# PROJECT AGREEMENT #G-1462p

# BETWEEN

# THE INTERNATIONAL SCIENCE AND TECHNOLOGY CENTER,

# THE NATIONAL CENTER FOR DISEASE CONTROL AND MEDICAL STATISTICS

# AND

# THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA

**Establishment of national sentinel-site, laboratory-based *Salmonella* surveillance system and outbreak response capacity for enhanced control of foodborne disease in the Republic of Georgia**

## (BTEP ID #119)

## Operative Commencement Date: April 1, 2007

**Definitions**
“Agreement” means an ISTC project agreement
“Party” means a Party to the Agreement Establishing an International Science and Technology Center
“Financing Party” means a Party providing funds for an ISTC project (The United States Department of Health and Human Services through the BTEP program);
“Partner” means an organization that has been approved by the ISTC Governing Board to participate in the ISTC Partner Program on a regular basis (The U.S. Department of Health and Human Services) and acts as an ISTC partner;
“Recipient” means an organization of the Russian Federation or other country of the former Soviet Union, which conducts work under an ISTC project agreement

**The International Science and Technology Center** (hereinafter referred to as "**the Center**"), **the National Center for Disease Control and Medical Statistics** (hereinafter referred to as "**the Recipient**"), and **the U.S. Department of Health and Human Services** (hereinafter referred to as the “**Partner**”), represented for the purpose of the signature of this Project Agreement (hereinafter referred to as "**the Agreement**") by their authorized representatives (with the Center, the Recipient, and the Partner hereinafter referred to collectively as "**the Signatory Parties**"),

TAKING INTO ACCOUNT THE FOLLOWING CONSIDERATIONS:

The United States of America, Japan, the Russian Federation and, acting as one Party, the European Atomic Energy Community and the European Community (with these two organizations hereinafter referred to as "**the European Community**") signed the Agreement Establishing the International Science and Technology Center on November 27, 1992 (hereinafter referred to as "**the ISTC Agreement**") and the Protocol on Provisional Application of the Agreement Establishing the International Science and Technology Center on December 27, 1993 (hereinafter referred to as "**the ISTC Protocol**"),

The Republic of Georgia, the Republic of Armenia, the Republic of Belarus, the Republic of Kazakstan, the Kyrgyz Republic, Norway, the Republic of Korea, the Republic of Tajikistan and Canada have acceded, and additional States may accede, to the ISTC Agreement and to the ISTC Protocol to participate in the activities of the Center,

The Center is a legal entity and has been registered by the Ministry of Foreign Affairs of the Russian Federation as an international organization with its headquarters in Moscow,

The Recipient is a legal entity within the Republic of Georgia,

The Partner, established as a U.S. Federal Department under U.S. law and having its principal office in Washington, DC, is a legal entity that has been approved by the Center’s Governing Board to participate in Center activities as an ISTC Partner, in accordance with the Memorandum of Agreement between ISTC and DHHS signed on July 6, 1999 and August 10,1999.

The Governing Board of the Center has approved a project to be funded by the Partner through the Center in the domain covered by the Agreement concerning cooperation in approved projects in the health sector to facilitate the non-proliferation of weapons and weapons expertise.

The Partner has agreed to provide financial support for such project, under the DHHS Biotechnology Engagement Program (BTEP) and in accordance with the Article II, paragraph 2 of the Memorandum of Agreement.

As set forth in the ISTC Agreement, funds received by a legal entity in connection with the Center's projects shall be excluded in determining the profits of that organization for the purpose of tax liability and funds received by persons in connection with the Center's projects shall not be included in these persons' taxable incomes,

All parties to this Project Agreement shall conduct this project of work consistent with the principles of the ISTC Statute provisions and applicable international conventions and agreements for which the USA and Republic of Georgia are Parties.

HAVE AGREED AS FOLLOWS:

**Article 1 - Scope of the Agreement**

1.1 The Recipient shall carry out the work plan set forth in Annex I according to the conditions of the Agreement, subject to the provisions of the ISTC Agreement, the ISTC Protocol, the Statute of the Center (hereinafter referred to as "**the ISTC Statute**"), and the Principles for Partner Participation in ISTC Activities, which govern in case of conflict. The activities carried out under the Agreement are entitled: **Establishment of national sentinel-site, laboratory-based *Salmonella* surveillance system and outbreak response capacity for enhanced control of foodborne disease in the Republic of Georgia** – BTEP Project ID#119; (hereinafter referred to as "**the Project**").

1.2 Subject to any special conditions in Article 11 or any amendments or exclusions by any other Articles, the detailed terms of the Agreement are specified in the Annexes that form an integral part of the Agreement. In the case of conflict between any provision in the Annexes and any other provision of the Agreement, the latter shall prevail.

1.3 The Partner may request through the Center access to the Project site for the consultation on and the evaluation of the progress of the Project. The Recipient shall use its best efforts to comply with such requests.

**Article 2 - Duration of the Project**

The duration of the Project is estimated to be 36 months from April 1, 2007 (hereinafter referred to as "**the Operative Commencement Date**")**.**

**Article 3 - Sub-agreements with Other Participating Institutions**

There are no sub-agreements relating to the Agreement.

**Article 4 - Financial Contribution of the Partner through the Center**

4.1 The total cost of the Project to the Center shall not exceed US$330,000.00 (Three hundred thirty thousand dollars and zero cents). This total includes:

(1) items to be reimbursed in cash to the Recipient in accordance with Article 4.3,
(2) grants in cash to be made by the Center directly to the individual participants in the Project (hereinafter referred to as "**Individual Participants**") for financial support of the Individual Participants in accordance with Article 4.4, and
(3) items to be provided in-kind by the Center to the Recipient in accordance with Article 4.5.

After further consideration of the costs and availability of the items to be provided, the Recipient may, with the concurrence of the Center's representative, interchange items between Articles 4.3 and 4.5 with corresponding adjustments of the cost estimates for each Article.

4.2 The Partner shall provide to the Center project funds consistent with the bilateral financial Memorandum of Agreement between the Center and the Partner no later than the Operative Commencement Date of the Project.

4.3 The Center shall reimburse the Recipient for expenditures by the Recipient in accordance with Annexes I and II. The estimated cost of such expenditures is US$27,754.

4.4 The Center shall make direct grants in dollars to Individual Participants in the Project in accordance with Annex I at an estimated cost of US$187,280. This amount can be increased at the request of the Recipient and with the concurrence of the Center's representative and of the affected Individual Participants provided the costs of Article 4.3 and/or Article 4.5 are reduced accordingly.

4.5 The Center's in-kind contributions to the Recipient are estimated at US$114,966. These in-kind contributions will be provided in accordance with the lists of items to be provided and the timetables set forth in Annex I in order to enable the Recipient to meet the work schedule for the Project. Failure by the Center to provide the in-kind contributions in a timely manner may give rise to a modification of the relevant provisions of the Agreement.

The Center's in-kind contributions, which are provided for exclusive use on the Project by the Recipient during the lifetime of the Project, include the following categories of items:

4.5.1 The Center shall provide in-kind equipment to the Recipient (if any) in accordance with Annex I (hereinafter referred to as "**Center Provided Equipment**"). Center Provided Equipment will be delivered to the Recipient at a CIS customs entry point specified by the Center. The Center will be responsible for clearance through customs, and the Recipient will be responsible for transporting the equipment from the customs entry point to the site of the Project. The equipment shall be inventoried, preserved, accounted for, and maintained throughout the Project by the Recipient. The equipment shall be used only in areas that are open for monitoring and auditing in accordance with Article 9. The title to Center Provided Equipment with an acquisition per item cost of less that $2,500 will vest in the Recipient once it has been provided. The title to all other Partner Provided Equipment will remain with the Center, unless mutually agreed otherwise.

4.5.2 The Center shall provide in-kind materials in accordance with Annex I (hereinafter referred to as "**Center Provided Materials**"). Center Provided Materials will be delivered to the Recipient at a CIS customs entry point specified by the Center. The Center will be responsible for customs clearance, and the Recipient will be responsible for transporting the materials to the site of the Project.

4.5.3 The Center shall provide in-kind services (if any) in accordance with Annex I (hereinafter referred to as "**Center Provided Services**").

4.5.4 The Center shall provide in-kind international travel by the Recipient in accordance with Annex I (hereinafter referred to as "**Center Provided Travel**"). The cost of the Center's contribution will not exceed US$26,000.

Center Provided Travel will be undertaken by participants in the Project only after advance approval for each trip by the Partner and notification to the Center. The Recipient shall send to the Partner and Center requests for travel not less than 30 days prior to the beginning of each trip unless a shorter time for advance request is approved by the Partner and then by the Center for a specific trip. The Center will provide directly to the traveler the funds to cover such travel, provided that such travel is approved by the Partner prior to the beginning of the travel.

The Center's responsibility does not include making arrangements for visits, passports, visas, or travel reservations but is limited to providing financial support, including funds to cover the costs of passport and visa fees as well as transportation and lodging, in accordance with the travel regulations of the Center.

The Recipient is responsible for ensuring that the financial support requested pursuant to this paragraph does not exceed the financial limit set forth above.

4.5.5 The Center shall provide in-kind the costs of certain bank transfer fees in accordance with Annex I (hereinafter referred to as "**Center Provided Bank Fees**"). They will be limited to fees necessary to transfer funds into the bank account or accounts of the Recipient and fees associated with the payment of cash to Individual Participants in the Project. They will be paid directly by the Center to the appropriate banks.

**Article 5 - Cash Payments by the Center to the Recipient**

5.1 Pursuant to Article 4.2, the Center shall make its payments to the Recipient through Dedicated Bank Account(s), as set forth in Article 6. 6 of Annex II in banks acceptable to the Center.

- An advance payment of US$4,018 which is the estimated level of expenditures by the Recipient during the first six months of the Project, as soon as possible following the Operative Commencement Date;
- Quarterly payments within one month of the receipt by the Partner and Center of progress or annual reports and associated cost statements in accordance with Article 7 and Annexes II and III. The amounts of the payments shall be estimates by the Center of the funds required to support the work plan set forth in Annex I during each of the succeeding quarters taking into account the cost statement from the previous period;
- A retention shall be made by the Center of US$11,500. The retention shall be released to the Recipient within one month following the approval by the Partner and Center of the last technical or financial document or other deliverable required by the Agreement.

5.2 Pursuant to Article 4.4, the Center shall make grant payments directly to Individual Participants in accordance with letters of agreement between the Center and the Individual Participants. The Center shall ensure that banking arrangements are established for these payments.

At the end of the third month following the Operative Commencement Date and every three months thereafter throughout the duration of the Project, the Recipient represented by the Project Manager who is identified in Annex I will provide the Partner and the Center with a list of grant payments that are due at that time to Individual Participants in accordance with the payment levels set forth in Annex I and the amount of time devoted to the Project by each Individual Participant as certified by the Project Manager. Such payments will then be promptly made as appropriate by the Center.

Since the Individual Participants will remain employees of the Recipient, the Center's act of direct grant payments to the Individual Participants will not transfer from the Recipient to the Partner or the Center any liability for damages caused by the Individual Participants during execution of the Projects or any liability for damages to the Individual Participants during execution of the Project.

**Article 6 - Cost Statements by the Recipient**

6.1 Quarterly cost statements shall be submitted by the Recipient to the Partner and the Center as follows:

To the Center, the Partner and the U.S. Counterpart Scientist:
– English: one copy via electronic transmission (e-mail or on diskette) and one printed copy;

The first statement is to be submitted no later than four months after the Operative Commencement Date and will cover the first three months of Project activity. Subsequent statements are to be submitted at three-month intervals following submission of the first statement. The statements will be appended to the relevant technical reports specified in Article 7. The cost statements will include the costs of grant payments directly to Individual Participants, but the requests for such grant payments in accordance with Article 5 should not be delayed pending preparation of the entire quarterly cost statements called for in this Article. Such payments may be nevertheless suspended by the Center in case if the cost statement for the previous quarter was not yet submitted to the Center.

6.2 A consolidated cost statement shall be submitted by the Recipient to the Partner and the Center within two months of the completion, cessation or termination of the work financed by the Partner as follows:

To the Center, the Partner and the U.S. Counterpart Scientist:
– English: one copy via electronic transmission (e-mail or on diskette) and one printed copy;

If such a statement is not submitted on time, the Center or the Partner may request in writing its submission. If the Center and the Partner do not receive the submission within thirty days after such a written request, the Center, in consultation with the Partner, may consider the previously claimed costs to be final and determine to make no further reimbursement.

6.3 Cost statements shall comply with the formats prescribed in Annex III.

**Article 7 - Reports and Other Project Outputs**

7.1 The Recipient shall submit the following reports in accordance with the format prescribed in Annex III as follows:
To the Center, the Partner and the U.S. Counterpart Scientist:
– English: one copy via electronic transmission (e-mail or on diskette) and one printed copy;

It is the responsibility of the Recipient, in consultation with the Partner, to indicate clearly what parts of reports and other project outputs contain invention or business confidential information and specify any limitations on circulation. For each report or other project output, an unrestricted version shall also be provided. All reports containing invention or business confidential information shall be handled by the Center according to established internal procedures.

- Quarterly progress reports covering each three-month period following the Operative Commencement Date to be submitted within one month after the end of each reporting period.

- Annual reports. For projects of duration of more than one year, an annual report will be submitted 13 months after the Operative Commencement Date and will cover the first year of project activity. For projects of duration of more than two years, a second annual report will be submitted 12 months later.

- Other reports. The Recipient and the Partner will define other reports in Annex I.

- A final report. A draft final report will be submitted to the Center and the Partner within two months of the completion of the Project work plan, cessation or termination of the Agreement, or the agreed completion date of the Agreement, whichever is the earliest. The Partner, in consultation with the Center, shall submit to the Center and Recipient its evaluation and comments on the draft final report within two months after receipt of the latter. The definitive final report will then be submitted by the Recipient to the Center and the Partner within one month after receipt of the Partner's evaluation. If the Partner does not submit an evaluation within two month, the draft final report shall be considered the definitive final report.

- Edited reports for publication will be provided as specified in Article 4.1 (c) of ANNEX II.

7.2 For the purposes of the Agreement, "deliverables" are defined as any significant outputs, including all reports, of the Project to be submitted in accordance with Annexes I, II and III.

**Article 8 - Ownership and Exploitation of Results**

8.1 The results arising from the Agreement shall be allocated between the Recipient and the Partner in accordance with Part E of Annex II. The Recipient and the Partner shall take appropriate action to exploit or commercialize the results and to make available the results to third parties in accordance with the framework specified in Part E of Annex II. Cooperation agreements with foreign institutions complementing, but not conflicting with, this Framework may be entered into by the Recipient and the Partner.

8.2 Prior to completion of the Project, the Recipient shall submit to the Center a Technology Implementation Plan developed in consultation with the Partner. For projects with a duration of eighteen months or longer, this Plan will be submitted 6 months prior to the anticipated Project completion date. For projects with a duration of less than eighteen months, the Plan will be submitted three months prior to the anticipated Project completion date.

8.3 Exploitation of results shall be limited to applications for peaceful purposes. In this regard, the Recipient and the Partner shall ensure that any results which could result in concerns over proliferation of weapons technology and transfer of sensitive technologies will be protected in accordance with relevant laws of the Republic of Georgia and international agreements and conventions to which the Republic of Georgia is a Party.

**Article 9 - Auditing and Monitoring**

9.1 Access by the Center to carry out on-site monitoring of all technical activities of the Project shall be granted by the Recipient, and information and assistance shall be given for the verification and evaluation of the Project activities as set out in Annex II.

9.2 Financial audits of costs may be carried out by the Center as specified in Annex II.

9.3 Auditing and Monitoring of institutions located in closed cities shall be carried out according to the procedures adopted at the sixth Governing Board Meeting of the Center.

**Article 10 - Amendments, Variations, or Additions**

The provisions of this Agreement and its Annexes may be amended or supplemented only by means of a written agreement signed by authorized representatives of the Signatory Parties. However, operational changes in Annex I, other than changes in the Project Manager, the Participating Institution, daily rates of leading persons of the Project and the overall schedule, can be made by agreement between the Center and the Recipient.

**Article 11 - Special Conditions**

**11.1 With respect to the Protection of Human Subjects**

(i) The CDC has reviewed the proposed activities and found that they do consist of research involving human subjects.

(ii) The project proposal must be reviewed in accordance with the U.S. law and international policies and regulations regarding biomedical research involving human subjects

(iii) The Implementing Agencies shall be responsible for ensuring that any research work conducted under this project Agreement shall be carried out consistent with The Public Health Service Act as Amended by the Health Research Extension Act of 1985 and the Federal Policy for the Protection of Human Subjects of 1991

(iv) The Recipient and the Partner shall follow the principles of *The Belmont Report, Principles and Guidelines for Protection of Human Subjects of Research* or *The World Medical Association Declaration of Helsinki, Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*, adopted by the 18th World Medical Assembly and revised in 1989.

**11.2 With respect to the use of Laboratory Animals**

(i) Laboratory animals and/or endangered species are not expected to be a subject of this research or be involved during the execution of work under this specific project.

(ii) However, if this proves otherwise, the project proposal must be reviewed in accordance with the U.S. law and international policies and regulations regarding biomedical research involving laboratory animals

(iii) The Implementing Agencies shall be responsible for ensuring that any activity carried out pursuant to this agreement and involving laboratory animals is in compliance with the Foreign State of Compliance, International Guiding Principles for Biomedical Research and the Public Health Service Policy on Humane Care and Use of Laboratory Animals as revised in September of 1986

**11.3 With respect to transport of Biological Samples**

Any export/import involving transportation of biological samples shall be conducted in accordance with the existing laws, regulations, and administrative procedures of the United States of America and the Republic of Georgia. For current information regarding this issue please contact the following:

(i) For U.S. exports: Department of Commerce, Bureau of Export Administration at (202) 482-4811.

(ii) For U.S. imports of etiologic agents of humans: Centers for Disease Control and Prevention, Office of Health and Safety at (404) 639-2453.

(iii) For U.S. imports of etiologic agents of livestock, poultry and other animals: United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services at (301) 734-3277.

**11.4 With respect to Manipulation of Genetic Material through the Use of Recombinant DNA Techniques**

(i) The CDC has reviewed the proposed activities and found that they do not consist of research involving recombinant DNA techniques for genetic manipulation.

(ii) However, if this proves otherwise, the project proposal must be reviewed in accordance with applicable U.S. law and international policies and regulations, including the current "NIH Guidelines for Research Involving Recombinant DNA Molecules." These guidelines can be found on the NIH website at http://www.nih.gov/od/oba or from the NIH Office of Recombinant DNA Activities (301-496-9838).

(iii) The BTEP Advisory Group may ask the investigators to initiate a review by the appropriate Recombinant DNA Advisory Committee (RAC) or Institutional Biosafety Committee (IBC) at any time.

**Article 12 - Disputes**

Disputes arising during performance of this Agreement including, in particular:
(i) A claim by the Recipient for any payments deemed due;
(ii) An interpretation of a provision of the Agreement; or
(iii) A request for relief or approval related to the Agreement,

shall be subject to the following procedure:

The Recipient shall submit any claim, demand, or request in writing to the Partner and to the Center. The Partner and the Center will prepare a joint response. Unless a longer period is specified in the Agreement, the written decision of the Partner and the Center shall be delivered to the Recipient within four weeks of the receipt of the submission.

Exceptionally, the Recipient may appeal the Partner's and Center's decision in writing through the Executive Director of the Center to the Governing Board of the Center within four weeks of the communication of the Partner's and Center's decision.

The decision of the Governing Board shall be final and binding (unless otherwise provided). Pending the final settlement of disputes, the Recipient shall, nevertheless, proceed diligently with the performance of the Agreement.

**Article 13 - Liability**

13.1 The Partner and the Center shall not be liable for any material loss, damage, or injury of any nature arising from, or in connection with, the performance of the work under the Agreement solely by virtue of financing the Project, including liability from direct grant payments to Individual Participants as set forth in Article 5.2.

13.2 The Partner and the Center shall not be liable to the Recipient or third parties for claims arising from:

– publication or transmission of any report in accordance with Articles 4 and 13 of Annex II unless it is shown that the Partner or Center have not taken reasonable steps to protect material clearly indicated as invention or business confidential information;

– the application of the contents of any report by a third party; or

– the handling or use of products which result from the Project.

13.3 The Center shall not be liable for nonperformance by the Partner or the Recipient of their obligations under the Agreement.

**Article 14 - Suspension and Termination of the Agreement**

14.1 Suspension

14.1.1 If the Center identifies a problem with the Project's performance through audit, monitoring, annual reports or other ways, and discussions between the Center and the Recipient which shall ensue pursuant to a notice given by the Center to the Recipient do not produce any results, the Center shall reserve the right to suspend, in consultation with the Partner, the project or, when feasible from technical and other points of view, a part of the Project, within thirty days after the Center issues to the Project Manager a notification of suspension which specifies the problem, the effective date and the period of the suspension. In case auditing and monitoring procedures stipulated in the Agreement and Annex II are breached by the Recipient, the suspension shall come into force ten days after the notification given to the Recipient if no corrective action has been taken during this period.

When the suspension becomes effective, the Center shall pay grants to the individual participants for the period they were engaged in the Project before the Center's declaration of suspension becomes effective. Any other payments or in-kind supplies to the Recipient shall in principle be suspended as long as the suspension remains in effect. The Recipient shall act in due diligence to mitigate any losses which may arise during this period.

Even when the suspension is in effect, the Center and the Recipient shall do the utmost to find a possible solution to the problem.

14.1.2 In case the Center and/or the Partner does not fulfill its obligations arising from the Project, namely in relation to Article 2 and 3, the Recipient shall reserve the right to suspend the Project within thirty days after the Recipient issues to the Executive Director of the Center a notification of suspension which specifies the problem, the effective date and the period of the suspension. Clauses of paragraph three of 14.1.1 shall be applied here as well.

14.2 Termination

14.2.1 When the Project is suspended by the Center, and the period of the suspension which is specified in the Center's notification expires and the Center and the Recipient are unable to find a solution, the Center shall, in consultation with the Partner, terminate the Project. In the event of partial suspension, the Center and the Recipient shall negotiate and agree upon possible measures including partial termination of the Project. If these negotiations do not produce any viable alternative plan, the Center shall reserve the right to terminate the entire Project.

Notwithstanding the termination, the Recipient shall submit reports and cost statements covering the period up to the termination and the following provisions of the Agreement shall continue to apply: Article 12 (Disputes), Paragraph 7 (Accounting Principles, Allowable Costs, and Transfer of Costs) and 8.2 (Equipment) of Annex I of the Agreement, and Part E of Annex II of the Agreement (Information and Intellectual Property).

If the Project is terminated, costs shall be limited to the allowable costs incurred by the Recipient prior to the suspension and other costs which the Center considers to be fair and reasonable having regard to commitments which have been reasonably entered into and which cannot be canceled or avoided.

14.2.2 When the Project is suspended by the Recipient, and the period of the suspension which is specified in the Recipient's notification expires and the Recipient and the Center are unable to find a solution, the Recipient shall terminate the Project. Clauses of paragraphs two and three of 14.2.1 shall be applied here as well.

14.3 Termination by Force Majeure Situations

When Force Majeure situations occur which make the Project implementation impossible, the Center in consultation with the Partner and the Recipient may terminate the Project with application of similar procedures as specified above.

14.4 Termination Forced due to the Violation of Laws or Regulations by the Recipient

When the Recipient has committed actions which obviously violate the national laws of the state where the Recipient is a legal entity or which obviously are contrary to the stated objectives of the Center or to other conditions specified under the ISTC Agreement or the ISTC Statute, the Center shall terminate the Project with immediate effectiveness upon written notification of termination to the Recipient. In this case, the Recipient shall promptly return to the Center all payments and goods previously provided to the Recipient. Notwithstanding any termination, Part E of Annex II of the Agreement will continue to apply.

**Article 15 - Correspondence**

15.1 Any written notice, request or consent required under the Agreement is deemed to have been given or made when delivered in person to an authorized representative of a Signatory Party or when sent by mail, telex, telegram, electronic mail or facsimile (receipt acknowledgment required) to such Signature Party at the following address:

For the Center:
International Science and Technology Center
32-34 Krasnoproletarskaya Str.,
Moscow 127473, Russia
Facsimile: +7(499)978-4926
Senior Project Manager: Tatiana Gremyakova

For the Recipient:
National Center for Disease Control and Medical Statistics
9 Asatiani Str, Tbilisi, 0177, Georgia
Facsimile: +(995 32) 31 14 85
Project Manager: Shota Tsanava

For the Partner
Office of Global Health Affairs
U.S. Department of Health and Human Services
5600 Fishers Lane, Room 18-90
Rockville, MD 20857
Facsimile: +1(301) 443 0742
BTEP Government Program Manager: LT Idongesit Inwang Essiet-Gibson

For the U.S. Counterpart Scientist:
US Centers for Disease Control and Prevention
1600 Clifton Road, MS-A38
Atlanta, GA, 30333, USA
Facsimile: +1(404) 639 2205
US Counterpart Scientist: Jeremy Sobel

15.2 Notice will be deemed to be effective as follows:

(i) in the case of personal delivery or mail, on delivery;

(ii) in the case of telexes, telegrams, electronic mail or facsimiles, within one (1) working day following confirmed transmission. A signed original will be provided by mail in all cases.

15.3 Each Signatory Party may change its address for notice hereunder by giving the other Party notice of such change pursuant to this Article.

**Article 16 - Annexes**

As specified in Article 1.2, the Annexes are an integral part of the Agreement. They are:

| | |
|---|---|
| Annex I | Work Plan |
| Annex II | General Conditions |
| Annex III | Formats for Progress and Cost Reports |
| Annex IV | Disclaimer |

**Article 17 - Entry into Force of the Agreement**

The Agreement shall enter into force on April 1, 2007.

Prepared in Moscow in the English language.

For the Center:

Norbert Jousten — Date
Executive Director
International Science and Technology Center

For the Recipient:

Paata Imnadze — Date
Director
National Center for Disease Control and Medical Statistics

For the Partner:

LT Idongesit Inwang Essiet-Gibson — Date
Government Program Manager
DHHS Biotechnology Engagement Program (BTEP)

# ANNEX I
# Work Plan

## I. Summary Project Information

### 1. Project Title

**Establishment of national sentinel-site, laboratory-based *Salmonella* surveillance system and outbreak response capacity for enhanced control of foodborne disease in the Republic of Georgia**

### 2. Project Manager

| | |
|---|---|
| **Name:** Shota Tsanava | |
| **Title:** MD, PhD | **Position:** Deputy Director |
| **Street address:** 9 M.Asatiani | |
| **City:** Tbilisi | **Region:** |
| **ZIP:** 0177 | **Country:** Georgia |
| **Tel.:** (995 32) 39 89 46 | **Fax:** (995 32) 31 14 85 |
| **E-mail:** tsana@ncdc.gov, ghaniashvili@yahoo.com | |

### 3. Participating Institutions

#### *3.1. Leading Institution*

| | |
|---|---|
| **Short reference:** NCDC | |
| **Full name:** National Center for Disease Control and Medical Statistics | |
| **Street address:** 9 M.Asatiani | |
| **City:** Tbilisi | **Region:** |
| **ZIP:** 0177 | **Country:** Georgia |
| **Name of Signature Authority:** Paata Imnadze | |
| **Title:** MD, PhD | **Position:** Director of NCDC |
| **Tel.:** (995 32) 39 89 46 | **Fax:** (995 32) 94 84 05 |
| **E-mail:** ncdc@ncdc.ge | |
| **Governmental Agency:** Ministry of Health, Labor and Social Affairs | |

#### *3.2. Other Participating Institutions*

**None**

### 4. Foreign Collaborators/Partners

#### *4.1. Collaborators*

| | |
|---|---|
| **Institution:** US Centers for Disease Control and Prevention | |
| **Street address:** 1600 Clifton Road, MS-A38 | |
| **City:** Atlanta | **Region/State:** GA |
| **ZIP:** 30333 | **Country:** USA |
| **Person:** Jeremy Sobel | |
| **Title:** MD, MP.H | **Position:** Medical Epidemiologist |
| **Tel.:** (404) 639 4633 | **Fax:** (404) 639 2205 |
| **E-mail:** qzs3@cdc.gov | |

***4.2. Partners***

| | |
|---|---|
| **Institution:** Biotechnology Engagement Program / US Department of Health and Human Services/Office of the Secretary/Office of Global Health Affaires | |
| **Street address:** Room 18-90 Parklawn Building, 5600 Fisher's Lane | |
| **City:** Rockville | **Region/State:** MD |
| **ZIP:** 20857 | **Country:** USA |
| **Signature Authority:** LT Idongesit Inwang Essiet-Gibson | |
| **Title:** M.S., MPH, Lieutenant, USPHS | **Position:** BTEP Government Program Manager |
| **Tel.:** + 1(301) 443-9624 | **Fax:** (301) 443 0742 |
| **E-mail:** Idongesit.Essiet-Gibson@hhs.gov | |
| **Project Coordinator:** Judit O'Connor | |
| **Title:** MP.H | **Position:** Project Coordinator |
| **Tel.:** (202) 222 0409 | **Fax:** (202) 955 3109 |
| **E-mail:** oconnor@cubrc.org | |

**5. Project Duration**

36 months

**6. Project Location and Equipment**

| Institution | Location, Facilities and Equipment |
|---|---|
| **Leading Institution** | National Center for Disease Control and Medical Statistics / Laboratory of Cholera and other Intestinal diseases<br>9. Asatiani str. 0177 Tbilisi. Georgia<br>Equipment existing in the laboratory:<br>Refrigerator 2<br>Incubator 2<br>Microscope 1 |
| **Participant Institution 1** | No |

## II. Specific information

### 1. Introduction and Overview

### 1. Introduction and Overview

**Goal:** Develop a *Salmonella* surveillance and control program in the Republic of Georgia, including sentinel-site based active *Salmonella* surveillance, outbreak response capacity, selective microbiologic food testing, and a public health campaign to help the citizens reduce their risk of infection by *Salmonella* and other pathogens.

**Background:** *Salmonella* species are the most common bacterial foodborne pathogens throughout the world, causing tens of millions of cases of diarrheal illness and a smaller but substantial number of severe systemic infections and deaths. *Salmonella* is a zoonotic disease with reservoirs in numerous species of animals, and foodborne transmission occurs through consumption of undercooked meats; cereals, fruits and vegetables contaminated with animal fecal matter; or by cross-contamination of any food during preparation, transport, storage or serving. In recent decades antimicrobial resistance of *S.* Typhimurium DT-104, *S.* Newport, and other species infecting humans has markedly increased, and published studies have documented increased morbidity and mortality in patients infected with resistant strains. From the turn of the 20th Century to the present day, robust public health surveillance systems for *Salmonella*, coupled with outbreak response capacity, have constituted the backbone of infectious disease surveillance systems in developed countries by supporting the development and sustainability of laboratory-based surveillance and emergency response for an array of other pathogens and guiding food safety policy.

The Republic of Georgia at this time possesses minimal capacity for *Salmonella* surveillance and disease control, because the essential laboratory capacity for *Salmonella* diagnosis is extremely limited. Few sporadic cases of salmonellosis are reported; surveillance for clinically (not laboratory based) diarrheal illness is in place. Nevertheless, focused outbreak investigations of foodborne illness by the National Center for Disease Control (NCDC) have demonstrated that large outbreaks of foodborne salmonellosis occur in the country, indicating a widespread but incompletely documented public health problem. It must be recognized that at this time, there is no functioning food safety authority in the Republic of Georgia and no governmental oversight whatsoever over the food supply, resulting in vulnerability of the population to infections through an unregulated food supply. The limited available evidence suggests that the incidence of foodborne disease is high. By creating a robust surveillance and response system for human infections with *Salmonella*, essential data and policy-driving impetus will be generated for the development of a modern food safety infrastructure in the country. This sequence of events occurred in the western world at the turn of the 20th Century and its benefits continue as *Salmonella* surveillance data remains a cornerstone of public health and a driver of food safety policies.

**Objectives:** Develop a national *Salmonella* surveillance and control program that will accomplish the following:

(1) Provide ongoing, timely, accurate information on the sources of infection with *Salmonella*, to drive specific control strategies that will reduce illness and death over the short and medium term
(2) Fortify the public health infrastructure and its respond to infectious disease outbreaks and its capacity to identify and subtype pathogens causing infectious disease within the public health system
(3) Monitor antimicrobial resistance of *Salmonella* isolates in Georgia, to guide clinical treatment standards
(4) Serve as a platform for subsequent development of surveillance for other enteric infections
(5) Establish the burden of disease of salmonellosis in the country, and thereby provide policy makers with evidence needed to implement food-safety programs that will reduce illness over the long term
(6) Provide essential ongoing experience to public health officials in the rigorous practice of laboratory diagnosis, epidemiologic data collection and analysis, and timely response to control and prevent illness
(7) Integrate Georgian public health professionals into international networks dedicated to surveillance and control of *Salmonella*, such as WHO-Global Salm Surv (WHO-GSS), PulseNet International (global network for molecular subtyping of *Salmonella* in public health), etc.

These outcomes can be attained using a sentinel-site design. In particular, systematic microbiological testing of persons ill with diarrhea provides a more representative sample of *Salmonella* cases than does passive, nationwide surveillance practiced in many western countries. In nationwide passive surveillance, culture of diarrheal stool samples is at the discretion of the physician, and therefore is biased towards more severely ill cases or those who can afford testing. Our proposed method of systematically culturing a subset of all persons presenting with diarrheal illness for medical care will, in fact, provide a more representative and less biased picture of salmonellosis in Georgia.

**Components of project:** This proposed 3-year project will consist of the following elements:

A. Re-establish *Salmonella* laboratory diagnostic capacity in sentinel sites in the Republic of Georgia and at the national reference laboratory

Laboratory diagnostic capacity is a *sine qua non* of *Salmonella* surveillance. The most common clinical syndrome, febrile diarrheal illness, is indistinguishable clinically from other enteric infections. In addition, *Salmonella* is unique among enteric pathogens in that it consists of over 2000 serotypes (e.g. *S.* Enteritidis, *S.* Typhimiurium, etc.); and subtyping bacterial isolates from human cases provides valuable information: for example, *S.* Enteritidis infection almost always originates in eggs, suggesting immediate and long-term control strategies. Clusters of human cases of rare *Salmonella* serotypes, even when the patients appear unrelated to each other, usually indicate a common-source outbreak that would not

have been otherwise recognized, but once identified can be investigated to prevent additional infections. While microbiologic identification of *Salmonella* and serogrouping with polyvalent antiserum is within the capacity of hospital laboratories in the Republic of Georgia, sub-typing bacterial isolates to identify the serotype requires expertise and an antisera library. Accordingly we will establish culture capacity at four regional laboratories, and serotyping capacity a central location, the National Center for Disease Control (NCDC). Additionally, we will establish capacity for pulsed-gel electrophoresis (PFGE) molecular subtyping at the NCDC reference lab. PFGE has proven a highly valuable and cost-effective tool for identification of geographically dispersed outbreaks and for confirming epidemiologic associations in outbreak investigations.

1. Laboratories at central hospital in Georgia's four largest cities will constitute regional *Salmonella* sentinel laboratories. These hospitals are located in Batumi and Kutaisi (western Georgia) and Tbilisi and Rustavi (Eastern Georgia).
    a. Lab personnel will receive standardized training on handling and culturing of stool samples, identification and serogrouping of *Salmonella*, and storage and shipping of *Salmonella* isolates.
    b. The laboratories will be inspected by project personnel and provided with required equipment and supplies
    c. Laboratories will receive clinical specimens from both outpatients and inpatients, to capture the clinical spectrum and serotype distribution of salmonellosis in Georgia
    d. Quality control will be established by dividing a subset of clinical samples for simultaneous testing at the hospital laboratory and at NCDC.

2. The Enteric Diseases Laboratory at the National Center for Disease Control (NCDC) will receive all *Salmonella* isolates from the sentinel laboratories.
    e. NCDC *Salmonella* reference laboratory will perform serotyping on all received *Salmonella* isolates
    f. Lab personnel will receive standardized training on culture and serotyping techniques
    g. Antisera for serotyping of *Salmonella* isolates will be provided by the World Health Organization Global Salm Surv (WHO-GSS) as a free service to its members
    h. Quality assurance will be established through WHO-GSS network's free quality assurance program, which includes periodic testing of blinded samples provide by the National Serum Institute of Copenhagen, Denmark.
    i. NCDC laboratory will use PFGE for molecular subtyping of *Salmonella* isolates, and join the international PulseNet molecular subtyping network.

B. Collect stool samples from a systematic sample of patients presenting with diarrheal illness to outpatient and inpatient facilities in the catchment areas of the four sentinel hospitals for *Salmonella* culture, and obtain basic demographic data on patients

1. A systematic selection of pediatric and adult outpatient and inpatient facilities in the areas served by the sentinel hospital laboratories will be made, and a subset selected for collection of stool samples with demographic information
2. An algorithm will be developed for systematic collection of stool samples from a subset of patients presenting with diarrhea, for a total of 1,000 samples per sentinel laboratory
3. Stools and demographic information will be forwarded to the local sentinel reference hospital for *Salmonella* culture.
4. Positive *Salmonella* cultures and demographic data will be forwarded to NCDC national reference laboratory for serotyping, entry into national surveillance database, and timely feedback to regional and local officials and clinicians

C. Develop and implement standard investigative protocol for outbreaks of *Salmonella*; develop an outbreak surveillance system

Epidemiologic outbreak investigations are essential for acute disease control and prevention of further cases. They are also the most efficient and effective way to link a pathogen to its source. For example, epidemiologic investigations of outbreaks first identified chicken eggs as the source of infection of *Salmonella* Enteritidis, the most common *Salmonella* serotype worldwide, leading to extensive and effective control measures in many countries.

1Guidelines for foodborne outbreak investigation will be developed, including active case finding, descriptive and analytical field studies, and clinical (human) and food sample collection.

2 Adaptable models of questionnaires, databases and report templates will be created

3. Procedures for deployment of integrated teams consisting of NDC, regional and local health officers will be developed
4. Ongoing outbreak investigations will provide on-the-job training for pubic health officials
5. Develop a standard surveillance form for reporting outbreaks of *Salmonella* and other foodborne pathogens as a primary public health event. This will allow systematic analysis of outbreaks over time, to provide information to direct disease control efforts (for example, for linking specific *Salmonella* serotypes to specific foods, identifying high-risk settings for outbreaks requiring public education, etc.).

D. Informatics: Develop database for *Salmonella* cases and database for *Salmonella* outbreaks, with common link

1. Build database for case-surveillance data (individual cases) including unique case-identifier, demographic and laboratory findings
2. Build database for outbreak surveillance data (outbreak as reported event), with unique outbreak identifier, and standardized fields on location number of cases, clinical outcomes, associated food(s), associated findings, and laboratory findings
3. Link databases by entering unique outbreak identifier for individual cases who became ill as part of recognized outbreak, and enter unique case identifiers in outbreak database for those confirmed cases who were part of the reported outbreak
4. Electronic surveillance databases will contain unique numerical IDs for patients but no information that will allow identification of an individual person.

E. Dissemination of surveillance and outbreak findings

1. Regular, timely reports of surveillance data and outbreak investigations will be provided to regional and local health authorities and clinical facilities providing laboratory samples. The purpose of collecting surveillance data is to drive public health action for disease prevention. Timely feedback of surveillance data to those who collect it and widespread dissemination to a broad audience is the key to its sustainable collection and effectiveness of resulting disease control actions.
2. Dissemination will be in the form of paper or electronic notification of laboratory testing results, and paper and electronic bulletins of summary surveillance data.

F. Develop a public health approach to reduction of illness from *Salmonella* in the Republic of Georgia

1. Theoretically, the primary responsibility for prevention of salmonellosis should rest with the manufacturers and sellers of foods, with guidance and enforcement by governmental foods safety authorities. However, the current reality in Georgia, which includes the lack of resources such as reliable power for refrigeration, the need to rebuild the governmental food safety regulatory and enforcement infrastructure, and other pressing national priorities, means that for some time active self-protection by consumers will be an important requirement to reduce salmonellosis and other foodborne illnesses. Data-driven public education campaigns have had measurable success in addressing foodborne illness in many settings. For example, identification of contaminated eggs as the main source of *S.* Enteritidis infection in the west led to a universal recommendation not to consume raw or undercooked eggs. Adaptation of this recommendation, as part of a program that included improved safety practices on farms, shipping facilities and restaurants, resulted in dramatic reductions in disease incidence in various countries.
2. Based on findings from surveillance and outbreak investigations, we will design a public education campaign to provide citizens and their families with information on reduction of risk of salmonellosis. We will include information on proper handling and cooking of high-risk foods, avoidance of cross-contamination, and special recommendations for persons at high risk and their caregivers, such as infants, immunosupressed persons, and the elderly. Experience in other countries indicates that such public education efforts can be successful but must be specific to the national dietary and hygienic practices of the population, as well as directed by data from outbreak investigations and surveillance with regard to the foods and practices that are locally implicated in *Salmonella* transmission.
    a. Formative research on Knowledge, Attitudes and Practices regarding foodborne illness in Georgia: focus groups and household survey and credible sources of information
    b. Based on formative research, develop public health campaign materials: Poster, flyers, radio and TV announcements
    c. Implement public education campaign
    d. Evaluate public education campaign by conducing post-campaign population survey to measure changes in KAPs related to food safety and foodborne illness
    e. Sustainability: identify partners that can propagate food safety message, such as Ministry of Education which may integrate the material into school curricula, TV and radio stations that may sustain public service messages, etc.

G. Special populations: Hospitalized patients and nosocomial salmonellosis

1. Nosocomial (healthcare facility related) *Salmonella* transmission is a well-documented, serious problem wherever hospital infection control measures are not stringently applied. Most *Salmonella* cases in Georgia are hospitalized patients, and some may represent cases of nosocomial infection, at increased risk for death because of underlying medical conditions. We will systematically investigate every hospitalized patient with salmonellosis to rule out nosocomial infection. Findings will be used in partnership with hospital infection control officers and infectious diseases specialists to promote infection control practices and prevent outbreaks.
2. Several hundred cases of *Salmonella* are identified in Georgia each year, almost all in hospitalized patient with systemic infections. These represent a fraction of *Salmonella* infections in the population, and are highly biased toward patients with severe underlying diseases or nosocomial infection.
    a. Cases of salmonellosis in hospitalized patients will be sought through active surveillance (weekly telephone contact between NCDC and hospital microbiology laboratories), and immediately investigated by hospital infection control staff to rule out nosocomial infection and to control additional spread.

b. Medical records of hospitalized patients with salmonellosis detected will be abstracted and data analyzed to produce a detailed description of hospital-associated salmonellosis, including the clinical and epidemiologic features of the patients, and the serotypes and antimicrobial resistance patterns of the pathogens.

H. Integration into international *Salmonella* networks

This project will be supported by WHO Global Salm Surv (http://www.who.int/salmsurv/en/), the international network of *Salmonella* laboratories, and PulseNet International (http://www.liebertonline.com/doi/pdf/10.1089/fpd.2006.3.36?cookieSet=1),the public health molecular subtyping network. These networks facilitate scientific exchange and provide services such as ongoing regular laboratory training, antisera supplies and quality assurance program for members.

In summary, we will establish a public health *Salmonella* surveillance, investigation and control program with the following elements. We will establish sentinel-site based active surveillance for *Salmonella* infections. We will re-establish laboratory diagnostic and subtyping capacity; include a systematically selected representative sample of outpatients and inpatients presenting with diarrheal illness to facilities; submit isolates for serotyping, antimicrobial resistance testing and molecular subtyping. We will develop capacity for, and conduct real-time foodborne disease outbreak investigations, and integrate epidemiologic and laboratory findings to effect immediate control measures. We will intensively investigate cases of salmonellosis in hospitalized patients to assess the possibility of nosocomial transmission and to propose control measures. We will widely disseminate surveillance and outbreak investigation findings, and use them to develop population-specific food-safety and hygiene messages for a public education campaign, which will be a decisive factor in reducing salmonellosis and other foodborne diseases in Georgia until a robust food safety regulatory infrastructure comes into existence. Every component of this project will be monitored along the lifetime of the project and modified as required.

**2. Expected Results and Their Application**

Result 1. Establishment of sentinel site *Salmonella* active surveillance in the Republic of Georgia

- Application 1.1: Extrapolate the burden of salmonellosis in Georgia, including morbidity, mortality and economic cost, for the purpose of allocating heath resources for control and prevention
- Application 1.2: Follow disease incidence trends over time, identify disease seasonality, geographic areas of risk, and assess effectiveness of control measures
- Application 1.3: Identify increases in cases in space or time that may represented unrecognized outbreaks of salmonellosis to be investigated and controlled.
- Application 1.4: Through feedback to reporting clinicians, laboratorians and local public health workers, strengthen the public health partnerships essential to disease monitoring and control.

Result 2. Re-establish diagnostic capacity for *Salmonella* culture, serotyping and PFGE subtyping

- Application 2.1: Capacity to conduct laboratory-based surveillance of *Salmonella*
- Application 2.2: Capacity for serotyping is essential for linking individual cases for purposes of epidemiologic investigations, and for linking human illness to contaminated foods. This will lead to more timely identification of outbreaks and their contaminated food source, and thereby to prevention of additional human illnesses.
- Application 2.3: PFGE subtyping is a powerful tool for confirming epidemiologic links between cases or between cases and contaminated food; it is essential in outbreaks of very common serotypes of *Salmonella*, where the serotype identity is insufficient to link cases and foods. This capacity will lead to more timely identification of outbreaks and their contaminated food source, and thereby to prevention of additional human illnesses.
- Application 2.4: Systematic monitoring of antimicrobial resistance in *Salmonella* isolates will allow dissemination of recommendations on appropriate antimicrobial therapy, with improved clinical outcomes for patients.
- Application 2.5: Allows for integration of Georgian scientists into international networks of *Salmonella* laboratory diagnosis and investigation, such as WHO-Global Salmsurv and PulseNet International, which provide valuable resources such as free antisera, quality assurance services, and periodic ongoing training. This will result in continual upgrading of the capacity and currency of laboratory workers, and leveraging the resources of international networks to ward disease control efforts in Georgia.

Result 3: Institutionalize foodborne disease outbreak investigation and establish surveillance system with reporting of outbreaks as public health even

- Application 3.1: Rapidly control outbreaks of *Salmonella* and other foodborne pathogens
- Application 3.2: Establishing outbreak surveillance database that will allow systematic analysis of relationship between outbreaks of foodborne illness and implicated foods
- Application 3.3: Over the long term, help define disease-control strategies based on proven sources of infection for specific serotypes of *Salmonella*

Result 4: Investigate cases of *Salmonella* in hospitalized patients
Application 4.1: rapidly identify and control nosocomial outbreaks of *Salmonella*

Result 5: Reduced disease transmission through public education for safer food preparation and hygiene
Application 5.1: Reduced illness and death in humans from *Salmonella* infection
Application 5.2: Reduced costs of illness to private and public sector

**3. Meeting ISTC Goals and Objectives**

1. This project will provide 31 weapons scientists the opportunity to direct their training and skills to study and control a serious public health problem that most likely is common in the Republic of Georgia
2. This project will promote integration of Georgian scientists into the international scientific community through the following: a) ongoing collaboration on this project with US epidemiologists laboratorians, and with international networks dedicated to training, diagnosis and control of Salmonella, c) joint authorship of peer-reviewed manuscripts, d) presentation of results in international meetings
3. This project will reinforce the transition to market-based economies responsive to civil needs by identifying ways in which private-sector clinical laboratories can be integrated into national infectious disease laboratory-based surveillance networks

**4. Scope of Activities**

General description of the activities within the project. Detailed description for each task follows.

**Task 1**

| Task description and main milestones | Participating Institutions |
|---|---|
| Establish laboratory capacity for *Salmonella* diagnosis and subtyping in the Republic of Georgia<br>Milestones:<br>1-1. Laboratory assessment questionnaire/protocol<br>1-2. Assess 5 regional laboratories<br>1-3. Isolation, transport, serotyping and PFGE protocols<br>1-4. Training of laboratory staff in four hospitals and NCDC<br>1-5. Receipt of lab equipment and supplies<br>1-6. Quality assurance protocol in place<br>**Evaluation of task 1**: Quality assessment testing results demonstrates proficiency in all laboratory techniques on blind samples. | 1- National Center for Disease Control and Medical Statistics<br>2-No<br>3-No |

| | Description of deliverables |
|---|---|
| 1 | Quarterly progress report describing proficiency of labs on quality assurance assessments |

**Task 2**

| Task description and main milestones | Participating Institutions |
|---|---|
| Select representative clinical facilities and obtain representative sample of 300 diarrheal stools/year/regional laboratory along with patient demographic information; transport positive cultures with demographic data of patient to NCDC<br>Milestones:<br>1-1. Patient selection protocol<br>1-2.Develop Questionnaire for epidemiological investigation (demographic data etc.)<br>1-3. Stool collection and transport protocol<br>1-4. Agreement by clinical facilities to implement stool specimen and demographic data collection in accordance with protocol<br>1-5. Bacteriological testing of collected stool samples in the regional laboratories.<br>1-6.Cultivation, confirmation, serotyping, molecular typing, antibiotic susceptibility testing of received Salmonella strains at the NCDC reference laboratory.<br>**Evaluation of task 2**: Obtaining required number of clinical samples and complete demographic data each quarter in accordance with sampling protocol. Proportion positive cultures that are received at NCDC. Proportion of positive cultures received at NCDC that are accompanied by patient demographic data. | 1- National Center for Disease Control and Medical Statistics<br>2-No<br>3-No |

| | Description of deliverables |
|---|---|
| 1 | Quarterly progress reports with appropriate public health recommendations as indicated by findings |
| 2 | Weekly feedback reports from regional hospital to clinical facilities with results of stool cultures |
| 3 | Bi-weekly feedback reports from reference lab to regional hospitals with results of serotyping and other testing |

| | |
|---|---|
| 4 | Bi-weekly report from NCDC to regional epidemiologists on status of *Salmonella* in Georgia by region |
| 5 | At 18 months, manuscript(s) detailing methods, findings, and public health recommendations |

**Task 3**

| Task description and main milestones | Participating Institutions |
|---|---|
| Develop and introduce into standard public health practice protocol and adaptable forms/questionnaires and database for investigation of foodborne disease outbreaks<br>Milestones:<br>1. Develop protocol, forms/questionnaires, database<br>2. Conduct training for NCDC staff and regional epidemiologists<br>3. Investigate at least 3 foodborne outbreaks per year<br>**Evaluation of task 3**: Proportion of outbreaks that were investigated in accordance with protocol within 5 days of detection | 1- National Center for Disease Control and Medical Statistics<br>2-No<br>3-No |

| | Description of deliverables |
|---|---|
| 1 | Quarterly progress reports documenting progress |
| 2 | (In conjunction with Task 2): Reports of outbreak investigation disseminated in regular bulletin to regions |
| 3 | If warranted by data: Manuscript: Investigation and control of outbreaks of Salmonella in Georgia |

**Task 4**

| Task description and main milestones | Participating Institutions |
|---|---|
| Construction of linked data bases for case-surveillance and for outbreak surveillance<br>Milestones:<br>1-1. Construction of case-surveillance database<br>1-2. Construction of outbreak-surveillance database<br>1-3. Acceptable proportion of cases entered into database within 3 days of laboratory diagnosis and acceptable proportion of outbreaks entered in to database within 30 days of occurrence.<br>**Evaluation of task 4**: Audit database for timeliness, completeness of data entry | 1- National Center for Disease Control and Medical Statistics<br>2-No<br>3-No |

| | Description of deliverables |
|---|---|
| 1 | Quarterly reports describing study progress |
| 2 | (In conjunction with Task 2): Weekly feedback reports from regional hospital to clinical facilities with results of stool cultures |
| 3 | (In conjunction with Task 2): Bi-weekly report from NCDC to regional epidemiologists on status of *Salmonella* in Georgia by region |
| 4 | (In conjunction with Task 2): At 18 months, manuscript(s) detailing methods, findings, and public health recommendations |

**Task 5**

| Task description and main milestones | Participating Institutions |
|---|---|
| Design and implementation of public health education campaign on food safety<br>Milestones:<br>1. Completion of formative research by survey and focus group on Knowledge, Attitudes and Practices regarding food safety<br>2. Piloted and validated protocol and material for public education campaign<br>3. Implementation of public health campaign<br>4. Conducting post-campaign KAP study<br>5. Identify partners to sustain public message<br>**Evaluation of task 5:** Annual post-campaign survey to assess changes in Knowledge, Attitudes and Practices of the population regarding food safety | 1- National Center for Disease Control and Medical Statistics<br>2-No<br>3-No |

| | Description of deliverables |
|---|---|
| 1 | Quarterly reports describing project progress |
| 2 | Report of population KAP survey findings |
| 3 | Public educational materials: Poster, radio and TV announcements |
| 4 | Manuscript: Implementation and assessment of public health campaign to reduce salmonellosis and other foodborne illnesses in Republic of Georgia |

**Task 6**

| Task description and main milestones | Participating Institutions |
|---|---|
| Active surveillance for hospital-acquired salmonellosis<br>Milestones:<br>1. Protocol for notification of cases to surveillance system<br>2. Standardized forms for investigation of case and chart abstraction<br>3. Protocol for prevention of nosocomial salmonellosis<br>**Evaluation of task 6**: Proportion of nosocomial salmonellosis outbreak that are reported and investigated within 3 days of occurrence | 1- National Center for Disease Control and Medical Statistics<br>2-No<br>3-No |

| | Description of deliverables |
|---|---|
| 1 | Quarterly reports describing project progress |
| 2 | (In conjunction with Tasks 2 and 3): in clued reports on nosocomial salmonellosis in regular bulletins to regional public health officials |
| 3 | If warranted by data: Manuscript on epidemiology and control of nosocomial salmonellosis |

**Task 7**

| Task description and main milestones | Participating Institutions |
|---|---|
| Integrate Georgian scientists and public health professionals into international networks of *Salmonella* diagnosis and control, and enhance collaboration through personnel exchanges<br>Milestones:<br>1. Georgian scientists attend regional meetings/training courses of the WHO-Global Salm Surv network in Russia or Kazakhstan and/or PulseNet International meetings<br>2. Georgian Scientists attend and present project findings at one international conference per year (e.g. Infectious Disease Society of America, International Conference on Emerging Infectious Diseases, etc.).<br>3. A Georgian epidemiologist and a Georgian laboratorian of project staff visit the U.S. Centers for Disease Control and Prevention for 1 month to work with US counterparts on data analysis and microbiological and molecular subtyping techniques.<br>**Evaluation of task 7:** Enhanced communication and collaboration between Georgian and US scientists. | 1- National Center for Disease Control and Medical Statistics<br>2-No<br>3-No |

| | Description of deliverables |
|---|---|
| 1 | Quarterly reports describing project progress |

**5. Role of Foreign Collaborators/Partners**

The US Centers for Disease control and Prevention (CDC) will provide the following contributions: Train NCDC scientists in culture diagnosis, serotyping and molecular typing of *Salmonella*, provide training and quality assurance for antibiotic susceptibility testing of *Salmonella*; consult on surveillance and epidemiologic studies of *Salmonella*; participation in analysis of epidemiologic and laboratory data, development, implementation and evaluation of diagnosis, treatment and control strategies

**6. Technical Approach and Methodology**

1. Analysis and interpretation of surveillance data: Standard methods and statistical package (Epi-Info) will be used. The staff of the Foodborne and Diarrheal Disease Branch of CDC consists of recognized experts on epidemiologic studies of enteric diseases and have published numerous related studies in the peer-reviewed literature (see below)

2. Laboratory diagnostic assays

a. Stool collection, transport in medium and culture: standard methods described in literature will be used (see bibliography below)

b. *Salmonella* serotyping: standard methods described in literature will be used (see bibliography below)

c. Pulsed Field Gel Electrophoresis: Standard PulseNet protocols for *Salmonella* will be used (see bibliography below)

d. Knowledge, Attitudes and Practices (KAPs) survey methodology: standard methods for sample size determination and sampling protocol will be used (see bibliography below)

**7. Technical Schedule**

| | Quarter 1 | Quarter 2 | Quarter 3 | Quarter 4 | Quarter 5 | Quarter 6 | Quarter 7 | Quarter 8 | Quarter 9 | Quarter 10 | Quarter 11 | Quarter 12 | Person*days |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Task 1** Establish lab capacity, QA | Protocol, purchase materials, train staff | Quarterly report | Quarterly report | Annual report | Quarterly report | Quarterly report | Quarterly report | Annual report | Quarterly report | Quarterly report | Quarterly report | Final report | |
| **Person*days** | **180** | **180** | **174** | **40** | **40** | **40** | **40** | **40** | **40** | **40** | **40** | **40** | **894** |
| **Task 2** Select clinical facilities, collect specimens | Protocol, train NCDC, regional epi, and clinical facility staff | Quarterly report. | Quarterly Report | Annual Summary | Quarterly Report | Quarterly Report | Quarterly Report | Annual Summary | Manuscript | Quarterly Report | Quarterly report | Annual Summary manuscript | |
| **Person*days** | **115** | **112** | **190** | **190** | **190** | **190** | **190** | **190** | **190** | **190** | **190** | **190** | **2127** |
| **Task 3** Outbreak investigation | Protocol. | Quarterly report, Training | Quarterly Report | Annual Summary | Quarterly Report | Quarterly Report | Quarterly Report | Annual Summary, Manuscript | Quarterly Report | Quarterly Report | Quarterly Report | Annual report | |
| **Person*days** | **105** | **102** | **102** | **102** | **102** | **102** | **102** | **102** | **102** | **102** | **102** | **102** | **1227** |
| **Task 4** Integrated surveillance database | Protocol and database construction | Quarterly Report | Quarterly Report | Annual Summary | Quarterly Report | Quarterly Report | Quarterly Report | Annual Summary | Quarterly Report | Quarterly Report | Quarterly Report | Annual Summary | |
| **Person*days** | **46** | **50** | **58** | **58** | **58** | **58** | **58** | **58** | **58** | **58** | **58** | **58** | **676** |
| **Task 5** Public education campaign | Protocol | Quarterly report Material development and validation | Quarterly report Material development and validation | Quarterly report | Quarterly report Pilot intervention | Quarterly report Household survey | Quarterly report Implementation | Quarterly report Implementation | Quarterly report Implementation | Quarterly report | Quarterly report Post-intervention Assessment | Final report | |
| **Person*days** | **0** | **0** | **0** | **90** | **95** | **400** | **100** | **0** | **0** | **95** | **400** | **95** | **1275** |
| **Task 6** Investigation of hospital-assoc. cases | Protocol, liaise with hospital staff | Quarterly report | Quarterly report | Quarterly report | Recommendations on prevention (if warranted by data) | Quarterly Report | Quarterly Report | Annual Summary | Quarterly Report | Quarterly Report | Quarterly Report | Annual Summary, Manuscript | |

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Person*days** | **70** | **71** | **100** | **100** | **100** | **100** | **100** | **100** | **100** | **100** | **100** | **100** | **1141** |
| **Task 7** Integrate scientists into international networks | | | WHO/GSS training course | International Conference | | work in CDC | | International Conference | | WHO/GSS training course | International Conference | | |
| **Person*days** | **0** | **0** | **14** | **14** | **0** | **63** | **0** | **14** | **0** | **14** | **14** | **0** | **133** |
| **TOTAL** | **516** | **515** | **638** | **594** | **585** | **953** | **590** | **504** | **490** | **599** | **904** | **585** | **7473** |

**8. Personnel Commitments**

**8.1. Individual participants**

**Leading Institution: NCDC**

**Category I (weapon scientific and technical personnel)**

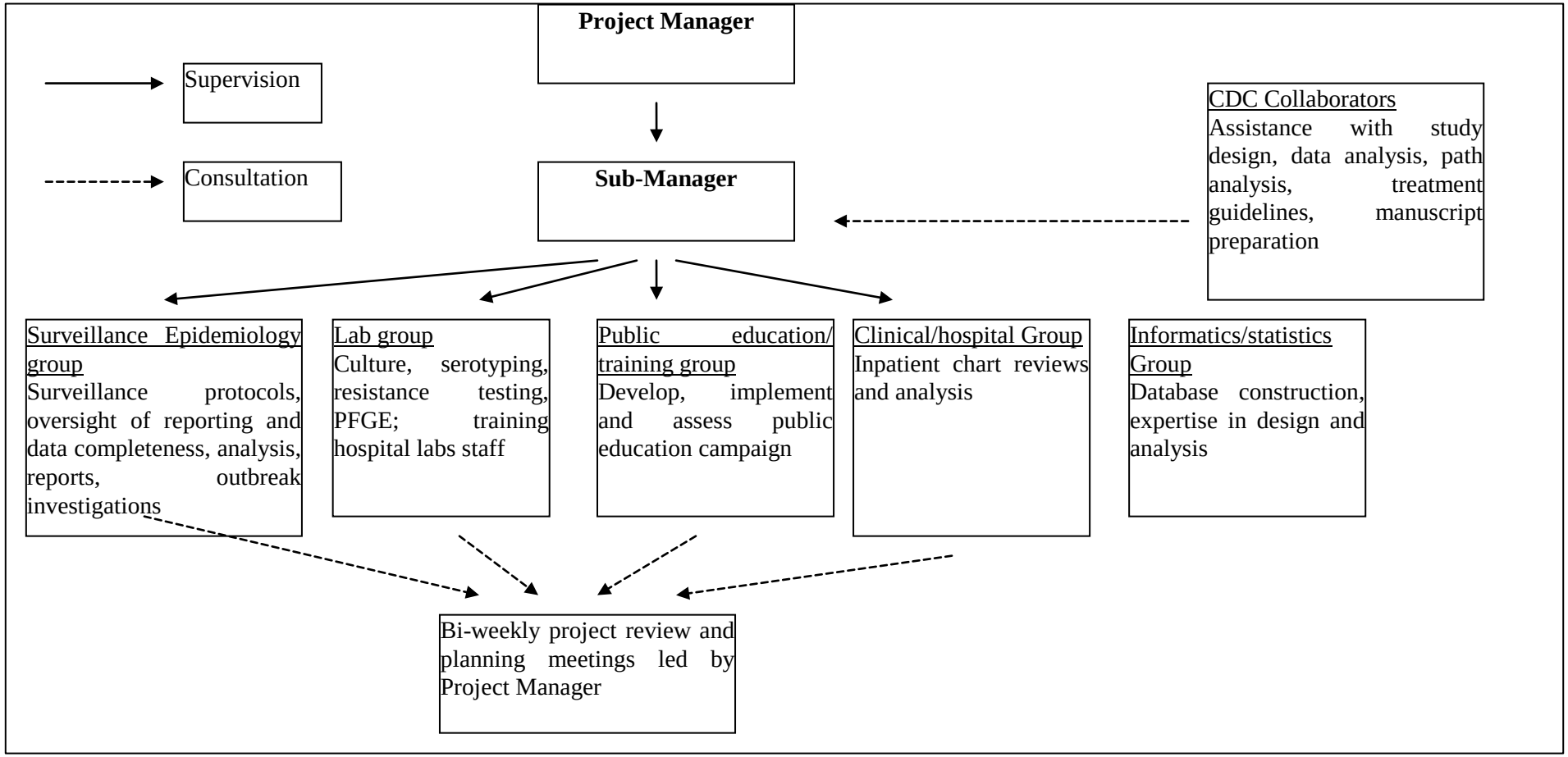
| Name | Birth Year | Scientific Title | Weapon Expertise Ref. | Function in project | Daily rate (US$) | Total days | Total grants (US$) |
|---|---|---|---|---|---|---|---|
| Tsanava Shota | 1957 | MD. PhD. | 3.4 | Project Manager | 35 | 588 | 20580 |
| Ghaniashvili Tamar | 1973 | BS | 3.4 | Associate Project Manager and Lead Epidemiologist | 35 | 390 | 13650 |
| Trapaidze Nino | 1966 | PhD. | 3.4 | Scientific leader | 30 | 130 | 3900 |
| Katsitadze Guram | 1934 | MD. PhD. Prof. | 3.4 | Scientific leader | 30 | 110 | 3300 |
| Tevzadze Liana | 1941 | MD. PhD. | 3.4 | Scientific Leader of bacteriology group | 30 | 300 | 9000 |
| Devdariani Lamara | 1941 | MD. PhD. | 3.4 | Bacteriological investigation, serotyping of Salmonella | 30 | 235 | 7050 |
| Lezhava Iamze | 1942 | BS | 3.4 | Bacteriological investigation, antibiotic susceptibility testing | 25 | 284 | 7100 |
| Tvauri Irina | 1947 | BS | 3.4 | Bacteriological investigation, biochemical identification | 25 | 210 | 5250 |
| Jincharadze Manana | 1964 | BS | 3.4 | Bacteriological investigation, biochemical identification | 25 | 210 | 5250 |
| Lashkarashvili Marina | 1961 | MD | 3.4 | Epidemiological investigation of newly isolated Salmonella strains | 25 | 498 | 12450 |
| Mamuchishvili Nana | 1961 | MD | 3.4 | Epidemiological investigation, epidemiological analysis | 25 | 284 | 7100 |
| Chlikadze Rusudan | 1963 | MD | 3.4 | Epidemiological investigation | 25 | 280 | 7000 |
| Sanadze Ketevan | 1965 | MD | 3.4 | Epidemiological investigation | 25 | 280 | 7000 |
| Chokheli Maiko | 1954 | MD | 3.4 | Statistical and epidemiological analysis | 25 | 224 | 5600 |
| Chikviladze Tamar | 1959 | MD | 3.4 | Bacteriological investigation | 25 | 280 | 7000 |
| Chubinidze Svetlana | 1970 | MD | 3.4 | Epidemiological analysis, working on database | 20 | 340 | 6800 |
| Chanturia Gvantsa | 1972 | BS | 3.4 | Molecular-biological investigation | 20 | 180 | 3600 |
| Kekelidze Merab | 1955 | MD. PhD. | 3.4 | Scientific researcher, molecular typing | 30 | 180 | 5400 |
| Mircxulava Merab | 1958 | MD. PhD. Prof. | 3.4 | Development of database | 30 | 120 | 3600 |
| Kalandadze Irina | 1970 | MD | 3.4 | Epidemiological investigation | 25 | 330 | 8250 |
| | | | | | **Total:** | 5453 | 148880 |

**Category II (other scientific and technical personnel)**

| Name | Birth Year | Scientific Title | Function in project | Daily rate (US$) | Total days | Total grants (US$) |
|---|---|---|---|---|---|---|
| Megrelisvili Tamar | 1953 | MD. PhD. | Epidemiological investigation in Infectious Hospital Tbilisi | 20 | 300 | 6000 |
| Kobuladze Dali | 1959 | MD | Epidemiological investigation in Kutaisi regional Hospital | 20 | 240 | 4800 |
| Gugushvili Nino | 1962 | MD | Epidemiological investigation in Batumi regional Hospital | 20 | 240 | 4800 |
| Dekanosidze Lali | 1962 | MD | Epidemiological investigation in Rustavi regional Hospital | 20 | 240 | 4800 |
| Doreuli Nunu | 1926 | - | Laboratory personnel | 18 | 250 | 4500 |
| Pirtskhalaishvili Kakhaber | 1973 | - | Laboratory equipment maintenance | 18 | 100 | 1800 |
| Zaridze Ketevan | 1973 | - | working on database, data entry | 18 | 350 | 6300 |
| Abazashvili Natalyia | 1975 | - | Laboratory personnel | 18 | 300 | 5400 |
| | | | | **Total:** | 2020 | 38400 |

**8.2. Managerial responsibilities**

The Project Manager will integrate scientific input from staff at NCDC and collaborators at CDC (USA). The Project Manager will oversee four principle groups of workers: epidemiologist, clinical laboratorians, basic research laboratorians, and clinicians/pathologists. A guiding principle of management in this project will be ongoing, regular contact between these groups to facilitate communication and reinforcement of project objectives. Specifically, bi-weekly meetings will be held for all project personnel for updates of work and discussion of goals, progress, needs and modifications of schedules and approaches to assure all staff are up-to-date on all aspects of the work and have an opportunity to voice concerns and contribute to the various studies. Quarterly report



**9. Financial Information**

**TABLE 1**

**Estimated Aggregated Expenditures by Recipient**

| | Category | Quarters 1 & 2 | | Year 1 | | Year 2 | | Year 3 | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | (1) | (2) | (1) | (2) | (1) | (2) | (1) | (2) | (1) | (2) |
| **1** | **Grant Payments:** | | | | | | | | | | |
| 1.1 | Category I | | 24480 | | 49785 | | 49810 | | 49285 | | 148880 |
| 1.2 | Category II | | 6028 | | 12506 | | 12920 | | 12974 | | 38400 |
| 1.3 | Category III | | | | | | | | | | |
| 1.4 | Category IV | | | | | | | | | | |
| | *Total Grant Payments* | | **30508** | | **62291** | | **62730** | | **62259** | | **187280** |
| **2** | **Equipment:** | | | | | | | | | | |
| 2.1 | Capital Equipment | | | | | | | | | | |
| 2.2 | Non-Capital Equipment | | 10800 | | 10800 | | | | | | 10800 |
| | *Total Equipment* | | **10800** | | **10800** | | | | | | **10800** |
| **3** | ***Materials/Supplies*** | **1568** | **48840** | **1568** | **48840** | **888** | **11699** | **783** | **7262** | **3239** | **67801** |
| **4** | **Bank Fees** | **150** | **300** | **205** | **421** | **205** | **422** | **205** | **422** | **615** | **1265** |
| **5** | **Other Direct Costs:** | | | | | | | | | | |
| 5.1 | Technological Energy | | | | | | | | | | |
| 5.2 | Communications | 350 | 80 | 350 | 80 | 350 | 80 | 350 | 80 | 1050 | 240 |
| 5.3 | Subcontracts/Seminars | 90 | 1040 | 90 | 1040 | 90 | 2080 | 90 | 2080 | 270 | 5200 |
| 5.4 | Logistics/Customs | 300 | 1220 | 300 | 1220 | 300 | 1220 | 300 | 1220 | 900 | 3660 |
| 5.5 | Other | 60 | | 60 | | 60 | | 60 | | 180 | |
| | *Total ODC* | **800** | **2340** | **800** | **2340** | **800** | **3380** | **800** | **3380** | **2400** | **9100** |
| **6** | Travel: | | | | | | | | | | |
| 6.1 | Internal *** | 1500 | | 3400 | | 3300 | | 3300 | | 10000 | |
| 6.2 | Outside CIS | | 4000 | | 10000 | | 10000 | | 6000 | | 26000 |
| | *Total Travel* | **1500** | **4000** | **3400** | **10000** | **3300** | **10000** | **3300** | **6000** | **10000** | **26000** |
| | **Overhead/Retainage** | …….. | …….. | …….. | …….. | …….. | …….. | …….. | …….. | 11500 | …….. |
| | ***Subtotals*** | **4018** | **96788** | **5973** | **134692** | **5193** | **88231** | **5088** | **79323** | **27754** | **302246** |
| | **Totals** | **100806** | | **140665** | | **93424** | | **84411** | | **330000** | |

Remarks: * (1) - Cash flow through Recipient Account
** (2) - Cash flow through ISTC
*** Include Local and inside CIS travel

## 10. Equipment and Materials Summary

### *10.1. Equipment Summary*

**TABLE 2**

EQUIPMENT/MATERIAL SUMMARY

**EQUIPMENT SUMMARY**
for Project Agreement # G-1462

To be provided in kind [ X ]
To be purchased by recipient [ ]

The ISTC will normally provide the most appropriate equipment that will perform the functions required; however, if very special reasons are given and explained in detail (Form PR-2E), the purchase of a particular make will be considered.

**Please list items in the order of their priority and put an 'X' in the column next to "Item no." if ISTC form PR-2E, "Data for a Single Equipment Item', has been completed for a given item and is attached.**

| Item No. | | DESCRIPTION OF ITEM | Date needed (quarter) | Qty | Unit cost (USD) | Amount (USD) |
|---|---|---|---|---|---|---|
| ***Leading Institution: NCDC*** | | | | | | |
| 1 | | Refrigerator / Freezer/ Ariston MTAA 45 11V | 1 | 5 | 1000 | 5000 |
| 2 | | General purpose incubator /**Thomas #**6127A24 Model 121 | 1 | 5 | 700 | 3500 |
| 3 | | Thomas TouchVortex,230V/**Thomas#**1232L69 Man# 945711 | 1 | 1 | 300 | 300 |
| 4 | | Computer Desktop /Fujitsu-Siemens/ ESPRIMO P5700 i915GV/ PIV541 3.2 GHz 1 GB DDR2 DVDRW 80GBSATA WIN XP prof | 1 | 1 | 965.24 | 965.24 |
| 5 | | Monitor / 17'' LCD / Fujitsu-Siemens/ S17-2 TFT Silver Line, 8ms, 500:1 DVI-D, TCO 03 | 1 | 1 | 405.86 | 405.86 |
| 6 | | Printer/ Samsung/ Samsung Laser Printer / ML-2250 22ppm, 16M**,** 1200 dpi, CPU 166 MHz, USB2.0/ LPT/ Cartridge/ Samsung Original/ Samsung Laser Cartridges/ SCX-4521D3/SEE for SCX-4521/SCX-4321-2500p.5%@A4 | 1 | 1 | 200.60 | 200.60 |
| 7 | | PRINTER/SAMSUNG/ Samsung all in One/ SCX452 1F+FAX33.6kb, 20ppm, 32mb, 25%-400%, ADF 30 pg | 1 | 1 | 428.30 | 428.30 |
| | | | | | **Subtotal:** | **10800** |
| | | | | | **Estimated TOTAL COST:** | **10800** |

Form PR-1E of 3/98

*10.2. Materials Summary*

**TABLE 3**

EQUIPMENT/MATERIAL SUMMARY

**MATERIAL SUMMARY**
for Project Agreement # G-1462

To be provided in kind [ X ]
To be purchased by recipient [ ]

The ISTC will normally provide the most appropriate equipment that will perform the functions required; however, if very special reasons are given and explained in detail (Form PR-2E), the purchase of a particular make will be considered.

**Please list items in the order of their priority and put an 'X' in the column next to "Item no." if ISTC form PR-2E, "Data for a Single Equipment Item', has been completed for a given item and is attached.**

| Item No. | | DESCRIPTION OF ITEM | Date needed (quarter) | Qty | Unit cost (USD) | Amount (USD) |
|---|---|---|---|---|---|---|
| ***Leading Institution: NCDC*** | | | | | | |
| 1 | | API 20 E 100 strips /Biomerioeux/ # 20160/ | 1, 5, 9 | 15 | 320 | 4800 |
| 2 | | API 20 E analytical profile index /unit/Biomerieux / #20190/ | 1 | 5 | 120 | 600 |
| 3 | | API 20 E reagent kit / 7 ampoules/ Biomerieux/ #20120 | 1, 5, 9 | 15 | 30 | 450 |
| 4 | | API NaCl 0.85 % Medium (5 ml) / 100 ampoules /Biomerieux/# 20230/ | 1, 5 | 14 | 100 | 1400 |
| 5 | | McFarland Standard/7 standards/Biomerieux/ #70900/ | 1 | 5 | 40 | 200 |
| 6 | | Hémoline performance diphasique/12 vials/Biomerieux/ #41995/ | 1 | 15 | 85 | 1275 |
| 7 | | Mueller Hinton 2 agar/500 g/Biomerieux/ #51075/ | 1, 5, 9 | 24 | 130 | 3120 |
| 8 | | Bismuth sulfite agar(WilsonBlair)/500g/Biomerieux/ #51065/ | 1 | 5 | 410 | 2050 |
| 9 | | Buffered peptone water/500 g/Biomerieux/ #51094/ | 1 | 16 | 80 | 1280 |
| 10 | | Endo agar/500 g/Biomerieux/ #51032/ | 1, 5, 9 | 21 | 160 | 3360 |
| 11 | | XLD agar/500 g/Biomerieux/ #51049/ | 1, 5, 9 | 15 | 150 | 2250 |
| 12 | | Hektoen enteric agar/500 g/Biomerieux/ #51050/ | 1 | 5 | 200 | 1000 |
| 13 | | Kligler iron agar/500 g/Biomerieux/ #51059/ | 1 | 15 | 110 | 1650 |
| 14 | | Salmonella Shigella agar/500 g/Biomerieux/ #51043/ | 1, 5, 9 | 21 | 130 | 2730 |
| 15 | | Trypcase-soy agar/500 g/Biomerieux/ #51044/ | 1 | 15 | 111 | 1665 |
| 16 | | Trypcase-soy broth/500 g/Biomerieux/ #51019/ | 1 | 15 | 80 | 1200 |
| 17 | | MacConkey agar /500g/ Biomerieux/ #51036 | 1 | 5 | 110 | 550 |
| 18 | | Motility test medium/100/pk/Becton Dickinson #221510 | 1, 5 | 16 | 200 | 3200 |
| 19 | | Cary Blair Transport medium CM519/500g/Oxoid/ CM0519B | 1, 5 | 16 | 200 | 3200 |
| 20 | | Tetrathionate enrichment broth Muller-Kauffman, 500g/ MERCK, Germany/ 110863 | 1 | 14 | 65 | 910 |
| 21 | | Salmonella enrichment broth Rappaport-Vassiliadis(RVS) 500g (MERCK, Germany/ 110236) | 1 | 12 | 55 | 660 |
| 22 | | Color Gram 2, kit/4 x 240 ml /Biomerieux / #55542/ | 1 | 15 | 88 | 1320 |
| 23 | | ID color Catalase/100 tests/Biomerieux / #55561/ | 1 | 10 | 58 | 580 |
| 24 | | ID indole TDA/200 tests/Biomerieux / #56541/ | 1 | 6 | 25 | 150 |
| 25 | | Oxidase reagent (0.75 ml)/50 ampoules/ Biomerieux/ #55635/ | 1 | 7 | 215 | 1505 |
| 26 | | Immersion oil /Sigma-Aldrich I0890-500ML | 1 | 6 | 125 | 750 |
| 27 | | Mineral oil /1 x 125 ml/ Biomerieux / # 70100 | 1 | 5 | 4 | 20 |
| 28 | | Avr II / 500 units/ BioLabs/ R0174L | 1, 5, 9 | 3 | 252 | 756 |
| 29 | | Xba I /15000 units/ BioLabs / R0145L | 1, 5 | 2 | 252 | 504 |
| 30 | | NEBuffer2 / 6 ml/ BioLabs / B7002S | 1 | 5 | 10 | 50 |
| 31 | | NEBuffer4 /6 ml/ BioLabs / B7004S | 1 | 5 | 10 | 50 |
| 32 | | Proteinase K (35 units/mg) / 100 mg/ SIGMA / P-2308 | 1 | 1 | 1000 | 1000 |
| 33 | | Seakem Gold Agarose /125 g/ Cambrex/ cat.N 50150 | 1 | 5 | 505 | 2525 |
| 34 | | TBE (Tris Borate EDTA buffer) powder blend, 5X | 1, 5, 9 | 12 | 30 | 360 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | concentrate, / T 7527 / 1 L / | | | | |
| 35 | | TE (Tris-EDTA buffer solution), 100Xconcentrate,/ 500 ml / Bio Chemika Ultra,/ SIGMA cat. N 86377 | 1, 5 | 2 | 135 | 270 |
| 36 | | Trizma base, / 5 kg / SIGMA T1503 | 1 | 1 | 500 | 500 |
| 37 | | Polaroid BW films 667,/ 2x10/pak / ROTH, L130.1 | 1, 5 | 10 | 30 | 300 |
| 38 | | Petri dishes (100x20mm) /SIGMA P5606-400EA | 1 | 7 | 164 | 1148 |
| 39 | | Corning Stripette serological pipettes, 1 ml/ SIGMA CLS4485-1000EA/ | 1 | 1 | 312 | 312 |
| 40 | | Corning Stripette serological pipettes, 5 ml/ SIGMA CLS4485-1000EA/ | 1 | 1 | 105 | 105 |
| 41 | | Corning Stripette serological pipettes, 10 ml/ SIGMA CLS4485-1000EA/ | 1 | 1 | 108 | 108 |
| 42 | | Transfer pipette sterile, fine tip,large bulb, bulb draw 4.3 ml / SIGMA Z350885-400EA | 1 | 4 | 158 | 632 |
| 43 | | Sterile cotton swabs, pkg /100, /bioMerieux / # 70610 | 1 | 4 | 28 | 112 |
| 44 | | Microscope slides /pkg72/case20 / SIGMA S8902-1CS/ | 1 | 1 | 343 | 343 |
| 45 | | Tips 0,1-10µl, / 96x10 pcs / DeltaLab,/ # 327-19 | 1 | 3 | 200 | 600 |
| 46 | | Tips 1-10µl,/ 96x10 pcs / DeltaLab / # 199084RC | 1 | 3 | 200 | 600 |
| 47 | | Tips 1-40µl,/ 96x10 pcs / DeltaLab / # 327-36R | 1 | 3 | 200 | 600 |
| 48 | | Tips 2-200µl, / 96x10 pcs / DeltaLab / # 327-34R | 1 | 3 | 200 | 600 |
| 49 | | Tips 100-1000µl,/ 96x10 pcs / DeltaLab / # 327-16 | 1 | 2 | 200 | 400 |
| 50 | | Ependorf tubes, 1,5 ml /4x500 pac / | 1 | 1 | 200 | 200 |
| 51 | | Falcone tubes, 50 ml polystyrene conical tube, 2000 RCF. Sterile./ 25/bag, 500/case / BD Biosciences, cat N 352073 | 1 | 1 | 200 | 200 |
| 52 | | Falcone tubes, 15 ml polystyrene conical tube, 1800 RCF. Sterile./ 125/bag, 500/case / BD Biosciences, cat N 352095 | 1 | 1 | 200 | 200 |
| 53 | | Powder-free latex gloves size S 100/pk/10pk / Aldrich Z305995-10PAK | 1 | 1 | 320 | 320 |
| 54 | | Powder-free latex gloves size M 100/pk/10pk / Aldrich Z306002-10PAK | 1 | 1 | 320 | 320 |
| 55 | | bio-Disc Ampicillin (AM)/(10µg) 4 x 50 / Biomerieux/ #54002 | 1, 5, 9 | 6 | 40 | 240 |
| 56 | | bio-Disc Amoxicillin-Clav.acid(AMC)/(20+10µg) 4 x 50/ Biomerieux/ #54632 | 1, 5, 9 | 3 | 40 | 120 |
| 57 | | bio-Disc Amoxicillin (AMX)/(25µg) 4 x 50/Biomerieux/ #54022 | 1, 5, 9 | 3 | 40 | 120 |
| 58 | | bio-Disc Chloramphenicol ©/(30µg) 4 x 50/Biomerieux/ #54072 | 1, 5, 9 | 6 | 40 | 240 |
| 59 | | bio-Disc Carbenicillin (CB)/(100µg) 4 x 50/Biomerieux/ #54112 | 1, 5, 9 | 3 | 40 | 120 |
| 60 | | bio-Disc Cefazolin (CZ)/(30µg) 4 x 50/ Biomerieux/ #54142 | 1, 5, 9 | 3 | 40 | 120 |
| 61 | | bio-Disc Nitrofurantoin (FM)/(300µg) 4 x 50/Biomerieux/ #54222 | 1, 5, 9 | 3 | 40 | 120 |
| 62 | | bio-Disc Fosfomycin (FFL)/ (50µg) 4 x 50/Biomerieux/ #54232 | 1, 5, 9 | 3 | 40 | 120 |
| 62 | | bio-Disc Gentamicin (GM)/(10µg) 4 x 50/Biomerieux/ #54262 | 1, 5, 9 | 3 | 40 | 120 |
| 64 | | bio-Disc Kanamycin (K)/(30µg) 4 x 50/Biomerieux/ #54282/ | 1, 5, 9 | 3 | 40 | 120 |
| 65 | | bio-Disc Nalidixic acid (NA)/(30µg) 4 x 50/Biomerieux/ #54292/ | 1, 5, 9 | 6 | 40 | 240 |
| 66 | | bio-Disc Amikacin (AN)/(30µg) 4 x 50/Biomerieux/ #54352/ | 1, 5, 9 | 3 | 40 | 120 |
| 67 | | bio-Disc Cefuroxime (CXM)/(30µg) 4 x 50/Biomerieux/ #54362/ | 1, 5, 9 | 3 | 40 | 120 |
| 68 | | bio-Disc Cefotaxime (CTX)/(30µg) 4 x 50/Biomerieux/ #54382/ | 1, 5, 9 | 3 | 40 | 120 |
| 69 | | bio-Disc Ticarcillin (TIC)/(75µg) 4 x 50/Biomerieux/ #54422/ | 1, 5, 9 | 3 | 40 | 120 |
| 70 | | bio-Disc Netilmicin (NET)/(30µg) 4 x 50/ Biomerieux/ #54572/ | 1, 5, 9 | 3 | 40 | 120 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 71 | | bio-Disc Streptomycin (S)/(10µg) 4 x 50/Biomerieux/ #54642/ | 1, 5, 9 | 3 | 40 | 120 |
| 72 | | bio-Disc Ceftriaxone (CRO)/(30µg) 4 x 50/Biomerieux/ #54662/ | 1, 5, 9 | 6 | 40 | 240 |
| 73 | | bio-Disc Cefoperazone (CFP)/(30µg) 4 x 50/Biomerieux/ #54662/ | 1, 5, 9 | 3 | 40 | 120 |
| 74 | | bio-Disc Sulfonamides (G)/(200µg) 4 x 50/Biomerieux/ #54692/ | 1, 5, 9 | 3 | 40 | 120 |
| 75 | | bio-Disc Aztreonam (ATM)/(30µg) 4 x 50/ Biomerieux/ #54492/ | 1, 5, 9 | 3 | 40 | 120 |
| 76 | | bio-Disc Ceftazidime (CAZ)/( 30µg) 4 x 50/Biomerieux/ #54522/ | 1, 5, 9 | 3 | 40 | 120 |
| 77 | | bio-Disc Norfloxacin (NOR)/(10µg) 4 x 50/Biomerieux/ #54782/ | 1, 5, 9 | 3 | 40 | 120 |
| 78 | | bio-Disc Imipenem (IPM)/(10µg) 4 x 50/ Biomerieux/ #54832/ | 1, 5, 9 | 3 | 40 | 120 |
| 79 | | bio-Disc Tobramycin (NN)/(10µg) 4 x 50/Biomerieux/ #54862/ | 1, 5, 9 | 3 | 40 | 120 |
| 80 | | bio-Disc Tetracycline (TE)/ (30µg) 4 x 50/ #54882/ | 1, 5, 9 | 3 | 40 | 120 |
| 81 | | bio-Disc Trimethoprim Sulfo. (SXT)/ (1,25+23,75µg) 4 x 50/Biomerieux/ #54902/ | 1, 5, 9 | 6 | 40 | 240 |
| 82 | | bio-Disc Ciprofloxacin (CIP)/(5µg) 4 x 50/ Biomerieux/ #54932/ | 1, 5, 9 | 3 | 40 | 120 |
| 83 | | bio-Disc Vancomicine (VA)/(30µg) 4 x 50/ Biomerieux/ #54932/ | 1 | 1 | 40 | 40 |
| 84 | | Poly A-S 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 27, 28, 30, 35, 38, 39, 40, 41, 46 3 ml vial / Statens Serum Institut / # 48954 | 1 | 7 | 100 | 700 |
| 85 | | Vi (IgM) - 3 ml vial / Statens Serum Institut / # 15514 | 1 | 1 | 100 | 100 |
| 86 | | O:2 A / 3 ml vial/ Statens Serum Institut / # 40270 | 1 | 1 | 119 | 119 |
| 87 | | O:4 B, 54 / 3 ml vial /Statens Serum Institut/ # 40271 | 1 | 1 | 79 | 79 |
| 88 | | O:5 B / 3 ml vial/Statens Serum Institut / # 40272 | 1 | 1 | 119 | 119 |
| 89 | | O:6 C1, C2 / 3 ml vial /Statens Serum Institut/ # 40273 | 1 | 1 | 119 | 119 |
| 90 | | O:7 C1, 54 / 3 ml vial /Statens Serum Institut/ # 40274 | 1 | 1 | 119 | 119 |
| 91 | | O:8 C2, C3, 54 / 3 ml vial /Statens Serum Institut / #40275 | 1 | 1 | 119 | 119 |
| 92 | | O:9 D / 3 ml vial /Statens Serum Institut/ # 40276 | 1 | 1 | 79 | 79 |
| 93 | | O:10 E1 / 3 ml vial /Statens Serum Institut/ # 40277 | 1 | 1 | 119 | 119 |
| 94 | | O:12 A, B, D / 3 ml vial /Statens Serum Institut/ # 57543 | 1 | 1 | 119 | 119 |
| 95 | | O:14 C1, H, K / 3 ml vial /Statens Serum Institut/ # 40278 | 1 | 1 | 119 | 119 |
| 96 | | O:15 E1, 54 / 3 ml vial /Statens Serum Institut/ # 40279 | 1 | 1 | 119 | 119 |
| 97 | | O:19 E4 / 3 ml vial /Statens Serum Institut/ # 40280 | 1 | 1 | 119 | 119 |
| 98 | | O:20 C3, 54 / 3 ml vial /Statens Serum Institut/ # 40281 | 1 | 1 | 119 | 119 |
| 99 | | O:22 G / 3 ml vial /Statens Serum Institut/ # 40282 | 1 | 1 | 119 | 119 |
| 100 | | O:23 G / 3 ml vial /Statens Serum Institut/ # 40283 | 1 | 1 | 119 | 119 |
| 101 | | O:24 H / 3 ml vial /Statens Serum Institut/ # 40284 | 1 | 1 | 119 | 119 |
| 102 | | O:25 H / 3 ml vial /Statens Serum Institut/ # 40285 | 1 | 1 | 119 | 119 |
| 103 | | O:27 B, D3 / 3 ml vial /Statens Serum Institut/ # 40286 | 1 | 1 | 119 | 119 |
| 104 | | O:34 E1 / 3 ml vial /Statens Serum Institut/ # 40287 | 1 | 1 | 119 | 119 |
| 105 | | O:46 D2, D3 / 3 ml vial /Statens Serum Institut/ # 40288 | 1 | 1 | 79 | 79 |
| 106 | | O:16 I / 3 ml vial /Statens Serum Institut / #40230 | 1 | 1 | 92 | 92 |
| 107 | | O:17 J / 3 ml vial /Statens Serum Institut/ # 40231 | 1 | 1 | 92 | 92 |
| 108 | | O:18 K / 3 ml vial /Statens Serum Institut/ # 40232 | 1 | 1 | 92 | 92 |
| 109 | | O:21 L / 3 ml vial /Statens Serum Institut/ # 40233 | 1 | 1 | 92 | 92 |
| 110 | | O:28 M /3 ml vial /Statens Serum Institut/ # 40234 | 1 | 1 | 92 | 92 |
| 111 | | O:30 N / 3 ml vial /Statens Serum Institut/ # 40235 | 1 | 1 | 92 | 92 |
| 112 | | O:35 O / 3 ml vial /Statens Serum Institut/ # 40236 | 1 | 1 | 92 | 92 |
| 113 | | O:38 P / 3 ml vial /Statens Serum Institut/ # 40237 | 1 | 1 | 92 | 92 |
| 114 | | O:39 Q / 3 ml vial /Statens Serum Institut/ # 40238 | 1 | 1 | 92 | 92 |
| 115 | | O:40 R / 3 ml vial /Statens Serum Institut/ # 40239 | 1 | 1 | 92 | 92 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 116 | | O:41 S / 3 ml vial /Statens Serum Institut/ # 40240 | 1 | 1 | 92 | 92 |
| 117 | | O:42 T / 3 ml vial /Statens Serum Institut/ # 40241 | 1 | 1 | 92 | 92 |
| 118 | | O:43 U / 3 ml vial /Statens Serum Institut/ # 40242 | 1 | 1 | 92 | 92 |
| 119 | | O:44 V / 3 ml vial /Statens Serum Institut/ # 40243 | 1 | 1 | 92 | 92 |
| 120 | | O:45 W / 3 ml vial /Statens Serum Institut/ # 40244 | 1 | 1 | 92 | 92 |
| 121 | | O:48 Y / 3 ml vial /Statens Serum Institut/ # 40247 | 1 | 1 | 92 | 92 |
| 122 | | O:50 Z / 3 ml vial /Statens Serum Institut/ # 40248 | 1 | 1 | 92 | 92 |
| 123 | | O:51 51 / 3 ml via l /Statens Serum Institut/ # 40249 | 1 | 1 | 92 | 92 |
| 124 | | O:52 52 / 3 ml vial /Statens Serum Institut/ # 40250 | 1 | 1 | 92 | 92 |
| 125 | | O:53 53 / 3 ml vial /Statens Serum Institut/ # 40251 | 1 | 1 | 92 | 92 |
| 126 | | O:54 54 / 3 ml vial /Statens Serum Institut/ # 40252 | 1 | 1 | 92 | 92 |
| 127 | | O:55 55 / 3 ml vial /Statens Serum Institut/ # 40253 | 1 | 1 | 92 | 92 |
| 128 | | O:56 56 / 3 ml vial /Statens Serum Institut/ # 40254 | 1 | 1 | 92 | 92 |
| 129 | | O:57 57 / 3 ml vial /Statens Serum Institut/ # 40255 | 1 | 1 | 92 | 92 |
| 130 | | O:58 58 / 3 ml vial /Statens Serum Institut/ # 40257 | 1 | 1 | 92 | 92 |
| 131 | | O:59 59 / 3 ml vial /Statens Serum Institut/ # 40258 | 1 | 1 | 92 | 92 |
| 132 | | O:60 60 / 3 ml vial /Statens Serum Institut/ # 40259 | 1 | 1 | 92 | 92 |
| 133 | | O:61 61 / 3 ml vial /Statens Serum Institut/ # 40260 | 1 | 1 | 92 | 92 |
| 134 | | O:62 62 / 3 ml vial /Statens Serum Institut/ # 40261 | 1 | 1 | 92 | 92 |
| 135 | | O:63 63 / 3 ml vial /Statens Serum Institut/ # 40263 | 1 | 1 | 92 | 92 |
| 136 | | O:65 65 / 3 ml vial /Statens Serum Institut/ # 40264 | 1 | 1 | 92 | 92 |
| 137 | | O:66 66 / 3 ml vial /Statens Serum Institut/ # 40265 | 1 | 1 | 92 | 92 |
| 138 | | O:67 67 / 3 ml vial /Statens Serum Institut/ # 40266 | 1 | 1 | 92 | 92 |
| 139 | | H:L l,v l,w l,z13 l,z28 l,z40 3 ml vial /Statens Serum Institut/ # 40297 | 1 | 1 | 100 | 100 |
| 140 | | H:E e,h e,n,x e,n,z15 3 ml vial /Statens Serum Institut/ # 40298 | 1 | 1 | 100 | 100 |
| 141 | | H:G f,g g,m g,p g,p,u g,q g,s,t m,t g,z51 g,z62 g,z63 3 ml vial /Statens Serum Institut/ # 40299 | 1 | 1 | 100 | 100 |
| 142 | | H:Z4 z4,z23 z4,z24 z4,z32 3 ml vial /Statens Serum Institut/ # 40366 | 1 | 1 | 100 | 100 |
| 143 | | 22667 H:q,s,t,p,u q, s, t, p, u 3 ml vial | 1 | 1 | 79 | 79 |
| 144 | | H:a / 3 ml vial /Statens Serum Institut/ # 40300 | 1 | 1 | 92 | 92 |
| 145 | | H:b / 3 ml vial /Statens Serum Institut/ # 23847 | 1 | 1 | 92 | 92 |
| 146 | | H:c / 3 ml vial/Statens Serum Institut / # 40301 | 1 | 1 | 92 | 92 |
| 147 | | H:d / 3 ml vial /Statens Serum Institut/ # 23849 | 1 | 1 | 92 | 92 |
| 148 | | H:i / 3 ml vial /Statens Serum Institut/ # 23850 | 1 | 1 | 60 | 60 |
| 149 | | H:g,m / 3 ml vial /Statens Serum Institut/ # 23851 | 1 | 1 | 60 | 60 |
| 150 | | H:g,p / 3 ml vial /Statens Serum Institut/ # 40302 | 1 | 1 | 92 | 92 |
| 151 | | H:k / 3 ml vial /Statens Serum Institut/ # 40303 | 1 | 1 | 92 | 92 |
| 152 | | H:r / 3 ml vial /Statens Serum Institut/ # 40304 | 1 | 1 | 92 | 92 |
| 153 | | H:y / 3 ml vial /Statens Serum Institut/ # 40305 | 1 | 1 | 92 | 92 |
| 154 | | H:z / 3 ml vial /Statens Serum Institut/ # 40306 | 1 | 1 | 92 | 92 |
| 155 | | H:z6 / 3 ml vial /Statens Serum Institut/ # 40307 | 1 | 1 | 92 | 92 |
| 156 | | H:z10 / 3 ml vial /Statens Serum Institut/ # 40308 | 1 | 1 | 92 | 92 |
| 157 | | H:z29 / 3 ml vial /Statens Serum Institut/ # 40309 | 1 | 1 | 92 | 92 |
| 158 | | H:z35 / 3 ml vial /Statens Serum Institut/ # 40310 | 1 | 1 | 92 | 92 |
| 159 | | H:z36 / 3 ml vial /Statens Serum Institut/ # 40311 | 1 | 1 | 92 | 92 |
| 160 | | H:z38 / 3 ml vial Statens Serum Institut/ # 40312 | 1 | 1 | 92 | 92 |
| 161 | | H:z39 / 3 ml vial /Statens Serum Institut/ # 40313 | 1 | 1 | 92 | 92 |
| 162 | | H:z41 / 3 ml vial /Statens Serum Institut/ # 40314 | 1 | 1 | 92 | 92 |
| 163 | | H:z42 / 3 ml vial /Statens Serum Institut/ # 40315 | 1 | 1 | 92 | 92 |
| 164 | | H:z44 / 3 ml vial /Statens Serum Institut/ # 40316 | 1 | 1 | 92 | 92 |
| 165 | | H:z57 / 3 ml vial /Statens Serum Institut/ # 40321 | 1 | 1 | 92 | 92 |
| 166 | | H:z60 / 3 ml vial /Statens Serum Institut/ # 40609 | 1 | 1 | 92 | 92 |
| 167 | | H:z67 / 3 ml vial /Statens Serum Institut/ # 40325 | 1 | 1 | 92 | 92 |
| 168 | | H:z71 / 3 ml vial /Statens Serum Institut/ # 40326 | 1 | 1 | 92 | 92 |

| | |
|---|---|
| **Subtotal:** | **67801** |
| **Estimated TOTAL COST:** | **67801** |

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**TABLE 3-1**

EQUIPMENT/MATERIAL SUMMARY

**MATERIAL SUMMARY**
for Project Agreement # G-1462

To be provided in kind [ ]
To be purchased by recipient [ X ]

The ISTC will normally provide the most appropriate equipment that will perform the functions required; however, if very special reasons are given and explained in detail (Form PR-2E), the purchase of a particular make will be considered.

**Please list items in the order of their priority and put an 'X' in the column next to "Item no." if ISTC form PR-2E, "Data for a Single Equipment Item', has been completed for a given item and is attached.**

| Item No. | | DESCRIPTION OF ITEM | Date needed (quarter) | Qty | Unit cost (USD) | Amount (USD) |
|---|---|---|---|---|---|---|
| ***Leading Institution: NCDC*** | | | | | | |
| 1 | | Printer cartridge | 1, 6 | 2 | 50 | 100 |
| 2 | | Printer paper | 1, 5, 9 | 99 | 5 | 495 |
| 3 | | Notebooks | 1 | 50 | 2 | 100 |
| 4 | | Binders | 1 | 30 | 4 | 120 |
| 5 | | Files | 1 | 70 | 3 | 210 |
| 6 | | Pens | 1, 5 | 100 | 1 | 100 |
| 7 | | CD | 1, 5, 9 | 9 | 1 | 9 |
| 8 | | Floppy disk | 1,5 | 10 | 1 | 10 |
| 9 | | Flash memory stick | 1 | 2 | 100 | 200 |
| 10 | | Stapler | 1 | 5 | 4 | 20 |
| 11 | | Staples | 1 | 30 | 1 | 30 |
| 12 | | Fuel | 1, 5, 9 | 1845 | 1 | 1845 |
| | | | | | **Subtotal:** | **3239** |
| | | | | | **Estimated TOTAL COST:** | **3239** |

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***10.4. Other Direct Costs Summary***

**TABLE 4**

OTHER DIRECT COSTS SUMMARY

**OTHER DIRECT COSTS SUMMARY**
for Project Agreement # G-1462

To be provided in kind [ X ]
To be purchased by recipient [ ]

**Detailed breakdown of Other Directs Costs to include planned activities under items 5.1, 5.2, 5.3, 5.4, 5.5 from Table 1 of the Project Agreement**

| Item No. | | DESCRIPTION OF ITEM | Date needed (quarter) | Qty | Unit cost (USD) | Amount (USD) |
|---|---|---|---|---|---|---|
| ***Leading Institution: NCDC*** | | | | | | |
| 1 | 5.2 | Express Mail | 1, 5, 9 | 6 | 40 | 240 |
| 2 | 5.3 | Car rent | 1, 5, 9 | 156 | 20 | 3120 |
| 3 | 5.3 | Public health campaign materials/publications | 5, 10 | 2 | 1040 | 2080 |
| 4 | 5.4 | Logistics/customs | 1, 5, 9 | 3 | 1220 | 3660 |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | **Subtotal:** | **9100** |
| | | | | | **Estimated TOTAL COST:** | **9100** |

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**TABLE 4-1**

OTHER DIRECT COSTS SUMMARY

**OTHER DIRECT COSTS SUMMARY**
for Project Agreement # G-1462

To be provided in kind [ ]
To be purchased by recipient [ X ]

**Detailed breakdown of Other Directs Costs to include planned activities under items 5.1, 5.2, 5.3, 5.4, 5.5 from Table 1 of the Project Agreement**

| Item No. | | DESCRIPTION OF ITEM | Date needed (quarter) | Qty | Unit cost (USD) | Amount (USD) |
|---|---|---|---|---|---|---|
| ***Leading Institution: NCDC*** | | | | | | |
| 1 | 5.2 | Mobile phone cards | 1, 5, 9 | 60 | 10 | 600 |
| 2 | 5.2 | Express Mail | 1, 5, 9 | 9 | 40 | 360 |
| 3 | 5.2 | Internet cards | 1, 5, 9 | 9 | 10 | 90 |
| 4 | 5.3 | Written translation | 1, 5, 9 | 27 | 10 | 270 |
| 5 | 5.4 | Logistics/customs | 1, 5, 9 | 3 | 300 | 900 |
| 6 | 5.5 | Charging of printer cartridges | 1, 5, 9 | 6 | 20 | 120 |
| 7 | 5.5 | Computer maintenance | 1, 5, 9 | 3 | 20 | 60 |
| | | | | | **Subtotal:** | **2400** |
| | | | | | **Estimated TOTAL COST:** | **2400** |

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**ANNEX II**
## General Conditions

Contents:

## Annex II General Conditions

### Part A - Implementation of the Work
### Article 1 - General Provisions

1.1 The Recipient shall make best efforts to achieve the objectives of the Project and shall comply with all laws of the Republic of Georgia applicable to the Project. If in the course of project implementation deliverables are identified that may qualify under export control restrictions, the Recipient takes responsibility for obtaining the corresponding export licenses, in a timely fashion and operating in compliance with all Russian, CIS and International laws and regulations.

1.2 The Recipient shall, in particular, comply with all applicable laws and regulations related to safety.

1.3 The Recipient shall notify the Center's Project representative and the Partner without delay of:
(a) any event or circumstance which may materially affect the Project, and
(b) any proposal for significant changes of key personnel during the Project.

### Article 2 - Subcontracting

2.1 Subcontracting shall require the advance written approval of the Center, with the concurrence of the Partner. However, approval shall not normally be given for subcontracting in any State that is not a Party to the ISTC Agreement unless the Center determines in writing that such subcontracting is essential for the Project.

2.2 The Recipient shall impose on a subcontractor the same obligations as apply to itself with respect to any rights of the Center or the Partner concerning the Project.

2.3 The provisions of Article 2.1 of this Annex shall not apply to Sub-Agreements pursuant to Article 3 of the Agreement or to orders for materials, equipment, and services which are incidental to or intended to facilitate the execution of the Agreement and placed in the normal course of business in accordance with the internal procedures and rules of the Recipient.

### Article 3 - Monitoring of the Work

3.1 The Center shall:
(a) Have access to portions of facilities where the Project is being carried out and to all equipment, documentation, information, data systems, materials, supplies, personnel and services which concern the Project for monitoring the progress of the Project as described in Annex I;

(b) Be provided with technical and cost information concerning the management and progress of the Project requested at any time; and

(c) Give the Recipient not less than 20 days advance notice of any intended on-site financial auditing or technical monitoring of the Project.

3.2 The Recipient has the right to protect those portions of facilities that are not related to the Project.

3.3 After completion or termination of the Project, the Recipient may utilize the facility or portion of the facility previously used for the Project for other work. However, all documentation and records including those associated with equipment, data systems, materials, supplies and services utilized for the Project must be maintained and available for review by the Center for up to two years following the Project's completion or termination.

3.4 The Recipient shall, if requested by the Center, participate and assist in meetings to review or evaluate the Project during the lifetime of the Project.

**Article 4 - Reports**

4.1 The Recipient shall submit the following reports, in a suitable quality to enable direct reproduction, to the Center and the Partner for approval:

(a) A final report, in English and Russian, covering all the work, the objectives, the results and the conclusions, including a suitable summary of all these aspects; and
(b) Reports, as mutually agreed, prepared in a suitable form for publication and satisfactory to the Partner and the Center.

4.2 The Recipient shall submit any additional reports or any other deliverables specified in the Agreement.

4.3 The Recipient should clearly identify any reports or portions of reports that contain invention or business confidential information as defined in Part E of this Annex. The final report shall include a statement that all inventions Made during the performance of work under the Agreement have been reported to the Center and to the Partner, or if no inventions were Made, a statement to that effect. The Recipient also may include a suitable disclaimer in any report against possible claims by third parties.

**Article 5 - Completion or Expiration of the Agreement**

5.1 The Agreement shall be deemed to be completed on the approval by the Center and the Partner of the last deliverable required or last payment by the Center, whichever shall be the later.

5.2 Subject and without prejudice to the provisions in Part D of this Annex, the Recipient shall be deemed to have discharged its obligations with respect to the performance of the work after the approval of all the reports and any other deliverables required by the Agreement.

**Part B - Payments**
**Article 6 - Payments by the Center to the Recipient**

Payments of allowable costs other than the Center's in-kind contributions, the Center's grant payments to Individual Participants and overhead payments shall be made in accordance with the following principles.

6.1 Cost statements shall be expressed in US dollars unless otherwise specified in the Agreement. All payments by the Center shall be made in that currency unless otherwise agreed.

6.2 The financial contribution by the Partner through the Center shall be paid in installments as specified in Article 5 of the Agreement.

6.3 If the Center or the Partner considers that the work has not effectively been commenced within three months of the payment of the first advance, the Center may require the reimbursement of the advance together with any interest earned on the advance. Any reimbursements will be returned to the Partner account.

6.4 If on completion, cessation, or termination of the work, the payments made by the Center exceed the actual allowable costs, the Recipient shall promptly reimburse the difference to the Center. Interest may be added to this amount at the prevailing market rate as determined by the Center one month after the reimbursement date specified by the Center. Any reimbursements will be returned to the Partner account.
6.5 Subject to Article 12 of this Annex, periodic payments made against cost statements shall be considered as advances until acceptance of the appropriate deliverables, in accordance with Annex I, or, if no deliverables are specified, until acceptance of the final report.

**Part C - Allowable Costs**
**Article 7 - Accounting Principles, Allowable Costs, and Transfer of Costs**

7.1 The original estimates of expenditures set forth in Annex I may be adjusted by the Recipient between categories without the prior approval of the Center, except for reductions in personnel costs and increases in travel costs, and provided that the transfers do not fundamentally affect the scope or content of the Project.

7.2 The Recipient shall ensure that no unnecessary cost or unnecessarily high or extravagant cost is charged to the Agreement.

**Article 8 - Direct Costs**

8.1 Personnel

8.1.1 Personnel costs shall be separated into four categories as described in Annex I and reflected in the reporting form in Annex III. Even though some or all of these costs may be reimbursed by the Center through direct grant payments to the Individual Participants, the Recipient is responsible for certifying the time devoted to the Project by the Individual Participants and for maintaining necessary documentation to support such certification.

8.1.2 Personnel costs shall be charged to reflect the actual eight-hour days, or one-half days when appropriate, worked by personnel assigned by the Recipient to the Project in accordance with Annex I. Work periods of less than four hours may not be charged.

8.1.3 Personnel costs for a specific period of time may not be charged to this Project if reimbursement (except regular employment salary) is being received from other sources for the same period of time.

8.1.4 The Project Manager may increase or decrease the time commitments of personnel by up to 10 percent during one year of any individual without approval of the Center, but may not change the daily rate without approval by the Center. The Project Manager may request more significant changes in the personnel commitments, including changes in the names of the personnel, at the beginning of each quarter with a brief explanation of the reasons for the changes. In unusual situations, the Project Manager may request changes during the quarter. The Center, in consultation with the Partner, will respond promptly to such requests. Changes in scientific personnel must provide for the new participants to have technical credentials and weapons experience comparable to those of the personnel they replace.

8.1.5 The Center will not reimburse personnel costs associated with holidays, annual vacations, overtime, or sick leave. Such additional costs, if any, are the responsibility of the Recipient.

8.1.6 The Project Manager shall ensure that the scheduling of annual leave by the Individual Participants does not interfere with accomplishment of the Work Plan in Annex I.

8.1.7 The Recipient is responsible for any medical expenses or compensation claims for injuries or other losses for personnel working on the Project which are directly or indirectly related to the Project.

8.1.8 Individual daily records of time devoted to the Project must be signed by all personnel assigned to the Project, and all records must be certified at least monthly by the Project Manager and for the Project Manager by another appropriate senior employee of the Recipient.

8.2 Equipment

8.2.1 Equipment shall be categorized as indicated in the reporting form in Annex III.

8.2.2 The cost of equipment used in the Project which is purchased, fabricated, or leased after the Operative Commencement Date may be charged as a direct cost. The total leasing cost of any piece of equipment shall not exceed the cost which would have been allowable for its purchase.

8.2.3 Notwithstanding Article 4.5.1 of the Agreement, the Center will retain the title to all the equipment provided to or procured by the Recipient using Center funds regardless of the acquisition per item cost of the equipment. The final decision of possible transfer of the title shall be taken by the Center, in consultation with the Finanacing Party by the time of completion, termination or cessation of the Project taking into account the specific legal, institutional and other factors in effect in the state of the Recipient at that time.

8.3 Materials

The costs of required materials shall be allowable costs. They shall be categorized as raw materials, laboratory supplies, safety devices and protective gear and other as indicated on the reporting form in Annex III.

8.4 Other Direct Costs

8.4.1 Other direct costs shall be categorized as indicated in the reporting form in Annex III.

8.4.2 Costs incurred by the Recipient in using its internal resources for performance of the Agreement such as costs associated with (a) testing facilities, (b) computer services, (c) special test equipment, (d) dedicated security services, and (e) dedicated accounting services, but excluding items covered by Article 9 of Annex II, may be charged as direct costs through valid cost allocation formulas approved by the Center to the extent such costs contribute to the Project, provided such facilities and services are open to access for monitoring and auditing in accordance with Article 9 of the Agreement. If costs incurred by the Recipient are not charged as direct costs, they may be presented as in-kind contributions of the Recipient.

8.5 Travel and Per Diem for the Recipient

Travel and per diem within the CIS shall be charged in accordance with the internal rules of the Recipient which are subject to approval by the Center. International travel shall be provided by the Center in accordance with Article 4 of the Agreement.

8.6 Sub-Agreements and Subcontracts

8.6.1 Subject to Article 2 of this Annex, costs of subcontracts shall be allowable costs and shall be included as discrete entries in the appropriate categories on the reporting form of Annex III. If the subcontractor is a scientific institution engaged in a sub-agreement pursuant to Article 3 of the Agreement, costs are allowable only to the extent that they would be allowable if incurred directly under the Agreement. In selecting a subcontractor other than a scientific institution pursuant to Article 3 of the Agreement, the Recipient shall compare prices and quality of several subcontractors and choose the most cost-effective offer. For any subcontract costing more than the equivalent of $25,000, the Recipient shall organize a bidding process. For any subcontract costing between $10,000 and $25,000 (equivalent) written quotations shall be obtained from three sources to the extent possible.

8.6.2 Should the Recipient enter into a sub-agreement with a scientific institution pursuant to Article 3 of the Agreement, the reporting form in Annex III shall include the costs incurred pursuant to the sub-agreement which shall be supported by detailed information.

**Article 9 - Overhead**

A fixed payment may be charged with respect to overhead which covers items such as general administration, institutional management, depreciation of buildings and general equipment, maintenance of building and grounds, telephones, heating, lighting, electricity for the buildings and general staff training.

The payment shall not exceed 10% of the direct Project costs, excluding equipment, travel and subsistence.

Since the overhead will be retained by the Center until acceptance of the final report, the Recipient need not include this item on the reporting form in Annex III.

**Article 10 - Costs Not Allowed**

Allowable costs shall not include, among others:

- any profit;
- any contributions to pension, medical, or other social funds;
- any provisions for possible future losses or liabilities;
- any taxes, including profit tax, value added tax, personal income tax, and local taxes, as well as any other tariffs, dues, custom duties, import duties, fees, or other imposed taxes or similar charges;
- any costs allocatable to other projects.

The Center will determine the use of any interest earned from funds provided by the Center or return on investment of such funds. Such interest or return on investment must be reported to the Center.

**Part D - Justification of Costs and Auditing**
**Article 11 - Books of Account and Documentation**

The Recipient shall maintain, in accordance with the accounting practices set forth in the Agreement, proper books of account and appropriate documentation, such as invoices and time sheets to support and justify the costs reported. These shall be made available for audits by the Center during the period of the Project and for a period of up to two years following the Project's completion or termination.

**Article 12 - Auditing**

12.1 Cost statements are subject to verification even after the Center has reimbursed costs. The Center has the right pursuant to the ISTC Agreement and ISTC Statute to carry out on-site auditing of all activities of the Project. The Recipient will be given not less than 20 days notice of any intended audit. For the purposes of the audit, the Recipient shall make accessible all portions of facilities, equipment, documentation, information, data systems, materials, supplies, personnel and services related to the Project.

12.2 The Recipient has the right to protect those portions of facilities that are not related to the Project.

12.3 The Recipient shall maintain all documentation and records including those associated with equipment, data systems, materials, supplies and services utilized for the Project and shall make such documents, records and, to the extent possible, personnel available for auditing for a period of up to two years following the Project's completion or termination.

12.4 The Center shall have the right to select Courts of Auditors or other organizations or individuals to carry out audits of the Project; they shall be entitled to the same rights, should they choose to exercise them, as the Center with respect to access to, and verification of, any document under the Agreement for the purpose of any audit.

**Part E - Information and Intellectual Property**
**Article 13 – Definitions**

13.1 "Intellectual Property" includes inventions, patents, copyrights and other forms of protection provided by statutes, such as, industrial designs, design patents, mask works, and trademarks, and has the meaning defined in Article 2 of the Convention Establishing the World Intellectual Property Organization, done in Stockholm on July 14, 1967, which states: “Intellectual Property shall include the rights relating to:

- literary, artistic and scientific works,
- performances of performing artists, phonograms, and broadcasts,
- inventions in all fields of human endeavor,
- scientific discoveries,
- industrial designs,
- trademarks, service marks, and commercial names and designations,

- protection against unfair competition,
- and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields."

13.2 "Information" includes technical data and computer software and means recorded data of any kind of a scientific or technical nature, regardless of the form or method of recording, and capable of being read by a human being or processed by a machine.

13.3 "Foreground Results" means Foreground Information and Foreground Intellectual Property.

13.4 "Foreground Information" means Information, including all kinds of results, generated in the execution of this Agreement.

13.5 "Foreground Intellectual Property" means rights in Intellectual Property generated in the execution of this Agreement by the Recipient or any person employed or engaged by the Recipient.

13.6 "Background Results" means Background Information and Background Intellectual Property.

13.7 "Background Information" means Information, excluding Foreground Information, owned or controlled by either the Recipient or Partner in the same or related fields as the research under this Agreement and generated outside this Agreement.

13.8 "Background Intellectual Property" means rights in Intellectual Property, excluding Foreground Intellectual Property, owned or controlled by either the Recipient or Partner in the same or related fields as the research executed under this Agreement and originating outside this Agreement.

13.9 "Business Confidential Information" is also known as trade secret information and means technical, commercial or financial information, which:

Has been held in confidence by its owner;
Is not generally known or available from other sources;
Has not been made available by its owner to other parties without an obligation concerning its confidentiality;
Has not been independently developed by the receiving party; and
Is not available to the receiving party without obligations concerning confidentiality.

13.10 "Invention Information" is Intellectual Property which is to be protected by a patent and on which a patent has not been filed.

13.11 "Made," when used in relation to any invention, means the conception or first actual reduction to practice of such invention.

13.12 "Unlimited rights" means the right to use, modify, reproduce, perform, display, release, or disclose Information in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so.

**Article 14 - Promotion of Technology and Project Results**

Confidentiality

14.1 Subject to Article 4.1(c), all reports or portions of reports properly marked as Invention Information or Business Confidential Information by the Recipient in consultation with the Partner shall be protected from public dissemination unless otherwise agreed by the Recipient and the Partner. Invention Information is treated as Business Confidential Information until a patent application has been obtained unless such information so disclosed is or becomes legitimately available to the receiving Signatory Party through other means or sources

without any covenant as regards its confidentiality. Nevertheless, Business Confidential Information may be disclosed if the disclosure is required by law, regulation, or court order.

14.2 Subject to any obligations under this Agreement and in accordance with applicable laws and regulations, the Signatory Parties agree to keep confidential any Invention Information or Business Confidential Information communicated to them by other Signatory Parties or third parties in relation to the execution of this Agreement, unless such information so disclosed is or becomes legitimately available to the receiving Signatory Party through other means or sources without any covenant as regards its confidentiality. Nevertheless, Business Confidential Information may be disclosed if the disclosure is required by law, regulation, or court order.

Technology Promotion

14.3 The ISTC shall be entitled to publish general information on this Agreement including the identities of the Recipient and Partner, the title and objective of the Agreement, its estimated costs and duration, and the names of managers and laboratories where the research is being carried out.

14.4 Each Signatory Party agrees to submit to each other Signatory Party for review and approval a copy of any proposed publication of Foreground Information at least thirty days before such publication.

14.5 Any public communication or publication concerning this Project will acknowledge the Recipient, the Partner and the cooperative support of the ISTC.

14.6 Subject to the restrictions of Article 14.1, each Party to the ISTC Agreement (hereinafter referred to as the "**ISTC Party**") and the ISTC have a non-exclusive, irrevocable, royalty-free license with the right to sub-license in all countries to translate, reproduce and publicly distribute scientific and technical journal articles, reports, and books directly arising under this Agreement. All publicly distributed copies of a copyrighted work arising from cooperation under this Agreement shall indicate the names of the authors of the work, unless an author explicitly declines to be named.

**Article 15 – Ownership of Intellectual Property and Foreground Information**

15.1 In accordance with the ISTC Statute, except for inventions created by United States Government employees, all rights worldwide to Intellectual Property arising under this Agreement, including patent protection for industrial property, belong to the Recipient (or its designee), which has the responsibility for providing adequate protection `of such Intellectual Property. The Recipient and the Partner have agreed to protect and allocate such Intellectual Property among each other as specified in Article 16 below. Rights to inventions made by United States Government employees or made in Partner's laboratory shall be determined by the United States.

15.2 All rights worldwide to Foreground Information arising under this Agreement belong to the Recipient (or its designee). The United States Government, as represented by Partner, is granted a non-exclusive, irrevocable, royalty-free, worldwide license of unlimited rights in Foreground Information.

**Article 16 - Protection and Exploitation**

**16.1 Intellectual Property Rights (IPR) Allocation**

(i) The work conducted under this project is expected to generate new intellectual property by the Recipient and the Partner:

(ii) The protection and allocation of intellectual property created or furnished in the course of the cooperative research activities pursuant to this Agreement shall be provided in accordance with the Articles 16.2, 16.3, 16.4, 16.5, 16.6, 16.7, 16.8, 16.9 of the Annex II.

(iii) Any publications or presentations of information developed by the project participants shall acknowledge their funding support and shall be cleared by the institutions involved according with the existing procedures. Joint work is expected to result in joint authorship of publications.

(iv) The development of any new commercial products and commercialization of results are not expected to be the issue during the term of the project

(v) However if this proves otherwise, the Recipient and its Partner agree to notify one another as well as other Parties of the Agreement in a timely fashion of any invention or copyrighted works arising under this Project and to seek protection for such intellectual property in a timely fashion.

(vi) The Recipient and the Partner shall be responsible for the maintenance, protection and preservation of all intellectual property during the term of the project

16.2 Ownership and Non-exclusive License: With the exception of inventions made by employees of the United States Government, the Recipient owns worldwide rights to Intellectual Property arising under this Agreement. The United States Government as represented by the Partner shall determine the rights in inventions made by United States Government employees or made in U.S. Government facilities. The United States Government, as represented by partner, is granted in all Intellectual Property arising under this Agreement a non-exclusive, irrevocable, royalty-free, worldwide (except for the territory of the United States) license to practice or have practiced for or on behalf of the United States. Upon the request of the Partner (or its designee), the Recipient entity (or its designee) shall enter into negotiation with United States commercial entities for licenses for commercial purposes on fair and reasonable terms in territories other than the United States in all Intellectual Property arising under this Agreement.

16.3 Commercialization in the United States: Upon request by Partner, the Recipient shall assign to the Government of the United States as represented by Partner, subject to a royalty-free, irrevocable non-exclusive license to the recipient, the entire right, title, and interest in any Intellectual Property in the United States, including inventions, patents on inventions, and copyrights arising under the Agreement. The Government of the United States will obtain and pay for all costs of obtaining patent protection in the United States on those inventions that the Recipient and Partner mutually agree to obtain patent protection in the United States (See Article 16.6). All uses of the Intellectual Property by or for the Government of the United States are royalty free. When the Government of the United States as represented by Partner or Partner's designee, negotiates and executes a license for commercial purposes to use Intellectual Property within the territory of the United States, which are purposes other than those by or for the Government, compensation will be sought for all uses of the Intellectual Property.

16.4 Compensation for inventors: In accordance with the policies of the Partner, which provide that the inventive entity shall receive at least 15% of royalties received, the inventors will receive a portion of the royalty income. The remaining royalties will be applied to cover or offset expenses incurred in obtaining and maintaining patent protection; and any remaining royalty income, after paying patent expenses, will be shared equally between the Recipient and Partner. However, the inventor, or inventors as a group, will always receive at least 15% of the total royalties received each year in accordance with the policies of the Partner.

16.5 Disclosure of inventions within two months: A written disclosure of invention will be provided by the Recipient (or its designee) to the Partner within two months of the date on which the invention is Made. See Article 17.2

16.6 Election to file patent applications within six months: The Recipient will notify Partner within six months of reporting an invention of each territory, except for the territory of the United States, in which the Recipient elects to protect the invention through patenting. In the territory of the United States, election to file will be by mutual agreement of the Recipient and Partner, and if the parties are unable to agree within eight months of reporting an invention and the Partner has not requested assignment under 16.3, either the Recipient or Partner may elect, by notifying the other party, to obtain patent protection in the United States and the party electing to file will pay all patent costs and will not share royalties with the Party not electing to file. If the Recipient files for a patent in the United States, the Government of the United States, as represented by Partner, shall have a non-exclusive, irrevocable, royalty-free license to practice or have practiced for or on behalf of the United States. See Articles 16.3 for patent costs and 17.3.

16.7 Filing of patent applications: The Recipient will file the first patent application within twelve months of reporting the invention. Partner has right to file patent applications in the countries in which the Recipient does not elect to file. If the Recipient does not elect to file within eight months of the date on which the invention is Made, the Partner may file applications in all countries in which the Recipient does not elect to file, and the Recipient

will assign title to the invention to the Partner in those countries in which the Partner has filed. The Recipient will retain a non-exclusive irrevocable, royalty free license in the territory where the Partner has filed. See Article 17.3

16.8 Exploitation of Results: The Technology Implementation Plan required by Article 8.2 of the Project Agreement shall contain a listing of all inventions Made under the Agreement, the status of pending patent applications, or patent numbers, licenses granted and in negotiation, and relate the commercial results of the research performed under the Agreement with the anticipated commercial results and intellectual property rights described in the proposal submitted for the Agreement.

16.9 The Recipient will grant to the United States Government, as represented by Partner, under reasonable terms and conditions the right to use by or for the Government Background Results owned by the Recipient which are necessary for the Partner to exploit Foreground Results, provided that the Recipient is free to disclose such Background Results, that no major business interests of the Recipient oppose the granting of such right, that in making this opposition such interests are not abusively restricting the exploitation of such right and that granting such right is not restricted by the law or obligations to a third party. The Recipient will notify the Partner, with factual statements in the next monthly technical report, of all situations where: the Recipient is not free to disclose such Background Results; or a major business interest opposes the granting of such right to such Background Results; or the disclosure of such Background Results is restricted by law or obligations to a third party.

**Article 17 - Reporting of Inventions**

17.1 The Recipient will disclose to the Partner and the ISTC in an ISTC-approved form every invention Made under this Agreement within two (2) months of the date on which such invention is Made. These disclosures must be in sufficiently complete technical detail to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purpose and operation of the invention.

17.2 The Recipient and the Partner will notify the ISTC of each territory in which each (or their designees) decides to protect inventions through patenting within six (6) months of the reporting of such inventions in accordance with Article 17.1 above.

17.3 The Recipient and the Partner will file patent applications in each territory in which each (or its designee) decides in accordance with Article 17.2 above to protect each invention through patenting. The first patent application will be filed in the territory where the invention was Made within twelve (12) months of reporting the invention in accordance with Article 17.1 above. The remaining patent applications will be filed in the other territories within respective time periods to ensure that the priority date of the first patent application is obtained for these later filed applications. The Recipient and the Partner will provide each other and the ISTC with copies of all patent applications each (or its designee) files.

**Article 18 - Background Results**

The Recipient and the Partner have identified and agreed that the following Background Results may be used in the performance of work under this Agreement and may be needed to practice any Foreground Results of this Agreement:
Recipient's Background Results: *none.*
Partner's Background Results: *none.*

Recipient and Partner represent that the above-identified Background Results are available for licensing as of the effective date of this Agreement.

**Article 19 - Conflicting Agreements, Laws and Regulations**

19.1 Recipient certifies that it has not and will not enter into any agreement with a third party that grants to the third party rights to Foreground Results that may affect the exploitation or commercialization of Foreground Results received by the Partner under this Agreement.

19.2 Recipient shall notify the Partner and the ISTC of any restrictions by government laws or regulations which may materially and adversely affect the rights necessary for the performance of the work or the exploitation and commercialization of Foreground Results.

## ANNEX III
## Formats for Progress and Cost Reports

### 1. Format for Technical Reports

Quarterly reports shall specify the progress, any actual or proposed deviations and modifications to the Work Plan in Annex I, and the results obtained. The reports shall contain sufficient information to enable assessment of the progress and cooperation within the Project. The details of the Annual Report shall be agreed upon at an appropriate time by the Recipient and the Center's Project representative. A suggested format for quarterly reports is as follows:

I. Summary of Technical Progress (By task in the Work Plan)
II. Milestones Completed
III. Summary of Personnel Commitments
IV. Major Equipment Acquired
V. Description of Significant Travel
VI. Current Technical Status (on schedule, behind schedule, ahead of schedule)
VII. Delays, Problems, Suggestions
VIII. IPR Annex

The quarterly report should be between three and five pages (single space).

### 2. Financial Forms

(The templates for reports are to be provided separately by the Center.)

### 3. Submission Dates for Technical and Financial Reports:

Technical and Financial reports are due two weeks after the end of each fiscal year quarter:

January 15
April 15
July 15
October 15

Additional time (two weeks) shall be granted for reconciliation (adjustments) of end-of-year balances.

## ANNEX IV

## DISCLAIMER

It is understood and agreed to by the Recipient of this ISTC project that:

The project funding commitment of the ISTC is subject to and limited by the funds which are actually available by the ISTC Financing Party(ies) for this project;

The funding for each project comes from ISTC Financing Parties and/or Partners who might make their ISTC financial contribution in whichever currency considered appropriate;

As a matter of practice, the ISTC at present signs all project agreements in a single currency, the US dollar;

The project support given to this project by the ISTC Financing Party(ies) and/or Partners of the ISTC may be affected by causes, including currency fluctuation, which may require adjustments in the project budget.