



IBCSG

Agreement on Use of Tissue

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IBCSG General Terms and Conditions for providing Tissue to a Recipient Institution

1. Custodianship

Recipient hereby acknowledges that the use of biological material (“the Tissue”) provided free of charge by the International Breast Cancer Study Group (IBCSG) – represented by the Biological Protocol Working Group (BPWG) acting on behalf of IBCSG’s Foundation Council – for research purposes is governed by the specific Agreement entered into between IBCSG and Recipient. You, as the Recipient, agree to fully comply with all such Conditions and to promptly report to the members of IBCSG BPWG any proposed changes in the research project (“the Project” as per Appendix 1 to the Agreement) and any unanticipated problems.

IBCSG governs the material collected for IBCSG trials and collaborative group trials for which it is the coordinating group.

IBCSG retains title and all rights to the Tissue. Nothing contained within this Agreement shall restrict IBCSG’s right to deal with in any manner as owner or distribute the Tissue and information to other entities should the need arise.

2. Use

You agree that you will use the Tissue only for the Project. You also agree that the Tissue will be used only by you and by individuals under your direct supervision on your research team, and you agree not to transfer the Tissue to any other person, institution, or entity. You agree that you, and individuals under your direct supervision on your research team, will use the Tissue in compliance with all applicable laws and regulations and keep in mind the finite nature of this Tissue. Every effort should be made to use the Tissue sparingly given that it is valuable and non-renewable. No Tissue blocks are to be completely depleted.

If IBCSG provides you with select clinical data information for use with the Tissue in the Project you submitted, only you, and individuals under your direct supervision on your Project team, will have access to this corresponding patient information. IBCSG is entitled to restrict the type of patient data to provide for this Project, and also whether or not any patient data is provided. You agree to hold in confidence all Tissue and corresponding patient data information.

3. Restricted Distribution and Control

You agree not to transfer or disclose the Tissue and information related thereto to any third party without the prior written permission of IBCSG. You will use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this Agreement. You ensure that any collaborator on your Project team agrees to the same restrictions and Conditions that apply to you as the Principal Investigator of the Project. You agree to inform IBCSG of any new collaborator that was not specified at the time the proposal was submitted to the IBCSG.



4. Confidentiality

For tracking purposes all Tissue is identified by the IBCSG patient identification number that is assigned by IBCSG at the time a patient is randomized into an IBCSG Trial.

- a) You agree to never use the Tissue or any biological material derived thereof (e.g. DNA, RNA or the information provided with the Tissue) to attempt to ascertain the identity of the individual from whom they were obtained.
- b) If IBCSG provides select clinical data information, then you agree to not attempt to ascertain the identity of the individual from whom the clinical data was obtained.
- c) You agree to maintain the confidentiality of the patient data at all times.
- d) You agree to destroy the clinical data (not the data generated from the biological material) once the project has been completed and the results published or presented, or upon request from IBCSG.

5. Ownership

You and your research team will retain ownership to the substances (e.g. DNA, RNA) created by using the Tissue, but IBCSG retains ownership rights to the biological material contained or incorporated therein. Therefore you must first have a written agreement from IBCSG before you provide a third party with the use of the substances.

6. Return of Materials / Prolongation

No tissue blocks are to be completely depleted. The unused Tissue must be returned to the IBCSG Tissue Bank six (6) months after the date this Agreement has been fully executed, unless the agreement is formally extended. It is the responsibility of the recipient to seek such a prolongation from IBCSG. Should you require a prolongation, a brief progress report needs to be submitted to IBCSG at that time, and every two (2) months thereafter.

In the event that you are not using and do not intend to use the Tissue and/or if this Agreement is terminated, you shall promptly return to IBCSG the remaining Tissue provided to you under this Agreement.

7. Regulations / Laws

You agree to adhere to the same ethical standards as IBCSG, and obtain institutional review board review and approval of research activities when required by law or regulation. (Please see 'IBCSG Tissue Bank Policies') As the Recipient you remain subject to both the regulations/policies of your country/institution and also to European or Swiss laws or regulations and policies, whichever is stricter.

You further agree to observe the Declaration of Helsinki, Good Clinical Practice and Good Laboratory Practice, in addition to the recommendation of the Council of Europe in the 'Additional Protocol to the Convention of Human Rights and Biomedicine Concerning Biomedical Research'.



8. Warranty

There is no warranty of fitness of Tissue for any particular purpose.

9. Liability

Recipient is liable for any inappropriate use of the Tissue. IBCSG accepts no responsibility for any damages to Tissue or for loss of Tissue which may arise from or in connection with the use or handling of the Tissue during the Project.

Any use of this material beyond the terms of this agreement requires prior review and approval by the IBCSG and, where appropriate, by an EC at the Recipient site. In the event of a breach or violation of this Agreement, IBCSG has the right to take other appropriate action, including but not limited to terminating this Agreement and seeking damages and/or specific performance.

10. Results

Recipient agrees to provide IBCSG an advance copy of any data generated by the use of the Tissue. Before data can be made publicly available at publication it must have prior IBCSG review and agreement. This data must be provided within XX (to be determined case by case based on suggested timelines of the project) months after the remaining Tissue is returned to IBCSG. The correlation with clinical data will be done at the IBCSG Statistical Center, unless IBCSG agreed otherwise.

11. Publication

Proper acknowledgement of IBCSG will be made in any publications resulting from the use of this Tissue, as already agreed. Publications should conform to the IBCSG Publication and Presentation Guidelines (appendix 2).

12. Governing Law and Jurisdiction

Notwithstanding its place of performance or execution, the Agreement and any amendments thereto shall be governed by and construed under and in accordance with the laws of Switzerland.

In case of any dispute, claim or controversy arising out of the execution and/or interpretation of the Agreement, Parties shall use their best efforts to solve it amicably. In the absence of such a settlement, exclusive jurisdiction will lie in the courts of Berne/Switzerland.

13. Subsequent Agreement

If any change in responsibility occurs and Recipient is no longer the Principal Investigator(s), IBCSG needs to be informed and a new agreement must be signed by the new Principal Investigator(s). The Tissue may not be transferred to a new Investigator without prior written permission of IBCSG.



14. Termination of Agreement

In the event of a breach or violation of this Agreement, IBCSG has the right to take other appropriate action, including but not limited to terminating this Agreement.

15. Acknowledgement and Additional Statements

Recipient agrees to provide IBCSG a statement at the time he returns the signed 'Agreement on Use of Tissue', about how confidentiality of data generated, or clinical data received from IBCSG will be maintained (e.g. password protected computers etc) and if he is provided with clinical patient data, a statement on the destruction of clinical patient data when this study is completed.



International Breast Cancer Study Group Agreement on Use of Tissue

Certification of Recipient:

I have read and understood the terms in the IBCSG Agreement on Use of Tissue and I and my research team agree to fully abide by them in the receipt and use of the biological material.

Recipient Signature: _____ Date: _____

Name: _____

Title: _____

Institution: _____

Address: _____

Tel: _____

Fax: _____

e-mail: _____

Please return this form to: Rosita Kammler

Translational Research Coordinator

IBCSG Coordinating Center

Effingerstrasse 40, 3008 Bern, Switzerland

FAX: +41 31 389 9229

Rosita.Kammler@ibcsg.org