Human Bio-specimen Case Study

What advice would you give the researchers proposing this project?

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Purpose of HREC review

Part of the function of an HREC ought to be to promote the conduct of ethical human research. In order to do that, there should be an engagement with the research community about what constitutes ethical human research. The common vocabulary available to both the committee and the researcher is the National Statement.

Purpose of this case study

The purpose of this case study is to think about the research in terms of the principles of the National Statement and to practice using that guide as the point of commonality between researchers and the Committee.

Ask yourself and your group:

Is this research?

What are the risks?

What are the potential benefits?

Does this project reflect the values of the National Statement?

- Research Merit and Integrity
- Respect
- Justice
- Beneficence

Cartoon by Paul Mason

Discussions

What questions would you ask around these principles?

- Who would you ask?
- Do you have sufficient expertise?
- Should you include the researcher(s) in these discussions?

What feedback would your group provide to the research team?

- What would you tell them?
- How would you convey that?
- Would you support and explain your decision?
- Is it part of the remit of an HREC to educate researchers?

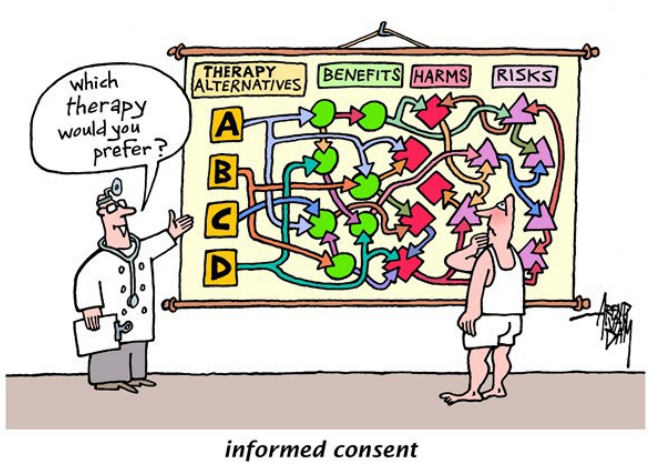
Reuse of Human Bio-specimens for Research

Experienced paediatric oncologist, Dr Patty approaches your committee for advice on extending research that she conducted from 2005 - 2010. The original research collected blood and bone marrow samples from teenagers who had been diagnosed as having Hodgkin's lymphoma along with their clinical history, treatment details and interviews over a 5 year period.

There has been significant work done in improving the testing of the bone marrow samples. Dr Patty would like to share the stored samples with a colleague, Dr Selma, to develop an improved test and then run a comparative study between the original method and the new one. They propose to re-run the tests that they originally conducted during the study and compare those results with the testing conducted with the new method. Dr Patty believes that the new test should be up to 10 times more sensitive as well as being quicker.

Consent

Consent was originally obtained from the parents with the patients providing their assent. The documentation included a statement requesting permission to store the samples to conduct unspecified, but related, future research.



Cartoon from the Cagle Post by Arend van Dam

Consent issues to consider

Would this project constitute “unspecified, but related, research”?

Is there a need to seek further consent?

Does it matter that those patients that survive would now be adults?

Are there any risks that might be associated with re-consenting a group of cancer patients 5 – 10 years after the initial research project?

Are there any additional privacy considerations involved in sharing the bio-specimens with researchers not on the original project?

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