

The European Prospective Investigation into Cancer and Nutrition (EPIC) study

The EPIC Access Policy

Mission statement

The EPIC collection of data and biological samples constitute an outstanding resource for medical research on chronic diseases. As a publicly funded multi-centre study, EPIC wishes to ensure that those resources are being put to the best possible use. The EPIC data and biospecimen are therefore available for investigators who seek to answer important questions on health and disease in the context of research projects that are consistent with the legal and ethical standard practices of IARC/WHO and the EPIC Centres (ECs).

The EPIC study is governed by the EPIC Steering Committee (EPIC SC) and the IARC Ethics Committee (IEC), as well as the institutional review boards of the ECs. The IARC acts as custodian for the EPIC database and the majority of biospecimen (hosted by the IARC Biobank, IBB), whereas biospecimen from the Swedish and Danish centres are stored nationally. A detailed description of EPIC resources is provided on the EPIC website (url: <http://epictest.iarc.fr/about/about.php>). Further details on procedures and principles for accessing EPIC resources are available in this document.

Definitions

1. EPIC Centre (EC): the original recruitment of study participants to the EPIC cohort was conducted by 23 ECs from 10 European countries. The ECs remain the owner of all data, biospecimen, as well as any derived data related to their recruited study participants.
2. EPIC Steering Committee (EPIC SC): the EPIC study is governed by the EPIC SC with representation from IARC, Imperial College, and the ECs, with a specific responsibility of coordinating research activities and the use of EPIC resources.
3. The IARC Biobank (IBB): the IBB is a centralized biological resource storage facility that harbours the majority of EPIC biospecimen collected by the EPIC Centres (<http://ibb.iarc.fr/>).
4. 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.
5. Biospecimen: include human tissues, cells, biological fluids/derived products and associated sample quality data. This includes DNA, plasma and serum samples from the EPIC biorepository.
6. Associated data: include anonymized data associated with biological samples, sample annotations, and data on sample quality.
7. IARC Ethics Committee (IEC): the role of the IEC is to provide ethical evaluation of all EPIC projects within its competence (<http://ethics.iarc.fr/>).

8. Investigator: the investigator is a scientist affiliated with a public research institution/organization based in any country who is applying to access EPIC data and/or biospecimen for the purpose of research.
9. User: the user is an investigator that has received the necessary approvals to access EPIC data and/or biospecimen.
10. Material Transfer Agreement (MTA): the MTA is an agreement developed and signed between IARC and the host institute of the user, which governs the terms and conditions under which biospecimen and data are transferred and used, as well as how the parties will collaborate.
11. Data Transfer Agreement (DTA): the DTA is an agreement developed and signed between IARC and the host institute of the user, which governs the terms and conditions under which data are transferred and used, as well as how the parties will collaborate.
12. Derived data: any data arising from the use of EPIC data and/or biospecimen, including all laboratory results such as genotyping results, results of biochemical analysis, or variables derived from EPIC baseline data or follow-up information.
13. Study results: all scientific results obtained from the use of EPIC data and/or biospecimen.

Principles applied to access EPIC data and/or biospecimen

Investigators affiliated with *bona fide* research organisations who seek to answer important research questions related to health and disease can request access to the EPIC infrastructure of data and/or biospecimen.

Specific EPIC principles

Research on EPIC data and/or biospecimen is conducted according to the following principles:

- EPIC data and biospecimen can only be used for research purposes;
- As an overarching principle, the EPIC data and biospecimen remain the property of the ECs as the originating source. Consequently, access to EPIC data and biospecimen will only be granted after consultation and agreement with the EPIC SC and the IEC, as well as with the ECs (local EPIC study PIs), and their ethics committees as required;
- All extensions to the use of EPIC data and biospecimen beyond the aims and objectives for which they were initially provided must also be approved by the EPIC SC and the IEC, as well as by the ECs (local EPIC study PIs), and their ethics committees as required;
- Any derived data resulting from the use of EPIC data and/or biospecimen (e.g. results of biochemical analysis or genotyping) remain the property of the ECs. As such, and to ensure the on-going enrichment of the EPIC cohort, users may be required to provide EPIC/IARC with all derived data;
- Users who have generated data by the use of EPIC biospecimen (e.g. results of biochemical analysis or genotyping) retain the exclusive right for up to 2 years

after EPIC SC approval to disseminate results based on those data. Any additional research conducted on those data by other investigators within 2 years of EPIC SC approval should be conducted with the approval of the users, and in collaboration with the users.

- The research should be submitted for peer-reviewed publication in timely manner, as a rule within two years after receiving the data and/ or biospecimen, or as agreed upon with EPIC SC;
- Any research conducted by a user using EPIC data and/or biospecimen is by definition conducted in collaboration with the EPIC SC and ECs as the originating source. As such, any publication arising from the use of EPIC data and/or biospecimen must acknowledge the EPIC SC and ECs according to the EPIC authorship guidelines (see *link to authorship guidelines on website*);
- The confidentiality and data protection principles of IARC apply to any research project where EPIC data and/or biospecimen are being used. This implies protecting the EPIC study participants' confidentiality, anonymity and consent at all times;
- Management for access purposes will be cost neutral to IARC and the ECs; requestors 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);

Access limitations

Access to EPIC data and/or biospecimen may be denied for several reasons, for example:

- Without compromising the future scientific value of the EPIC biospecimen collection, the requested samples volume is too large in the context of the specific research project, or the available sample volume is insufficient for delivery of samples;
- The project overlaps with ongoing or planned projects/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 specifically considered by the EPIC SC. 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 EPIC's mission and goals towards public health or not in compliance with the above guiding principles. EPIC is committed to respecting and protecting the rights, privacy and consent of its

research participants at all times. Access is therefore intended only for scientific investigators pursuing research questions that are consistent with the informed consent agreements provided by individual research participants.

- The EPIC SC and ECs reserve 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. Individual ECs have the ultimate authority over the data and biological specimens originating from their local EPIC sub-cohorts, and may individually refuse the use of their data or samples for specific research projects.
- Regarding use of EPIC instruments (e.g. questionnaires etc.), permission should be granted by the EPIC SC. With respect to national instruments (e.g. local questionnaires etc.), written permission is required from the respective EC.

Compliance of proposed studies with EPIC informed consent and ethical regulations will be reviewed by the EPIC SC and the IEC.

How to submit an application for gaining access to EPIC data and/or biospecimen?

The investigator is required to submit a Project application form (PF1 Form, *link to the Form on the Website*) for review by the EPIC SC. In the case of projects on type 2 diabetes or cardiovascular diseases, access requests are handled directly by the EPIC-InterAct and EPIC-Heart consortia, respectively. < *link to the "Contact us" specific section of the Website*>.

Requests can be made by contacting either:

- The Chair of the EPIC Working Group that is most relevant to the proposal (*link to the "Contact us" specific section of the Website*);
- An EPIC Principal Investigator in an appropriate geographical location i.e. a local EPIC Centre (*link to the "Contact us" specific section of the Website*);
- The EPIC SC directly (epicadmin@imperial.ac.uk)

It is strongly advised to contact the relevant Working Group chair as a first step, who can guide the investigator through the PF1 application process. The active involvement of the EPIC SC and the ECs throughout the research project will provide the user an important knowledge base when analyzing and interpreting EPIC data, as well as ensure that the interests of the EPIC study as a whole are considered.

For research requiring the use of biospecimen, upon approval of the EPIC SC, the user is required to liaise with the ECs of Sweden and Denmark (see *link to the contacts for Sweden and Denmark on the Website*) to gain additional approval for accessing biospecimen that are not stored at the IARC biobank.

How are access applications assessed?

All PF1 proposals will be reviewed by the EPIC SC, consisting of two Principal Investigators from each EC. The relevant EPIC contact (e.g. Working Group Chair) or the

investigator presents the PF1 proposal orally on one of the EPIC SC conference calls that are held monthly and chaired by Imperial College. The deadline for submitting a PF1 application is 10 days prior to the relevant conference call (the EPIC WG leader can inform the investigator of when the next conference call is held).

The Steering Committee will take into consideration:

- The scientific excellence of the proposal;
- The strategic priority of the proposal, with respect to ongoing studies in the specific research area within EPIC, avoiding unnecessary duplication of work;
- The research strength of the individual/group submitting the request, including scientific quality and ability to administer the project;
- Compliance of the proposed study and investigators with EPIC's overall and local ethics and informed consent;
- The availability of biological samples, if these are requested

How to gain access to EPIC data and/or biosamples following approval from the EPIC SC?

Once the request has been approved by the EPIC SC, the user must complete the following steps to gain access to EPIC data and/or biospecimen:

- The IARC Ethics Questionnaire must be submitted to the IEC for ethical approval.
- For studies where data *and* biospecimen are requested
 - Subject to ethics approval by the IEC, a Biobank Request form (CIRC 68 11/2013) must be completed by the user and sent to the IARC Biobank. In addition, a request should be prepared in collaboration with the EPIC contact (e.g. working group leader) to gain access to the relevant data that will be prepared at IARC. These documents will enable the IARC Biobank to prepare the requested samples and the related MTA (CIRC 70 12/2013).
 - Research on EPIC data and/or biospecimen follows the above-mentioned principles and is governed by the EPIC Material Transfer Agreement (CIRC 70 12/2013), which must be signed by the user and a legal representative of the research organisation of the user.
 - 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.
- For studies where data *only* are requested
 - Subject to ethics approval by the IEC, a request should be prepared in collaboration with the EPIC contact (e.g. working group leader) to gain access to the relevant data that will be prepared at IARC; these will enable

IARC to prepare the requested data and the related DTA (CIRC 71 01/2014).

- Research on EPIC data follows the above-mentioned principles and is governed by the EPIC Data Transfer Agreement (CIRC 71 01/2014, url: *link to DTA on website*), which must be signed by the user and a legal representative of the research organisation of the user.
- Upon receipt of the signed DTA, the IARC will proceed with preparation of the relevant data for the project.

The requested data and/or biological samples will be made available for use in a timely and responsible manner taking into account the need to assure data validity and sample integrity.

During the study

The user must

- Accept and undertake research in the context of the ownership of samples and data as stipulated in the IARC MTA (CIRC 70 12/2013) or DTA (CIRC 71 01/2014);
- Provide plans for publication of the study results in peer reviewed journals within two years of reception of the data and/or biospecimen (or clear justification for the requirement of a longer period);
- For studies where biospecimen are being used, report on progress made within the project (using form CIRC 69 11/2013), every 6 months until completion of the study and remaining samples, if any, have been returned back to IARC (as stipulated in the MTA/DTA);
- 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 EPIC data and biospecimen.

At the end of the study

The user must

- 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 70 12/2013);
- If requested, provide EPIC/IARC with a copy of the derived data that have been generated within the project through use of the EPIC data and/or biospecimen (raw data or other relevant format as agreed upon with the EPIC SC) within 2 years of receiving the data and/ or biospecimen.

Acknowledgment in publications

In addition to acknowledging the ECs by complying to the EPIC authorship guidelines, the user must acknowledge the sources of all biological resources in any publication that arises from access to, and use of, the IBB resources, including EPIC biospecimen. All



publications must include at a minimum the following acknowledgment: “the research was made possible using the data/samples provided by the IARC Biobank”.

Reference Documents

Project Application Form (PF1)

IEC Questionnaire

Biobank Request Form (CIRC 68 11/2013)

Material Transfer Agreement (MTA) (CIRC 70 12/2013)

Data Transfer Agreement (DTA) (CIRC 71 01/2014)

Project Progress Report Form (CIRC 69 11/2013)

The EPIC Publication Guidelines