Institute of Health Carlos III

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Spanish National Biobank Network

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SOP
Whole Blood

Blood Products Working Group

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Collection, Processing and Storage of Whole Blood Samples

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1 ABBREVIATIONS

- **EDTA:** Ethylenediaminetetraacetic acid. EDTA attracts calcium ions, thus blocking the coagulation cascade (dipotassium salt K2, or K3).
- **ACD:** Citric acid, citrate and dextrose in amounts of 0.9, 2, and 2 g, respectively, in 120 ml of distilled water. It is used to obtain plasma for coagulation and platelet function assays. It is used in collection and storage for transfusion since it preserves the blood longer, particularly the survival of erythrocytes: 21-32 days-70% survival. It changes the calcium concentration.
- **CPD:** Citrate - Phosphate -Dextrose.
- **CPD-A:** Citrate - Phosphate –Dextrose-Adenine

2 DEFINITIONS

- Anticoagulant: a substance that prevents blood clotting.
- Lipemia: presence of lipids (cholesterol, triglycerides and phospholipids) in the blood, which in normal conditions usually ranges from 400 to 700 mg per 100 ml of blood.
- Jaundice: too much bilirubin in the blood to be removed.

3 OBJECTIVE

The objective of this procedure is to define the course of action and to establish the basic quality guidelines with respect to collecting and handling and to the processing of whole blood samples that will be deposited in biobanks belonging to any center or hospital affiliated to the National Biobank Network.

4 SCOPE

This procedure applies to all whole blood samples that are extracted in order to be processed and stored in a biobank. This protocol does not detail the occupational health and safety processes regarding biohazardous materials and/or chemical products, and it is recommended that the personnel follow the Health and Safety rules established in each center.

5 MATERIALS AND SERVICES

- Courier Service holding a permit for the transport of biological materials:

Material	*UN Classification*		*Packing instructions*				*Comments*
	Class	*No.*	*ADR*	*RID*	*ICAO*	*IMDG*	
Infectious samples affecting humans	*6.2*	*2814*	*620*	*620*	*692*	*620*	*Materials groups 2, 3, 4*
Diagnostic specimens	*6.2*	*3373*	*650*	*650*	*650*	----	*Materials groups 1, 2, 3*

- For non-infectious samples: Bag or container for internal transport in the hospital.
- For infectious or hazardous samples: Transport container for dangerous substances that complies with the effective legislation: Royal Decree 664/97, following "Packing Instruction 620 (IATA - ICAO 602)"
- Syringes and/or material required for collecting blood.
- Blood collection tube for hemogram and/or hematology, with:
  - EDTA as anticoagulant (purple stopper). (In case determination of metals like lead, cadmium, zinc etc. is required, the tube with anticoagulant should be free of these metals, as well as all material that comes into contact with the blood)
  - Citrate as anticoagulant (yellow stopper)
  - Heparin as an anticoagulant (green stopper)
- Sterile Pasteur pipettes
- Blood collection tube racks
- Cryotube racks
- 1.5 - 2ml sterile cryotubes
- Markers and ballpoints
- Gloves to protect staff who are handling blood and/or biohazardous materials
- Filter paper
- Lab coat to protect against spills and spatters
- Sufficient and appropriate labels for collection tubes
- Label printer
- Cryo storage boxes
- Ultra-freezer -80ºC

6 DEVELOPMENT

6.1. COORDINATION FOR THE COLLECTION AND PROCESSING OF BLOOD SAMPLES

6.1.1. Blood must be collected after the patient has signed the informed consent for donating samples to the biobank. It is recommended that the time between blood collection and freezing at -80ºC be defined based on the type of studies for which the sample is intended; thus, based on preliminary tests, it has been determined that:

a) Optimum time for cell studies: maximum 1.5 hours after extraction; and

b) Optimum time for virological studies: maximum 24 hours after extraction.

6.1.2. Blood is collected via peripheral venipuncture. The people in charge of carrying out this procedure and of programming extractions must coordinate with biobank staff to ensure that the blood collection tubes with anticoagulants are properly identified and that a proper collection and reception of the sample is guaranteed.

6.1.3. It is advised to take the maximum possible information concerning the sample at the time of extraction:

- Date and time of withdrawal.
- Type of anticoagulant.
- Incidents not related to the protocol.

6.2. VERIFICATION AND IDENTIFICATION OF THE TUBES

6.2.1. Check patient information, while always maintaining privacy and ethics as guaranteed by Organic Law 15/1999, of December 13, on the Protection of Personal Data, and other relevant national laws applicable to this process, and ensure the correct relationship between the properly labeled blood collection tubes and patient information.

6.2.2. Label a blood collection tube containing anticoagulant to obtain whole blood aliquots. The type of anticoagulant used must be the most appropriate one for studies for which the sample is intended. Based on previous experience, the following is advised:

a) Cell proliferation studies - leukocytes: Heparin.

b) DNA extraction: EDTA.

c) Cryopreservation of red blood cells: ACD, CPD-A or CPD

6.3. COLLECTION OF WHOLE BLOOD

6.3.1. Immediately after extraction, gently invert the tube 5 times to mix the blood well with the corresponding anticoagulant.

6.3.2. Transport the blood to the laboratory for processing in a time not exceeding the maximum time after extraction of the sample defined for each study, while following the safety guidelines for the transport of biological material established by each center. The blood must be transferred to the biobank at room temperature, never cold.

6.3.3. In the biobank properly labeled and identified microtubes for storage of whole blood must be prepared. Depending on the age, incidents or the physical condition of the patient, the volume of blood that is received may vary even though withdrawals should approximate the following reference values to allow its processing and use:

AGE OF PATIENT	AVERAGE BLOOD VOLUME
0-2 YEARS	0.5 – 2 mL
3-5 YEARS	2.5 – 5 mL
6-11 YEARS	5-10 mL
> 12 YEARS	10-15 mL
> 18 YEARS	<25 mL

Table 1: Relationship age – extraction volume.

6.3.4. Carefully transfer at least 0.5ml of whole blood to the appropriately labeled and identified cryotube(s).

6.3.5. Next, place the microtubes in cryo storage boxes and store them in a -80ºC deep freezer.

6.3.6. Record the location of the stored sample in the corresponding software of each biobank.

6.4. MAINTAINING TRACEABILITY AND DATA ASSOCIATED TO THE SAMPLE

Biobanks advise to gather the maximum amount of information possible concerning the sample, both at the time of reception and after processing and storage, and depending on the studies for which they will be used, for example:

- Date and time of receipt and/or processing
- Degree of hemolysis
- Volume of blood received
- Degree of lipemia
- Degree of jaundice
- Degree of coagulation
- Incidents during processing

7 REFERENCE DOCUMENTATION

- Standard ISO 9001:2008. Quality management systems. Requirements.
- Standard ISO 6710 which establishes the color code for tubes according the anticoagulant used.

8 RELATED DOCUMENTATION

- Declaration of Helsinki. http://ohsr.od.nih.gov/helsinki http://www.wma.net/e/policy/b3.htm
- Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities

- Research Council of Canada, August 1998. http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm
- Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series. http://www.mrc.ac.uk/pdftissue_guide_fin.pdf

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