

# **The European Prospective Investigation into Cancer and Nutrition (EPIC-Europe) Study**

## **EPIC-EUROPE DATA AND BIOSPECIMEN ACCESS POLICY**

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## 1. Introduction

### 1.1. Historical background

The European Prospective Investigation into Cancer and Nutrition ("**EPIC-Europe**") study is a longitudinal cohort of approximately 520,000 individuals recruited from 23 centres across ten countries (Denmark, France, Germany, Greece, Italy, Norway, Spain, Sweden, The Netherlands, United Kingdom). The EPIC-Europe study was initiated in 1990 with the objective of understanding the causes of cancer with an emphasis on the role of diet and lifestyle. Initial participant recruitment occurred from 1992-1999 and follow-up of the participants is on-going. Blood specimens were obtained at recruitment from approximately 350,000 participants.

After more than fifteen years of follow-up, more than 65,000 EPIC-Europe Study Participants had been diagnosed with cancer, making EPIC-Europe one of the world's largest epidemiological investigations on the determinants of cancer. The cohort has since been expanded to studies on diabetes, cardiovascular disease, obesity, neurodegenerative diseases, and inflammatory bowel diseases.

As a publicly funded multi-centre study, EPIC-Europe has been hosted since its inception by the International Agency for Research on Cancer ("**IARC**"), the cancer research agency of the World Health Organization ("**WHO**"), located in Lyon, France.

### 1.2. Mission statement

The EPIC-Europe cohort constitutes an outstanding resource for research related to health and chronic diseases. The institutions that together established the EPIC-Europe study, wish to maximize the life-time value of the EPIC-Europe research assets and ensure that they are put to the best possible use for the benefit of public health.

The EPIC-Europe Resources are therefore made available to the international research community, with as few restrictions as possible, for investigators who seek to answer important questions on health and chronic diseases. Such research must be conducted in compliance with internationally recognized standards and applicable laws and regulations, and in a manner that is consistent with the legal and ethical frameworks of IARC/WHO and the EPIC Centres, as laid out in this Policy.

### 1.3. Purpose and scope of the Policy

This EPIC-Europe Data and Biospecimen Access Policy (the "**Policy**") provides guidance and detailed information on the governance and regulatory framework of the EPIC-Europe study, and the principles and procedures according to which access to EPIC-Europe Resources may be granted, in line with the mission stated above.

It may be amended or updated from time to time, and the latest version will always be made available on the EPIC-Europe website: <https://epic.iarc.fr/>.

## 2. Definitions

The capitalized terms and expressions used in the Policy are defined below or in other sections, and the meaning is the same whether used in singular or plural.

**EPIC-Europe Resources:** EPIC-Europe Biospecimens and EPIC-Europe Data, as defined hereafter.

**EPIC-Europe Study Participants (or “Study Participants”):** Individuals who were recruited at one of the EPIC Centres which together make up the EPIC-Europe study.

**EPIC-Europe Biospecimens:** The biospecimens collected by the local EPIC Centres from EPIC-Europe Study Participants which are stored in the EPIC-Europe biorepository at IARC. These include human tissues, cells, biological fluids/ derived products such as DNA, plasma and serum samples, and associated sample annotations and quality data. Such data may also qualify as Personal Data to the extent it may identify, either directly or indirectly, an EPIC-Europe Study Participant.

**EPIC-Europe Data:** The data available within the EPIC-Europe data repository held at IARC, and/or data generated from the use of EPIC-Europe Resources. These include the de-identified individual-level data collected from the Study Participants (“**Study Data**”); and the biological data or variables derived from the use of EPIC-Europe Biospecimens and/or baseline data, including all laboratory results such as, genotyping results, results of biochemical analysis etc. (“**Derived Data**”) all of which may qualify as Personal Data.

**Personal Data:** Any information relating to an identified or identifiable natural person (for the purpose of this Policy, “natural person” refers to a Study Participant); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

**Research Applicant:** A bona fide scientist, who is applying for access to EPIC-Europe Resources for the purpose of health-related research in the public interest.

**Approved Research Project:** A research project proposed by the Research Applicant for which approval of the EPIC SC, the IEC, as well as the relevant local ethic(s) committee(s), as may be required by the respective EPIC Centre(s), has been obtained.

**Approved Investigator:** A Research Applicant whose application has resulted in an Approved Research Project. For the purpose of this Policy, all obligations applying to the Approved Investigator shall also apply to “**Approved Users**” i.e., other personnel who also need access to the EPIC-Europe Resources, as the case may be, and who shall be under the direct supervision and responsibility of the Approved Investigator and his/her institution when handling EPIC-Europe Resources.

**Research Results:** All scientific results obtained from the use of EPIC-Europe Resources within an Approved Research Project.

**Agreement:** An agreement established between IARC and an Approved Investigator’s institution, to lay down the terms and conditions under which access is provided to EPIC-Europe Resources for the purpose of an Approved Research Project. For the purpose of this Policy, Agreement shall also be meant to include the existing bilateral Collaborative Research Agreements (“**CRA**”) between IARC and the respective EPIC Centres.

**Policy:** The current EPIC-Europe Data and Biospecimen Access Policy, including other EPIC-Europe operating procedures and documents referenced herein.

### 3. Governance of the EPIC-Europe Study

#### 3.1. EPIC Centres and EPIC Principal Investigators (PIs)

The Study Participants which together make up the EPIC-Europe study, were recruited by

23 academic/ research institutions (the “EPIC Centres”) across 10 European countries: Denmark (Copenhagen, Aarhus), France (Paris), Germany (Heidelberg, Potsdam), Greece<sup>1</sup> (Athens), Italy (Turin, Varese, Florence, Naples and Ragusa), Norway (Tromsø), Spain (Asturias, San Sebastian, Murcia, Navarra, Granada, Barcelona), Sweden (Malmö, Umeå), The Netherlands (Bilthoven, Utrecht) and The United Kingdom (Cambridge, Oxford). The continued participation of the EPIC Centres and collaboration within the EPIC-Europe study is regulated by a series of bilateral Collaborative Research Agreements (CRA) established between IARC and all EPIC Centres. Additional legal instruments governing the transfer of EPIC-Europe Data to IARC will be established, where required by the respective EPIC Centres.

The EPIC Centres retain ownership of the EPIC-Europe Resources and decisions on access to their respective EPIC-Europe Resources remain at their discretion.

Each EPIC Centre is represented scientifically within EPIC-Europe by one or two Principal Investigator(s) (the “**EPIC PI(s)**”) who are affiliated to the respective EPIC Centres.

A list of the EPIC Centres and EPIC Principal Investigators can be found on the EPIC-Europe website.

### **3.2. EPIC-Europe Steering Committee**

The EPIC-Europe Steering Committee (the “**EPIC SC**”) is the governing and decision-making body of the EPIC-Europe study. It is composed of all the EPIC PIs, including a chair nominated by the EPIC SC. All decisions are normally taken by consensus. In exceptional cases of a decision requiring a vote, this is decided upon by a quorum of two representatives from IARC and two representatives from each participating country; such decision submitted to a vote requires a two-thirds majority.

The EPIC SC meets on a monthly basis by teleconference, and once a year via an in-person meeting. Discussions and decisions are recorded in the EPIC SC minutes, including approval of research projects and the use of EPIC-Europe Resources.

Scientific research conducted within EPIC-Europe is coordinated within working groups (the “**EPIC-Europe Working Group(s)**” or “**Working Group(s)**”) that represent major areas of research activity. New research proposals are first discussed within the relevant Working Group(s), and following input from the Working Group members, proposals are then reviewed by the EPIC SC.

### **3.3. IARC Ethics Committee**

The IARC Ethics Committee (the “**IEC**”) is composed mainly of external independent members with diverse expertise and backgrounds, and a representation from both IARC and WHO. The current IEC composition and mandate, as well as information on submission procedure, reference guidelines and useful resources are available on the IEC website: <https://ethics.iarc.fr/>.

All EPIC research proposals are reviewed and approved by the IEC. In addition, the IEC undertakes a review of the EPIC-Europe cohort every 5 years.

### **3.4. IARC: Coordinator, host, and custodian of EPIC Resources**

The International Agency for Research on Cancer (IARC) is the cancer research agency of the World Health Organization (WHO), a Specialized Agency of the United Nations, headquartered

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<sup>1</sup> EPIC Resources originating from Greece are currently not available for access.

in Lyon, France. As an intergovernmental institution/organization of the UN System, IARC operates within a particular legal and regulatory framework, under the general principles of public international law and the applicable international treaties and conventions. In order to ensure the independent exercise of its functions and fulfilment of its public health mandate, it enjoys privileges and immunities under international law, and is subject to IARC/WHO's rules, regulations and policies, as adopted by its governing bodies.

Accordingly, it has the obligation to ensure the highest ethical and professional standards are adhered to in any research activities it engages into. This includes, without being limited to, matters related to research with human biological material, and data protection and privacy related matters. For such matters, in addition to its governing bodies and the IARC/WHO regulatory framework, IARC seeks guidance from the IEC (see 3.3) and the IARC Data Protection Officer ("**DPO**") as appropriate (see 4.2).

IARC serves as coordinator of the EPIC-Europe study and acts as the host and custodian of the majority of the EPIC-Europe Resources –with the exception of the EPIC-Europe Biospecimens from Sweden and Denmark. IARC is represented within the EPIC SC by two EPIC PIs who are supported by other IARC scientists actively involved in the EPIC-Europe study, and a data manager. In addition, Imperial College London supports coordination activities.

### **3.5. IARC Biobank**

The IARC Biobank ("**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/>). It also provides support for pre-analytical sample processing and shipment. The EPIC-Europe Biospecimens are stored in the IBB.

## **4. General principles governing access to EPIC-Europe Resources**

### **4.1. Pre-conditions for access**

#### *Research Applicants*

A Research Applicant must:

- have relevant experience and expertise;
- be capable of leading or participating in state-of-the-art, professional and ethical research;
- be affiliated to a public/ non-profit research and/or academic institution, with adequate resources, and the infrastructure required to conduct the proposed research and to ensure that the EPIC Resources will be stored, used and processed securely and in accordance with applicable legal and regulatory requirements.

#### *Research purpose*

EPIC-Europe Resources have been entrusted by the EPIC Centres to IARC, as custodian, for the purpose of non-commercial research exclusively related to health and chronic diseases. In line therewith, the research proposed by the Research Applicant is expected to be driven by a general interest objective, with an intention to disseminate Research Results through peer-reviewed publications and to share any Derived Data to the wider scientific community for future research.

#### *Contact with EPIC-Europe Working Group(s)*

Research Applicants who wish to access EPIC-Europe Resources are encouraged to liaise with the chair of the relevant EPIC-Europe Working Group. The Research Applicant can consult the

EPIC-Europe website to identify the relevant EPIC-Europe Working Group for guidance in preparing their research application.

#### *Compliance with EPIC-Europe Access Policy*

It is the Research Applicants' responsibility to ensure that they have read and understood the Policy and that they, as well as their institution and other potential Approved Users under their direct supervision and responsibility who may need access to EPIC-Europe Resources, as applicable, will be able to fully comply with the Policy. To this effect, Research Applicants should liaise with their institution's administration at the earliest stage to avoid potential complications or issues arising down the line.

## **4.2. Ethical principles and data protection regulations**

### *Ethical principles*

As a general principle, any research to be performed with the use of/access to EPIC-Europe Resources must comply with internationally recognized ethical standards and must be ethically and scientifically reviewed and approved by an appropriate independent board or committee.

All EPIC-Europe projects require approval by the IEC. In addition, approval by the relevant EPIC Centre's local ethics committee may be required in some cases, in which case responsibility lies with the associated local EPIC PI(s).

The Approved Investigator and their institution remain responsible for ensuring that they comply with applicable ethical guidelines, or other regulatory requirements that may apply to their research and use of the EPIC-Europe Resources.

### *Data protection and privacy principles*

As an overarching principle, EPIC-Europe Resources remain the property of the respective EPIC Centres as the originating source and are entrusted to IARC as custodian. EPIC-Europe Data held at IARC are de-identified, the individual identifiers being kept solely by the respective local EPIC Centres.

IARC, as EPIC-Europe Data custodian, in collaboration and close consultation with relevant bodies such as the EPIC SC, the IEC, and/or the IARC DPO:

- assesses the compliance of EPIC-Europe Data storage, use, processing and/or transfer, with the applicable data governance framework; and
- determines the means and purposes of the data processing in compliance with applicable policies and regulations.

In connection therewith, IARC ensures that Personal Data:

- is processed fairly, for legitimate purposes and in a transparent manner in relation to the Study Participants;
- has been collected by the EPIC Centres for specified, explicit and legitimate purposes and will not be further processed in a manner that is incompatible with those purposes;
- is adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed;
- is kept accurate and, where applicable, up to date; and
- is stored and processed in a manner that ensures appropriate security of the Personal Data.

Further restrictions may be imposed based on specific regulatory requirements applicable to the EPIC Centre that has provided the Study Data to IARC.

Approved Investigators and their respective institutions are expected to adhere to the highest standards of data protection, confidentiality, and privacy principles, regardless of whether EPIC-Europe Data are accessed remotely, physically transferred, or derived from EPIC-Europe Biospecimens. This also implies protecting and respecting the Study Participants' anonymity and consent at all times. Under no circumstances may Approved Investigators reverse-engineer Personal Data or attempt in any way to identify Study Participants.

IARC also acknowledges that Approved Investigators and their respective institutions remain subject to national data protection legislation, including where applicable the General Data Protection Regulation of the European Union ("**GDPR**") or other similar data protection regulations.

For the avoidance of doubt, by virtue of their privileges and immunities under national and international law, WHO and IARC are not subject to EU (incl. the GDPR) and/or any national data protection legislation. Notwithstanding the foregoing, ensuring the appropriate protection of Personal Data is of the utmost importance to WHO and IARC. To this effect, IARC complies with the "Personal Data Protection and Privacy Principles for UN System Organizations", UN-HCLM 2018 (the "[UN Principles](#)"), the WHO regulatory framework and more specifically, the [IARC Data Protection Policy](#). The aforementioned UN Principles and policies are in line with internationally recognized standards.

The IARC DPO is available to provide advice and guidance to IARC, the EPIC SC and EPIC Centres, as well as the EPIC Approved Investigators and Approved Users. The IARC DPO is also available as a contact point for Study Participants. Contact details are available on the EPIC-Europe website.

#### **4.3. Remote access to EPIC-Europe Data**

IARC has established a high performance and highly secured platform (the "**Scientific IT Platform**") to serve as centralized repository for all EPIC-Europe Data. The Scientific IT Platform is governed under clearly defined procedures to ensure adequate controls and the highest level of protection and security of the data hosted therein, in accordance with the WHO regulatory framework and IARC policies.

By providing remote access to de-identified data via the Scientific IT Platform, IARC aims to address data protection and privacy concerns, and to avoid physical transfer of EPIC-Europe Data. Accordingly, where the Research Applicant requests access to EPIC-Europe Data for the purpose of the proposed research project, access will be granted remotely via the Scientific IT Platform. Access remains subject to the research project being approved beforehand by the EPIC SC, and the relevant bilateral Agreement being signed between IARC and the Approved Investigator/Approved Investigator's institution governing access to the EPIC-Europe Data via the Scientific IT Platform.

Physical transfer of EPIC-Europe Data will only be considered on an exceptional basis. In such case the Research Applicant must justify the need for physical transfer of the requested EPIC-Europe Data, and clearly demonstrate that the research goal cannot be achieved by accessing/analyzing the EPIC-Europe Data remotely via the Scientific IT Platform. In case of a physical transfer of EPIC-Europe Data, IARC will ensure contractually that the data recipient will adhere to the data protection and privacy principles as described in section 4.2 as a minimum standard. The relevant EPIC Centre(s) may also add further restrictions in such cases.

## 5. Approval of research applications

All proposed research projects within EPIC-Europe requiring access to EPIC-Europe Resources are subject to prior review and approval by the EPIC SC and the IEC, as well as the relevant local ethics committee(s) as may be required by the respective EPIC Centre(s).

All relevant EPIC forms, operating procedures and other documents are available on the EPIC-Europe website.

### 5.1. Review and approval of research applications

A Research Applicant complying with the pre-conditions mentioned in clause 4.1 must complete a **Project Application Form (“PF1”)** for review by the EPIC SC.

#### *Review and approval by the EPIC SC*

Depending on the nature of the proposed project, the research application may be subject to different levels of review by the EPIC SC. Research applications requesting access to existing EPIC-Europe Data will likely undergo an expedited review. Research applications requesting access to EPIC-Europe Biospecimens will undergo a more detailed review.

The EPIC SC will in any case take the following into consideration when reviewing a research application:

- The scientific excellence of the proposal;
- The strategic priority of the proposal, with respect to ongoing studies in the specific research area within EPIC-Europe, avoiding unnecessary duplication of work;
- The research strength of the Research Applicant and their group submitting the research proposal, including scientific quality and ability to administer the project – the Research Applicant will have to show evidence of relevant expertise, available resources and financing for the successful completion of the project;
- Compliance of the proposed study and Research Applicant with EPIC-Europe’s overall and local ethics and data protection governance;
- The availability of EPIC-Europe Biospecimens, if these are requested, and whether they are essential for the proposed project;
- Where applicable, whether the research goal can be achieved via remote access to the EPIC-Europe Data using the Scientific IT Platform, as the prioritized mechanism for data access; or
- If a physical transfer of EPIC-Europe Data is requested, whether this is duly justified and could be considered on an exceptional basis.

As a general principle, the EPIC SC and the EPIC Centres reserve the right to reject a research application and appropriate feedback will normally be provided in such cases. The respective EPIC Centres have the ultimate authority over the provision and/or use of EPIC-Europe Resources originating from their local EPIC sub-cohorts and may individually refuse the use of their Study Data and/or EPIC-Europe Biospecimens for specific research projects.

Note: EPIC-Europe specific instruments (e.g., EPIC-Europe Questionnaires etc.) are open access and can be obtained by contacting [epic@iarc.who.int](mailto:epic@iarc.who.int). With respect to national instruments (e.g., local questionnaires etc.), written permission is required from the respective EPIC Centre(s).

### *Review and approval by the IEC*

Once the research application has been approved by the EPIC SC, the research application must be reviewed by the IEC for ethical approval. The IEC website provides all the required information for submission, including relevant dates.

## **6. Access to and use of EPIC-Europe Resources for Approved Research Projects**

### **6.1. Obtaining access to EPIC-Europe Biospecimens**

An Approved Investigator requiring access to EPIC-Europe Biospecimens for the purpose of an Approved Research Project must submit a request to the IARC Biobank (as per applicable procedure).

The IARC Biobank reviews the request, and coordinates preparation of the requested EPIC-Europe Biospecimens, the costing as per the IBB standard costs, and the relevant documentation including the associated Agreement.

Upon receipt of the fully-signed Agreement, the IARC Biobank proceeds with shipment of the requested materials.

Additional terms and conditions may have to be included in the Agreement, or an additional Agreement may be required to cover data-related aspects, i.e., if the EPIC-Europe Biospecimens are accompanied with associated data that qualify as Personal Data; or if the Derived Data expected to be generated from the use of the provided EPIC-Europe Biospecimens qualify as Personal Data under applicable data protection regulations.

Investigators requesting access to EPIC-Europe Biospecimens will contribute to the cost of data and sample retrieval, preparation and shipment according to standard costs published by the IBB ([http://ibb.iarc.fr/docs/LSB\\_price\\_list.pdf](http://ibb.iarc.fr/docs/LSB_price_list.pdf)).

### **6.2. Obtaining access to EPIC-Europe Data**

#### *Remote access*

An Approved Investigator requiring access to EPIC-Europe Data must prepare a request, in consultation with the relevant EPIC-Europe contact (e.g., EPIC-Europe Working Group chair or EPIC-Europe PI) to be submitted to the EPIC-Europe data manager at IARC. Access will be granted remotely via the IARC Scientific IT Platform (see 4.3), for the purpose of the Approved Research Project exclusively.

The EPIC-Europe data manager reviews the request, and coordinates preparation of the requested datasets on the Scientific IT Platform, as well as the relevant documentation including the associated Agreement.

Upon receipt of the fully signed Agreement, detailed instructions are provided to the Approved Investigator and Approved User(s), as applicable, regarding access to the Scientific IT Platform. These instructions include access credentials that are unique to the Approved Investigator/User; access credentials must be kept confidential and should not be shared with another person under any circumstances.

### *Physical data transfer*

If remote access to the requested EPIC-Europe Data is not adequate for the specific purpose of the Approved Research Project, for example for consortium-based projects that require pooling of datasets, and the EPIC-Europe SC has exceptionally granted approval for physical data transfer, the same procedure as above applies.

The EPIC-Europe data manager reviews the request, and coordinates preparation of the requested datasets, the relevant documentation and Agreement, as well as the technical details to ensure fully secured data transfer. Upon receipt of the fully signed Agreement, the requested EPIC-Europe Data are transferred to the Approved Investigator for the purpose of the Approved Research Project exclusively.

### *Data access fees*

IARC reserves the right to charge data access fees to Approved Investigators and Approved Users who have been granted access to EPIC-Europe Data.

## **6.3. Use of EPIC-Europe Resources during performance of the Approved Research Project**

EPIC-Europe Resources are made available for use in a timely and responsible manner, taking into account the need to ensure data validity and sample integrity.

Throughout the Approved Research Project, it is essential for the Approved Investigator to keep the EPIC SC and the relevant EPIC Centre(s) informed and actively involved. This will provide an important knowledge base when analyzing and interpreting EPIC-Europe Data, as well as ensure that the interests of the EPIC-Europe study as a whole are considered and preserved.

During performance of the Approved Research Project, the Approved Investigator must:

- Undertake research in accordance with permitted use and applicable ownership rights;
- Provide plans for publication of the Research Results in peer-reviewed journals within two years of receipt of, or access to, the EPIC-Europe Resources; or otherwise provide clear justifications for the requirement of a longer period;
- Report on progress made within the project on a yearly basis, until completion of the project and until remaining EPIC-Europe Resources have been returned back to IARC, destroyed or otherwise (as stipulated in the Agreement);
- Ensure compliance with this Policy and the terms and conditions of the executed Agreement(s) and applicable laws and regulations. Approved Investigators/Users found to be in breach of the Agreement(s) will be denied future access to EPIC-Europe Resources.

Any extension of the approved access to/use of EPIC-Europe Resources beyond the aims and objectives of the Approved Research Project for which they were initially granted or provided must be approved by the EPIC SC and the IEC, as well as the respective EPIC Centre(s) and the local ethic(s) committee(s) as may be required. In case such extension implies a modification of the purpose of the processing of Personal Data, such modification requires prior approval from IARC as the EPIC-Europe Data custodian, who may seek additional approval from the EPIC SC. For this purpose, the Approved Investigator must submit an amendment to its original PF1, and an amendment to the Agreement may also need to be executed.

## **6.4. Completion of the research project**

Upon completion of the Approved Research Project, the Approved Investigator must:

- Report on the outcome of the project, including submitted publications;

- Return to IARC, or destroy, any unused EPIC-Europe Biospecimens, as stated in the applicable Agreement and in accordance with instructions from IARC, unless otherwise agreed upon;
- Return to IARC, or destroy, any transferred EPIC-Europe Data, as stated in the applicable Agreement and in accordance with instructions from IARC, unless otherwise agreed upon;
- Cease all access to the EPIC-Europe Data through the Scientific IT Platform;
- Provide IARC and the EPIC SC with a copy of any Derived Data that have been generated within the project through use of the EPIC-Europe Resources (e.g., results of biochemical analyses or genotyping), in raw data or other relevant format as agreed upon with the EPIC SC, within two years of receiving or accessing the EPIC-Europe Resources to ensure the ongoing enrichment of the EPIC-Europe cohort;
- To the extent such Derived Data qualify as Personal Data under applicable data protection regulations, notify IARC and the EPIC SC at the earliest stage;
- If requested, provide IARC and the EPIC SC with a report on compliance with applicable data protection regulations, in particular where the research is deemed to give rise to additional risks to the rights and freedom of Study Participants (e.g., due to an increased risk of re-identification or the use of genomic data).

## 7. Publication of Research Results and intellectual property rights

### 7.1. Publication

As a general and prevailing principle, the Approved Investigator is expected to disseminate the Research Results to the public through appropriate means, including via peer-reviewed scientific publications. To this end, the Research Results should be submitted for peer-reviewed publication in a timely manner, i.e., as a standard rule within two years after accessing or receiving the EPIC-Europe Resources, or as otherwise agreed upon with the EPIC SC.

Any research conducted by an Approved Investigator using EPIC-Europe Resources is by definition conducted in collaboration with the EPIC SC and the EPIC Centres as the originating sources. Accordingly, any publication arising from the use of EPIC-Europe Resources must acknowledge the EPIC SC and EPIC Centres and comply with the **Publication Guidelines for EPIC-Europe related studies** (the “*EPIC-Europe Publication Guidelines*”).

In addition, the Approved Investigator must acknowledge the contribution of the IBB where applicable, by including at the minimum the following acknowledgment: “*the research was made possible using the data/samples provided by the IARC Biobank*”.

### 7.2. Use of Research Results and intellectual property

The overall ownership of and responsibility for the EPIC-Europe Resources, including Derived Data to the extent such data fall under property rights, remain with the respective originating EPIC Centres with general custody being entrusted to IARC. As EPIC-Europe coordinator and custodian, IARC does not have the authority to share or provide access to EPIC-Europe Resources for purposes other than **non-commercial, research and academic purposes**, in accordance with the EPIC-Europe mission and general principles (see 1.2 and 4.1), and as approved by the EPIC SC.

In line with the above, the EPIC-Europe Resources should not be used for gain or commercial profit or benefit, nor for or in connection with the filing of patents or similar intellectual property protection. Likewise, the Approved Investigator should not seek to obtain any such intellectual property protection in respect of any Derived Data arising from the use of EPIC-Europe Resources.

Approved Investigators who have generated data by using EPIC-Europe Resources retain the exclusive right for up to two years after EPIC SC approval to disseminate their Research Results based on those data. Such exclusivity does not and should not alter or affect in any way the Approved Investigator's obligations under the Policy and the terms and conditions of the executed Agreement(s), including with regard to applicable data protection regulations. Any additional research conducted on those generated data by other investigators is subject to (i) compliance with the above-mentioned authorized purposes, and the general principles of the Policy; (ii) approval of, and an established collaboration with, the Approved Investigator; (iii) the EPIC SC being informed via appropriate means; and (iv) research being conducted within two years of EPIC SC approval.

Exceptionally, where further development and exploitation of the Research Results are judged essential or potentially highly beneficial for public health purposes, IARC as the custodian of EPIC-Europe Resources should be contacted beforehand. As a general and fundamental principle, it would have to be clearly demonstrated that such outputs will be developed in a manner that will best deliver health patient benefit and wider public good; and will not be exploited in a manner that is divergent or contrary to that goal. Should the case arise, any industrial or commercial exploitation of Research Results would remain subject to prior approval of IARC, the EPIC SC and the EPIC Centres, and a separate agreement to be established and negotiated in good faith between the parties concerned.