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## **ALFRED ETHICS COMMITTEE POLICY: ETHICS APPROVAL FOR GENE BANKS AND GENETIC REGISTERS**

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The Ethics Committee has endorsed the following principles to guide consideration of future proposals relating to gene banks or genetic registers:

1. Genetic registers have the potential to substantially advance the prevention and treatment of many diseases. They also raise a number of particular ethical issues.
2. In general, for the Ethics Committee to consider approving the establishment of a gene bank, the following conditions should be met:
  - gene banks should be established under the control of experienced and highly reputable researchers;
  - the bank should be established within an academic research environment;
  - the researchers involved must be aware of the potential ethical issues associated with access to data from the bank and have adequate resources and strategies in place to deal appropriately with them.
3. The Committee will, in the first instance, approve the establishment of the gene bank and the specific project linked to the application. Future research involving different markers will require further separate applications before approval will be given.
4. Individuals providing samples to the registry should be provided with the following choices about matters which may be discovered from samples. He or she may:
  - wish to be informed of all results that may have a bearing on the future health of the individual or his or her offspring;
  - wish to be informed of results which are of medical significance and for which effective treatment is available;
  - wish not to be informed under any circumstances.
5. Individuals should ideally be provided with the following choices for the handling of samples they provide:
  - use for the specific purposes specified in the plain language statement, with the specimen to be discarded;
  - preserve the sample for use in future studies of the disease in question (e.g. cardiovascular disease) as approved by the Ethics Committee;
  - preserve the sample for use in future studies of any disease as approved by the Ethics Committee.
6. Individuals providing samples for a gene bank should be aware that they must disclose upon request any adverse information about their risk of future illness which is provided to them as a result of genetic testing to life insurance and superannuation companies. Possession of this information may increase their premiums or may have them denied cover (or employment) altogether.
7. Individuals should also be aware of the possibility that information held by the gene bank may be discoverable by court of law.
8. Researchers in charge of gene banks should have detailed arrangements in place to deal with requests for information by patients and (if the patient is deceased) by his or her relatives. In dealing with such requests, the researchers must ensure that:
  - a process is in place to determine what information will be provided and to whom;

- a knowledgeable individual should be available to explain the significance of the results and the appropriate course of action to be followed by the recipients of the information.
9. The researcher in charge of the gene bank should also have a protocol to determine what information should be provided unsolicited to individuals as a result of findings generated by the research. Generally the Ethics Committee should be informed of such actions.

## **FURTHER INFORMATION**

Any enquires regarding applications, Ethics Committee processes, documentation, or variations to the principles outlined above should be directed to the Ethics Manager.

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