ANNEX 1.

IARC policy on access to human biological materials

A1.1 Definitions

1.1 The IARC Biobank (IBB): the IBB is a centralized biological resource storage facility for samples collected from studies conducted worldwide by IARC in collaboration with international partners (http://ibb.iarc.fr/).

1.2 The Laboratory Services and Biobank Group (LSB): LSB is responsible for the management of the IBB. The Group also provides services in pre-analytical sample processing and shipment.

1.3 Biological resources: include human tissues, cells, biological fluids/derived products, and associated sample quality data.

1.4 Sample collections: include biological resources based on common characteristics (e.g. sera from individuals from a population-based study; a clinical collection of breast cancer tissues).

1.5 Associated data: include anonymized data associated with biological samples, sample annotations, and data on sample quality.

1.6 Steering committee for multicentre studies: the steering committee has a coordinating role for a particular study, with responsibilities for coordinating research activities, including with regard to use of the study's biological resources.

1.7 IARC Principal Investigator (PI): the PI is the IARC scientist who is responsible for the sample collection at IARC.

1.8 IARC Custodian (CU): the CU is the IARC scientist to whom the responsibility for the sample collection was assigned after the departure of the original IARC PI.

1.9 Biobank Steering Committee (BSC): the BSC is the committee that oversees the biobanking activities at IARC.

1.10 Biobank Application sub-Committee (BAC): the BAC is the sub-Committee appointed by the BSC to assist in the handling of requests for human sample access.

1.11 IARC Ethics Committee (IEC): the role of the IEC is to provide ethical evaluation of all IARC projects within its competence (http://ethics.iarc.fr/).

1.12 Requestor: the requestor is a scientist affiliated with a public research institution or organization based in any country who is applying to access IARC sample collections for the purpose of research.
1.13 User: the user is a requestor who has received the necessary approvals to access IARC samples.
1.14 Material Transfer Agreement (MTA): the MTA is an agreement developed and signed between IARC and the host institute of the requestor, which governs the terms and conditions under which the parties will collaborate.
1.15 Study results: all laboratory results obtained from the use of IARC samples.

A1.2 Sample access: principles and policies

A1.2.1 Introduction

The IARC Biobank (IBB) comprises one of the largest and most varied collections of cancer-related samples in the world. The IBB is publicly funded by IARC Participating States and research grants and hosts more than 50 different studies, led or coordinated by IARC scientists.

Over the years, IARC has developed or coordinated a considerable number of large molecular epidemiological studies involving specimen collections. These studies are extremely diverse in their size, design, and governance and in the type of biomarker analyses involved. Study designs include case series, prevalence studies, case–control studies, and cohort studies. Most of the samples in the IBB are body fluids, including plasma, serum, and urine as well as extracted DNA samples.

A table of biospecimens stored at IARC is available on the IBB website (http://ibb.iarc.fr/docs/collection_table.pdf). The table provides details of sample origin, primary study design, key words describing the collection, and the name of the IARC PI/CU to contact for further information by potential requestors.

The IBB includes, as part of its governance structure, the Biobank Steering Committee (BSC) and the IARC Ethics Committee (IEC). The BSC oversees the IBB and provides advice to the Director in terms of the strategic development of IARC biobank activities. The IEC provides ethical guidance and evaluates all IARC projects within its competence.

A1.2.2 Guiding principles

The mission of IARC includes promoting cancer research internationally. As a publicly funded international organization with a mandate for collaborative research, IARC wishes to ensure that biospecimens stored within the Agency are being put to the best possible use. Within this context, the samples stored at IARC are available for research projects consistent with IARC's scientific goals and the IARC/WHO legal and ethical standard practices.

The principle of access means that samples and data entrusted to the Agency should be put to best possible scientific use taking into account the best interest of the participants and for public benefit. In particular, IARC PIs and CUs are encouraged to identify new potential uses and users of the resources and to make cancer researchers worldwide aware of these progressions in scientific research.

Access to and use of IBB biological samples are governed by the following principles:
- As an overarching principle, the biological samples stored under the Agency's custodianship in the IBB remain the property of the national collaborating centre as the original source, unless otherwise specified under a separate agreement. Consequently, access to IBB biological samples for third parties will only be granted by IARC after consultation and agreement with the relevant national centre and the IARC PI/CU as applicable.
- Applications by requestors for access to IARC's biological samples will be required to follow the sample request procedure described below.
- The confidentiality and data protection principles of IARC also apply to the IBB by maintaining participants' confidentiality and anonymity; the rights, privacy, and consent of participants must be protected and respected at all times.

- IBB biological samples will be made available for use in a timely and responsible manner taking into account the need to ensure data validity and sample integrity.
- IBB biological samples can only be used for research and non-profit purposes.
- All extensions to the use of human biological material beyond the aims and objectives for which samples were initially collected and provided, subject to the above-mentioned overarching principle, must also be approved by the IEC and be in line with the medium- and long-term objectives of IARC.
- To ensure ongoing enrichment of the IARC biological sample collections, users will be required to provide IARC with the results arising from specific analyses (including biological sample analysis, derived variables, etc.) carried out using the data and/or samples provided by the IBB, unless otherwise specified in a previous agreement.
- Management for access purposes will be cost-neutral to the IBB; requestors will contribute to the cost of sample retrieval, pre-analytical processing, and shipment according to standard costs published by the IBB.
- IARC reserves the right to refuse any request without a necessity to provide justification for decisions made, although appropriate feedback will normally be provided regarding a refusal for access.

A1.3 Limits on the use of IBB biological samples

IBB biological samples can only be used for research and non-profit purposes by investigators affiliated with public sector research organizations. Access may be denied for certain specific reasons, for example:
- The available sample volume is insufficient for delivery of samples without compromising the future scientific value of the collection.
- The project overlaps with ongoing or planned projects or analyses, leading to unnecessary duplication of work and a waste of materials and other resources.
- The scientific quality of the project is considered inadequate. Scientific quality and ability to administer the project will be more specifically considered by the IARC PI/CU and the IEC. The applicant will have to show evidence of expertise, resources, and financing for the successful completion of the project.
- There are ethical or legal issues with the proposal, including, for example, when the proposed use is not consistent with the specified purpose of the specimen collection in the original informed consent.
- The proposed project is in contradiction with IARC's mission and goals towards public health or against the above-mentioned guiding principles.

A1.4 Procedure for accessing IARC biological resources and monitoring

A1.4.1 Sample request procedure

Access to IARC biological samples is a six-step procedure, summarized in Fig. A1.1.

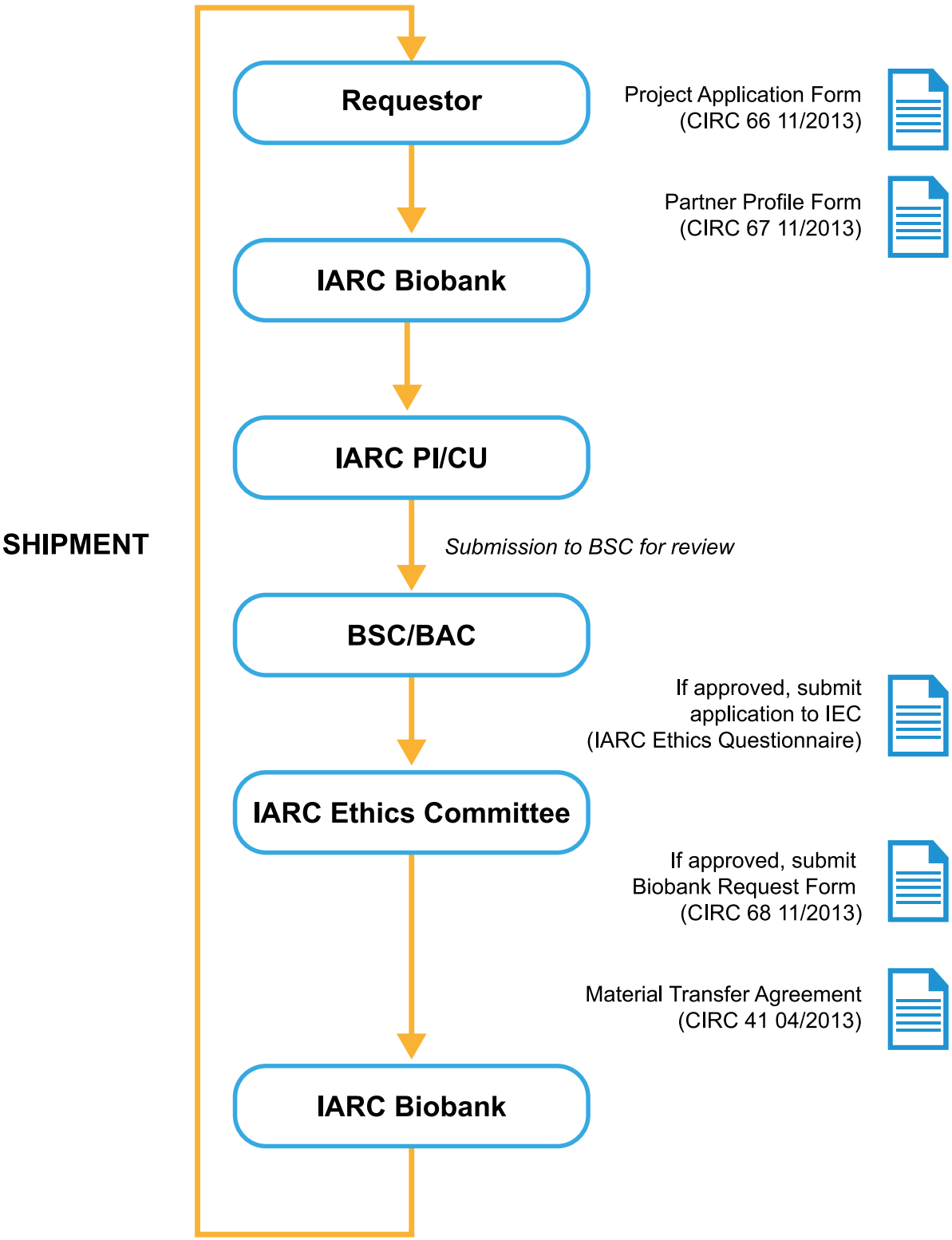
Step 1: Requests for accessing IARC biospecimens should be initially directed to the IARC Biobank (ibb@iarc.fr). The requestor will be required to complete a Project Application Form (CIRC 66 11/2013) and a Partner Profile Form (CIRC 67 11/2013) to provide information on project, requestor, and requesting institute.

Step 2: After review of the Project Application Form and Partner Profile Form, the IARC Biobank submits the request to the IARC PI/CU, to assist in the handling of the request.

Step 3: The IARC PI/CU will carry out an initial review of the request for recommendation to the BSC/BAC.
- In the case of multicentre studies with already defined procedures, the IARC PI/CU will contact the steering committee of the study, when there is one in place (e.g. the steering committee for the European Prospective Investigation into Cancer and Nutrition [EPIC] study). The relevant steering committee will review the request according to its established protocol and provide feedback through the IARC PI/CU.

Step 4: Once the request has been approved by the BSC/BAC, or the relevant steering committee when applicable, the requestor is informed. The IARC Ethics Questionnaire must then be submitted to the IEC for ethical approval.

Fig. A1.1. Sample request procedure. BAC, Biobank Application sub-Committee; BSC, Biobank Steering Committee; CU, IARC custodian; IEC, IARC Ethics Committee; PI, IARC principal investigator.



Step 5: Subject to ethical approval by the IEC, a Biobank Request Form (CIRC 68 11/2013) must be completed by the requestor and sent to the IARC Biobank, together with all required supporting documents; these will enable the IARC Biobank to prepare the requested samples and the related MTA (using form CIRC 41 04/2013).

Step 6: Upon receipt of the signed MTA and payment of relevant sample access charges, the IARC Biobank will proceed with shipment of the samples for the project.

A1.4.2 Monitoring and follow-up

In order for the IARC Biobank to monitor use of IARC biological resources, the requestor will be required to submit a Project Progress Report (using form CIRC 69 11/2013) on a 6-monthly basis after samples have been sent.

A1.5 Responsibilities of the requestor/requesting institution

In submitting requests to access IARC biological resources, requestors have the following responsibilities.

A1.5.1 Requesting and receiving

Requestors should:
- be affiliated to a recognized academic or other public research organization;
- follow the sample request procedure described above, and accept the provisions and general principles contained in the present policy;
- pay all sample access charges as invoiced by the IARC Biobank; and
- comply with any request to discard sample(s) if notified by IARC that subject(s) have withdrawn permission for the use of donated sample(s).

A1.5.2 During the study

Requestors should:
- accept and undertake research in the context of the ownership of samples and data as stipulated in the IARC MTA (CIRC 41 04/2013);
- provide plans for publication of the study results in peer-reviewed journals within 1 year of reception of the samples (or provide clear justification for the requirement of a longer period);
- report on progress made within the project (using form CIRC 69 11/2013), every 6 months until the study has been completed and remaining samples, if any, have been destroyed or returned to IARC (as is stipulated in the MTA); and
- ensure compliance with the terms and conditions of the MTA; users found to be in breach of the MTA will be denied future access to the IARC biological resources.

A1.5.3 At the end of the study

Requestors should:
- report on the outcome of the study upon completion, including publications (using form CIRC 69 11/2013);
- return any unused samples to IARC, unless otherwise stated in the MTA (CIRC 41 04/2013); and
- provide IARC with a copy of the results generated within the project through use of the IARC biological resources (raw data or other relevant format agreed upon with IARC) within 6 months of publication.

A1.6 Acknowledgement in publications

Full acknowledgement of the sources of all biological resources must be included in any publications that arise from access to and use of the IBB resources. All publications must include at a minimum the following acknowledgement: “The research was made possible using the data/samples provided by the IARC Biobank.” In addition, where applicable, the acknowledgements must refer to the original sample source centre as well as the source of funding. Specific authorship rules may apply in some instances; these will be agreed upon on a case-by-case basis.

A1.7 Reference documents

7.1 IARC Policy on Access to Human Biological Materials (IARC/Access Policy/Group-BSC/EN/11/2013): http://ibb.iarc.fr/docs/iarc-policy-access.pdf
7.2 Project Application Form (CIRC 66 11/2013): http://ibb.iarc.fr/docs/IBB_ProjectForm.dot
7.3 Partner Profile Form (CIRC 67 11/2013): http://ibb.iarc.fr/docs/IBB_PartnerForm.dot
7.4 IARC Ethics Questionnaire: http://ethics.iarc.fr/Submission/index.php
7.5 Biobank Request Form (CIRC 68 11/2013): http://ibb.iarc.fr/docs/IBB_RequestForm.dot
7.6 MTA Form (CIRC 41 04/2013): http://ibb.iarc.fr/access/index.php
7.7 Project Progress Report Form (CIRC 69 11/2013): http://ibb.iarc.fr/docs/IBB_ReportForm.dot