

## Health-related findings

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### Contents

What are health-related findings? .....	1
Does this affect my research? .....	1
What do I need to consider? .....	1
What do I need to prepare? .....	2
When should I relay health-related findings? .....	2
When should I not relay health-related findings? .....	3

### What are health-related findings?

When undertaking research involving human participants, you may make a finding that has potential health or reproductive importance to one of your participants. A participant may also disclose a health or reproductive finding that is not related to the proposed project. For more information on feeding back such findings, refer to the [Framework on the feedback of health-related findings in research](#), published by the Medical Research Council and Wellcome Trust.

### Does this affect my research?

If your research involves human participants, you must consider the potential for the generation of health-related findings (HRFs).

If your research has the potential to generate HRFs, you will need to develop your own policy on whether to feedback HRFs to participants and include it in your ethics application. This may differ from project-to-project. You will also need to make your policy clear as part of/an appendix to your [participant information sheet](#).

Your policy must be clear, justifiable and supported by evidence where possible. You should follow any relevant good practice guidelines that have been published for your discipline or in the country where the study is taking place.

### What do I need to consider?

- The probability of identifying HRFs;
- The potential severity of the HRFs and the certainty with which this is known;
- The nature of the test, for example the predictive value of the test and the chance of false positives;

- The clinical utility of the HRF;
- Whether potential HRFs are likely to be actionable, that is whether there are available and accessible strategies for prevention, management or treatment of the condition;
- Personal implications of the HRF such as cost of treatment to the participant and emotional consequences; and
- The cost of follow up testing, support and treatment from the NHS or other publicly-funded bodies.

### **What do I need to prepare?**

In all cases, the benefit of informing participants of HRFs should considerably outweigh any potential harm that could be caused by reporting back. If you decide to pass HRFs to your participants, you will need to ensure the following are in place:

- Include clear information on your study's HRF feedback policy in the consent process.
- Obtain consent from the participant to be informed of any HRF.
- Establish a clear process for relaying the information i.e. how, when and by whom feedback will be delivered.
- Adhere to all applicable data protection legislation.
- Provide the participant with information relating to the implications of the HRF and its clinical significance.
- Make the participant aware that the HRF is not a diagnosis and that it is not an alternative for medical advice.
- Advise the participant on who to seek advice, counselling or treatment from.
- Budget for the cost of relaying HRFs in your initial funding application. Not having done this is not an acceptable reason for not informing participants of HRFs. However, in some large-scale studies, where the results may have significant benefits to society, logistical or budgetary constraints may be appropriate reasons for not relaying HRFs to participants.

### **When should I relay health-related findings?**

- You have consent from the participant to do so.
- The HRFs have significant clinical importance i.e. they are predictive of a disease/condition.
- The HRFs can be clinically and/or analytically validated without the participant incurring a significant cost.
- Treatment is available/likely to be available in future/lifestyle changes could improve the condition.
- You have the funds available to be able to relay the relevant information in a sensitive and appropriate manner.

## **When should I not relay health-related findings?**

- Predictability of disease is low.
- There is currently no treatment nor is there a likelihood of treatment becoming available in future.
- The HRFs cannot be clinically and/or analytically validated.
- You do not have the funds available to be able to relay the relevant information in a sensitive and appropriate manner.

*Document updated: 19 June 2018*