

Note: This model form is offered as a template to assist or inform members of the International Cancer Genome Consortium and other interested projects. Projects are invited to include or delete elements indicated by square brackets ([]), so as to adjust this form according to the nature of their project, while continuing to reflect the guidelines of the ICGC. This form is not intended to be proscriptive; however, it does reflect the best considerations of the ICGC Consent and Data Access Policies Working Group. We hope it will provide a starting point and a useful guide for creating consent materials for ICGC projects.

**INTERNATIONAL CANCER GENOME CONSORTIUM RESEARCH STUDY
MODEL CONSENT BROCHURE
[Retrospective/Secondary Use Research]**

Letterhead/Logo

__[Research Study Name]__
__[PI/Institution]__

Thank you for reading this consent brochure. Please take your time to decide if you want to participate. Discuss this with your family and friends if you would find this helpful. Please feel free to ask any questions that will help you make your decision.

1. What is the __[Research Study]__ and how have I been chosen to participate?

The __[Research study]__ is a research study designed to __[Aim/goals]__. __[PI]__ from __[Institution]__ is conducting this study. This study is coordinated by __[Institution]__ and is funded by __[Funder]__. It has been approved by __[Ethics review body]__. Data from this study will contribute to the International Cancer Genome Consortium (ICGC).

You were chosen because you are currently in the __ [project] __/are registered in the __ [registry] __ [OR] because you participated in a previous study [OR] you agreed to be contacted for future research. Participation in this new study is voluntary and your decision to participate or not will not affect your medical care or that of your family. We are planning to recruit __[No.]__ of people to participate in this ICGC study on _____.

2. What is the International Cancer Genome Consortium (ICGC) and what are its aims?

It is widely accepted that cancer is a disease that results from genetic changes in the cells that make up the body. Researchers are seeking to understand more about these genetic changes as well as how they may be caused by or interact with environmental factors such as infection, exposure to chemicals (e.g., in tobacco smoke), diet, radiation (e.g., in sunlight).

The ICGC is an international effort to coordinate a large number of research projects aimed at establishing a comprehensive catalogue of the genetic changes that are present in many types of cancer. It is hoped that both novel preventive strategies as well as new treatments may be developed from these discoveries.

Members of the ICGC will study approximately 50 different types of cancer. Some of these are relatively common, while other cancers are rarer. Also, because some groups of people in different parts of the world are more or less likely to suffer from one type of cancer than another, the ICGC is coordinating this international research project, in which the countries [insert countries] have agreed to participate. We expect that other countries will join as well.

3. What does my participation involve?

Participating in ___[research study]___ means agreeing to:

1. **Use of previously collected tissues:** Your consent will allow us to use for research your tissue samples from the ___ [project] ___/___ [registry] ___.
2. **[If necessary:] Consent for an additional blood/saliva/urine sample:** If an adequate sample is not available for this project, we will ask you for another. By giving your consent you agree to donate [contribute] and allow us to use approximately xx of ___ [e.g. blood/urine/saliva] ___ for research purposes. DNA ___[and other materials]___ will be extracted from these samples. It is possible that your sample will undergo whole genome sequencing, a process in which we determine many or all of the features of your DNA. This information will not be returned to you.
3. **Access to Health Information:** By giving your consent you give us permission to access relevant health information. Such medical records may include those found in hospitals, general practice records, diagnoses by private specialists you have seen in the past, and information that is held on you by ___[organisation/in administrative health/governmental databases]___.

In addition to the above:

Re-contact in the Future: We are also asking for your permission to re-contact you in the future, in the event that we need additional samples or information related to this ICGC study. If you agree to be re-contacted, your future involvement would be entirely optional. Not everyone who gives permission will be re-contacted and you can decline to be re-contacted if you wish. You can still participate in this ___[ICGC research study]___ if you decline to be re-contacted.

Please tick the appropriate box:

I agree that ___[research study]___ can re-contact me in the future to ask me to provide additional samples or information related to this ___ [ICGC research study] ___ or to invite me to participate in a new study.	yes no <input type="checkbox"/> <input type="checkbox"/>
---	---

4. How will my samples and data be stored and protected?

Your tissue and other samples, the data derived from any analyses of those samples and your personal information found in your health records will be coded to protect your confidentiality. Staff at ___[Institution]___ will ___[remove personal identifiers, such as your name and address, and replace them with a unique code – country specific?]___. This unique code will enable us to link the information from different datasets, for example, ___[e.g., your health record]___ to your samples. Only these staff will hold the key that connects your code to data that can identify you. We will not give this link out to researchers. They will only receive coded information and will not have access to your identity. This system will help enable us to keep your identity confidential. Specifically, we will:

- Keep your personal details separate from your coded data ___[e.g. through the use of filing systems/computers dedicated to this project]___ ;
- Use stringent security measures to prevent unauthorized use, including: strict access controls, computer security and data encryption techniques, confidentiality agreements and staff training. Information regarding these systems is available from ___[contact name/website]___.

Only your coded data will be deposited in the ICGC database, to be used by national and international researchers for ___[No.]___ years. ___ [Your samples may also be shared for approved studies between several teams in the country or among ICGC members] ___. ___[Coded samples may shared with other researchers for quality control purposes]___. ___[[Institution] will be the custodian of your samples]___.

At the local level, we will be able to re-link your personal details with your coded data, but this will only be done in order to make sure the database records are correct (quality assurance) or in case you want to withdraw from the study.

5. Who can access my data?

One of the purposes of the ICGC is to support the sharing of coded data with the international research community (who may include national and international researchers from academia, charitable organisations and private companies, such as drug companies) in order to achieve its goal of facilitating and accelerating research into the causes and control of cancer. The ICGC respects the individuals who contribute to ICGC projects and will strive to protect their confidentiality. To accomplish these aims, the ICGC has established a policy that data from participants be organized and placed into two databases, that are either Open or Controlled-Access.

- **Open-access:** Information in this database will be publicly accessible, but will not contain any information that could be used to identify you specifically.
- **Controlled-access:** This database will only contain your coded medical information and information from the more detailed analyses of your coded samples.

The information in the controlled-access database will be available only to researchers wishing to gain access to data whom have submitted a request and received approval from the ICGC Data Access Compliance Office (DACO). The DACO is the centralized office that manages data access requests. Where required, researchers will have to obtain ethics approval and sign appropriate agreements to receive DACO approval. They must agree not to disclose or transfer controlled-access data to anyone else or to use it for purposes other than those agreed to by the ICGC. Researchers must also agree that they will not attempt to re-identify you from your coded data. If you have agreed to be re-contacted to provide additional samples or follow-up information for this study or for new research, __ [process for re-contact] __ NO identifying information about you, such as your name, address or telephone number will be put into either the public or controlled databases for this project.

The results of research studies using ICGC project data may be used for teaching, further research, publications or presentations at scientific meetings. Your identity will be kept confidential in any such presentations, reports or publications. All data will be presented as group data, rather than individual data.

6. What are the benefits?

The most important health benefits from the work done by ICGC members will be realized many years from now, and will largely help future generations. It is not expected that you will receive any direct individual benefit or personal results. General research results will be made available to all participants and any other people who might be interested through the ICGC website (www.icgc.org) __[and e.g., study website/newsletter]__. For those without internet access, you can contact __[contact info]__.

7. Are there any risks for me?

- **Physical Risks:** There are very minor risks involved in your participation beyond inconvenience and discomfort. Some people experience bruising or may faint after giving blood. However, all procedures will be carried out by suitably qualified staff and your welfare is their priority.

The storage of your tumour and blood/saliva/urine samples involves minimal risk, as rigorous security measures __[e.g. Describe]__ are in place at __[Institution]__. All samples will be kept at __[Location]__.

- **Privacy and Security Risks:** There is a remote risk that the genetic information generated by ICGC projects could eventually be linked to genetic or medical information in other databases. It is also possible, but highly unlikely, that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. If these happen, you may be identified; this potential identification could then lead to social risks such as

discrimination or loss of privacy. However, we will make every effort to protect the confidentiality of your information.

Access to this information will not be offered to third parties such as employers, insurance companies or other family members __[unless required by law or a court order]__.

8. What if something is found?

Your ICGC samples and data are not intended to be used for your diagnosis or treatment and therefore no individual results will be returned to you. [specific information on how this will be done where required by law/ethics]

9. Will there be any commercialization?

ICGC members have agreed not to make claims, such as patents, on primary research data __ [e.g. examples?] __ . However, the use of your data and samples might one day lead to the commercialization of a medical or genetic test or product. This may be done by a university or hospital, a commercial company or both working in partnership. This means that researchers, including, potentially, commercial companies, may benefit financially. You will not derive any personal financial advantage from this commercialization.

10. Will I be paid for participation?

Your participation is on a voluntary basis. You will not be paid [you will be reimbursed for your expenses].

11. How can I withdraw from the __[Study]__?

You are free to withdraw at any time from your participation in __[Study]__ and without giving any reason. You can withdraw by telephoning us at __[Tel no.]__ or by writing to __[PI/Contact]__. __[You will receive a letter to confirm your withdrawal.]__

If you withdraw from the __[Study]__, your remaining samples __ [will be destroyed and] __, the data derived from any analyses done on your samples, and other personal information will be no longer used __[by the study]__. If your coded data has been added to the Controlled-Access Database, the information that links you to that database will be destroyed. Coded samples and data that have been previously distributed will continue to be used. Coded data placed in the Open-Access database cannot be withdrawn, but no additional information will be added.

12. What if I have concerns?

If you decide to participate but have any concerns in the future, you can telephone us at __[Tel no.]__ and ask to speak to __[Contact name]__. Alternatively, you can write a letter or an email to __[Name, position, address, email address]__.

AGREEMENT TO PARTICIPATE

__ [Name of person] __ has explained the __ [research study] __ to my satisfaction. By signing this, I agree to the use of my previously collected tissue, the collection of [blood, urine, DNA] if necessary and to allow access to my health information. I have also made my choice regarding re-contact in the future. I agree to participate and will receive a copy of this after I sign it.

PARTICIPANT INFORMATION

Name _____
Signed _____ Date _____

INVESTIGATOR OR HIS/HER DESIGNEE CONFIRMATION

I described the __ [research study] __, including the conditions of participation, to the participant. Any questions were answered. I explained that participation was voluntary.

Investigator/Designee name _____
Signed _____ Date _____

TRANSLATOR INFORMATION (if applicable)

I was present during the meeting between __ [the research team member/designee] __ and the participant. I translated, for the participant, this consent form and all information presented regarding the __ [research study] __.

Translator name _____
Signed _____ Date _____

APPROVAL

The __ [research study] __ was approved by the __ [Research Ethics Committee] __ on __ [Date] __.