Framework on the feedback of health-related findings in research
March 2014

Summary

Scope and background
In the course of a study involving human participants, researchers may make a finding that has potential health or reproductive importance to an individual participant (health-related findings or “HRFs”). Whether and how HRFs should be fed back to the research participant is currently subject to intense debate. Given the absence of guidance and lack of evidence and consensus on how HRFs should be handled, this framework has been developed to help researchers identify and consider the relevant issues when designing and implementing a policy on the feedback of HRFs.

We do not consider it appropriate to advocate a single approach to the feedback of HRFs across all studies because further empirical evidence is needed on the harms and benefits associated with feedback and, since research contexts vary widely, the balance of public and individual harms and benefit must be assessed on a study-by-study basis.

Requirements for researchers
When establishing a study involving human participants or re-consenting participants for follow-on research to an existing study, researchers are expected to:

• have a policy that indicates whether or not HRFs will be fed back to individuals that can be clearly articulated, and be able to demonstrate the reasoning behind their policy to research participants, funders and the Research Ethics Committee;

• include clear information on the study policy on the feedback of HRFs in the consent process; and

• in cases where the policy is to provide individual feedback on HRFs, develop a practical feedback pathway that is adequately resourced.

This framework sets out:

• background to the debate around HRFs (section A);

• our expectations of researchers (section B);

• points to consider in deciding whether individual feedback of HRFs is appropriate for the study (section C);

• points to consider in determining what information should be included in the consent process (section D);

• points to consider in designing feedback pathways where feedback is to be provided (section E);

• hypothetical case studies showing possible approaches to HRFs in different settings (section F); and

• a glossary (section G).

The following table summarises points for researchers to consider. These are also the points that Research Ethics Committees are likely to ensure researchers have addressed. The links provided in the table enable quick access to the detailed sections of the framework.

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| Policy on feedback of HRFs | - The policy must be **clear, justifiable** and **supported by evidence** where possible.  
- A **one size fits all approach is not appropriate**: different policies will be appropriate for different studies since research contexts vary widely.  
- Factors to consider are set out in the next section. |
| Specific points to consider in developing a policy |  
**What is the likely nature of the HRFs?**  
- Factors to consider include:  
  - the **probability** of identifying an HRF;  
  - the potential **severity** of the HRF and the certainty with which this is known;  
  - the **nature of the test**, for example its predictive value and chance of false positives;  
  - the **clinical utility** of the HRF; and  
  - whether there are available and accessible strategies for prevention, management or treatment of the condition.  
  
**What is in the best interest of participants?**  
- **Potential benefits and harms** of feedback should be assessed – based on available evidence in the field – to determine what is likely to be in participants’ best interests.  
  
**What is good practice?**  
- Relevant **good practice guidelines** should be followed.  
  
**What is the context of the study?**  
- Where the study is taking place may affect the potential benefits and harms, for example where healthcare may not be available and accessible to the study population.  
- Consider whether **vulnerable populations** are involved.  
  
**What are the practical implications for the study?**  
- **Logistical issues**, such as access to participants’ contact details may affect the approach to feedback.  
- The **costs of providing feedback** and follow up must be sustainable and should be in proportion to the potential benefits of feedback.  
  
**What is the nature of any existing consent?**  
- **Secondary users** of tissue or data should be aware of the existing consent and follow agreed policies and practice.  
  
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- **Whether it is anticipated that HRFs will be fed back.**  
- The **scope of feedback** that may be provided.  
- **Whether the primary healthcare provider will be involved.**  
- Whether or not, and to what extent, participants have a **choice** about what feedback to receive.  
  
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- **How and when HRFs are likely to be identified and who is likely to do this.**  
- Whether the finding will need to be **verified** to confirm whether it is analytically accurate.  
- **Who will be involved** in the feedback pathway to ensure there is appropriate expertise in assessing findings and delivering feedback.  
- **How and when feedback will be delivered.**  

A. Introduction and context

Background
1. During a study involving human participants, researchers may make a finding that has potential health or reproductive importance. Potential ‘health-related findings’ (HRFs) include incidental or unsolicited findings – a finding “which is discovered in the course of conducting research, but is beyond the aims of the study”¹ – and pertinent findings that relate to the aims of the study. HRFs may result from many types of research involving human participants, such as imaging and genetic studies and studies involving physiological measurements or assays. Depending on the research context and the type of tests involved, HRFs will vary in both their nature and the frequency with which they arise. HRFs may arise in clinical trials, stand-alone studies, or in longitudinal studies that involve a range of tests conducted by different researchers over an extended period of time.

2. Since potential HRFs are identified from research investigations, rather than from data or samples gathered for specific medical investigation or diagnosis, further analysis or tests will often be required to assess their significance. In addition, clinical or technical expertise beyond that of the research team may be required in the assessment and reporting back of an HRF. Complex issues such as these mean that the most appropriate way to manage HRFs in research is currently a topic of intense debate.²

Legal, ethical, policy and practice considerations
3. Research has not identified any legal cases on researchers’ responsibilities relating to HRFs in the UK. Since the position is untested, it is unclear whether, and if so to what extent, researchers owe a specific duty of care to participants under UK laws with respect to HRFs. It is important to note that the lack of a clear legal position does not affect the ethical considerations that should be taken into account by researchers and the law may be different in other jurisdictions.

4. The balance of the benefits and harms is a critical issue in ethical considerations around the feedback of HRFs. While a risk/benefit assessment may be straightforward in some cases, this analysis is often hampered by a lack of evidence on the benefits and risks of providing feedback. Empirical evidence is needed to better understand the implications of feedback of different kinds of HRF in order to inform policy in this area.

5. Feedback pathways must be adequately resourced and therefore the feedback of HRFs may increase demand on research funding. The follow up of HRFs is also likely to require support from the health service, as participants seek further information, tests or interventions, with particular implications where healthcare is publicly funded. To ensure resources are managed wisely and in the public interest, the use of research funding and publicly-funded health services to support feedback should be in proportion to the potential benefit to research participants. This means that there is an argument that feedback should only be provided when there is a clear benefit to individual participants.

6. In addition, researchers generally seek to avoid a situation where a research participant does not distinguish between health research and medical care. In considering whether and how to provide feedback on HRFs, it is important to maintain, as far as possible, a clear distinction between health research and medical care.

Development of the framework
7. In the absence of evidence and clear ethical, legal and policy consensus on how HRFs should be handled, this framework has been developed to help researchers identify and consider the relevant issues when designing and implementing a policy on the feedback of HRFs.

8. The development of this framework has been informed by a wider project, including: a review of the international literature focused on the legal and ethical issues;³ a review of existing policies and practice in the UK and US; an analysis of the costs and timescales associated with
feedback in genetics and imaging studies; research on public attitudes towards the feedback of HRFs, which found that generally there is a strong preference for feedback particularly where a condition is serious and treatable; and a workshop focusing on the legal issues associated with HRFs.

9. In developing this framework we have also considered global policy discussions and developments around HRFs in research and clinical practice, such as the Canadian Tri-Council Policy Statement; the US National Heart Blood and Lung Institute's guidance on incidental findings; the report of the US Presidential Commission for the Study of Bioethical Issues; and the American College of Medical Genetics recommendations on the return of incidental findings in clinical sequencing. This framework adopts a pragmatic approach that is less prescriptive than a number of these statements, to take into account the variety in different research studies and the gaps in the evidence base.

10. We will continue to monitor discussions and the growing evidence base around HRFs and other developments that may affect how researchers approach the issue, such as dynamic consent. This framework will be kept under review in light of these developments and updated as necessary.

B. What do we expect of researchers?

11. The framework applies to HRFs from all types of research involving human participants, wherever the research is conducted, both within and outside the UK. This framework is relevant to researchers establishing new studies or re-consenting participants for follow-on research to an existing study. This framework relates to the feedback of HRFs to individuals and does not consider the feedback of aggregated research findings where these are not meaningful at the individual level. Our policies on aggregated research findings are described elsewhere and it is important that researchers consider how they will make aggregated research findings available to research participants.

12. We consider that it is appropriate for researchers to feed back HRFs where the potential benefits of feedback to an individual clearly outweigh the potential harms and it is feasible to do so. However, at this time, we do not consider it appropriate to advocate a single approach to the feedback of HRFs because further empirical evidence is needed on the harms and benefits associated with feedback; and, since research contexts vary widely, the balance of public and individual harms and benefit must be assessed on a study-by-study basis.

13. As a minimum requirement, we expect researchers to carefully consider issues around HRFs when establishing a study involving human participants or re-consenting participants for follow-on research to an existing study. In particular, researchers must:

- have a policy that indicates whether or not HRFs will be fed back to individuals that can be clearly articulated, and be able to demonstrate the reasoning behind their policy to research participants, funders and the Research Ethics Committee (see section C);

- include clear information on the study policy on the feedback of HRFs in the consent process (see section D); and

- in cases where the policy is to provide individual feedback on HRFs, develop a practical feedback pathway that is adequately resourced (see section E).
C. Points to consider in developing a policy to individual feedback of HRFs

The decision on whether or not to provide individual feedback of HRFs involves a number of considerations including:

i  What is the likely nature of health related findings?
The type of HRFs that may be identified will depend on the nature of the study and could include pertinent findings and incidental findings. In deciding how to address such HRFs, researchers should consider a range of factors, including:
- 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; and
- 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.

Factors relating to the study population, such as age, may also be relevant.

It may be more straightforward to understand and anticipate pertinent findings than incidental findings, as the nature of the test and conditions associated with the HRF will be known in advance. Nevertheless, researchers should use the information available to them to consider the types of incidental finding that might arise.

Researchers may need to seek clinical expertise in considering these factors and should use this information to help them consider the relative benefits and harms of providing feedback on HRFs to participants in the context of their study.

ii  What approach is in the best interests of participants?
Researchers should consider the potential benefits and harms of providing feedback to individuals of HRFs to ascertain what approach is likely to be in the best interests of participants. While there is no definitive view on how the characteristics of a HRF determine whether it should be fed back, models are emerging to support a risk/benefit analysis. Wolf et al. have proposed three categories of findings associated with proportionate responses: strong net benefit (disclose); possible net benefit (may disclose); and unlikely net benefit (do not disclose). 10 For a range of genetic variants Berg et al. considered the potential impact of the condition and whether the finding was “medically actionable” to establish a model for defining an appropriate response. 11

iii  What is considered good practice?
In the UK, practices around HRFs vary widely between disciplines and institutions. 12 However, guidance is beginning to emerge, for example the Royal College of Radiologists has produced recommendations for the management of incidental findings in research imaging. 13 We expect researchers to follow any relevant good practice guidelines in the country where the study is taking place.

iv  What is the context of the study?
Researchers should take into account the context in which a study is taking place, including where the study is taking place and whether the study involves vulnerable populations.

Sponsors have a responsibility to understand the legal environment in which a study is conducted and comply with any local requirements relating to HRFs. When developing a study policy on HRFs, the points to consider and ethical principles underlying a decision should be the same wherever the research is taking place. However, the nature of the potential benefits and harms associated with feeding back a particular HRF are likely to depend on the context in which the study is taking place. For example, in low-income settings, considerations relating to the availability of and realistic prospect of access to care and the capacity of health systems and health professionals to provide advice and support are likely to be relevant to the development and implementation of a policy on
HRFs. In instances where a particular HRF is unlikely to be actionable because of a lack of access to healthcare by the study population, it may not be appropriate to feedback this HRF, even if it would usually be fed back in a setting where care and treatment were available. Where a study is taking place across more than one country, researchers should consider how to address potential differences in standards of care. Where relevant, researchers should also refer to our guidance notes on research involving people in low and middle income countries.

In research involving vulnerable populations such as children or adults without capacity to make decisions for themselves, researchers should carefully consider how participants and/or their representatives would make decisions about and respond to feedback.

V  What are the practical implications for the study? Researchers should consider how logistical issues might affect whether they are in a position to provide feedback of HRFs. For example, will researchers have up-to-date contact details for participants in order to deliver feedback through an appropriate route?

The passage of time between when a participant was recruited to a study and when they would receive feedback had some impact on the strong preference for feedback found in a recent public attitudes study. Various approaches have been proposed to handle this, ranging from providing feedback over an indefinite period to not providing feedback after the study funding has ended. To inform the development of the policy for their study, researchers should consider when in the course of a study HRFs may be identified and when they will have contact with the research participant.

There will often be resource implications associated with the feedback of HRFs. Researchers should consider the potential resource needs of the approach that they plan to adopt to ensure that this is sustainable; proportionate to the potential benefit to research participants; and does not inappropriately compromise the aims or viability of the study. Research on public attitudes towards HRFs showed that a majority of participants agreed that due to the potential benefits to society, large scale studies should still go ahead even when they cannot provide feedback due to logistical or cost reasons.

VI  In existing studies, what is the nature of the original consent? The nature of any existing consent, where relevant, is important because of its impact on participants’ expectations. Where researchers are secondary users of data or samples obtained by another, it is important that they understand the nature of any consent in place and follow the policies and practice set out in the data access or material transfer agreement.

Where studies involve re-consenting participants, researchers should consider the nature of the original consent. However, the approach to feedback in the original consent cannot be relied upon as the sole argument underpinning either its continuance or the development of a new approach to feedback. For example, the fact a study has had a policy of not providing feedback under any circumstances in the past may not be sufficient to justify the continuation of this approach in the future.
D. Points to consider in the consent process

The consent process plays an important role in managing participants’ expectations about individual feedback. The consent process should include information on the feedback of HRFs, to enable participants to make an informed decision about taking part in the research and, if relevant, to allow participants to make a choice about whether they want HRFs to be fed back to them.

It is important that information provided to potential participants is accessible and clear. The following issues should be covered in the consent process where relevant:

i **Will HRFs be fed back to individuals?**
In all studies researchers should explain to participants whether or not HRFs will be reported to individuals. Where feedback will be provided, approaches are likely to vary on a study-by-study basis and researchers may wish to provide information on whether they expect to return feedback on a routine basis, or whether this would only occur in exceptional circumstances.

Findings will often be identified from research data by members of the research team who are not clinically trained. Researchers should therefore consider informing participants about the limitations of detecting potential HRFs. Researchers should also make it clear to potential participants that while they may be collecting health data and returning certain findings as part of the study, participation in the research not a substitute for a health check or clinical investigation.

ii **What is the scope of feedback that a participant could receive?**
In studies where feedback will be provided, it is important that researchers clearly communicate the types of findings that could be fed back to potential participants. Important information might include the likelihood of a relevant HRF being made and the characteristics of conditions where feedback would be considered, for example where an HRF indicates a condition that is serious but actionable.

Researchers should consider including information on potential positive, negative and wider implications of feedback. This may include information on the implications of the HRFs for others, for example the participant’s relatives in the case of genetic findings.

Researchers should consider providing accessible information on how feedback would be delivered and, where feasible, the support that would be available to a participant to follow up and seek the additional help they need. Any involvement of the participant’s primary healthcare professional should be mentioned explicitly in the consent process. Where healthcare is not publicly funded, researchers should indicate if the participant or their insurer will be responsible for paying for follow up clinical tests or interventions.

iii **Do participants have a choice about what feedback to receive?**
Some research participants may not want information on a potential HRFs fed back to them. In studies where feedback will be provided, it is therefore important for researchers to clearly communicate to potential participants whether and how the conditions of the study allow them to opt-out of receiving HRFs. In some cases it may not be appropriate to offer an opt-out from feedback, for example where the HRF indicates a condition with public health implications, such as an infectious disease.

Where relevant, researchers should also make it clear to participants whether they can choose to receive feedback on certain types of HRFs, but not others.
E. Points to consider in designing the feedback pathway

In studies where the policy is that feedback on HRFs will be provided, it is important that the feedback pathway should be considered at the outset. Research contexts can vary widely, for example in the nature of the expertise of those involved and the relationship between the researcher and the participants, and researchers should consider these factors in order to design an appropriate feedback pathway. The feedback pathway should include robust processes for decision-making in order to ensure that in any given case the approach to feedback is consistent with the wider policy of the study and the consent in place. Researchers should ensure that all elements of the feedback pathway are appropriately costed and resourced. In particular the researcher should confirm with the sponsor that appropriate indemnity or insurance cover is in place with respect to the feedback process.

The following points should be taken into account in designing the feedback pathway:

i  How will potential HRFs be identified?
Researchers should consider how their research analysis will lead to the identification of HRFs, which may be more straightforward for pertinent than incidental findings. Researchers should also consider the skills, expertise and seniority of the individual or team who may first identify a potential HRF. It should be clear how and when this individual will make a decision about whether the HRF needs to be considered further. Researchers should consider arrangements to access relevant expertise to assess the HRF, if this is likely to be necessary.

ii  Does the finding need to be verified?
Following initial identification of an HRF in an individual participant, further analysis may be needed to verify the HRF to ensure its accuracy. For example, a clinical grade test may be needed on an independent sample, since sample handling in a research setting can be less tightly controlled than in a clinical setting. It may be necessary to involve the participant before analytical validity can be assured, for example where they need to provide a new sample or be present for a test.

Researchers should consider how any analytical verification will be achieved and how to appropriately involve the participant in this process, where necessary.

iii  Who will be involved in the feedback pathway?
Researchers should consider how to ensure that the right people are involved in the feedback pathway to ensure that it is clear, robust and incorporates appropriate expertise.

Consideration should be given with regard to integrating clinical expertise where it is likely to be needed. The role of the participant’s primary healthcare professional, such as their GP in the UK, should also be considered, for example whether it is appropriate to involve them in the feedback pathway and at which stage they should be informed of the finding.

iv  How and when will feedback be delivered?
Researchers should consider:

- whether the feedback would be delivered directly to the participant or via their primary healthcare professional;
- how the feedback would be delivered, for example in a face to face meeting or over the telephone; and
- how the feedback would be delivered in a timescale that is appropriate to the finding identified.

Researchers should also consider how the feedback pathway will enable participants receiving feedback to access the necessary follow up, for example referral to a specialist. However, it is important to maintain, as far as possible, a distinction between health research and medical care by recognising that it is not the researchers’ responsibility to provide medical care after feedback has been provided.
F. Case studies

Example 1: One approach to genetic findings and cardiovascular disease
A UK study is being established to examine the link between certain genetic variants and the development of cardiovascular disease in adults. The study is expected to identify known variants associated with a high risk of cardiovascular disease at individual level, as well as identifying potential new variants linked to cardiovascular disease. Researchers develop a policy on HRFs as they develop the protocol.

The research team decides to provide feedback to individuals carrying variants known to be associated with hypertrophic cardiomyopathy (HCM) and a high risk of sudden cardiac death. The link between HCM variants and sudden cardiac death is well-established in the literature and the National Institute for Health and Care Excellence recommends the use of implantable cardioverter defibrillators for familial cardiac conditions with a high risk of sudden death, including hypertrophic cardiomyopathy. The researchers develop a feedback mechanism where a clinical geneticist on the research team reviews potential cases and delivers feedback to the individuals, with relevant counselling and further testing to assess the analytical validity of the result, where this is appropriate. This enables individuals to decide whether to seek follow up treatment through the NHS. At consent the participants are given information about the tests that will be performed and told that they will be informed if HCM variants are identified. Researchers decide that they will not allow individuals to opt-out of receiving their result, so their participation in the study is conditional on receiving this feedback.

The research team decides not to provide individual feedback on any new genetic variants that appear to be associated with cardiovascular disease, since the link will not be well proven. However, they decide to make information on these new variants available on the study website, as well as seeking to publish these findings in a journal.

This approach is reviewed by the Research Ethics Committee as part of the ethical review of the study.

Example 2: Contrasting approaches in surveys of infectious disease
A study in a number of countries in Africa aims to assess the prevalence of HIV in the general population to investigate the effectiveness of different public health strategies in reducing transmission of HIV. The study will use clinical grade tests to assess individuals’ HIV status. Researchers decide that given the importance of an individual knowing their HIV status in order to seek treatment and reduce the risks of transmitting the virus to others, they will provide routine individual feedback of HIV test results. Antiretroviral therapy is available in the regions where the study is taking place. Participation in the study is voluntary and potential participants are told as part of the consent process that participation is on the basis that they will receive feedback of their HIV test results. Individuals who do not want to know their HIV status will therefore not be eligible to participate in the study.

A large research study in the UK will examine the prevalence of sexually transmitted infections among young people and their association with sexual behaviours. To cover a large sample size at a reasonable cost, the study will use tests and processes that are not clinical grade. These tests are accurate enough for the purposes of the research study, but they are associated with a relatively high rate of inaccurate results at an individual level. The research team therefore decide that it is not appropriate to return findings to individuals as the results may be misleading. Potential participants are told during the consent process that they will not receive any feedback.
Example 3: One approach to findings made by secondary researchers in a cohort study
Researchers establish a cohort study with participants aged between 20 and 40. In the initial phase of the study, measurements will be taken from the participants, who will also provide tissue samples and additional information through questionnaires. The participants give broad consent for these tissue and data to be used in health-related research. The consent includes the use of the tissue and data in pseudonymised form by researchers outside the core research team. The participants consent to receive feedback on HRFs that are serious and actionable.

A secondary researcher plans to use the cohort resources to examine the links between certain genetic variants, the environment and the risk of developing cancer in adults. The study is expected to identify known variants associated with a high risk of developing cancer at individual level. This project is to take place three years after the cohort study has been established.

The secondary researcher agrees with the core research team to provide feedback relating to individuals carrying BRCA2 variants known to be associated with a high risk of developing breast cancer. The link between BRCA2 variants and cancer risk is well-established in the literature and the National Institute for Health and Care Excellence recommends that women with BRCA2 variants should be screened from aged 30 to enable early diagnosis and treatment.

The secondary researcher will undertake their research using pseudonymised data and therefore does not have access to the participants’ identities and contact details. The secondary researcher therefore agrees to return findings of the BRCA2 variants to the research team, who will then link the pseudonymised data to the identity of the participant. The core research team develop a feedback mechanism where a clinical geneticist on the core research team reviews potential cases and delivers feedback as part of their clinical role. Relevant counselling and further testing to assess the analytical validity of the result is provided where this is appropriate.

This approach is to feedback is reviewed by the Research Ethics Committee as part of the ethical review of the secondary study, in light of the existing consent arrangements.

Example 4: One approach to feedback in an imaging study
Researchers are planning a cognitive psychology study that will involve taking structural and functional MRI scans of the brain. The structural MRI scans will not be diagnostic grade, but these may still detect potential abnormalities. The researchers decide that they will report back incidental findings that are potentially serious and where treatment options are available. Participants consent to take part in the study on this basis.

The researchers include a management pathway for incidental findings in the study protocol. Any potential abnormalities noted by the researcher and/or radiographer will be referred to a consultant neuroradiologist for review. This arrangement is established with the consultant neuroradiologist before the study starts. If the consultant neuroradiologist considers that the incidental finding needs to be investigated further, the researcher and consultant will write to the participant to invite them to a meeting with the consultant. At this meeting the finding will be explained to the participant and they will be given a choice whether they would like further investigations to follow up the finding.

Where a participant wants a finding to be followed up, the consultant will arrange for the necessary clinical evaluation as part of their clinical role. At this point the consultant will ask permission to refer the finding to the participant’s GP, whether the finding is to be followed up or not.
G. Glossary

**Actionable**
When a strategy is available and accessible to ameliorate a condition or reduce the risk of developing a condition, through interventions such as treatment, screening or preventative measures.

**Aggregated research findings**
The generalisable conclusions of the research that cannot be connected back to a specific individual.

**Clinical utility**
When a result or finding is proven to relate to a particular condition or risk of developing a condition, enabling clinical action to be taken.

**Dynamic consent**
A process that allows participants to monitor how their data and/or samples are being used and change their consent. Dynamic consent is being considered as a potential new model in research.

**Health-related finding**
A finding that has potential health or reproductive importance, which is discovered in the course of conducting research, including both pertinent findings and incidental or unsolicited findings.

**Incidental or unsolicited finding**
A finding that has potential health or reproductive importance, which is discovered in the course of conducting research, but is unrelated to the aims of the study.

**Pertinent finding**
A finding that has potential health or reproductive importance, which is discovered in the course of conducting research, and is related to the aims of the study.


3. HeLEX Centre for Health, Law and Emerging Technologies (2009) Ethical, legal and social issues arising from the use of GWAS in medical research: Literature Review for the Wellcome Trust

4. Opinion Leader, Wellcome Trust and Medical Research Council (2012) Assessing Public Attitudes to Health Related Findings in Research


8. American College of Medical Genetics and Genomics (2013) ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing
Wellcome Trust policy position on research involving human participants
10 Ibid. 1


13 The Royal College of Radiologists (2011) Management of incidental findings detected during research imaging

14 Ibid. 4

15 Ibid. 4