



PARTNER PROJECT AGREEMENT #G-2100p

BETWEEN

THE INTERNATIONAL SCIENCE AND TECHNOLOGY CENTER,

**THE NATIONAL CENTER FOR DISEASE CONTROL AND PUBLIC HEALTH
OF GEORGIA**

AND

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

Molecular Epidemiology of Multidrug Resistant and Extensively Drug Resistant Tuberculosis in country of Georgia

Operative Commencement Date: February 1, 2014

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 Public Health of Georgia** (hereinafter referred to as "**the Recipient**"), and **the US Department of Health and Human Services, US Centers for Disease Control and Prevention (CDC)** (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 Kazakhstan, 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: ***Molecular Epidemiology of Multidrug Resistant and Extensively Drug Resistant Tuberculosis in country of Georgia*** – (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 24 months from February 1, 2014 (hereinafter referred to as "the Operative Commencement Date").

Article 3 - Sub-agreements with Other Participating Institutions

The scope of work of each institution which takes part in the Project, the organizational structure of the Project, as well as financial requirements of such an institution, are defined and stipulated in Annex I. The Institute shall serve as the coordinating institution for all aspects of the Project, including the coordination of requests for payments for carrying out the work. In this regard, within 30 days after the Operative Commencement Date (or other appropriate time period mutually agreed upon), the Institute shall conclude sub-agreement with **National Center for Tuberculosis and Lung Diseases** which cover all aspects of the involvement of these institutions in the Project and which clearly define the scope of work and responsibilities of each institution. These sub-agreements will provide an essential part of the legal, institutional, and financial framework for the execution of the Project. All rights and obligations of the Center and of the Institute as well as other conditions set forth in the Agreement shall be included in the sub-agreements. A copy of the sub-agreements shall be submitted to the Center without delay after the execution. The Institute and all participating institutions in such sub-agreements will hereinafter be referred to collectively as "the Recipient."

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\$ 100,000.00 (One hundred 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\$4,340.

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\$53,240. 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\$42,420. 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 than \$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\$9,100.

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\$ 0 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\$4,340. 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:

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- 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: Patrick Russo

For the Recipient:
National Center for Disease Control and Public Health of Georgia
9 Asatiani Str, Tbilisi, 0177, Georgia
Facsimile: +995 32 243 30 59
Project Manager: Ekaterine Zangaladze

For the Partner
U.S. Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop A-05
Atlanta, GA, 30329, USA
Facsimile: +1(404) 235 0293
Biosecurity Coordinator: Eduardo Gomez

For the U.S. Counterpart Scientist:
US Centers for Disease Control and Prevention
Division of Tuberculosis Elimination, Centers for Disease Control and Prevention
1600 Clifton Road N.E., Mailstop E-10
Atlanta, GA 30333, USA
Tel.: +1(404) 639 5310
Senior Epidemiologist: Patrick Moonan

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 February 1, 2014.

Prepared in Moscow in the English language.

For the Center



David Cleave
Acting Executive Director
ISTC

05/02/14
(date)

For the Recipient



Amiran Gamkrelidze
General Director
National Center for Disease Control
and Public Health

10.02.2014
(date)

For the Partner



Eduardo Gomez
Biosecurity Coordinator
U.S. Centers for Disease
Control and Prevention
Program

14 Feb 2014
(date)



ANNEX I
Work Plan #G-2100
I. Summary Project Information

1. Project Title

Molecular Epidemiology of Multidrug Resistant and Extensively Drug Resistant Tuberculosis in country of Georgia

2. Project Manager

Name: Ekaterine Zangaladze	
Title MD PhD :	Position Chief Researcher, Laboratory Division, Department : of Molecular biology
Street address: 9, M. Asatiani St.	
City: Tbilisi	Region: Caucasus
ZIP: 0186	Country: Georgia
Tel.: (+ 995 32) 231 14 06	Fax: (+ 995 32) 243 30 59
E-mail: molbio@ncdc.ge; zangaladze@yahoo.com;	

3. Participating Institutions

3.1. Leading Institution

Short reference: NCDC	
Full name: National Center for Disease Control and Public Health of Georgia	
Street address: 9, M. Asatiani St.	
City: Tbilisi	Region: Caucasus
ZIP: 0186	Country: Georgia
Name of Signature Amiran Gamkrelidze	
Authority:	
Title MD; PhD :	Position Director General of NCDC :
Tel.: (+995 32) 239 8946	Fax: (+ 995 32) 243 30 59
E-mail: a.gamkrelidze@ncdc.ge	
Governmental Agency: Ministry of Labour, Health and Social Affairs of Georgia	

3.2. Other Participating Institutions

Participant Institution 1

Short reference: NCTBLD	
Full name: National Center for Tuberculosis and Lung Diseases	
Street address: 50 Maruashvili St.	
City: Tbilisi	Region: Caucasus
ZIP: 0101	Country: Georgia
Name of Authority: Mamuka Japaridze	
Title : MD	Position : Director of NCTBLD
Tel.: (+995 32) 291 02 51	Fax: (+995 32) 291 02 51
E-mail: mamuka.japaridze@tbgeo.ge	
Governmental Agency: Ministry of Labour, Health and Social Affairs of Georgia	
Sub-manager: Marine Janjgava	
Title : MD; PhD	Position : Head of Tuberculosis Control and Management Office
Tel.: (+995 32) 291 02 12	Fax: (+995 32) 291 02 51
E-mail: marijntp@yahoo.com	

4. Foreign Collaborators/Partners

4.1. Collaborators

Institution : Division of Tuberculosis Elimination, Centers for Disease Control and Prevention	
Street address: 1600 Clifton Road N.E., Mailstop E-10	
City: Atlanta	Region/State : Georgia
ZIP: 30333	Country: USA
Person: Patrick Moonan	
Title: DrPH, MPH, FACA	Position : Senior Epidemiologist at the International Research and Programs Branch
Tel.: 404-639-5310	Fax: 404-639-8959
E-mail: bng3@cdc.gov	

32

4.2. Partners

Institution U.S. Centers for Disease Control and Prevention	
Street address: 1600 Clifton Road NE, Mailstop A-05	
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5. Project Duration

24 months

6. Project Location and Equipment

Institution	Location, Facilities and Equipment
Leading Institution	National Center for Disease Control and Public Health (NCDC) – 7 floor building, Training Center, , Administrative offices, NCDC Richard G. Lugar Central Public Health Reference Laboratory – Culture Repository, Bacteriological, Virological, Cell Culture, Molecular Epidemiology Laboratories, well equipped to carry out research on TB and other pathogens.
Participant Institution 1	National Center for Tuberculosis and Lung Diseases (NCTBLD) - Outpatient Department, Inpatient department, TB Control and Management office and Training Center, National Reference Laboratory – with necessary basic equipment for TB research.

DB
34

II. Specific information

1. Introduction and Overview

The emergence of drug-resistant tuberculosis (TB), in particular, multidrug-resistant tuberculosis - MDR TB (defined as resistance to at least isoniazid and rifampin) and extensively drug-resistant tuberculosis - XDR TB (defined by WHO as strains which are resistant to isoniazid and rifampin plus resistance to key second line drugs including a fluoroquinolone - e.g., levofloxacin, moxifloxacin, and resistance to an injectable drug - either kanamycin, amikacin, and/or capreomycin), seriously challenges the success of WHO-recommended Directly Observed Treatment Strategy (DOTS) for detection and cure of TB, as well as global tuberculosis control (4).

MDR-TB has been detected in every region of the world, with the highest rates found in countries of the former Soviet Union, including Georgia. Although there has been a small decline in TB rates in Georgia over the last few years, TB remains an enormous public health problem in Georgia. According to the official statistical data in 2012, a total of 4,975 TB cases were reported; the incidence and prevalence of TB was 84 cases and 111 cases per 100,000 population, respectively. Georgia has the high rates of drug resistance with a prevalence of MDR TB- 9.2% among new TB cases and 31.2% among previously treated TB cases. According to MDR TB surveillance study using phenotypic antimicrobial susceptibility assays conducted within the BTEP /ISTC project in Georgia (BTEP #12 G-610) the prevalence of MDR TB were 10.5% in newly diagnosed patients and 53% in retreated cases. However, the extent of XDR TB in Georgia has yet to be determined.

Work done through previous BTEP project (BTEP #12 G-610), the Georgian genotyping program using IS6110-based insertion sequence restriction length fragment polymorphism (RFLP) was established. In the frame of previously funded CRDF project in Georgia (CRDF # 2935) Molecular Genetic Assay Genotype MTBDRplus (HAIN Lifescience) for rapid testing of MDR-TB was successfully implemented.

Present project is the logical sequel and further development of the previous BTEP and CRDF funded projects. In this study we propose to use a combination of different molecular techniques Spoligotyping, Mycobacterial Interspersed Repetitive Unit –Variable number of tandem repeat (MIRU-VNTR) and IS6110 RFLP analysis to better understand the transmission dynamics of TB in Georgia. Spoligotyping increases the volume of isolates that can be genotyped, and rapidity of genotyping. More rapid and reliable genotyping results may allow for earlier detection and control of TB transmission. Spoligotyping alone is of limited value in epidemiologic investigations due to low discrimination but can be useful in evolutionary studies. MIRU typing has become an important method for high-resolution genotyping *M. tuberculosis* clinical isolates. This method is internationally adopted as one of the reference method for TB molecular epidemiology. IS6110 RFLP typing, “gold standard” in the molecular epidemiology of TB has been used in many epidemiologic investigations, but it has been found to be of little use in evolutionary studies. But IS6110 RFLP analysis together with PCR-based methods such as spoligotyping and MIRU-VNTR typing largely overcome these difficulties. Hence implementation of new molecular approaches in investigation of TB is highly important.

We propose 2-year project that aims to study molecular epidemiology of TB through implementation of modern molecular methods and establishment of genotyping program for TB surveillance and research in Georgia. The activities appointed by three tasks will assure to achieve the aims/ research objectives of the proposal.

According to the Task 1 *M. tuberculosis* isolates will be collected from a country wide survey for determining rates of both primary and secondary multi-drug resistance, epidemiological data will be collected and analyzed to identify risk factors associated with XDR TB. Task 2 focuses on the expansion of an existing genotyping program in Georgia by introducing PCR based methods spoligotyping and MIRU analysis which, along with IS6110 RFLP analysis will be used for molecular typing of MDR / XDR strains isolated in the course of this project. On the basis of results from molecular typing studies molecular epidemiology of MDR/XDR TB in Georgia will be characterized (Task 3).

The project will be realized by the NCDC Richard G. Lugar Central Public Health Reference Laboratory which is equipped with advanced technologies for molecular researches.

2. Expected Results and Their Application

This project is in the Applied Research category.

Project covers Epidemiological, microbiological and molecular biological aspects of TB. Also it provides training opportunities for Georgian collaborators.

The establishment of a Georgian genotyping program with capabilities to perform spoligotyping and MIRU analysis on *M. tuberculosis* isolates along with IS6110RFLP analysis will give the ability to study *M. tuberculosis* clones circulating in community in Georgia, to highlight chains of transmission and identify associations between patients that were not identified by conventional contact tracing methodologies. Findings from the proposed studies will be extremely important for developing and implementing further public health interventions to control TB in Georgia

3. Meeting ISTC Goals and Objectives

This project corresponds to ISTC goals; the project involves collaboration between the Georgian NCDC, formerly involved in bioweapons research for the Soviet Union, and the Georgian NCTBLD with US collaborators, which include CDC. The present project concerns MDR and XDR TB, which is a major public health problem in Georgia, and leads to establishment of *M. tuberculosis* genotyping program at the Georgian NCDC by introduction of modern molecular methods and provides training for Georgian collaborators. Findings from this project will be useful for developing and implementing appropriate strategies to control TB in Georgia.

4. Scope of Activities

Task 1

Task description and main milestones		Participating Institutions
To determine the magnitude of, and risk factors for the development of extensively drug-resistant TB (XDR TB) in Georgia. Preliminary activities to be implemented: - Design the study and write the study protocol. - Develop a questionnaire for epidemiological studies - Get approval of the study by the IRB board. <i>M. tuberculosis</i> isolates, recovered from patients in Georgia will be collected from a country wide survey. Culture examination and drug susceptibility testing (DST) will be performed at NCTBLD Microbiological laboratory using standard methodology. <i>M. tuberculosis</i> isolates that are MDR-TB will have second line DST performed to determine XDR TB. Collection of cases and <i>M. tuberculosis</i> isolates will last approximately 18 months period. During this period 220-250 MDR isolates will be collected country wide for molecular studies. In addition, epidemiological data available on all these patients will be collected and analyzed to identify risk factors associated with XDR TB. 1st quarter – preliminary works; 2nd-6th quarters - conducting survey; 6th-7th quarter - data entry, analysis, evaluation, preparation of manuscript.		1-NCDC 2-NCTBLD
Description of deliverables		
1	Protocol development	
2	Quarterly reports	
3	Epidemiologic analysis	
4	Abstract, presentations and publication	

Task 2

Task description and main milestones	Participating Institutions
Expand the existing genotyping program in Georgia to include PCR-based methods - Spacer Oligonucleotide Genotyping (Spoligotyping) and Mycobacterial	1-NCDC

interspersed repetitive unit (MIRU) analysis

Preliminary activities to be implemented:

- Design the study and write the protocol.
- Get approval of the study by the IRB board.
- Purchase necessary equipment, materials and reagents.
- Train the NCDC person on modern molecular techniques

Existing Georgian genotyping program will be expanded and genotyping program using IS6110 RFLP analysis, Spoligotyping and MIRU analysis will be established, which will greatly enhance TB research capabilities in Georgia and will have impact on TB control efforts.

Phenotypically MDR and XDR *M.tuberculosis* isolates will be subjected to IS6110-RFLP analysis, spoligotyping and MIRU typing. Internationally recognized standard methodologies will be used for performing molecular typing studies. Application of spoligotyping will give the ability to compare diversity of DNA polymorphism of *M.tuberculosis* isolates on the basis of similarity of the DR locus and identify spoligotypes. Standard method based on 24 loci will be used for performing MIRU typing, which was shown to be a reliable and new reference method for TB molecular epidemiology.

Molecular typing of *M. tuberculosis* isolates will be performed at NCDC Richard G Lugar Central Public Health Research Laboratory. A molecular typing specialist from NCDC will be trained on molecular typing methodologies at the beginning of the grant period. The training will last approximately 1 month. In addition, in the first quarter of year 1, equipment and supplies to carry out molecular typing studies will be ordered. It is anticipated that a minimum 250 *M.tuberculosis* strains will be studied. Data from genotyping studies will be analyzed in conjunction with epidemiologic data with assistance by CDC collaborators. It is anticipated that data from Task 2 will be presented at national and international scientific meetings and that a manuscript will be submitted for publication in a peer-reviewed journal.

1st – 2nd quarter – preliminary works;

3rd-10th quarters - conducting molecular typing studies;

10th-11th quarter - data entry, analysis, evaluation, preparation of manuscript.

12th quarter – data analysis, preparation of manuscript

Description of deliverables

1	Protocol development
2	Quarterly reports
3	Laboratory training
4	Abstract, presentations and publication

Task 3

Task description and main milestones	Participating Institutions
Molecular epidemiology of TB in Georgia will be characterized on the basis of results from molecular typing studies employing IS-6110 RFLP analysis, spoligotyping and MIRU typing. IS6110 RFLP typing, "gold standard" in the molecular	I-NCDC

epidemiology of TB has been used in many epidemiologic investigations, but it has been found to be of little use in evolutionary studies. But IS6110 RFLP analysis together with PCR-based methods such as spoligotyping and MIRU typing largely overcome these difficulties. Combination of internationally recognized typing methods for *M. tuberculosis* clinical isolates will permit to learn transmission dynamics of TB and identify clones circulating in Georgia, which is especially important not only for optimal surveillance and disease control in our country, but also for the study of global emergence and worldwide distribution of drug-resistant strains.

Application of spoligotyping will give the ability to determine which *M. tuberculosis* isolates recovered from patients in Georgia have spoligotypes that are common in the world and which spoligotypes are specific for Georgia and to investigate whether the Beijing family of *M. tuberculosis* isolates had spread to Georgia.

MIRU typing is internationally recognized standard method for TB molecular epidemiology. MIRU has been used in many epidemiological investigations for tracing TB transmission at the strain level. In addition, MIRU markers can also provide useful predictions for classifying strains into genetic lineages, which are facilitated by freely accessible, on-line strain identification databases such as MIRU-VNTRPlus (<http://www.miru-vntrplus.org>) and TB-lineage (<http://www.cs.rpi.edu/~bennek/tbinsight/tblineage>).

Molecular epidemiology of tuberculosis in Georgia will be characterized with assistance by CDC collaborators. It is anticipated that data from Task 3 will be presented at national and international scientific meetings and that a manuscript will be submitted for publication in a peer-reviewed journal.

Description of deliverables	
1	Protocol development
2	Quarterly reports
3	Training
4	Abstract, presentations and publication

5. Role of Foreign Collaborators/Partners

Foreign scientists and collaborators will provide overall guidance and consultation on the major tasks of the project:

The role of foreign collaborators will include training of Georgian collaborators in molecular typing techniques of *M. tuberculosis* and assistance in advanced laboratory techniques. Training will take place in laboratories of our collaborators in 1 year of the grant period. Collaborators will also assist in quality control measures, in data analysis and interpretation. They would assist for project participants to join international meetings and provide comments to the technical reports

E-mail will be used to maintain close communication throughout the grant period.

6. Technical Approach and Methodology

Task 1: To determine the magnitude of, and risk factors for the development of extensively drug-resistant TB (XDR TB) in Georgia.

DB
32

M. tuberculosis isolates collected through the project period that will show to be MDR TB will be subjected to second-line DST to determine the magnitude of XDR among MDR isolates.

Culture studies will be performed at the NCTBLD National Reference Laboratory (NRL) on solid Lowenstein Jensen (LJ) media and liquid Middlebrook 7H9 broth in Bactec 960MGIT System using standard methodology.

DST studies will be performed on *M. tuberculosis* isolates recovered from patients in Georgia to the first and second line antituberculosis drugs.

DST to the first line drugs will be performed in 7H9 broth in Bactec MGIT 960 system using following drug concentrations: Isoniazid - 0.1 mkg/ml, Rifampicin - 1 mkg/ml, Streptomycin - 1 mkg/ml, Ethambutol - 5 mkg/ml.

DST to the second-line drugs will be performed by the proportion method on solid LJ media with following drug concentrations: Ethionamide - 40 µg/ml, Cycloserine - 60 µg/ml, Ofloxacin - 2 µg/ml, PAS - 0.5 µg/ml, Kanamycin - 30 µg/ml, Capreomycin - 40 µg/ml.

Questionnaire for epidemiological studies will be developed; data on all patients enrolled into study will be collected and analyzed to identify risk factors for XDR TB.

Task 2: Expand the existing genotyping program in Georgia to include PCR-based methods - Spacer Oligonucleotide Genotyping (Spoligotyping) and Mycobacterial interspersed repetitive unit (MIRU) analysis

IS6110 RFLP genotyping of *M. tuberculosis* isolates was first initiated in Georgia through the BTEP grant (BTEP #12 G-610). Genotyping program in Georgia will be expanded with MIRU typing and spoligotyping. The technique of spoligotyping is based on polymorphisms found in the DR locus present in all *M. tuberculosis* complex isolates. The DR locus contains multiple direct repeat sequences separated by unique spacer sequences. The spacer sequences are used as molecular markers. Following DNA extraction and amplification of the whole DR region by PCR, the amplified DNA is hybridized to spacer oligonucleotides covalently linked to a membrane ("Reversed Line Blot") to detect the presence or absence of 43 different spacer sequences. The hybridization pattern obtained is subsequently visualized by incubation with streptavidin-peroxidase, chemiluminescence and autoradiography.

We plan to introduce MIRU typing and spoligotyping as an additional tools in Georgian TB control. MIRU typing in conjunction with Spoligotyping and IS6110RFLP analysis can be used to identify *M. tuberculosis* strain clusters that, under the proper conditions, may represent a chain of recent TB transmission or an outbreak, and will thus help to focus TB control efforts.

Training in MIRU typing and spoligotyping methodology is expected to commence during the first quarter of the project.

Task 3. To characterize molecular epidemiology of MDR/XDR TB in Georgia

Molecular epidemiology of TB in Georgia will be characterized on the basis of results from molecular typing studies employing IS6110 RFLP analysis, spoligotyping and MIRU typing. Genotyping will be performed according to internationally recognized standard methodologies.

IS6110 RFLP analysis is considered the "gold standard" for the molecular epidemiology. IS6110 RFLP analysis is based on the use of a restriction endonuclease *PvuII*, which cleaves IS6110 at a single asymmetric site and yields chromosomal fragments which can be separated by agarose gel electrophoresis. Hybridization probe is targeted at the 3' fragment of IS6110, whereby each IS6110 insertion site will yields a single hybridizing band. In this study computer-assisted analysis of IS6110 fingerprints will be carried out using Bio-Numeric software (Applied Maths).

Spoligotyping is a more rapid, PCR-based amplification method for genotyping *M. tuberculosis* isolates. The technique of spoligotyping is based on polymorphisms found in the DR locus present in all *M. tuberculosis* complex isolates. Following DNA extraction and amplification of the whole DR region by PCR, the amplified DNA is hybridized to spacer oligonucleotides covalently linked to a membrane to detect the presence or absence of 43 different spacer sequences. The hybridization pattern obtained is subsequently visualized by incubation with streptavidin-peroxidase, chemiluminescence and autoradiography. The data from spoligotyping will be collected in Microsoft Access.

MIRU typing is PCR-based standard method for TB molecular epidemiology. MIRU-VNTR genotyping of Mycobacteria rely on PCR amplification using primers specific for the regions of the VNTRs and on the determination of the sizes of the amplicons, after electrophoretic migration. These sizes reflect the numbers of the amplified VNTR copies. The final result is a numerical code, corresponding to the repeat number in each VNTR locus. Such numerical genotypes are portable and very convenient for both intra-laboratory comparative studies. In our study on-line strain identification database - MIRU-VNTRPlus (<http://www.miru-vntrplus.org>) can be used to find genetic lineages among strains.

Data from genotyping studies will be analyzed in conjunction with epidemiologic data with assistance by CDC collaborators.

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\$)
Zangaladze Ekaterine	1956	PhD	3	Project Manager	50	250	12,500
Kutateladze Tamar	1955	PhD	3	SP-Molecular typing	40	80	3,200
Zakalashvili Mariam	1964	MS, Biology	3	SP-Molecular typing	35	102	3,570
Total:						432	19,270

Category II (other scientific and technical personnel)

Name	Birth Year	Scientific Title	Function in project	Daily rate (US\$)	Total days	Total grants (US\$)
Merabishvili Tsira	1963	MD	Epidemiologist	30	96	2,880
Jvarelia Nino	1964	MD	Epidemiologist	30	136	4,080
Total:						6 960

Participant Institution 1: NCTBLD

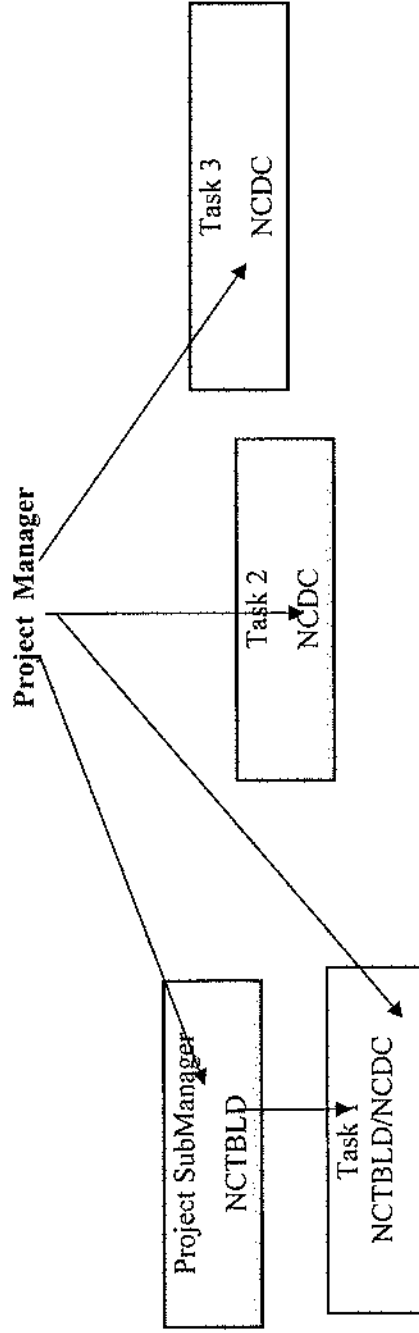
Category I (weapon scientific and technical personnel)

Name	Birth Year	Scientific Title	Weapon Expertise Ref.	Function in project	Daily rate (US\$)	Total days	Total grants (US\$)
Janjgava Marine	1960	PhD	3	SubManager	40	275	11,000
Aspindzelashvili Rusudan	1952	PhD	3	Leading expert, Microbiological Investigation	35	286	10,010
Total:						561	21,010

Category II (other scientific and technical personnel)

Name	Birth Year	Scientific Title	Function in project	Daily rate (US\$)	Total days	Total grants (US\$)
Kinkladze Inga	1976	Microbiologist	Microbiological Investigation	25	80	2,000
Khurcilava Iza	1964	Microbiologist	Microbiological Investigation	25	80	2,000
Nanava Ucha	1978	Data Base Specialist	Data Base	25	80	2,000
Total:					240	6,000

8.2. Managerial responsibilities



9. Financial Information

TABLE 1

Estimated Aggregated Expenditures by Recipient

Category	Quarters 1 & 2		Year 1		Year 2		Total	
	(1)	(2)	(1)	(2)	(1)	(2)	(1)	(2)
1 Grant Payments:								
1.1 Category I		9685		19 885		20 395		40 280
1.2 Category II		3 240		6 480		6 480		12 960
1.3 Category III		0		0		0		0
1.4 Category IV		0		0		0		0
<i>Total Grant Payments</i>		12 925		26 365		26 875		53 240
2 Equipment:								
2.1 Capital Equipment								
2.2 Non-Capital Equipment		3 210		3 210				3 210
<i>Total Equipment</i>		3 210		3 210				3 210
3 Materials/Supplies		28219		28 219		0		28 219
4 Bank Fees		318		674		312		986
5 Other Direct Costs:								
5.1 Technological Energy								
5.2 Communications								
5.3 Subcontracts/Seminars		360		715		190		905
5.4 Logistics/Customs								
5.5 Other		360		715		190		905
<i>Total ODC</i>		360		715		190		905
6 Travel:								
6.1 Internal ***								
6.2 Outside CIS		6 500		6 500		2 600		9 100
<i>Total Travel</i>		6 500		6 500		2 600		9 100
Overhead/Retainage							4 340	
<i>Subtotals</i>		51 532		65 683		29 977	4 340	95 660
Totals	51 532	51 532	65 683	65 683	29 977	29 977	100 000	100 000

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

TABLE 1-1

Estimated Aggregated Expenditures by Leading Institution

Category	Quarters 1 & 2		Year 1		Year 2		Total	
	(1)	(2)	(1)	(2)	(1)	(2)	(1)	(2)
1 Grant Payments:								
1.1 Category I		4 435		9 380		9 890		19 270
1.2 Category II		1 740		3 480		3 480		6 960
1.3 Category III		0		0		0		0
1.4 Category IV		0		0		0		0
<i>Total Grant Payments</i>		6 175		12 860		13 370		26 230
2 Equipment:								
2.1 Capital Equipment								
2.2 Non-Capital Equipment		3 210		3 210				3 210
<i>Total Equipment</i>		3 210		3 210				3 210
3 Materials/Supplies		27 947		27 947		0		27 947
4 Bank Fees		263		525		163		688
5 Other Direct Costs:								
5.1 Technological Energy								
5.2 Communications								
5.3 Subcontracts/Seminars				695		180		875
5.4 Logistics/Customs		340						
5.5 Other								
<i>Total ODC</i>		340		695		180		875
6 Travel:								
6.1 Internal ***								9 100
6.2 Outside CIS		6500		6500		2600		9 100
<i>Total Travel</i>		6500		6500		2600		9 100
Overhead/Retainage							1750	
<i>Subtotals</i>		44 435		51 737		16 313	1750	68 050
Totals	44 435		51 737		16 313		69 800	

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

TABLE 1-2

Estimated Aggregated Expenditures by Participant Institution 1

Category	Quarters 1 & 2		Year 1		Year 2		Total	
	(1)	(2)	(1)	(2)	(1)	(2)	(1)	(2)
1 Grant Payments:								
1.1 Category I		5250		10 505		10 505		21 010
1.2 Category II		1500		3 000		3 000		6 000
1.3 Category III		0		0		0		0
1.4 Category IV		0		0		0		0
<i>Total Grant Payments</i>		6750		13 505		13 505		27 010
2 Equipment:								
2.1 Capital Equipment								
2.2 Non-Capital Equipment		0		0		0		0
<i>Total Equipment</i>		0		0		0		0
3 Materials/Supplies		272		272		0		272
4 Bank Fees		55		149		149		298
5 Other Direct Costs:								
5.1 Technological Energy								
5.2 Communications								
5.3 Subcontracts/Seminars		20		20		10		30
5.4 Logistics/Customs								
5.5 Other		20		20		10		30
<i>Total ODC</i>		20		20		10		30
6 Travel:								
6.1 Internal ***								
6.2 Outside CIS								
<i>Total Travel</i>								
Overhead/Retainage							2 590	
<i>Subtotals</i>		7 097		13 946		13 664	2 590	27 610
Totals		7 097		13 946		13 664		30 200

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-2100 kind [X] To be provided in 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)
<i>Leading Institution: NCDC</i>					
1	Miniblotter 45 with Washing Manifold F2 cat no: Immunetics, MN100-45	1	1	1600	1600
2	Plate cushions for MN45 Cat no: Immunetics, PC200	1	10	161	1610
Subtotal:					3 210
Estimated TOTAL COST:					3 210

Form PR-1E of 3/98

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10.2. Materials Summary

TABLE 3

EQUIPMENT/MATERIAL SUMMARY						
MATERIAL SUMMARY for Project Agreement #G-2100 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	Tips, ART 200 Barrier, 200µL, 2069-RT Sterile, 960/pk)	1	1	212	212	
2	Tips, ART Barrier 10 REACH; 100-1000uL; (800/pk) Thermo Scientific; cat P-2079	1	1	195	195	
3	Film developing tank, Fischer scientific, 50-267-70	1	2	132	264	
4	Respirators, 3M™ N95 and P95 Filtering Facepiece, Fisher Scientific, 18-999-473, Pack of 20;Case of 8 PK	1	1	195	195	
5	Gloves, N-DEX Original; Fisher Scientific, Cat. No 19-050-269B (size:M) pack of 100;	1	7	52	364	
6	Microcentrifuge tube (sterile), 2mL, high-impact resistant, screw-cap with integral O-ring, USA Scientific, cat. # 1420-9600; Pk of 200	1	2	100	200	
7	Eppendorf tube natural 1.5ml, Sigma, pk of 1000; Z606340	1	1	72	72	
8	Corning Polypropylene Cryogenic Vial, External Threaded, Self-standing, 2,0-ml, Sterile, 430659;(50/pk; 500/case)	1	1	350	350	
9	Graduated Transfer Pipets, 3.9mL, small Bulb, Sterile, Graduated To 1mL, 500/Pack, Thermo scientific,cat:212-20S	1	1	150	150	
10	Cardboard Tube Storage Boxes with 81-cell divider; Daigger PK of 12, cat; 2860A	1	1	95	95	
11	3130xL Genetic Analyzer Capillary Array, 50 cm, Applied Biosystems, cat no: 4315930	2	2	1400	2800	
12	96 well PCR plates, nonskirted, Thermo Scientific, AB-0600 , 25 plates/pk	2	1	156	156	
13	96 well Semi-Skirted PCR Plates, supplier - Sorenson Bioscience 35800; VWR cat no: 14216-140; case of 252	2	1	240	240	

14	Adhesive PCR Film, Thermo Scientific, AB-0558 100 sheets/pk	2	1	200	200
15	ABI DS-31 Matrix Standard Kit	2	1	247	247
16	Watman Paper, size 50 x 60cm, Pack of 50; Fisher Scientific, Cat. No. 09-301-196	2	1	435	435
17	Nylon Membranes, Amersham Hybond N+ Cat. No RPN303B ,30cmx3m	2	1	470	470
18	Kodak BioMax XAR Film from Carestream health, size 8 in. x 10 in. , 50/pack – individually wrapped ; Fischer Scientific, cat no 1651579	2	1	1590	1590
19	GBX Developer/Replenisher; Sigma, Cat No P7042- 5GA	2	1	160	160
20	GBX Fixer/Replenisher Sigma Cat No P7167-5GA	2	1	133	133
21	Chloroform- Isoamyl alcohol mixture, Sigma C0549- 1PT	2	2	147	294
22	Hydrochloric acid solution, volumetric, 1N, Sigma,71926-1L	2	2	45	90
23	Sodium Hydroxide solution, 4N, Sigma 71535-1L	2	1	75	75
24	Sodium Citrate, Sigma, C8532; Pack size – 1 kg	2	2	154	308
25	UREA, Sigma, U 5378, Pack size – 1 kg	2	2	148	296
26	Seakem GTG Agarose, Lonza, Cat. No 50070; pack size – 25gr	2	1	275	275
27	Hexadecyltrimethylammonium bromide, Sigma, H5882-100G	2	2	75	150
28	EDTA , Sigma, E5134 - 250G	2	1	118	118
29	Disodium Phosphate Dihydrate – Na ₂ HPO ₄ *2H ₂ O; Sigma,71643-1KG	2	1	195	195
30	SDS speccially pure, Fisher Scientific, cat no : 50-300- 411H-500gr	2	1	185	185
31	Glycerol, Sigma G5516-500ML	2	1	147	147
32	Lysozyme, Sigma, L6876, pack size – 1 g	2	2	87	174
33	ProteinaseK, FisherScientific, Promega PRV3021, 100mg/pk	2	1	165	165
34	Pvu II., NEW ENGLAND BioLabs, Cat. No, RO151L	2	1	290	290
35	1 kb DNA Ladder, Fisher Scientific, Promega, Cat. No G5711	2	1	165	165
36	100 bp DNA Ladder; 250µL; Promega Corporation PRG2101; Fisher Scientific, No.:G2101	2	1	156	156
37	Streptavidin POD-conjugate, Roche cat no: 11089153001; 500 U	2	1	290	290
38	ECL nucleic acid detection reagents, Cat.-Amersham- Nr RPN2105	2	3	575	1 725
39	ECL Direct Nucleic Acid Labelling and Detection System, Amersham Pharmacia Biotech, RPN 3001	2	1	1 200	1 200
40	Spoligotyping kit, Ocimum Biosolutions, cat no IM9701	2	1	1 200	1 200
41	Hot Star Taq DNA Polymerase kit (1000 U), QIAGEN 203205	2	2	687	1 374
42	dNTP's set, 4x250 µl; ROCHE 11969064001 Fisher Scientific -50-720-4097	2	1	342	342
43	Mapmarker1000, Rox labeled, EUROAGENTEC, MW- 0195- 80Rox ;	2	1	850	850

44	GeneScan 1200 LIZ Size Standard, Applied Biosystems, 4379950	2	1	1050	1050
45	PCR Low Ladder Set, Sigma D7808	2	1	274	274
46	Hi-Di Formamide, ABI 4311320, 25 ml;	2	1	50	50
47	POP-4 Polymer for 3130/3130xl Genetic Analyzers, ABI 4352755	2	1	850	850
48	M.tuberculosis standard culture-H37Rv; ATCC#25618	2	1	1 766	1 766
49	Oligonucleotide primers	2	48	100	4800
50	Probe for RFLP analysis	2	1	150	150
51	Middlebrook and Cohn 7H9 Broth – 500g; Fisher Scientific, Cat.No 271310;	1	1	200	200
52	Middlebrook OADC Enrichment (in 20 x 148mm screw-cap tube); BBL; 20mL; Pack of 10 Cat.No. B11886	1	1	215	215
Subtotal:					27 947
Participant Institution 1: NCTBLD					
53	Eppendorf tube natural 1.5ml, Sigma, pk of 1000; Z606340	1	2	70	140
54	Loop, Inoculation; Sterile; Polystyrene; Volume: 10µL; Pack of 500; Fisher Scientific ;22-170-203	1	2	66	132
Subtotal:					272
Estimated TOTAL COST:					28 219

Form PR-1M of 3/98

10.4. Other Direct Costs Summary

TABLE 4

OTHER DIRECT COSTS SUMMARY						
OTHER DIRECT COSTS SUMMARY for Project Agreement #G-2100 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	5.4	Logistics and customs	1-2	1	340	340
2	5.4	Logistics and customs	3-4	1	355	355
3	5.4	Logistics and customs	5-8	1	180	180
Subtotal:						875
Participant Institution 1: NCTBLD						
4	5.4	Logistics and customs	1-2	20	1	20
5	5.4	Logistics and customs	5-8	10	1	10
Subtotal:						30
Estimated TOTAL COST:						905

Form PR-10D of 3/04

ANNEX II
General Conditions

Contents:

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

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Article 2	-	Subcontracting
Article 3	-	Monitoring of the Work
Article 4	-	Reports
Article 5	-	Completion or Expiration of the Agreement
Part B	-	Payments
Article 6	-	Payments by the Center to the Recipient
Part C	-	Allowable Costs
Article 7	-	Accounting Principles, Allowable Costs and Transfer of Costs
Article 8	-	Direct Costs
Article 9	-	Overhead
Article 10	-	Costs not Allowed
Part D	-	Justification of Cost and Auditing
Article 11	-	Books of Account and Documentation
Article 12	-	Auditing
Part E	-	Information and Intellectual Property
Article 13	-	Definitions
Article 14	-	Promotion of Technology and Project Results
Article 15	-	Ownership
Article 16	-	Protection and Exploitation
Article 17	-	Reporting of Inventions
Article 18	-	Background Results
Article 19	-	Conflicting Agreements, Laws and Regulations



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 Financing 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.

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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.

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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.

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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:

March 15
June 15
September 15
December 15

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