

Model article on data protection and medical research

1. Medical researchers are required to respect the fundamental right to the protection of personal data of their participants.

2. In the particular context of medical research, respect for the fundamental right to the protection of participants' personal data requires researchers:

- To inform participants about the nature of the research purpose or purposes, and to process participants' data only for the purpose or purposes so indicated
- To inform participants about the nature of the persons (or class of persons) who will be using or accessing the data, and to restrict use or access only to the persons so indicated
- To inform participants about the arrangements for the disposal or destruction of the data once the research is completed, and to dispose of or destroy the data in the way so indicated
- To make best efforts to maintain the data in a secure storage environment

3. The fundamental right to the protection of personal data does not require that participants' personal data should be held in an anonymised (or pseudonymised) form. However, it does require that participants should be told in what manner and form their data will be held and data should then be held in the manner and form so indicated.

4. The information referred to in paras 2 and 3 is required to be given to prospective participants in an accessible and timely form so that they have a fair and reasonable opportunity to decide whether or not to participate.

5. An act that infringes one or more elements of the right to the protection of personal data is unlawful unless:

- (i) the act is covered by the participant right holder's authorising consent; or
- (ii) the act is justified by one of the exceptional reasons specified in para 9.

6. The participant right holder's 'authorising consent' (within the meaning of para 5(i)) will be valid only where all of the following conditions are met:

- The consent is given freely (as the unforced choice of the right holder)
- The consent is informed
- The right holder has the capacity to consent and, at the time of giving consent, is competent to do so
- The consent is signalled unequivocally, such that there is no possible doubt that the right holder is consenting.

7. The validity of the participant right holder's 'authorising consent' does not depend upon it being limited to research into one specified disease or condition. The research purposes may be expressed broadly or generically. However, if there is any doubt about whether a particular act by researchers falls within the scope of the participant right-holder's consent, the consent should be construed restrictively, and the burden should be on the researcher to clarify and confirm that a covering authorisation is in place.

8. A participant has the right to withdraw his or her consent at any time and for any reason. When consent is withdrawn, researchers are required to take all practicable steps to ensure that there is no further processing of the participant's data.

9. An act will be justified by an 'exceptional reason' (within the meaning of para 5(ii)) if it is necessary in order:

- to protect the vital interests of the right holder (but only where the right holder is incapacitated); or
- to protect more important rights of another right holder; or
- to protect a vital public interest