PUBLIC

ALSPAC Disclosure Policy

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Revision History

Version	Reviewed By	Date	Description
1.0	N/A	01/03/2011	This is the first version.
1.1	David Jewell	21/05/2014	No changes required
1.2	Jess Harvey and ALEC	18/12/2025	Added policy title page and version history Minor formatting changes No further changes

ALSPAC Ethics & Law Committee

Policy regarding disclosure of biomedical information to participants

The policy is that information shall not, as a general rule, be disclosed to participants.

This general policy should only be set aside when it is reasonably certain that the benefits of disclosure clearly outweigh any possible risks to the participants or their families. This in turn will arise when three conditions are met:

1. **That an item of data gives clear, unequivocal information of an existing or future health problem.**
2. **That the health problem identified is amenable to treatment of proven benefit**
3. **That the participant has indicated beforehand that they wish to be informed if such a problem is identified.**

A number of principles have informed the discussions of the Committee:

- Individuals have consented to participate in the study on the clear understanding that all measures are for research purposes only and not to inform decisions about their health. To emphasise this, it is often stated explicitly in the information given to participants.
- As a corollary, it is frequently repeated that the tests that participants undergo are not a check on their health, and that if participants are worried they should go to their own doctors.
- The relationship between researcher and participant differs from that between doctor and patient. Crucially the duty of care is different. The primary concern of a researcher is to acquire information for the benefit of humankind.
- Disclosing information will not necessarily be beneficial to participants. Individuals will differ in their approach to receiving information about themselves, and for some it could result in negative, unforeseen consequences.
- In practice, some measurements are undertaken in order to define more precisely their relationship to future health problems. In this instance the risk to any individual cannot be known, and therefore the information should not be divulged to them.

This policy should be applied in all circumstances, including:

- All biophysical measurements, whether they are the primary purpose of a study or incidental findings identified in the course of a study
- All questionnaire results that have been administered to identify health problems. Answering questions does not equate to knowing the outcome of the whole questionnaire, and therefore participants do not already know or understand their own data.
- The results of tests where analyses take place some time after the samples were taken. This arises if biological samples are analysed in batches after they have been taken. If it is thought that feedback of abnormal results will be important and necessary, the Committee may try to ensure that such delays are minimised.
- In particular, tests to identify either specific genes or more extensive genetic sequencing.

The only circumstances where this does not apply is where measurements have been taken in the presence of the participants, where the information would have to be concealed from the participants, such as height, weight, blood pressure, etc. This exception is made more on practical grounds than from any application of principle.

This policy does not in any way countermand the long-standing practice that ALSPAC provides the results of completed studies to all participants as soon as possible. This is usually done in the form of a newsletter.

There is one particular difficulty that can be predicted. This arises when advances in technology or in the understanding of disease processes so that important measurements can be made on biological specimens taken some time before. It is in the nature of a long-term study like ALSPAC that such circumstances will inevitably arise. Because participants could not have been asked at the time that the specimens were taken, the general principle

would be not to disclose the information. This might be overridden if it was felt sufficiently important to seek further consent from participants; or if the condition identified were so severe that the argument for disclosing the information outweighed other considerations.

Duty to inform participants: In line with its previous conclusion, the Committee felt that the decision whether to inform individuals should be taken by the Committee, drawing on advice from clinical experts. This would keep such decisions independent of the researchers and would be consistent with the Committee's role of protecting the interests of participants.

Panos Maghsoudlou
Chair, ALSPAC Ethics & Law Committee
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