Annex 2: CHAIN OF CUSTODY, RECEIPT AND RETURN OF SAMPLES, STATEMENT OF WORK, DELIVERABLES AND REPORTING

1. RECEIPT AND RETURN OF SAMPLES, CHAIN OF CUSTODY

(i) The ICRC will by email inform the Bidder about the need for the DNA profiling, specifying the number and type of biological samples to be profiled. The Bidder's ICRC services or evidence management section will work with the appropriate point of contact at the ICRC to efficiently organize the transfer of the samples from the ICRC to the Bidder using the appointed courier services. Parties will communicate the details of shipment at least 5 working days in advance.

(ii) Shipments of biological samples (BRS, exclusion and PM samples) will be delivered by the ICRC to the Bidder using the courier service, appointed by the ICRC. The return of remaining samples from the Bidder to the ICRC will also be arranged by the ICRC.

(iii) The Bidder will immediately notify the ICRC via email each time a shipment of samples under this Frame Agreement is received by the Bidder.

(iv) All biological samples provided by the ICRC will have a fully documented chain of custody record, so the integrity of the evidence can be maintained during the DNA profiling. The ICRC will include a signed chain of custody form in each shipment.

(v) The Bidder shall preserve the chain of custody form originally received from the ICRC, where the Bidder shall record the status of each sample received. The Bidder shall sign a chain of custody form indicating receipt when a shipment of samples arrives in the Bidder's laboratory, scan the form and send it back to the ICRC by email. Any damage to the shipping container that would compromise the integrity of the samples must be communicated to the ICRC by email immediately upon discovery.

(vi) The Bidder will follow strict chain of custody procedures for all the samples and at all times.

(vii) The Bidder will use a Laboratory Information Management System (LIMS) and/or hard copy form to develop and maintain the chain of custody as well as provide detailed sample tracking. The Bidder's LIMS will track and retain information for the following processes:

- Property evidence management,
- Laboratory processing,
- Reagent lot numbers and usage,
- DNA analysis.

(viii) The chain of custody documentation from the Bidder's LIMS and/or hardcopy form include:

- An electronic inventory for all samples received,
- Tracking/movement of samples for the DNA Profiling,
- Return of samples back to the ICRC.

(ix) The ICRC will send to the Bidder by email an electronic manifest document (Excel spread sheet), that will allow the Bidder to perform rapid and accurate inventory and accession of evidence while simultaneously reducing the possibility for transcription error in data entry. On the return of samples, the Bidder must return by the email the same Excel spread sheet with added status/condition of samples (e.g. remaining material returned (bone piece/bone powder, DNA extract) or sample used up).

(x) The codes on the samples will be compared to the manifest in real time to indicate a match or mismatch. After all specimens on a shipment are accessioned, the data will be used to create a discrepancy report and update the data in the Bidder's LIMS.

(xi) The Bidder's LIMS will provide an interface for users to obtain:

- Sample codes,
- Inventory of submitted items,
- Determine sample numbers,
- Produce tray assignments,

- Initiate sample tracking,
- Print out worksheets for Laboratory processing (DNA profiling).

(xii) Processing of PM samples in the laboratory will begin with a complete inventory of the submitted specimen. All PM samples must be photographed prior to the DNA profiling. The photo documentation and written descriptions of PM samples must be provided to the ICRC together with the result Report.

(xiii) The computer network locations used for the storage of sample information and data will be access controlled, permitting only to those individuals directly involved in the processing to view or modify the contents. Similarly, the Bidder's LIMS contains multiple user access levels further limiting certain capabilities to supervisors or managers.

(xiv) The final status of each sample received by the Bidder, must be clearly documented in the signed chain of custody form returned to the ICRC. The Bidder shall return to the ICRC all unused samples, as well as remaining material of processed samples (in case of PM samples also bone powder and dry DNA extracts) and shall so indicate it on the signed chain of custody form. If a sample was fully used by the Bidder, the signed chain of custody form returned to the ICRC shall indicate so. All original packaging including from fully used samples must be returned to the ICRC.

(xv) The ICRC will agree with the Bidder on a suitable date for the return of samples and arrange the return of remaining DNA material using the appointed courier service. Before the return of samples, the Bidder must send an email of notification (electronic manifest document) to the ICRC specifying which samples will be included in the shipment, as defined in the point (iv). The ICRC will review the electronic manifest document and inform by email the Bidder that the document has been reviewed and that the sample(s) can be prepared to return to the ICRC. A secured file transfer via ICRC FTP solution must be used to avoid transferring files and attachments through email.

(xvi) The remaining DNA extracts from BRS and Exclusion samples will be destroyed by the Bidder 12 months after the delivery of results or earlier if requested by the ICRC, and in accordance with Bidder's internal procedures and Article 8 of the Data Processing Frame Agreement in Annex 3. The Bidder will inform the ICRC of the destruction of BRS DNA extracts and share the inventory list of all destroyed material.

(xvii) The Bidder shall return to the ICRC all remaining samples (e.g. unused or partially used BRS, exclusion samples and PM samples (including bone/tooth powder and DNA extracts)) as stated in article 7. Term and termination of the Frame Agreement.

(xviii) Only after communicating in a written notice and receiving ICRC's approval, the Bidder will undertake all the final actions.

2. STATEMENT OF WORK

2.1. General Obligations

(i) After receiving the biological samples from the ICRC, the Bidder will proceed with a DNA profiling as per ICRC's request and instructions.

(ii) The Bidder must currently be accredited to ISO/IEC 17025 standard and all work taken must be under the umbrella of accredited processes, unless otherwise agreed to with the ICRC. Any change in the scope or status of accreditation will be communicated immediately with the ICRC. The Bidder undertakes regular proficiency tests, preferably at least 1 testing bone samples, and paternity type testing /reporting.

(iii) The Bidder will ensure that necessary quality control procedures are in place and implemented during the whole process of DNA profiling (i.e. positive and negative analysis controls, reagent blanks, staff elimination DNA profiles).

(iv) The Bidder must demonstrate that it has robust and validated techniques for DNA extraction from challenging PM samples. In parallel, similar methods should be demonstrated for the amplification, analysis and reporting of DNA profiles (e.g. low-level DNA samples or degraded DNA samples).

(v) The Bidder will provide for the ICRC all the SOPs and guidelines used in the workflow under which the ICRC's samples are processed. The ICRC must keep the SOPs and guidelines confidential and not copy, reproduce or distribute them.

(vi) The Bidder will conduct technical and administrative reviews of all data/results and documentation for each processed sample before delivering the results and reports to the ICRC.

(vii) The ICRC will not pay for the failures attributed to Bidder's errors or omissions at any step of DNA profiling (e.g. staff contamination, failed ladder or PCR positive control, etc.). Re-testing that occurs as a result of Bidder's mistake will be included in the initial price.

(viii) The Bidder shall not use samples, extractions, electropherograms as well as the genetic profiles obtained from samples provided by the ICRC, for scientific, commercial or purposes other than agreed under this contract and without the prior written consent of the ICRC.

(ix) The Bidder will store and eventually return the remaining and unused biological samples ensuring best practice to avoid contamination or damage to the sample.

2.2. Genetic Analysis

2.2.1. Sample Codes

The Sample code is unique sample identifier assigned by the ICRC to all samples delivered to the Bidder.

The Bidder shall respect and use at all times the ICRC's sample code and shall not modify it in any way (e.g. by adding suffix or prefix, sample or process description, etc.).

Both Parties can agree in written on the additional use of codes assigned by the Bidder (laboratory code), in cases where the sample code provided by ICRC proves incompatible with the Bidder's input system. In such cases, the Bidder will agree with the ICRC on a unique identification numbering (e.g. assigning laboratory code (number), starting with two-digit number specific for the ICRC, followed with the another two-digit number that would be context specific (ICRC Delegation) and the rest of the numbers could be uniquely assigned to each sample processed by the Bidder).

The Bidder could utilize laboratory codes for samples for internal tracking purposes and will ensure that each laboratory code is associated with one and only one sample code assigned by the ICRC.

All reported data will be associated with the ICRC's sample code. In cases where additionally the Bidder's laboratory codes were used, the Bidder shall always clearly and unequivocally specify both laboratory code and the corresponding ICRCs' sample code.

2.2.2. DNA Testing

A. As detailed in the request for DNA Profiling from the ICRC (e.g. specified ICRC Delegation), the Bidder shall conduct one or more the following DNA tests:

(i) Nuclear (STRs, Y-STRs) and mtDNA testing of PM (bone and/or tooth) samples taken from human remains;

(ii) Re-testing or additional testing of PM samples for nuclear DNA (STRs, Y-STRs);

(iii) Nuclear (STRs, Y-STRs) and, if necessary, mtDNA testing of BRS (Blood on FTA and Buccal cells on FTA/Filter Paper) from family members of the missing and Exclusion samples.

(iv) Re-testing or additional testing of BRS samples if necessary.

B. Re-testing requiring additional payment will be conducted only in written agreement with the ICRC. Re-testing of BRS and exclusion samples shall be discussed with the ICRC on a case by case bases. Re-testing of PM samples shall be discussed with the ICRC in all cases when reportable (see "STR analysis" below) or full DNA profiles are not obtained, and the Bidder reasonably believes, based on its vast experience with skeletal remains, that a partial or full profile is likely to be obtained if a different methodology is applied on the remaining portion of the same sample or on a new sample.

2.2.3. DNA Extraction and Quantification

(i) DNA from samples will be extracted and quantified according to the instructions in the Bidder's SOPs.

(ii) All PM DNA extracts regardless of quantification results must undergo at least one round of amplifications.

(iii) All quantification results must be submitted to the ICRC in the form of Excel report, containing all relevant information (e.g. inhibition, degradation).

(iv) If the PM sample is inhibited according to the quantification results, the Bidder must have the robust method for the removal of inhibitors.

2.2.4. STR and Y-STR DNA Profiling

PCR Amplification

DNA extracts will be PCR amplified according to the Bidder's SOP. Specific loci and kits to be used will be determined for each ICRC Delegation separately. All PM DNA extracts regardless of quantification results must undergo at least one round of amplifications.

BRS and exclusion samples will be amplified once using the STR kit requested by the ICRC.
PM samples will be amplified twice (single extraction and dual amplification strategy).

Capillary Electrophoresis
The products of PCR amplification will be run on AB 3500xl Genetic Analyzer. If another instrument will be used the Bidder must inform the ICRC prior to the sample testing.

Analysis and Interpretation of autosomal STR and Y-STR Genetic data
All raw data from fragment separation will be analyzed using GeneMapper ID-X software or similar software and interpreted independently by two DNA analysts. All the Bidder's DNA analysts must have extensive experience analyzing PM STR data using the appropriate software.

The Bidder will have SOPs, guidelines and protocols for the interpretation of STR data based on internal validations studies and will provide these to the ICRC. The Bidder will share the results of validation studies to the ICRC upon request.

2.2.5. STR DNA data analysis (Review and Technical Review)

(i) Two qualified DNA analysts will independently evaluate the results and interpret the DNA data and document all analyses and outcomes. For the BRS and exclusion samples this process involves the analysis by a qualified DNA analyst and a technical review conducted by a second qualified DNA analyst. For PM samples all data must be independently analyzed and interpreted by two DNA analyst.

(ii) The use of validated and NDIS approved expert automated systems rather than qualified analysts must be approved in writing by ICRC prior to implementation.

(iii) The STR-analysis of a BRS and exclusion samples shall not be considered as successful until genotypes for all tested STR loci are obtained. The Bidder is obliged to re-test samples (using new extraction or re-amplification, as appropriate) at least once to obtain full profile, included in the agreed price. If after testing two times, the sample fails to produce a full STR profile, the analysis will be considered complete.

(iv) The STR-analysis of a PM samples shall not be considered as successful until genotypes for at least 12 full STR loci have been generated and accepted by the ICRC, while a complete STR loci profile is preferred. The Bidder shall apply full consensus approach in interpretation of STR profiles obtained from PM samples.

In cases where PM samples yield 7 to 11 full STR loci, the Bidder shall re-test (re-amplify or re-extract) the sample, altering conditions within the boundaries of the Bidder's SOPs as necessary to achieve a reportable (≥12 loci) or complete profile. This re-testing will be included in the price. If re-testing does not result in successful DNA profile, the Bidder will deliver the result within the applicable DNA analysis report, and its compensation will not be affected as long as the Bidder has followed the procedures laid down in the Frame Agreement.

For samples that have 6 or less full reportable loci, the Bidder must inform the ICRC and agree in writing if the additional re-testing should be conducted or not. In such events, the Bidder will deliver the result within the applicable DNA analysis report, and its compensation will not be affected as long as the Bidder has followed the procedures laid down in this contract.

(v) In the case of massive contamination observed in the STR profiles of the PM sample, that cannot be sourced to laboratory handling, the Bidder will re-extract sample. If the contamination is reproducible, the ICRC will cover the costs of testing. If the contamination is not reproducible, the Bidder bears the cost of re-testing.

(vi) For all PM STR profiles, that do not show the evidence of contamination, the Bidder must report all observed alleles, regardless if the number of reported full loci is below 10. The ICRC will decide later how to proceed with such samples (e.g. send a new sample for DNA profiling or request additional testing with a different STR kit).

(vii) The Bidder must clearly label samples and clearly report results so that the ICRC can easily distinguish between re-injection, re-amplification and new extraction for the same sample.

(viii) The Bidder will ensure that each electropherogram (EPG) includes the allele calls and allele heights. In a case of the rare/microvariant allele, the Bidder must also deliver to the ICRC a pdf of enlarged locus with rare allele and relevant allelic ladder and related rare/microvariant allele calculation form.

2.2.6. MtDNA Profiling (if requested)

The ICRC will, in a written notice, request mtDNA analysis if needed. The Bidder will perform mtDNA profiling following its related SOPs and guidelines.

2.2.7. DNA profiling using MPS technology, Reporting and Kinship Analysis

The ICRC will, in a written notice, request MPS analysis if needed. The Bidder will perform MPS profiling and reporting following its related SOPs and guidelines.
The Bidder will provide kinship analysis Report for each case of tested reference and post-mortem samples.

3. DELIVERABLES AND REPORTING

The following shall be deliverables required under this Frame Agreement:

(i) After having concluded the profiling (including all re-testing) of the biological samples, the Bidder will deliver all results and documentation associated to each sample to the ICRC. In all cases where applicable the data (results and document) will be shared by using the ICRC's system for secure transfer of documents (e.g. Privateftp system)

(ii) The Bidder will for all samples tested provide the ICRC with all details related to the DNA profiling:
- complete inventory of the submitted specimen (including photo evidence for PM samples);
- Chain of Custody and all relevant information related to the processed samples from the Bidder's LIMS;
- All data related to the DNA profiling (DNA quantification results, raw genetic data (for tested samples, all relevant controls and ladders), PDF files of each obtained EPGs, STR profiles in Excel files, DNA analysis reports and Expert opinions).
- Analysis method, panels, bins and information on size standard used for DNA profiling;
- In case of mtDNA analysis, all data related to mtDNA profiling (DNA quantification results, raw genetic data, mtDNA analysis results and reports and Expert opinions)
- In case of DNA profiling using MPS, all relevant data related to MPS analysis.

(iii) Expert Opinion and DNA Report of the analysis including inspection and description of samples, processing details (including all information related to re-testing), DNA typing methods, type of

detection obtained results (detailed information including Quantification results and genotypes with laboratory and ICRC codes in digital format, genetic profiles in digital text or spreadsheet and preferably pdf format), Conclusion and Summary.

(iv) Upon receiving all required results and documentation associated to the DNA profiling, the ICRC has two months to review the data and confirm that no additional re-work is needed.

(v) The Bidder is responsible to deliver by postal service original and signed Invoices for all services.

(vi) The Bidder must send corresponding signed hardcopies of original Chain of Custody Forms by courier service together with any unused or partially used (remaining) biological samples originally sent by the ICRC.