# Checklist for Tissue Banking Consent Form


**GCIG Group:**_____

**Protocol Title:**_____

**Protocol Version and Date:**_____

| Element | Yes | No | N/A |
|---|---|---|---|
| **Introduction** | | | |
| Invitation to take part in the research study. | | | |
| Brief description of and purpose of the research. | | | |
| **Research to be conducted** | | | |
| Details and methods of testing to be carried out (e.g. biochemical, genetic) | | | |
| Details of material to be removed / used | | | |
| a) access to tissue collected within the treatment process/already collected | | | |
| b) consent to remove additional material<br>- blood samples (incl. volume and frequency)<br>- additional tissue | | | |
| Details of samples to be retained for open–ended research and/or any future research including genetic research | | | |
| Consent for access to study medical records | | | |
| Disclosure of any potential commercial benefits and if the subject will receive money or other benefits. | | | |
| Specify the length of time the specimen will be stored eg your sample/tissue will be stored as long as analysis can be carried out. | | | |
| **Potential risks** | | | |
| Details of risks including invasive procedures, possible discomforts, psychological distress etc. | | | |
| Details of any results and by which method may be conveyed to the participant and any potential consequences clearly stated e.g. counselling for family members, health insurance etc. | | | |
| When appropriate, statement that the particular treatment or procedure may involve risks to the subject which are currently not foreseeable. | | | |
| **Expected benefits** | | | |
| Details of any benefits the participant may expect from taking part in the research. When there is no intended benefit, the participant should be made aware of this. | | | |
| **Research which will NOT be done** | | | |
| Details of research which will definitely not be conducted on samples collected eg reproductive cloning | | | |
| **Subject care** | | | |
| Stated that participation is voluntary, without detriment to future patient care. | | | |
| Option and mechanism by which donor may withdraw consent/samples from research.<br>• Will patients be able to request the destruction of their biological specimen? *(not possible if the data is de-identified and unlinked).*<br>• Who will guarantee destruction? | | | |
| The alternative procedure(s) that may be available to the participant, and their important potential benefits and risks. | | | |

| | | | |
|---|---|---|---|
| **Ethical and cultural considerations** | | | |
| Details of ethical review and IRB/EC requirements. | | | |
| Information is in plain language, comprehensible to the target population including any cultural considerations e.g. if interpreter required; cultural/community leader input required. | | | |
| That the subject or subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial. | | | |
| **Interstate/Overseas research** | | | |
| Details of where samples will be sent and any national/international legal requirements | | | |
| **Participant's responsibilities** | | | |
| What will be required of the participant during the research. | | | |
| Expected duration in the study. | | | |
| **Compensation/research related injury and research costs** | | | |
| The compensation and/or treatment available, if any, in the event of research-related injury. The person(s) to contact in the event of research-related injury. | | | |
| The anticipated pro-rated payment, if any, for participating in the research. | | | |
| The anticipated expenses, if any, to the subject for participating in the research. | | | |
| **Confidentiality, access to medical information and data protection** | | | |
| That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws/regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential. | | | |
| Degree of anonymisation / coded data | | | |
| That the sponsor, monitor(s), auditors, IRB/EC and the regulatory authority(ies) will be granted direct access to the subject's original study medical records for verification of research procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorising such access. | | | |
| That the GCIG group will store information on samples and subjects (if subjects can be identified this should be clearly stated) and assurances that samples will be stored carefully. | | | |
| In case of transfer to another country / continent, details of where samples will be sent and any national/international legal requirements. | | | |
| **Administrative** | | | |
| Footer specifying the version number and/or date, and site identifier. | | | |
| Contact details for further information regarding the research, the rights of subjects and complaints regarding the research, including principal investigator and key research staff. | | | |
| **Informed Consent Form** | | | |
| Statement that the subject is to receive a copy of the signed and dated Subject Information and Consent Form. | | | |
| Collection / use of samples sub-divided as a, b, etc with options provided to participate in all **or** part of the research (tick boxes options provided). | | | |

| | | | |
|---|---|---|---|
| Agreement on use of material for future ethically approved research | | | |
| Option for subject to be contacted in future about participation in more research. | | | |
| Signature and date fields for participant/legally acceptable representative) and person conducting consent process (where required witness should also be included) | | | |

Comments (continue on separate form if required):_____
_____
_____
_____
_____
_____

**Checklist Prepared by:**_____ **Date:**_____
**(name, position)**

**Checklist Approved by:** _____ **Date:**_____
**(name, position)**