ 1300 C11D 255999 BT04669000 S49012		

TERM

Award Duration	6 months	
The Project Agreement consists of:	(1) Cover Sheet	
•	(2) Award General Terms & Conditions	
	(3) Appendix A: Project Personnel	
	(4) Appendix B: Project Budget	
	(5) Appendix C: Standard Provision - U.S. I	Department of Defense, DTRA
	(6) Documents Incorporated by Reference: I	Proposal "MG-13-15"

SIGNATURES

Principal Investigator Signature	Typed Name/Title	Date
Authorized Institute signature / stamp	Typed Name/Title	Date
GRDF Signature / Stamp	Typed Name/Title	Date
	George Khokhobashvili/Executive Director	

GENERAL TERMS AND CONDITIONS

ARTICLE 1 - PROGRAM DESCRIPTION.

The purpose of the Agreement is to support the activities described in the Grantee's Proposal titled "Influenza Study of Backyard Animals in Georgia", hereby incorporated by reference. Grantee agrees to use all Grant support (including both funds and in-kind) and other support and the Grantee Contribution only for such activities.

ARTICLE 2 - AGREEMENT PERIOD.

Unless/until extended by Amendment, the Agreement Period commences upon 01 November 2014, and terminates upon expiration of the duration noted in the Grant Agreement Cover Sheet.

ARTICLE 3- BUDGET.

Grantee agrees to comply strictly with the Budget set forth in Attachment B (hereafter referred to as "Budget") and may not move funds between line items without GRDF approval.

ARTICLE 4 - ELIGIBLE COSTS.

Grantee may use Grant funds only for Grantee's verifiable, reasonable, allocable and allowable direct costs necessary for performance of the activities specified in the Project. All such costs must comply with the terms and conditions of the Agreement and must be incurred and expended in the Agreement Period.

ARTICLE 5 - AMOUNT OF GRANT FUNDS

The maximum amount of Grant funds and GRDF Grant support available to the Grantee is the Total Grant Ceiling specified on the Cover Sheet. GRDF's aggregate liability arising out of or relating to the Agreement may not under any circumstances exceed the Total Grant Ceiling. The Principal Organization is solely responsible for any overruns.

ARTICLE 6 - REPORTS.

Grantee shall be required to submit technical and financial reports in a format to be provided by GRDF. Reports shall be submitted electronically to GRDF. Grantee shall submit interim progress reports every quarter from the effective date of the award. Grantee shall submit a final technical and financial report with 30 days of the expiration of the award. The Grantee will also submit Development Report within nine months upon expiration of the award.

ARTICLE 7 - NOTIFICATION OF CERTAIN EVENTS.

Grantee shall notify GRDF, in writing, of the occurrence of any of the following events:

- A. Any significant change in the methodology or procedures being used in the Project from those discussed in the proposal;
- B. Any significant or major findings, breakthroughs, or events of unusual interest;
- C. Any problems, delays or adverse conditions that will materially affect the Project, its objectives or time schedules and actions being taken to address them;
- D. Any changes in key personnel or their status on the Project; and
- E. Any change in a Principal Investigator's institution, mailing address, telephone or fax numbers, or e-mail address;
- F. Any change in or absence of a Principal Investigator or project key personnel for a period longer than thirty (30) days;
- G. Any change in key personnel's level of effort devoted to the Project;
- H. Any significant change in the Project objectives or scope;

All changes in key personnel, budget reallocation requests (per subparagraph (I) above), and/or changes in Project objectives or scope are subject to GRDF approval.

ARTICLE 8 - PAYMENTS.

Grantee will receive payment for allowable Eligible Costs on a cost-reimbursable basis and in accordance with the Budget. All expenses must be documented with appropriate receipts and invoices. Payments will be made in reimbursement to Grantee, unless specifically authorized in advance for individual travel and consumable materials and supplies.

ARTICLE 9 - KEY PERSONNEL.

Principal Investigators and other Project Personnel are subject to approval prior to initial assignment and any replacement. Approval is hereby provided for Project Personnel specifically named in Attachment A. Departure of one or more Key Personnel, or his/her/their repeated or extended absence from the Program, may be cause for termination of the Agreement by GRDF.

ARTICLE 10- TIMEKEEPING.

Eligible individual financial support costs will be based on actual level of effort of Project Personnel and must be supported by individual timesheets subject to the following provisions:

- a. Individual timesheets, signed by both the requesting Project Personnel and the responsible Principal Investigator. Timesheets are to be maintained daily and submitted to the Principal Investigator on a monthly basis for review and approval.
- b. Project Personnel must use a GRDF-provided timesheet template, unless an alternative template has been approved. Timesheets will be completed based on actual time worked on GRDF-funded activities, with working hours being recorded on the provided timesheet template.
- c. The Principal Investigator is responsible for monitoring and documenting Project Personnel's compliance with timekeeping and reporting requirements; ensuring that Project Personnel are trained and informed on the timekeeping and reporting requirements; ensuring the timely collection of timesheets from all Project Personnel on the project each month; reviewing of timesheets for accuracy; certifying the accuracy of the timesheets collected; ensuring that payment requests are submitted to GRDF in a timely manner; and maintaining timesheet records for the Project.

ARTICLE 11 - INDIVIDUAL FINANCIAL SUPPORT.

Payments to individual project participants will be made in the form of individual grants (grant of physical person) to each designated Project Participant. Payments of individual grants will be made directly to individual bank accounts designated by GRDF for the benefit of the individual participant in accordance with current CRDF/GRDF procedures

ARTICLE 12 - MATERIALS, EQUIPMENT, SUPPLIES AND SERVICES.

Principal Organization shall submit all requests for purchase of materials, equipment, supplies or services to GRDF in such form and detail as may be specified in the applicable CRDF/GRDF procedures. Payments are made on behalf of the PO by GRDF directly to the approved vendor(s), unless otherwise agreed in writing by GRDF

ARTICLE 13 - EQUIPMENT.

Items over \$1,000 or local currency equivalent per unit acquisition cost and with a usable life of longer than one year shall be defined as Equipment. Purchase of equipment is subject to the following provisions:

- a. No Equipment other than items identified in the Budget may be acquired under this Agreement
- b. All Equipment must be clearly and prominently marked as having been provided (or financed) by GRDF.
- c. All equipment and other property acquired under this Agreement must remain available to and be used for the Project, and may not be sold, leased, mortgaged or otherwise transferred, or used for any non-Project purpose, be located and maintained at the premises of the Grantee or an authorized Collaborator, as appropriate, and remain accessible for viewing, examination or audit unless GRDF agrees otherwise in writing.
- d. Unless otherwise stipulated Equipment and other physical property received by the Grantee or Collaborator under this Agreement is supplied in the capacity of technical assistance and is transferred to the Grantee or Collaborator as authorized by GRDF.
- e. Title to Equipment and other property acquired under this Agreement will vest in the Grantee or Collaborator, as appropriate, unless otherwise directed by GRDF in writing.

- f. Use of any Equipment or other property acquired under this Agreement by military end-users or for military purposes is expressly prohibited.
- g. The Grantee shall ensure that all Equipment and other property provided under this Agreement is maintained in a manner consistent with its specifications and reasonable care, security and maintenance.
- h. In the event this Agreement is terminated for cause or the Grantee is in material breach thereof, GRDF may, at its sole discretion, require that any Equipment and property acquired under this Agreement be returned to GRDF or transferred to a third party as directed by GRDF. The shipping costs related to the return or transfer of the Equipment and property will be borne by GRDF.
- i. Within <u>thirty</u> days of receipt of Equipment, Grantee will prepare and return to GRDF an itemized receiving report, signed by an authorized representative, confirming receipt in apparent good order and working condition and registration of the Equipment on the Grantee's balance sheet. The report will be in a form to be provided by GRDF.

ARTICLE 14 - TRAVEL.

All travel undertaken by Grantee must be authorized in writing by the GRDF Representative at least 10 business days in advance and is subject to the following provisions:

- a. Travel Allowances (meals, incidentals & lodging expenses) may not exceed current US government rates.
- b. All air transportation purchased must be at the "lowest logical airfare" subject to the Fly America Act. "Lowest logical airfare" is defined as the lowest cost alternative that accommodates business commitments at the place of departure and travel destination. Premium-, Business-class and first-class tickets are not allowable expenses under this Agreement.
- c. Traveler's medical insurance is required for the duration of each trip.
- d. Brief trip reports detailing the purpose and outcome(s) of travel undertaken must be submitted by individual travelers no later than 30-days following return.

ARTICLE 15 - FLY AMERICA ACT.

The following provisions shall govern the air transportation of persons and property utilizing funds provided under this Agreement.

- a. Any air transportation to, from, between, or within a country other than the U.S. of persons or property, the expense of which will be assisted by GRDF funding, must be performed by or under a code-sharing arrangement with a U.S.-flag carrier if service provided by such a carrier is available. Tickets (or documentation for electronic tickets) must identify the U.S. flag air carrier's designator code and flight number.
- b. For the purposes of this requirement, U.S. flag air carrier service is considered available even though:
 - 1. Comparable or a different kind of service can be provided at less cost by a foreign air carrier;
 - 2. Foreign air carrier service is preferred by or is more convenient for the agency of traveler; or
 - 3. Service by a foreign air carrier can be paid for in excess foreign currency.
- c. The following rules apply unless their application would result in the first or last leg of travel from or to the U.S. being performed by a foreign-flag carrier.
 - 1. A U.S.-flag air carrier shall be used to destination or, in the absence of direct or through service, to the farthest interchange point on a usually traveled route
 - 2. If a U.S.-flag air carrier does not serve an origin or interchange point, a foreign-flag air carrier shall be used only to the nearest interchange point on a usually traveled route to connect with a U.S. flag air carrier.
- d. If a U.S.-flag carrier involuntarily reroutes the traveler via a foreign-flag air carrier, the foreign-flag air carrier may be used notwithstanding the availability of U.S.-flag air carrier service.
- e. Travel to and from the United States: Use of a Foreign-Flag Air Carrier is permissible if:
 - 1. The airport abroad is the traveler's origin or destination airport, and use of U.S.-flag air carrier service would extend the time in a travel status by at least 24 hours more than travel by a foreign-flag air carrier; or
 - 2. The airport abroad is an interchange point, and use of U.S.-flag air carrier service would increase the number of aircraft changes the traveler must make outside of the U.S. by 2 or more, would require the traveler to wait four hours or more to make connections at that point, or would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.

- f. Travel Between Points Outside the United States: Use of a foreign-flag air carrier is permissible if:
 - 1. Travel by foreign air carrier would eliminate two or more aircraft changes en route;
 - 2. Travel by a U.S.-flag air carrier would require a connecting time of four hours or more at an overseas interchange point; or
 - 3. The travel is not part of a trip to or from the United States and the use of a U.S. flag carrier would extend the time in a travel status by at least six hours more than the travel by foreign air carrier.
- g. Short-Distance Travel: For all short-distance travel, regardless of origin and destination, use of a foreign-flag air carrier is permissible if the elapsed travel time on a scheduled flight from origin to destination airport by a foreign-flag air carrier is three hours or less and service by a U.S.-flag carrier would double the travel time.
- h. In the event that individual Project Personnel traveling under this Agreement invokes one of above-referenced exceptions to the Fly America regulations, he/she must provide a written "CERTIFICATION OF UNAVAILABILITY OF U.S.-FLAG CARRIERS stating: "I [the traveler] hereby certify that the transportation service for personnel (and their personal effects) or property by certified U.S. air carrier was unavailable for the following reason(s): [State appropriate reason(s) as set forth above].

ARTICLE 16 – INSTITUTIONAL SUPPORT.

- a. Principal Organization shall submit request for Institutional Support funds to GRDF in such form and detail as may be specified in the applicable CRDF/GRDF procedures. Payment is made by GRDF directly to the Institute bank account.
- b. Institutional Support funds must be utilized for direct and/or indirect institutional expenses related to the execution of the Project. Such costs may include, but are not limited to, renovation to research facilities, payment of utilities costs and administrative expenses related to the Project, and other Project-related costs.
- c. Unless otherwise indicated, Institutional Support payment under this Agreement will be made on a costreimbursable basis

ARTICLE 17 – INTELLECTUAL PROPERTY.

Attachment C: Special Terms & Conditions contains the Intellectual Property provisions for this Agreement.

ARTICLE 18 - CONFLICTS OF INTEREST.

All Grantees shall adhere to the highest ethical standards in all matters related to the Agreement, and shall assure that the Project Personnel adhere to those standards.

For purposes of this Article—

"Conflict of Interest" means a family or other personal relationship, a business or financial interest, or any other relationship, interest or activity that

- (i) impairs (or might impair) his/her objectivity in performing his/her obligations under this Agreement;
- (ii) makes him/her unable to render impartial assistance or advice under this Agreement; or
- (iii) gives him/her an unfair competitive advantage.

"Interest" means a relationship of any kind from which a person or organization derives (or might derive) pecuniary or in-kind benefits.

No Grantee or Project Personnel may participate in any decision involving the obligation of Grant funds or the use or disposition of Grant funds if he/she knows, or reasonably should know, that such participation involves an actual or potential Conflict or Interest, or the appearance of such a Conflict of Interest.

To implement this requirement the Grantee will:

Disclose promptly to GRDF any close family relationship or interest that may constitute or create a Conflict of Interest or the appearance of a Conflict of Interest;

 Refrain from participating in, and from using his/her personal influence in connection with, decisions where such participation may involve a Conflict of Interest or the appearance of a Conflict of Interest except:

To provide information when requested, or

To provide information known to him/her indicating that a proposed or existing transaction could be contrary to this policy.

- Refrain from dealing on behalf of GRDF with organizations or persons on transactions involving the obligation of Project funds or the use or disposition of Project Resources except after full disclosure and with the express written authorization of GRDF Agreement Representative.
- o Assure that Project Personnel comply with the requirements of this Article.

The Grantee will monitor its relationships and interests, and those of the Project Personnel, on an ongoing basis and will report any relationships or interests that might violate the provisions of this Article.

ARTICLE 19 - WHISTLEBLOWER POLICY.

It is the policy of CRDF Global that grantees, vendors and contractors are encouraged and expected to report possible violations of laws, rules and regulations, as well as fraudulent or dishonest use or misuse of CRDF Global resources or property, violations of CRDF Global's conflict of interest policy and other serious misconduct. Reports may be made directly to CRDF Global management (who can be contacted via the main CRDF Global website www.crdfglobal.org or via the Global Compliance hotline available at https://crdfglobal.aiertline.com/gcs/welcome?locale=en. All information will be treated confidentially and all complaints will be investigated by CRDF Global management and regularly reported to the Audit Committee of the Board of Directors. CRDF Global will not retaliate, nor will CRDF Global tolerate retaliation by any of its employees, against any grantee, vendor or contractor who makes a good faith report pursuant to this policy; even if an investigation shows that there has not been a violation.

ARTICLE 20 - CONFIDENTIAL INFORMATION.

Confidential information, as used in this Agreement, means: 1) information or data of a personal nature about an individual or 2) information or data submitted by or pertaining to the Grantee, Secondary Collaborators, subcontractors, subawardees or GRDF.

All aspects of this Agreement, except its financial aspects and information specifically designated as confidential in accordance with the provisions set forth in this Agreement, are considered accessible to the public. Confidential information, as defined in (1) and (2) above, shall not be disclosed without the prior written consent of the Grantee, Project Personnel, or GRDF.

In addition to the types of confidential information described above, information which might require special consideration with regard to the timing of its disclosure may derive from studies or research, during which public disclosure of preliminary invalidated findings could create erroneous conclusions which might threaten public health or safety if acted upon.

GRDF reserves the right at any time, or from time to time, during the Agreement Period to designate certain information to be used, generated or compiled pursuant to Agreement activities as "confidential information." In the event that this right is exercised, Grantee agrees to comply with any written instructions that GRDF may provide with respect to the handling or retention of such information.

ARTICLE 21 - DEBARMENT AND OTHER RESPONSIBILITY MATTERS.

By signing this Agreement, the Grantee certifies that neither it nor any individual Project Personnel is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from activities subject to the debarment or suspension, by any US Federal or local department or agency. Grantee is responsible for notifying GRDF immediately in writing if it or individual Project Personnel becomes debarred, suspended, declared ineligible or voluntarily excluded from activities to subject to debarment or suspension or is proposed for debarment.

ARTICLE 22 - COMPLIANCE WITH LAW.

In performing its duties under the Agreement, Grantee shall ensure that it strictly complies with all applicable laws and mandatory public policies (including, but not limited to, those relating to corporate operations, taxation, employment and the environment), and shall be solely responsible for all costs, risks and delays resulting from doing so, or the failure to do so.

ARTICLE 23 - FOREIGN TAXES AND RELATED CONSIDERATIONS.

Funds provided under this Agreement may not be used to pay any customs, duties, taxes, fees or other such levies and costs incurred within the territory of the Grantee's country. Grantee shall inform GRDF immediately, in writing, of any tax or duty imposed on funds or materials provided by GRDF under this Agreement. Grantee shall comply with all applicable local tax regulations and reporting requirements, and Grantee may choose to seek advice from appropriate tax authorities or other professionals to ensure their compliance.

ARTICLE 24- RECORDS, AUDIT & ACCESS.

Financial and other records pertinent to this Agreement shall be retained for a period of not less than three (3) years from the expiration date of this Agreement. Timely, unrestricted access to Agreement records will be provided to GRDF, its representatives and Funders in order to make audits, examinations, excerpts, transcripts, and copies of such documents. This right also includes timely and reasonable access to the Grantee's facilities where Agreement-related activities are being performed and access to Grantee project personnel. The rights of access in this paragraph are not limited to the required retention period, but must last as long as records are retained.

ARTICLE 25 - MONITORING AND EVALUATION.

GRDF will appropriately monitor and evaluate ("M&E") the financial and programmatic progress of Agreement activities. Grantee agrees to cooperate with all reasonable requests for assistance in connection with such M&E, including but not limited to facilitating site visits, closely tracking the performance and impact of Program activities and maintaining and providing records or other information pertinent to such activities. Grantee also agrees to prepare and submit required reports (if any) in a timely manner

ARTICLE 26 - ANIMAL WELFARE.

Any Non-U.S. Grantee whose project involves the care or use of vertebrate animals at a foreign institution or foreign field site also require approval of research protocols by the Grantee's IACUC. If the project is to be funded through an award to a foreign institution or through an individual fellowship award that will support activities at a foreign institution, GRDF will require a statement of compliance that the activities will be conducted in accordance with all applicable laws in the foreign country and that the International Guiding Principles for Biomedical Research Involving Animals (see http://www.cioms.ch/) will be followed.

ARTICLE 27 - LIABILITY.

Grantee agrees and shall require individual Project Personnel to agree that GRDF shall have no liability to the Grantee, Project Personnel or any other entity or person for any claims arising out of, or related to, the performance of this Agreement or the representations or warranties made by the Grantee and Project Personnel herein except if, and to the extent, due to the negligent, willful or intentional misconduct of GRDF, its officers, employees or agents. In addition, except as prohibited by applicable law, all parties to this Agreement assume their own respective liability that may be incurred, including attorney's fees, in defending any action as a result of performance under this Agreement to the extent such liability is a result of the party's negligent, willful or intentional misconduct. The Grantee is advised to take such steps as may be deemed necessary to insure or protect themselves, their employees and property.

ARTICLE 28 - FORCE MAJEURE.

No party shall be liable for any failure to perform its obligations under this Agreement, if such failure results from any Acts of God, Acts of War, riot, civil unrest, flood, earthquake or other similar cause beyond such party's reasonable control (including any mechanical, electronic or communications failure, but excluding failure caused by a party's financial condition or negligence).

ARTICLE 29 - SUSPENSION.

At any time during the Agreement Period, GRDF may suspend the Agreement for any reason for up to 60 days, or longer if deemed necessary. Suspension may be in whole or in part and shall be effective on the date stated in a written notice to Grantee. The notice will identify the type of action taken and instruct Grantee to cease incurring costs for Project activities, subject to any exceptions stated.

ARTICLE 30 - TERMINATION.

At any time during the Agreement Period GRDF may take any one or more of the following actions: [a] unilaterally terminate the Agreement for convenience with fifteen days' notice [b] unilaterally terminate the Agreement due to Grantee's material breach or noncompliance with the terms and conditions of the Agreement, Grantee insolvency, or upon the direction of any cognizant government official or requirement of applicable law; [c] terminate by mutual agreement of the Parties; or [d] terminate at Grantee's request. Termination shall be effective on the date stated in a written notice to Grantee.

ARTICLE 31 - RESOLUTION OF DISPUTES.

The Parties will exert their best efforts to consult and resolve all issues in connection with the Agreement amicably, equitably and in a mutually satisfactorily manner. Issues that cannot be resolved by communications between the contact persons specified on the Cover Sheet will be reviewed by each Party's senior management. Any remaining issues may be resolved by any agreed non-judicial procedure, absent agreement on which the sole recourse of either Party shall be the courts in Tbilisi, Georgia. Claims may not include losses, damages or other relief based on harm that could have been avoided or mitigated by reasonable actions of the claiming Party or any exemplary, consequential or punitive damages, however described.

ARTICLE 32 - AMENDMENTS.

The Agreement may only be modified by a written amendment signed by both Parties.

ARTICLE 33 - PUBLICATIONS.

Publication of results of the research project in an appropriate professional journal is encouraged as an important method of recording and reporting scientific information. One copy of each accepted publication should be forwarded to GRDF, CRDF and DTRA as a courtesy.

 Upload the Publication to the DTRA Basic and Fundamental Research Community Portal (<u>www.dtrasubmission.net/portal</u>) (file name should be the Grant number and 'Publication', e.g. HDTRA1-11-1-9999 Publication) of less than 10 MB.

The Grantee agrees that in the release of information relating to this Agreement, such release shall include the following statement, "The project or effort depicted was or is sponsored by the Department of the Defense, Defense Threat Reduction Agency. The content of the information does not necessarily reflect the position or the policy of the federal government, and no official endorsement should be inferred."

For purposes of this provision, information includes news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association proceedings, symposia, etc.

ATTACHMENT A: PROJECT PERSONNEL

The following Principal Investigator(s) and/or other staff ("Project Personnel") are deemed essential to successful implementation of the activities specified in the Project:

Name	Institution	DOB
Ann Machablishvili	National Center for Disease Control and Public Health	28/03/1977
Lela Urushadze	National Center for Disease Control and Public Health	27/11/1973
Ivane Daraselia	National Center for Disease Control and Public Health	21/04/1987

These individuals may not be replaced without prior written approval of GRDF.

The Principal Investigator is responsible for overseeing the technical work to be performed under the Project; for providing technical leadership; for preparing and submitting payment requests and required reports in accordance with GRDF guidelines and the policies of his/her respective institution; for ensuring that activities are coordinated with his institution, Project Personnel, and Collaborator(s); and for managing the Project in compliance with terms of this Agreement.

ATTACHMENT B: BUDGET

The approved award budget and schedule of payments is hereby incorporated by reference.

60211 Grantee Award Budget and Schedule of Payments 2013 Georgia Mini- Grants

INDIVIDUAL FINANCIAL SUPPORT	(IFS)			
Participant Names		Total # Person- hours	Hourly rate	TOTAL
Ann Machablishvili		80	\$7.50	\$600
Lela Urushadze		80	\$7.50	\$600
Ivane Daraselia		80	\$7.50	\$600
	INDIVIDUA	L FINANCIAL	SUPPORT	\$1,800

PROJECT	EQUIPMENT	
Item D	Description	TOTAL
Sequence reagents for MiSeq		\$5,200
TRIzol® Reagents		\$450
Qubit® RNA BR Assay Kit		\$200
	EQUIPMENT	\$5,850
	SUPPLIES & SERVICES	\$1,000
	GOLI ELEGIA GERVIGES	Ψ1,000

EQUIPMENT, SUPPLIES & SERVICES	\$6,850
TRAVEL	\$1,280
INSTITUTIONAL SUPPORT	

GRANTEE BUDGET \$9,930

ATTACHMENT C: STANDARD PROVISIONS

U.S. DEPARTMENT OF DEFENSE, DEFENSE THREAT REDUCTION AGENCY

- Agency Terms & Conditions. This Agreement and the activities thereunder are subject to the U.S. Department of Defense,
 Defense Threat Reduction Agency General Terms and Conditions for Grant Awards. The full text of those Terms and
 Conditions may be found at the following link:
 https://www.dtrasubmission.net/portal/Library/Terms%20and%20Conditions%20v2%20%28International%29%28IMAY12
 %29_WAWF.pdf
- 2. <u>Intangible Property</u>. Rights in copyrights, technical data and computer software, data required for a response to a Freedom of Information Act (FOIA) request, and other forms of intangible property, shall be provided in accordance with DoDGARs §32.36.
 - a) The recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under an award. DoD Components reserve a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.
 - b) Recipients are subject to applicable regulations governing patents and inventions, including Governmentwide regulations issued by the Department of Commerce at 37 CFR Part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements."
 - c) The Federal Government has the right to:
 - i. Obtain, reproduce, publish or otherwise use the data first produced under an award; and
 - ii. Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes
 - d) In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the DoD Component that made the award shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the DoD Component that made the award obtains the research data solely in response to a FOIA request, the DoD Component may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the DoD Component, the recipient, and applicable subrecipients. This fee is in addition to any fees the DoD Component may assess under the FOIA (5 U.S.C.552(a)(4)(A)).

The following definitions apply for purposes of paragraph (d) of this section:

- i. Research data is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples). Research data also do not include:
 - a. Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and
 - b. Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.
- ii. Published is defined as either when:
 - a. Research findings are published in a peer-reviewed scientific or technical journal; or
 - b. A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.
 - c. Used by the Federal Government in developing an agency action that has the force and effect of law is defined as when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law
- e) Title to intangible property and debt instruments acquired under an award or subaward (rather than developed or produced under the award or subaward) vests upon acquisition in the recipient. The recipient shall use that property for the originally-authorized purpose, and the recipient shall not encumber the property without approval of the DoD Component that made the award. When no longer needed for the originally authorized purpose, disposition of the intangible property shall occur in accordance with the provisions of §32.34(g).
- 3. <u>Patent Rights.</u> All awardees shall comply with the following, in accordance with 37 CFR §401.14. Note: "Contractor" equals "Grantee", "Subcontractor" equals "Subawardee", and "Subcontract" equals "Subaward".

a) Definitions

- i. Invention means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).
- ii. Subject invention means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this contract, provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.
- iii. Practical Application means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.
- iv. Made when used in relation to any invention means the conception or first actual reduction to practice of such invention.
- v. Small Business Firm means a small business concern as defined at section 2 of Pub. L. 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in government procurement and subcontracting at 13 CFR 121.3–8 and 13 CFR 121.3–12, respectively, will be used.
- vi. Nonprofit Organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c) and exempt from taxation under section 501(a) of the Internal Revenue Code (25 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute
- b) Allocation of Principal Rights. The Contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. 203. With respect to any subject invention in which the Contractor retains title, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.
- c) Invention Disclosure, Election of Title and Filing of Patent Application by Contractor
 - i. The contractor will disclose each subject invention to the Federal Agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the contract under which the invention was made and 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, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the Contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the contractor.
 - ii. The Contractor will elect in writing whether or not to retain title to any such invention by notifying the Federal agency within two years of disclosure to the Federal agency. However, in any case where publication, on sale or public use has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.
 - iii. The contractor will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. The contractor will file patent applications in additional countries or international patent offices within either ten months of the corresponding initial patent application or six 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
 - iv. Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the agency, be granted.
- d) Conditions When the Government May Obtain Title. The contractor will convey to the Federal agency, upon written request, title to any subject invention:
 - i. If the contractor fails to disclose or elect title to the subject invention within the times specified in (c), above, or elects not to retain title; provided that the agency may only request title within 60 days after learning of the failure of the contractor to disclose or elect within the specified times.
 - ii. In those countries in which the contractor fails to file patent applications within the times specified in (c) above; provided, however, that if the contractor has filed a patent application in a country after the times specified in (c) above, but prior to its receipt of the written request of the Federal agency, the contractor shall continue to retain title in that country.

- iii. In any country in which the contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.
- e) Minimum Rights to Contractor and Protection of the Contractor Right to File
 - i. The contractor will retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the contractor fails to disclose the invention within the times specified in (c) above. The contractor's license extends to its domestic subsidiary and affiliates, if any, within the corporate structure of which the contractor is a party and includes the right to grant sublicenses of the same scope to the extent the contractor was legally obligated to do so at the time the contract was awarded. The license is transferable only with the approval of the Federal agency except when transferred to the successor of that party of the contractor's business to which the invention pertains.
 - ii. The contractor's domestic license may be revoked or modified by the funding Federal agency to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions at 37 CFR part 404 and agency licensing regulations (if any). This license will not be revoked in that field of use or the geographical areas in which the contractor has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the funding Federal agency to the extent the contractor, its licensee, or the domestic subsidiaries or affiliates have failed to achieve practical application in that foreign country.
 - iii. Before revocation or modification of the license, the funding Federal agency will furnish the contractor a written notice of its intention to revoke or modify the license, and the contractor will be allowed thirty days (or such other time as may be authorized by the funding Federal agency for good cause shown by the contractor) after the notice to show cause why the license should not be revoked or modified. The contractor has the right to appeal, in accordance with applicable regulations in 37 CFR part 404 and agency regulations (if any) concerning the licensing of Government owned inventions, any decision concerning the revocation or modification of the license.
- f) Contractor Action to Protect the Government's Interest
 - i. The contractor agrees to execute or to have executed and promptly deliver to the Federal agency all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions to which the contractor elects to retain title, and (ii) convey title to the Federal agency when requested under paragraph (d) above and to enable the government to obtain patent protection throughout the world in that subject invention.
 - ii. The contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the contractor each subject invention made under contract in order that the contractor can comply with the disclosure provisions of paragraph (c), above, and to execute all papers necessary to file patent applications on subject inventions and to establish the government's rights in the subject inventions. This disclosure format should require, as a minimum, the information required by (c)(1), above. The contractor shall instruct such 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.
 - iii. The contractor will notify the Federal agency of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than thirty days before the expiration of the response period required by the relevant patent office.
 - iv. The contractor agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, "This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention."
- g) Subcontracts
 - i. The contractor will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental, developmental or research work to be performed by a small business firm or domestic nonprofit organization. The subcontractor will retain all rights provided for the contractor in this clause, and the contractor will not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.
 - ii. The contractor will include in all other subcontracts, regardless of tier, for experimental developmental or research work the patent rights clause required by (cite section of agency implementing regulations or FAR).
- h) Reporting on Utilization of Subject Inventions. The Contractor agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor 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 contractor, and such other data and information as the agency may reasonably specify. The contractor also agrees to provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in

- accordance with paragraph (j) of this clause. As required by 35 U.S.C. 202(c)(5), the agency agrees it will not disclose such information to persons outside the government without permission of the contractor
- i) Preference for United States Industry. Notwithstanding any other provision of this clause, the contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject inventions in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency upon a showing by the contractor or its assignee 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.
- j) March-in Rights. The contractor agrees that with respect to any subject invention in which it has acquired title, the Federal agency has the right in accordance with the procedures in 37 CFR 401, and any supplemental regulations of the agency to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such a request the Federal agency has the right to grant such a license itself if the Federal agency determines that:
 - i. Such action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.
 - ii. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee or their licensees;
 - iii. Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee or licensees, or
 - iv. Such action is necessary because the agreement required by paragraph (i) of this clause 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.
- k) Special Provisions for Contracts with Nonprofit Organizations. IF the contractor is a nonprofit organization, it agrees that:
 - i. Rights to a subject invention in the United States may not be assigned without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions, provided that such assignee will be subject to the same provisions as the contractor;
 - ii. The contractor will share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (when the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;
 - iii. The balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, will be utilized for the support of scientific research or education; and
 - iv. It will make efforts that are reasonable under the circumstances to attract licensees of subject invention that are small business firms and that it will give a preference to a small business firm when licensing a subject invention if the contractor determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the contractor. However, the contractor agrees that the Secretary may review the contractor's licensing program and decisions regarding small business applicants, and the contractor will negotiate changes to its licensing policies, procedures, or practices with the Secretary when the Secretary's review discloses that the contractor could take reasonable steps to implement more effectively the requirements of this paragraph (k)(4).
- Communication. All DTRA-related disclosures, confirmatory licenses to the government, patent applications, and other communications should be submitted in accordance with Article 21m. Questions should be submitted to basicresearch@dtra.mil.
- m) Invention Reporting. 37 CFR Part 401 invention reporting requirements are summarized in the general terms and conditions available at:

 https://www.dtrasubmission.net/portal/Library/Terms%20and%20Conditions%20v2%20%28International%29%281MAY12%29_WAWF.pdf. Unless otherwise indicated in the "Submission to DTRA" column, the grantee is required to upload the following types of invention information using iEdison. iEdison (https://s-edison.info.nih.gov/iEdison/), is a single web interface for government grantees to report details of inventions and patents. If the grantee organization is not already an iEdison registrant, then registration with iEdison is required prior to submission of the below invention reports
- 4. <u>Human & Animal Subjects</u>. By signing this agreement or accepting funds under this agreement, the recipient assures that it will comply with applicable provisions of the following national policies concerning live organisms:

a) For human subjects:

- i. 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 Department of Defense at 32 CFR Part 219.
- ii. The recipient shall adhere to DTRA local clause 252.223-9002–Protection of Human Subjects (Aug 2010). The full text of this clause is as follows: All research under this grant involving human subjects must be conducted in accordance with 32 CFR 219, 10 USC 980, and DoDD 3216.02, as well as other applicable federal and state regulations. Grantees must be cognizant of and abide by the additional restrictions and limitations imposed on the Do regarding research involving human subjects, specifically as regards vulnerable populations (32 CFR 219 modifications to subparts B-D of 45 CFR 46), recruitment of military research subjects (32 CFR 219), and surrogate consent (10 USC 980). DTRA\Directive 3216.01 of June 9, 2010 establishes the DTRA Human Subjects Protection Program, sets forth the policies, defines the applicable terms, and delineates the procedures necessary to ensure DTRA compliance with federal and DoD regulations and legislation governing human subject research. The regulations mandate that all DoD activities, components, and agencies protect the rights and welfare of human subjects of study in DoD-supported research, development, test and evaluation, and related activities hereafter referred to as "research". The requirement to comply with the regulations applies to new starts and to continuing research. The DTRA directive requires that research using human subjects may not begin or continue until the Defense Threat Reduction Agency's Research Oversight Board (ROB) has reviewed and approved the proposed protocol.

Grantees and subcontractors are required to submit a valid federal assurance for their organization (institution, laboratory, facility) that has been issued by either DoD or the Department of Health and Human Services, and documentation of review of proposed protocols by the local Institutional Review Board (IRB) to include consent forms for any planned research using human subjects to the DTRA ROB for its review through the Grants Officer's representative (if assigned) or the Grants Officer. The ROB review is separate from, and in addition to, local IRB review.

A study is considered to involve human research subjects if: there is interaction with the subject (even if simply talking to the subject qualifies; no needles are require); and 2) if the study involves collection and/or analysis of personal/private information about an individual, or if material used in the study contains links to such information. Written approval to begin research or subcontract for the use of human subjects under the proposed protocol will be provided in writing from the DTRA ROB, through the Grants Officer. A copy of this approval shall be maintained by both the Grantee and the government. Any proposed modifications or amendments to the approved protocol or consent forms must be submitted to the local IRB and the DTRA ROB for review and approval. Examples of modifications/amendments to the protocol include but are not limited to:

- a. a change of the PI;
- b. changes in duration or intensity of exposure to some stimulus or agent;
- c. changes in the information requested of volunteers, or changes to the use of specimens or data collected; or changes in perceived or measured risks or benefits to volunteers that require changes to the study.

Research pursuant to such modifications or amendments shall not be initiated without IRB and ROB approval except when necessary to eliminate apparent and immediate hazards to the subject(s). Research projects lasting more than one year require IRB review at least annually, or more frequently as required by the responsible IRB. ROB review and approval is required annually. The Grantee or subcontractor must provide documentation of continued IRB review of protocols for ROB review and approval in accordance with these Terms and Conditions. Research must not continue without renewed ROB approval unless necessary to eliminate apparent and immediate hazards to the subject(s). Non-compliance with any provision of this clause may result in withholding of payments under the grant pursuant to the grant's payments clause(s) and/or grant termination pursuant to the grant's termination clause(s).

The government shall not be responsible for any costs incurred for research involving human subjects prior to protocol approval by the ROB.

b) For animals, the recipient shall adhere to:

- i. Requirements for animal acquisition, transport, care, handling, and use in 9 CFR Parts 1-4, Department of Agriculture rules implementing the Laboratory Animal Welfare Act of 1966 (7 U.S.C. 2131-2156) and 9 CFR Subchapter A, Parts 1 through 4).
- ii. Rules of the Departments of Interior (50 CFR Parts 10-24) and Commerce (50 CFR Parts 217-227) implementing laws and conventions on the taking, possession, transport, purchase, sale, export, or import of wildlife and plants, including the: Endangered Species Act of 1973 (16 U.S.C. 1531-1543); Marine Mammal Protection Act (16 U.S.C. 1361-1384); Lacey Act (18 U.S.C. 42); and Convention on International Trade in Endangered Species of Wild Fauna and Flora.

iii. DTRA local clause 252.235-9001–Prohibition of Use of Laboratory Animals (Jul 2010). The full text of this clause is as follows: The grant recipient shall obtain approval from the US Army Medical Research and Material Command (MRMC), Animal Care and Use Review Office (ACURO) prior to conducting research on live nonhuman vertebrates. Studies involving non-human primates, dogs, cats, or marine mammals will require a site visit by an ACURO laboratory animal veterinarian as a condition of approval. DoD may also conduct site visits involving research on other animals when deemed appropriate. The animal research facility is responsible for notifying the DoD sponsor if Association for the Assessment and Accreditation of Laboratory Animal Care accreditation is lost or the facility is under USDA inspection. DoD also has the right to a site inspection under these circumstances.

The grant recipient (including subcontractors) is expressly forbidden to use laboratory animals in any manner whatsoever without the express written approval of MRMC ACURO. The grant recipient shall complete the ACURO Animal Use Appendix for Research Involving Animals found at the following web site: https://mrmc-www.army.mil/index.cfm?pageid=Research_Protections.acuro_AnimalAppendix. Submit the completed ACURO appendix, contact information, the DTRA grant number and a copy of the grant for processing to the email address listed at the ACURO website. Once ACURO approves the effort, the grant recipient will receive written approval to begin animal use from the US Army MRMC ACURO by separate email. The grant recipient shall promptly provide a copy of the approval to the Grants Officer and Grants Officer representative. After approval, changes or protocol amendments must be submitted to and approved by ACURO before implementation. The grant recipient, or subcontractors as appropriate, shall submit the most recent U.S. Department of Agriculture Animal Care Inspection Report annually in accordance with the CDRL. Noncompliance with any provision of this clause may result in the termination of the grant.

- 5. <u>Representations and Assurances</u>. By accepting funds under this Grant, the recipient assures that it will comply with applicable provisions of the following national policies:
 - a) Environmental Standards. By signing this agreement or accepting this agreement or accepting funds under this agreement, the recipient assures that it will identify to the awarding agency any impact this award may have on the quality of the human environment, and provide help the agency may need to comply with the National Environmental Policy Act (NEPA, at 42 U.S.C. 4321, et. seq.) and to prepare Environmental Impact Statements or other required environmental documentation. In such cases, the recipient agrees to take no action that will have an adverse environmental impact (e.g., physical disturbance of a site such as breaking of ground) until the agency provides written notification of compliance with the environmental impact analysis process.
 - b) Drug-Free Workplace. The recipient agrees to comply with the requirements regarding drug-free workplace requirements in Subpart B (or Subpart C, if the recipient is an individual) of 32 CFR Part 26, which implements Sections 5151-5160 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, Title V, Subtitle D; 41 U.S.C. 701, et seq.).
 - c) Officials Not to Benefit. No member of or delegate to Congress, or resident commissioner, shall be admitted to any share or part of this agreement, or to any benefit arising from it, in accordance with 41 U.S.C. 22.
 - d) Preference for U.S. Flag Carriers. 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.
 - e) Cargo Preference. The recipient agrees that it will comply with the Cargo Preference Act of 1954 (46 U.S.C.1241), as implemented by Department of Transportation regulations at 46 CFR 381.7, which require that at least 50 percent of equipment, materials or commodities procured or otherwise obtained with U.S. Government fund under this agreement, and which may be transported by ocean vessel, shall be transported on privately owned U.S.-flag commercial vessels, if available.
 - f) Military Recruiters. Military recruiting on campus under this award shall be as specified in the DoDGARs §22.520, Military Recruiting and Reserve Officer Training Corps Program Access to Institutions of Higher Education. As a condition for receipt of funds available to the Department of Defense (DoD) under this award, the recipient agrees that it is not an institution of higher education (as defined in 32 CFR Part 216) that has a policy or practice that either prohibits, or in effect prevents:
 - i. The Secretary of a Military Department from maintaining, establishing, or operating a unit of the Senior Reserve Officers Training Corps (in accordance with 10 U.S.C. 654 and other applicable Federal laws) at that institution (or any sub element of that institution);
 - ii. Any student at that institution (or any sub element of that institution) from enrolling in a unit of the Senior ROTC at another institution of higher education;
 - iii. The Secretary of a Military Department or Secretary of Homeland Security from gaining access to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of military recruiting in a manner that is at least equal in quality and scope to the access to campuses and to students that is provided to any other employer; or

- iv. Access by military recruiters for purposes of military recruiting to the names of students (who are 17 years of age or older and enrolled at that institution or any sub element of that institution), their addresses, telephone listings, dates and places of birth, levels of education, academic majors, and degrees received, and the most recent educational institutions in which they were enrolled. If the recipient is determined, using the procedures in 32 CFR Part 216, to be such an institution of higher education during the period of performance of this agreement, the Government will cease all payments of DoD funds under this agreement and all other DoD grants and cooperate agreements to the recipient, and it may suspend or terminate such grants and agreements unilaterally for material failure to comply with the terms and conditions of award.
- 6. <u>Publications and Acknowledgement of Sponsorship</u>. Publication of results of the research project in an appropriate professional journal is encouraged as an important method of recording and reporting scientific information. A courtesy copy of each accepted publication shall be uploaded directly in to the web-based reporting system previously described herein. The recipient agrees that in the release of information relating to the grant, such release shall include the following statement:

"The project or effort depicted was or is sponsored by the Department of the Defense, Defense Threat Reduction Agency. The content of the information does not necessarily reflect the position or the policy of the federal government, and no official endorsement should be inferred."

For purposes of this provision, information includes news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association proceedings, symposia, etc.

When issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with federal money, all recipients receiving federal funds, shall clearly state: (i) the percentage of total costs of the program or project which will be financed with federal money, and (ii) the dollar amount of federal funds for the project or program.

CURRICULUM VITAE



PERSONAL INFORMATION

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Telephone +995 5 99 299965 (cell); +995 322 398946 (work)

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E-mail a_machablishvili@hotmail.com

Nationality Georgian

Date of birth MARCH 28, 1977
Place of birth TBILISI, GEORGIA

WORK EXPERIENCE

• Dates (from - to) 2011 - up today

Name and address of employer
 National Center for Disease Control and Public Health (NCDC)

9M.Asatiani st. Tbilisi 0177 Georgia

Position held Chief specialist at Laboratory Department

• Dates (from - to) 2007 - up today

• Dates (from - to) 2006 - 2010

• Name and address of employer NCDC, 9M.Asatiani st. Tbilisi 0177 Georgia

Position held Head of Influenza Laboratory

• Dates (from - to) 2003-2006

Name and address of employer NCDC, 9M.Asatiani st. Tbilisi 0177 Georgia

Position held Virologist at Department of poliomyelitis and other enteroviruses

• Dates (from – to) 2002-2003

Name and address of employer NCDC, 9M.Asatiani st. Tbilisi 0177 Georgia

• Dates (from – to) 2001-2002

Name and address of employer NCDC, 9M. Asatiani st. Tbilisi 0177 Georgia

• Position held Epidemiologist of organization-methodical department

EDUCATION

• Dates 2009 - up today

education

Principal subjects Epidemiology and Public Health

• Title of qualification awarded PhD will be awarded

• Dates (from - to) 2010 - 2011

education

Principal subjects Epidemiology and Biostatistics

• Title of qualification awarded Certificate in Emerging Infectious Disease Research

• Dates (from - to) 2004

education

• Principal subjects Nonproliferation issues

• Title of qualification awarded Certificate of The NIC visiting fellows program

• Dates (from - to) 1994-2000

education

• Faculty Preventive Medicine

TRAININGS

Date 2013

Principal subjects EIDSS

Name of organization Black&Veatch, Georgia

providing training

Date 2012

Principal subjects Microneutralization assay performance

Name of organization University of Florida, US

providing training

• Date 2012

Principal subjects Designing a National Bulletin for Influenza Surveillance

Name of organization WHO, Latvia

providing training

Date 2011

• Principal subjects Antiviral susceptibility training for influenza viruses

Name of organization providing training
 National Institute for Public Health, Netherlands

• Date 2011

• Principal subjects Transport of Infectious Substances

• Name of organization WHO, Slovenia

providing training

• Date 2010

• Principal subjects Influenza Virus full genome sequence & phylogenetic analysis

• Name of organization National Institute for Medical Research, London, UK

providing training

Date 2008

Principal subjects Influenza virus molecular diagnostics

Name of organization Laboratorie Nationale de Sante, Luxembourg providing training

• Date 2007

Principal subjects Seasonal influenza virus diagnostics

· Name of organization CDC, Atlanta, US

providing training

Date 2007

Principal subjects Avian influenza virus diagnostics

Name of organization VLA, UK

providing training

Date 2006

Principal subjects Reproductive epidemiology

Name of organization CDC, Atlanta, US

providing training

• Date 2006

• Principal subjects Introduction to Analytical Epidemiology

Name of organization WRAIR, US

providing training

• Date 2005

• Principal subjects Introduction to Epidemiology and Surveillance; Analysis of Surveillance Data and

Conduct of Outbreak Investigations

• Name of organization WRAIR, US

providing training

Date 2005

• Principal subjects Influenza virus isolation, molecular biology and serology

• Name of organization NAMRU-3, Cairo, Egypt

providing training

• Date 2005

Principal subjects Laboratory Training on Especially Dangerous Pathogens

• Name of organization AFRIMS, Bangkok, Thailand

providing training

Date 2003

Principal subjects
 Cell Culture workshop

• Name of organization Institute of poliomyelitis and viral encephalitis, Moscow, Russia

providing training

• Date 2002

Principal subjects Course on laboratory management and skills

strengthening for the diagnosis of epidemic prone diseases

Name of organization WHO/CSR Lyon, France

providing training

• Date 2002

Principal subjects 'Epidemiology & Surveillance Strategies for Health Promotion

Name of organization American International Health Alliance providing training

ABSTRACTS/POSTERS

Incidence, Severity, and Impact 2012, An isirv International Conference on Seasonal and Pandemic Influenza, 5-8 September, Munich, Germany

Molecular analysis and characterization of 2012 Georgian influenza H3N2 HA reveals genetic ties to the WHO recommended 2013/2012 H3N2 vaccine candidate, A/Victoria/361/2011

The Fourth ESWI Influenza Conference 11-14 September Malta, 2011

EPIDEMIOLOGICAL CHARACTERISTICS OF LABORATORY CONFIRMED FATAL INFLUENZA CASES DURING THE 2009-2010 AND 2010-2011 INFLUENZA SEASONS IN GEORGIA

ESCAIDE, Stockholm 26-28 October, 2009 Enhanced influenza surveillance in Georgia in the context of the emergence of novel influenza A(H1N1) virus

The 4th Annual CEIRS Network meeting August 3-5, 2010, New York, US The ecology and evolution of avian influenza A viruses in wild birds in Georgia

The Third ESWI Influenza Conference VILAMOURA PORTUGAL, 14-17 SEPTEMBER 2008

Influenza Sentinel Surveillance in Georgia

ARTICLES

Pios One 2013

Avian influenza surveillance in wild birds in Georgia: 2009-2011

Influenza research and treatment

2012

Influenza associated mortality in Georgia, 2009-2011

PloS Neglected Epidemiologic Aspects of an Emerging

Tropical Diseases

Focus of Visceral Leishmaniasis in Tbilisi, Georgia

2011 PloS Neglected tropical Diseases

AWARD Young Scientist award

Date 2008

Event The Third ESWI conference, Vilamoura, Portugal

CRDF GLOBAL MINI-GRANT PROPOSAL FORM

Proposals must be completed in English Deadline for receipt of proposals is October 31, 2013, 5 p.m. (Tbilisi Time)

CRDF GLOBAL MINI-GRANT PROGRAM
Director's NameAmiran Gamkrelidze
Name of Primary ApplicantAnn Machablishvili
Current Position/Title of the Applicant - Chief specialist, Influenza Laboratory, NCDC&PH
Date of Ph.D.Defense (or year expected, if degree not yet received)Ph.D student
Telephone #+995 5 99299965Fax
E-Mail addressa machablishvili@hotmail.com
Amount requested from CRDF Global: \$9930
Title of project/activity:Influenza Study of Backyard Animals in Georgia
SIGNATURES By signing this proposal, I certify that all the information contained herein is accurate to the best of my knowledge: Director: Amiran Gamkrelidze
Primary Applicant: _Ann Machablishvili
Additional Researcher:Lela Urushadze
Additional Researcher:Ivane Daraselia3
Additional Researcher:
Additional Researcher:
Date:30/10/2013

PROJECT ABSTRACT

Give a one-paragraph description of the project/activity

Influenza Study of Backyard animals in Georgia

Human influenza pandemics demonstrate the important role of zoonotic influenza viruses in the origin of pandemic influenza viruses. Recently circulating several influenza viruses such as avian influenza A/H7N9 and A/H5N1 and swine origin A/H3N2v may mutate into forms easily transmissible from human to humans and thus become concern to public health.

Since no zoonotic influenza viruses have been detected and studied so far among domestic animals in Georgia, objectives of the proposed study are: identification of influenza viruses circulating among backyard pigs and poultry; and characterization of influenza viruses through sequencing and phylogenetic analyses.

The study will be conducted in Kakheti Region representing leading region in cattle-breeding and poultry raising in the country. Sick animals with influenza-like illness will be swabbed and Animal Swab Collection Form will be completed. Each specimen will be screened for influenza A by real-time RT-PCR method and positive samples will be further characterized through sequence study.

The proposed study will generate data regarding the circulation of zoonotic influenza viruses in pigs and poultry in Georgia. Phylogenetic analysis of influenza viruses will provide us with findings for understanding influenza virus evolution.

The study will enhance project scientists' skills to perform sequence analysis and benefit in their further carrier.

Proposal Narrative

Describe in detail the proposed activity/project, its goals and anticipated outcomes; and its expected duration (should not exceed six months). Explain the expected involvement of (or benefit to) students and/or junior scientists. Do not exceed one page.

Influenza Study of Backyard Animals in Georgia

Human influenza pandemics demonstrate the important role of zoonotic influenza viruses in the origin of pandemic influenza viruses. Past experiences show that pigs serve as "mixing vessels" for emergence of viruses with pandemic potential. Influenza viruses can be transmitted from pigs to humans and vice versa resulting in occurrence of reassortment viruses. Recently circulating several influenza viruses such as avian influenza A/H7N9 and A/H5N1 and swine origin A/H3N2v may mutate into forms easily transmissible from human to humans and thus become concern to public health.

Georgia is located on the route of migrating birds and different species of aquatic birds are found there. In 2006 highly pathogenic influenza virus A/H5 was detected in two wild swans in Adjara (western Georgia). Recent studies demonstrate circulation of various influenza A subtypes among wild bird in our country.

Georgia is the agriculture country; farming and livestock breeding is very popular there. Since no zoonotic influenza viruses have been detected and studied so far among domestic animals in our country, the objectives of the proposed study are: identification of influenza viruses circulating among backyard pigs and poultry; and characterization of zoonotic influenza viruses through sequencing and phylogenetic analyses.

The study will be conducted in Kakheti Region, Eastern Georgia that represents leading region in cattle-breeding and poultry raising in the country. Number of villages will be selected for door to door visits. If a study participant reports sick animals displaying an influenza-like illness appropriate animal samples will be collected and Animal Swab Collection Form will be completed. Samples in virus transport medium will be transported with cold boxes to NCDC&PH laboratory. Animal sampling will be performed by using necessary Personal Protective Equipment (PPE).

Each specimen will be screened for influenza A by real-time RT-PCR method that focuses upon a conserved region of the M gene. Positive samples will further characterized through sequencing using MiSeq at R. Lugar Central Research Laboratory of NCDC&PH.

The proposed study duration is 6 months: during the first four months that coincides with influenza season (January-April) in Georgia field works will be performed followed by laboratory investigations. Approximately 150-200 specimens will be collected during the project period.

The proposed study will generate data regarding the circulation of zoonotic influenza viruses in swine and poultry in Georgia. Phylogenetic analysis of influenza viruses will provide us with findings for understanding influenza virus evolution.

The study will be beneficial for young scientists involved in the project to enhance their skills to use sophisticated sequencing device as well as profound their knowledge in data analysis.

The proposed budget requested for implementation of project activities implementation will cover field works; incentives for project scientists and costs related to laboratory reagents' purchase.

PROPOSED BUDGET

Materials and Services (please list) (Thoroughly describe and justify all items over \$1,000 in Budget Narrative)	Amount requested from CRDF Global	Co- funding amount, if any	TOTAL
Sequence reagents for MiSeq	5200		5200
2. TRIzol® Reagent	450		450
3. Qubit® RNA BR Assay Kit	200		200
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Materials and Services Total			5850
Travel Expenses (please list) (Thoroughly describe and justify all items over \$1,000 in Budget Narrative)			
Transportation fee (petrol)	800		800
2. Per diem	960		960
3. Accommodation	320		320
4.			
5.			
6. If more space is needed, please add rows			
Travel Expenses Total			2080
Other Expenses			
Incentives for project staff (3 persons X 6 months)	1800		1800
2. Contingency funds	200		200
Other Expenses Total			2000
Institutional Support (Up to 10% of Materials and Services total)	<u> </u>		
Total Project Costs			9930

Budget Narrative

Explain expenses, including justification for all equipment over \$1,000 and description of all travel expenses. Do not exceed one page.

For sequence reaction kits for MiSeq instrument will be procured: NEBNext Ultra RNA Library Prep Kit (96 reactions – 4 000USD), NEBNext Multiplex Oligos for Illumina, Index Primers Set 1 (for 96 reactions – 600 USD); NEBNext Multiplex Oligos for Illumina, Index Primers Set 2 (for 96 reactions – 600 USD); in addition Qubit® RNA BR Assay Kit (for 100 reactions – 200USD); TRIzol® Reagent (450USD). Total budget for reagents will be 5 850 USD.

Field works will be carried out during the first 4 months of the project: 2 trips a month (8 trips in total). Two persons will perform field activities for two days each time. Travel expenses will include: per diem 30 USD per person (totally 960 USD); petrol cost approximately 100 USD each field trip (totally 800 USD); accommodation fee 20 USD per person (totally 320 USD).

In the proposed study 3 scientists will be involved in the project performance: Primary researcher will plan and manage project activities; the first additional researcher will participate in field works and perform lab testing; the second researcher will be veterinarian responsible for sampling sick animals. To encourage scientists work each of them will be paid 100 USD during six months period, total budget for incentives will consist of 1800 USD.

The budget includes contingency expenses as well – 200 USD.

Based on above mentioned information, in summary requested amount for the implemental project activities equal to 9930 USD.	tion of

Policy and Standards for Plagiarism

Policy

- A. CRDF Global will not provide funding to an application in which plagiarism exists.
- B. All applications for funding submitted to CRDF Global will be thoroughly screened for plagiarism against a large number of sources including published research papers, books, conference abstracts, and websites.
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 - b. Making minor alterations to previously published text and presenting it without proper formatting and citation. Simply changing some of the words within previously published text does not make it your original writing. To avoid plagiarism, the writing must be your original words, sentence structure, and organization. This is another common error.
 - c. Presenting the original writing of another person, even if it hasn't been previously published, as the work of the applicant(s). If someone contributes writing to your proposal, that person must be one of the listed participants (principal investigator or named team member) in the proposal. Even if another person agrees to write text for your proposal and agrees not to be named in the proposal, the use of that person's writing as if it is your own is plagiarism.
 - d. Copying a sentence or obviously unique phrases from another source without formatting and attribution. Stealing a little bit is still stealing. If the text is clearly recognizable as derived from a previously published source then it must be formatted with proper attribution.
 - e. Giving the correct attribution (citation) at the end of copied text but not formatting the text to clearly indicate that it is taken from the cited source. In the sciences and engineering, it is not sufficient to simply give the citation—if the text is from another source it must be clearly formatted to show that.

I affirm that I have read and understand the above policy and standards for plagiarism, and I agree to adhere to them.

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Signature / 9	Date	-