

Human Research Ethics Committee

QUESTIONS FOR INVESTIGATORS CONCERNING THEIR PROJECT AND ANY GENETIC COMPONENT

1. Does your project entail the collection of information or samples for genetic analysis?
2. Does the protocol describe arrangements made for information and counselling to be given to potential participants when being recruited?
3. Has consent for genetic analysis specified that this will be for work relevant to this study only? or to other studies of this condition? or to any study?

Has the participant been counselled before informed consent has been requested?

4. What information about the participant will be available with the samples?
 - Full identification and access to clinical information?
 - Limited information e.g. demographic, diagnostic, clinical but not sufficient identification to permit subsequent tracing or data retrieval?
 - None?

Has the participant been counselled before informed consent has been requested?

5. Will the samples with or without the above categories of information be made available to any third party?

Has the participant been counselled before informed consent has been requested?

6. Is commercial exploitation of data or concepts derived from the samples planned or will it be permitted? Will there be direct gain to your Department or you personally?

Has the participant been counselled before informed consent has been requested?

CHECKLIST 1:



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**CHECKLIST (2) TO DETERMINE WHETHER PROPOSED STUDY
COMPLIES WITH ETHICAL REQUIREMENTS.**

<u>INFORMATION – CLINICALLY ACQUIRED:</u>	YES	NO
GENETIC?	<input type="checkbox"/>	<input type="checkbox"/>
CLINICALLY ACQUIRED Clinically justified procedure.	<input type="checkbox"/>	<input type="checkbox"/>
AVAILABLE TO PATIENT	<input type="checkbox"/>	<input type="checkbox"/>
<u>INFORMATION – RESEARCH ACQUIRED:</u>		
GENETIC?	<input type="checkbox"/>	<input type="checkbox"/>
RESEARCH ACQUIRED	<input type="checkbox"/>	<input type="checkbox"/>
FEEDBACK	<input type="checkbox"/>	<input type="checkbox"/>
NO FEEDBACK	<input type="checkbox"/>	<input type="checkbox"/>
IDENTIFIED	<input type="checkbox"/>	<input type="checkbox"/>
DE-IDENTIFIED.	<input type="checkbox"/>	<input type="checkbox"/>
ADEQUATE COUNSELLING ARRANGED Availability including timing and cost issues. Adequacy of resources e.g. qualification of Personnel follow-up.	<input type="checkbox"/>	<input type="checkbox"/>
NO ADEQUATE COUNSELLING ARRANGED. Availability including timing and cost issues. Adequacy of resources e.g. qualification of Personnel follow-up.	<input type="checkbox"/>	<input type="checkbox"/>

CHECKLIST 2

If your project contains any genetic testing please complete this form and add it to the application package.



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LIST OF QUESTIONS FOR POTENTIAL PARTICIPANTS TO ASK INVESTIGATORS ABOUT RESEARCH INVOLVING GENETIC TESTING

You have been invited to participate in research involving genetic materials.

You may be interested in asking the researcher these questions after you have looked over the written information, and before you consent to be involved in the research project.

1. What do you think you might find out in this research?
2. Will I be able to get my results?
3. Who else will get a copy of my results?
4. If I choose to find out the results, what will this mean to me?
5. If I agree to participate what arrangements have been made for my independent counselling and who is the independent counsellor?
6. How might the results affect my family?
7. If I choose to get the results, how long will it be before I get them?
8. If I choose to get the results, who will help me to understand what they mean for me and my family?
9. What will happen to my **specimen or sample**? Will it be used in other studies?
10. Will my results have any effect upon my job, my being able to get insurance, **or my status in legal matters**?
11. What will happen if this research leads to the manufacture of commercial products?

For more information about ethical issues concerning this research you may contact

**Ms Jill Davis: Manager Research Ethics Unit
Telephone 9496 4034**

There is more general information about genetic research ethics issues at http://www.nhmrc.gov.au/your_health/egenetics/index.htm

CHECKLIST 3

If your project contains any genetic testing, please complete this form and add it to the Participant Information and Consent Form as the final page