

Guidance on feeding back results and reporting disclosures

One benefit to participating in a research study is to receive the final report. Many studies also offer to inform participants about how they did on a particular aspect of the study, such as their balance, etc. However, it is not always possible to know at the outset what information and findings the study could generate.

The following guidance is provided as a tool for researchers and reviewers alike to use when considering what information should/should not be fed back to participants, as well as what should/should not be disclosed and to whom.

■ There are two types of findings/results that can arise from any research study.

ANTICIPATED FINDINGS

These are results from the measures that you intend to use, such as those measuring reading age, IQ levels, etc.

INCIDENTAL FINDINGS

Incidental findings are not the same as anticipated findings because they are unexpected. A good way to think of incidental findings are as side effects to the methods used. For instance, you will know there is the possibility of finding an abnormality during an MRI scan, but you are not undertaking the MRI scan in order to find that abnormality, nor could you predict that that participant would have that abnormality.

Recommendation: It is suggested that prior to seeking ethical approval you list the different types of findings that could arise from your particular research study, and consider how you will treat these findings.

■ Feedback vs Disclosures

For the purposes of this guidance, we will treat disclosure separately to feedback.

- **Feedback** should be defined as informing participants of anticipated and promised results from their participation. However, this does not include high risk findings that could result in disclosures (see below).
- **Disclosures** should be defined as informing participants of incidental findings and 'high risk' anticipated findings, such as suicidal ideation.

FEEDBACK

When deciding what and how to feed back anticipated results you should take into consideration the following:

- What information would the participants want to know?
- What results are easily explainable to participants, and what require additional support?
- What results are directly applicable/of use to participants?

It is also important to assess to possible impact the results could have on participants and/or others as this will help shape how you feedback the results, who informs the participant and what support should/could be offered. For example, there is a difference between feeding back how a participant did in a reading comprehension questionnaire compared to their assessed level of IQ, and a further difference if the IQ result relates to their child.

Whether or not you intend to pass results back to the participants/others, you must make this decision at the outset and ensure it is made clear on the recruitment literature. If you are feeding back results, you should also decide and detail what support will be available.

DISCLOSURES

Information requiring (or potentially requiring) disclosure could be predicted, for example if you are administering questionnaires assessing suicidal ideation. It could also be incidental to the research, such as an abnormality showing on an MRI scan, or a participant's urine sample demonstrating that they are pregnant. No matter how the information arises, researchers should assess the likelihood of such information becoming known and agree upon a method for dealing with such situations prior to commencing the research. In addition, the information sheet should explain to participants the likelihood of such results and also how they will be dealt with.

It should be noted that because some research results may not be clinically definitive, there will often be a need to provide interpretation and/or take into account the context of results when feeding these back to participants. In such cases feedback should usually be given via the participant's GP or a similarly qualified individual, rather than directly to the participant themselves by the researcher. In these circumstances, explicit consent to do this would need to be obtained before the study started.

■ Things to consider

- The seriousness of the information.
- Are there any statutory requirements to disclose data collected (for example in cases of suspected child abuse or communicable disease)?
- The impact not/disclosing the information will have and on whom. NB: This goes beyond the immediate impact on participants and can include their families, and also insurance, their job, etc.
- Who should any disclosure be made to? If not the participant, how will they be informed?
- What support or additional investigations can/will be offered to participants?
- Are the methods proper diagnostic tools (this especially applies to questionnaires, etc)? Also, is the researcher administering the tools qualified to make such a diagnosis and disclose the information?
- Will you need to inform someone other than the participant? If so, the participant may have to agree to this beforehand (for example if informing their GP). What then happens if they refuse to give consent to you informing them?