

**MEMORANDUM OF UNDERSTANDING
TO ENHANCE COOPERATION IN THE FIELD OF NATIONAL BLOOD SAFETY IN
GEORGIA**

Global Healing, a non-governmental organization (hereinafter – “GH”), represented by its president Mr. Luke IFLAND, on one side;

Ministry of Labour, Health and Social Affairs of Georgia (hereinafter - “MoLHSA”), represented by the Minister – Mr. David SERGEENKO;

LEPL L. Sakvarelidze National Centre for Disease Control and Public Health (hereinafter – “NCDC”), represented by its Director General – Mr. Amiran GAMKRELIDZE and

LEPL “Agency of State Regulation of Medical Activities” (hereinafter - ASR), represented by its head – Mr. Gia TVALAVADZE on the other side;

and

Jo Ann Medical Center Blood Bank (hereinafter - “JAMC BB”), represented by its director – Mr. Levan AVALISHVILI, on the third side;

Hereinafter collectively referred to as “Parties”, acknowledge this as an addendum to a previous Memorandum signed on August 3, 2011 between Global Healing, the NCDC, and the Jo Ann Medical Center Blood Bank, that extends the scope of inclusion of the Government Agencies and specifies the competencies, authorities and the activities to be carried out by the parties.

The parties reaffirm the goals, objectives, responsibilities and support outlined in the Memorandum concluded on August 3, 2011. Implementation of this Memorandum is related to the Memorandum concluded on August 3, 2011 and shall be considered together with it to improve blood safety project in Georgia (hereinafter - “Project”).

The overall objective of the project is to outline how the Parties shall cooperate to create and sustain a legal framework of policies, guidelines and legislation, as well as the necessary infrastructure, budget and human resources to support a robust and effective regulatory system that will be responsible for enforcement of compliance of facilities engaged in the collection, storage, transportation, testing, processing, manufacture, and/or transfusion of blood and blood products with the internationally accepted standards of the World Health Organization, American Association of Blood Banks, and/or the European Union (hereinafter - “regulatory system”).

Article 1. The goal of the Memorandum

The goal of this memorandum is to: 1) clarify the organizational structure and responsibilities of each party needed to support the regulatory system as outlined in Annex 1; and 2) formally commit to the program timeline and deliverables in Annex 2.

Article 2. Timeline

This Memorandum shall extend the duration of the Parties' active cooperation until the period of termination of the activities stipulated by Annex 2 of this Addendum, but no later than February 2016.

Article 3. Competencies and Responsibilities of the Parties

In addition to the competencies and responsibilities outlined in the Memorandum of August 3, 2011, the Parties agree to the following:

1. Global Healing

- 1.1. Organize and finance qualified specialists to travel to Georgia for trainings required for the success of the project.
- 1.2. Provide initial working drafts in English of clinical practice guidelines, standards of operation for blood banks and transfusion services, and assessment tools to be reviewed by a Georgian working group for editing and approval.

2. Ministry of Labour, Health and Social Affairs

- 2.1. Apply all the efforts regarding all necessary legal policies, infrastructure, budget and human resources to the NCDC and ASR in order to support a robust and effective regulatory system according to internationally acceptable guidelines, including Standards of Operation of Blood Banks and Transfusion Services and Clinical Practice Guidelines for Blood and Blood Products.
- 2.2. **Development of the legal regulatory mechanisms, which will support ASR to be in line with internationally acceptable standards conducting its inspection/control function;** supports the NCDC to coordinate corrective actions, education and training, statistical collection and analysis, and related activities.
- 2.3. On a continual basis, ensure review and revision of legal policies and processes related to the regulatory system by a qualified group of local and/or international experts.

3. National Center for Disease Control and Public Health

- 3.1. Host a working group, composed of local blood safety stakeholders, to discuss and review all issues surrounding national blood safety and specifically the development of a national donor recruitment and national regulatory system.
- 3.2. Provide and/or coordinate sufficient training to enable blood banks and transfusion services to comply with national legal policies regulating their operations.

4. Agency of state regulation of medical activities

- 4.1. Inspection of blood centers and hospital transfusion services to ensure compliance with national blood-related policy according to the rules and regulative norms which will be admitted and implemented at the moment of inspection. Frequency, volume and depth of the inspections should be defined by the legislation..
- 4.2. Reform the inspection methodology according to the new regulatory policy. This may require, but not be limited to, the use of a new assessment tool, enhanced reporting guidelines and timeline, and collaboration with other public health agencies.

5. Jo Ann Medical Center Blood Bank:

- 5.1. Provide fulfillment and active support to the objectives, tasks, responsibilities of this Memorandum and the memorandum concluded on August 3, 2011.

6. The Parties agree to the following:

Global Healing, ASR, NCDC and MoLHSA shall work in conjunction to ensure that the national blood service in Georgia is uniformly safe and reliable. All parties understand that the objectives outlined in this Addendum address only immediate needs in Georgia and that long-term objectives for the national blood service shall be determined, though not implemented, before the conclusion of the term of this Addendum.

Article 4. Final Provisions and Other Issues of the Memorandum:

1. Each party recognizes that this Memorandum shall complement rather than supersede the Memorandum of August 3, 2011.
2. All active assistance by Global Healing stipulated hereof and the Memorandum of August 3, 2011 shall cease following completion of the timeline outlined in Annex 2 of this memorandum, but not later than February, 2016. After active assistance is completed, Global Healing will provide remote consultation and resources to the ASR, NCDC and MoLHSA related to the regulatory system.
3. Execution of this project does not entail future financial, technical or other kind of support by Global Healing to any of the Parties.
4. This Memorandum shall enter into force upon signature of all signatories.
5. The Memorandum shall be governed by the Georgian Laws.
6. The Memorandum is made in 5 (five) original copies each in English and Georgian languages having equal legal power.

[Signature page follows]

CONTACT INFORMATION OF THE PARTIES:

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AND SOCIAL AFFAIRS OF GEORGIA**

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David SERGEENKO, Minister

Signature _____

Date: 10.02.2014

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Luke IFLAND, President

Signature _____

Date: 8-4-2014

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Amiran GAMKRELIDZE, Director General

Signature _____

Date: 09.02.2014

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Levan AVALISHVILI, Director

Signature _____

Date: 09.02.2014

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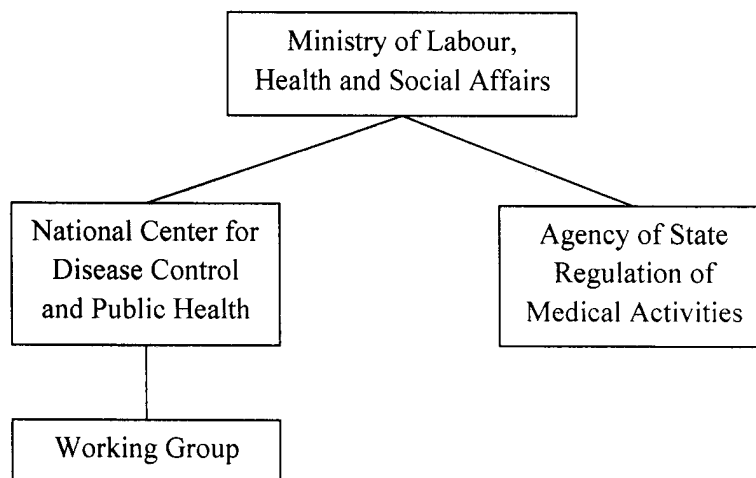
Gia TVALAVADZE, Head

Signature _____

Date: 09.02.2014

ANNEX 1

ORGANIZATIONAL STRUCTURE AND RESPONSIBILITIES



Ministry of Labour, Health and Social Affairs

- Enforce legal mandate for the NCDC and ASR, in order to carry out all the necessary measures for compliance of regulatory legislation related to blood safety, including guidelines and protocols, with the internationally acceptable standards, through support of necessary resources.
- Establish the working group.

Agency of State Regulation of Medical Activities

- Inspection of blood donor centers, laboratories and hospital transfusion services, according to the rules and regulative norms which will be admitted and implemented at the moment of inspection.
- Report findings to the Ministry and inspected facilities and develop corrective recommendations

National Center for Disease Control and Public Health

- Overall coordination, planning of state blood programs
- Host national blood donor awareness campaigns and donor recruitment support
- Collect, analyze and interpret epidemiological data to make evidence-based decisions
- Provide training to blood banks and hospital transfusion services to facilitate compliance with national regulations
- Implement corrective and preventive action plans based on epidemiological surveillance and facility inspections

Working Group

- Provide feedback and edits on national policy, guidelines and other legal documents or technical advice submitted by GLOBAL Healing

ANNEX 2

PROGRAM TIMELINE

- 2014**
- February**
1. NCDC: Identify responsible persons for ongoing national donor recruitment.
 2. GH: Send Georgian-language versions of relevant reference documents for national and institutional quality management to trainees (e.g. ISOs).
 3. GCB, JAMC: Finalize supply chain for aphaeresis consumables.

- 2014**
- Interim Tasks**
- February**
1. JAMC/GCB/NCDC: Submit monitoring & evaluation data through GH-developed tool.
 3. JAMC: Establish hospital transfusion committee.
 4. GH: Submit standards of operation for blood banks and transfusion services to NCDC. Submit assessment tools to be used by ASR.

- Training Trip #1 in Georgia**
- February**
1. GH: Train JAMC to operate and maintain apheresis collection devices. Train JAMC on quality principles, internal audits and how to develop quality improvement plans; conduct internal audits using assessment tool. Continue training ASR and NCDC staff in national quality systems; conduct preliminary external audit of JAMC using assessment tool. Meet with Tbilisi State Medical University (TSMU) to discuss collaboration for medical education. Draft national blood policy with mission, vision, timetable and deliverables with NCDC.
 2. NCDC: Host meeting with working group to review standards of operation and assessment tool, discuss content and provide feedback.

- Interim Tasks**
- March**
1. NCDC: Apply input from working group to standards of operation. Submit to MoLHSA
 2. JAMC: Submit input on assessment tools after internal audits to NCDC. Create quality improvement plans (QIPs) and share with GH.
- April**
1. Working group: Review clinical practice guidelines, discuss content and provide feedback to NCDC.
 2. NCDC: Apply input from JAMC on assessment tool. Submit to MoLHSA.

- Training Trip #2**
- May**
1. GH: Host 2-day symposium on national standards of operations. Review reporting from blood centers to government agencies to suggest improvements on harmonization of reporting from blood centers. Develop

inspection reporting guidelines with ASR, NCDC. Send donor recruitment specialist to strategize with NCDC donor recruiters for World Blood Donor Day. Create calendar of donor recruitment activities for NCDC. Suggest database solution for donor recruitment at JAMC.

Interim Tasks

June

1. ASR/NCDC (in the framework of their responsibilities): to the extent possible, apply regulatory norms (international standards, guidelines etc.) which are in the process of the implementation to JAMC. Results should be reported to WG.
2. NCDC: Coordinate blood drives and events related to World Blood Donor Day.

July

1. NCDC: Apply input from working group on clinical practice guidelines and submit to MoLHSA.
2. GH: Send protocols on platelet use and emergent blood needs.
3. Working group: Identify opportunities for local continuing medical education and review the issues of accreditation/certification. Send English-language outline of current mandates along with ideas for improvement to GH.

September

1. TSMU: Provide feedback on tools related to platelet use and emergent case management. Send outline of transfusiology curriculum in English to GH.
2. Working group: Review and incorporate GH input on harmonization of reporting documents and guidelines.
3. GH: Provide input on accreditation/certification and continuing medical education provided by TSMU.

Training Trip #3

October

1. GH: Send quality specialists to train individual JAMC, GCBB and NCDC staff on follow-up topics, targeting gaps highlighted by June modeling. Discuss harmonization of reporting for blood centers. Review hospital transfusion committee at JAMC. Examine opportunities to improve platelet use and emergent cases at 3 primary users of blood. Discuss accreditation/certification and continuing medical education with NCDC.
2. JAMC: Establish transfusion committee at NCDC-designated hospital.

Interim Tasks

Nov-Dec

1. NCDC: VNRBD benchmark at 10% of national collections.
2. NCDC: Perform preliminary assessments and SWOT analyses of 3 blood centers (excluding JAMC and GCBB).
3. GH: Create curriculum outline for platelet use and emergent case management to be reviewed by TSMU.

4. MoLHSA/NCDC: Rollout harmonized reporting guidelines documents.
5. GH: Provide suggestions related to certification of blood service staff.
6. JAMC/GCBB/NCDC: Submit M&E data through GH-developed tool.

2015

Interim Tasks

January-March

1. NCDC/JAMC/GCBB: Develop training program for other blood centers with timeline, intended to create donor recruitment and quality management departments on a national scale. Develop plan for hospitals to create blood transfusion committees.
2. JAMC/GCBB: Review and revise QIP based on annual progress, share with GH.
3. GH: Create educational materials, work aides for platelet use and emergent case management.
4. TSMU: In the format of cooperation with GH, review GH curriculum outline for platelet use and emergent case management and provide feedback to GH.

Training Trip #1

March

1. GH: Conduct parallel training with GCBB and JAMC of other blood center staff in quality management and donor recruitment. Continue training ASR staff on national blood service regulation. Present information about platelet use and emergent case management. Provide mechanism to monitor and evaluate platelet use and emergent blood needs. Stakeholder meeting regarding staff certification and continuing medical education.

Interim Tasks

April-May

1. NCDC: Conduct annual facility audit; share report with GH

June

1. NCDC: Coordinate blood drives and events related to World Blood Donor Day. Send report to GH.

July-Sept

1. NCDC/ MoLHSA: Identify program strengths and weaknesses for final joint evaluation.

Training Trip #2

October

1. GH: Continue training ASR staff on national blood service regulation. Continue training JAMC, GCBB on quality management. Establish hospital transfusion committee at NCDC-designated hospital. Transfer finalized medical curriculum to TSMU for institutionalization; guest lecture by GH physician at TSMU on platelet use and emergent case management. Stakeholders meeting on platelets, emergent cases, massive transfusions.

Interim Tasks

Nov-Dec

1. NCDC: VNRBD benchmark at 25% of national collections.
2. TSMU: Determine timeline and plan to integrate curriculum and educational materials on platelet use and emergent case management.
3. JAMC/GCBB/NCDC: Submit M&E data through GH-developed tool.

2016

Trip #1

February

1. GH: Competency and proficiency testing of trainees from JAMC, GCBB, NCDC, ASR.
2. JAMC/GCBB/NCDC/ASR: Feedback, final requests to Global Healing.
3. GH: Meeting with JAMC, GCBB, NCDC, MoLHSA, ASR about progress to date and path forward with formal report to follow.