

Use of Cell Lines in Research

Researchers obtaining samples for use as Cell Lines in research are to consider the following and ensure the research Protocol and Information Statement & Consent Forms cover the following points accordingly.

References:

- National Statement on Ethical Conduct in Human Research (Chapters 3.2, 3.4. 3.5 & 3.6)
- Researchers **establishing** a Biobank for storing cell lines for research purposes should also refer to the <u>Biobank</u> <u>guidelines</u>

Please note: Researchers requesting samples be collected or retained for use in future research from any source will be either adding to an existing bank or will be establishing a Bank

What is the purpose of creating the cell line e.g. single research project and/or future research projects? 1. Note: Participants/patients (donors) should be given an explanation in lay terms of what a cell line is and why they are established. 2. Where will the cell line be stored? 3. Will the cell line be shared with other researchers – within Australia and/or overseas? Note: as per the National Statement tissue should always be considered re-identifiable. What controls will be placed on use/sharing of the cell line i.e. researchers are to be provided with evidence of 4. ethics approval (from the requesting organisation/researcher) prior to transferring the cell line for research purposes and an agreement regarding use will be in place e.g. Research Agreement, Material Transfer Agreement. 5. A record of the use and sharing of cell line is to be maintained by the custodian / researcher including evidence of appropriate ethical approval from recipients of the cell line. Will the donor be notified of future use? Will the donor be notified of any findings in the future e.g. health related? 6. 7. Is Commercial use likely? Will the donor receive a financial benefit e.g. if used for commercial purposes? Is a financial benefit to the researchers likely? Donor's may rescind consent for the cell line and request it be destroyed but only for future use from that point i.e. it may not / will not be possible to withdraw cell lines already used in research or shared with other researchers. Clarify the process for a donor or their parent / guardian to notify such withdrawal. (Note: How will this be managed by the researchers should a withdrawal of consent occur?) Donors (minors) whose parent/guardians have consented on their behalf must be re-consented at 18 years of age. 9. Outline how this will be managed and, if unable to be contacted, the protocol to be followed (e.g. apply to HREC for a waiver of consent for future use of the cell line in research).