Institutional Review Board

Checklist: Tissue Banking

IC for Collection and Storage of Human Tissue or Specimens for Future Research

NUMBER | HRP-420

IRB Number	
Abbrev. Protocol Name	
Investigator	

A. Banking considerations (Check all that apply.)

☐	1. This study involves specimen collection and storage for future research either as its primary purpose or as an optional component.
☐	2. There is a separate optional tissue banking IC, or within the main IC there is a separate section for the optional tissue banking. (Note: for a tissue banking study, the tissue banking ICF = the main ICF) N/A: ☐

B. The following information should be included in the ICF regarding banking (Check all that apply.)

☐	1. What is being collected: A description of the tissue (or specimens) to be collected.
☐	2. How is it being collected: A description of how the tissue (or specimens) will be collected.
☐	3. Consent: A place for subjects to record their choices about participating in tissue banking.
☐	4. Additional Risks, if any: If the collection of samples involves additional procedures to those that would be performed as part of the underlying clinical trial, or involves the collection of samples in a greater volume than would be collected as part of the underlying clinical trial, an explanation of the additional risks, if any. N/A: ☐
☐	5. Tissue banking is optional: A statement that the subject's agreement to the collection of specimens (and protected health information (PHI), if applicable) for transfer to a tissue bank is not a condition for enrollment in this or any research study, or for future care or treatment, and that a subject can participate in the main study and not be part of the optional specimen banking component of the study. N/A, this study is only for tissue banking: ☐
☐	6. A description of the measures that will be taken to guard against loss of privacy and confidentiality.
☐	7. Intended future use(s) of the specimens: A description of: (a) The types of investigators or entities to whom the samples (and PHI, if applicable) may be distributed, and (b) The purposes for which the samples (and PHI, if applicable) may be used. The IC is to describe the intended future use(s) of the specimens (and PHI, if applicable) with as much specificity as possible.
☐	8. Withdraw consent: If the samples (and PHI, if applicable) will be coded, a statement that the subject is able to withdraw consent at any time to future use, except where it is impossible to achieve the withdrawal because the tissue bank has already distributed the samples, the samples have been completely exhausted, or the code to match the sample to the subject is no longer available.
☐	9. Who to contact to withdraw: If the samples will be coded, a statement indicating who to contact if the subject wishes to withdraw consent to the future use of the samples.
☐	10. Risks: A statement that a risk of storing samples for future research includes possible loss of confidentiality and, if genetic testing is part of the protocol, a statement to the effect that the results of genetic tests, if inadvertently disclosed, could negatively affect access to insurance or employment, or could have an impact upon family or social relationships.
☐	11. Subject will not be contacted by the tissue bank: A statement that the subject will not be contacted by the tissue bank or by secondary recipients of the stored specimens. However, if the IRB does allow such contact, the ICF should state the circumstances under which such contact may occur. N/A: ☐
☐	12. Commercial products: *If applicable*, a statement that the specimens may be used in the development of commercial products including the development of cell lines and whether the subject will receive any benefit/monetary gain from this development.
☐	13. Direct benefit: A statement addressing whether or not the subject will receive any direct benefit from participation in the specimen banking component of the research protocol.
☐	14. Will results be communicated: A statement describing whether or not the results of research performed on the specimens will be communicated to the subject, or to the subject's study doctor, primary care doctor, and/or placed in the subject's medical record. If so . . . If research results **are** to be communicated to the subject, the subject's study doctor, the subject's primary care doctor, or placed in the subject's medical record, the potential benefits and risks of such transfer and placement of information must be described in the ICF. N/A, this study is only for tissue banking: ☐
☐	15. Money or other remuneration: *If applicable*, an explanation that Avera, or a member of the research team will receive money or other remuneration from the tissue bank for the collection or use of the samples. No explanation is necessary if the payment is intended solely as reimbursement for the direct costs of the collection of the materials and transfer to tissue bank.
☐	16. Identifiable PHI: Will identifiable PHI accompany the specimen supplied to a tissue bank? *If so, the ICF may include:* ☐ An expiration date or expiration event for the potential research to be performed on the subject's samples and PHI; ☐ A statement describing the particular identifiers (PHI) that will be disclosed to the tissue bank.

At this time I recommend the research be: (Please check one, and sign/date)

- ☐ APPROVED.
- ☐ Approved with Conditions, Minor Clarifications and/or Modifications back to the IRB Office. *Note conditions below*
- ☐ Approved with Conditions, Major Clarifications and/or Modifications back to the Full IRB Meeting. *Note conditions below*
- ☐ Do Not Recommend approval at this time. List Reasons. (Convened board must agree by a vote if study is not approved.)

Comments Section:

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Name Date