

Research subjects' rights

An Information Sheet for Tourettes Action Research Conference Delegates, 28 March 2009

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The concept of research ethics originates from the time of World War II, when many events greatly disturbed both researchers and the general public. When the harmful and potentially deadly research methods used as part of Nazi experiments were revealed, a debate began alerting the scientific community to the need for reflection on research ethics. Thereby, the concept of rules and recommendations for research was born.

Your rights

In association with the Nuremberg trials¹ after World War II, *The Nuremberg Code of 1947* was formulated - the first official code for medical research. Among other things, the Code established that informed consent is necessary, that the risks to research subjects must be minimized and that research must have positive consequences for the community. Further, it points out that each subject has the right to terminate participation in an experiment at any time, and that the researcher leading such an experiment is to terminate it if it seems likely that a subject is being harmed.

Since then, other important declarations and rules have followed, for example *The Declaration of Helsinki*² by the World Medical Association. This declaration is specifically directed at biomedical research on humans, including research on human material and data. Some of the declaration's statements relating to research subjects' rights are:

- The **research protocol should include** information about **why the study is performed**, and **provisions for treating** and /or **compensating subjects who are harmed as a consequence of participation** in the research study.
- Medical research involving humans need to be conducted by staff with the appropriate scientific training and qualifications. **The responsibility for the protection of research subjects must always rest with the physician** or other health care professional and **never the research subjects, even though they have given consent.**
- **Participation** by competent individuals as subjects in medical research **must be voluntary.**
- Every precaution must be taken to **protect the privacy of research subjects and the confidentiality of their personal information** and to **minimize the impact** of the study on **their physical, mental and social integrity.**
- The potential participant **must be adequately informed of** the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the **anticipated benefits and potential risks of the study and the discomfort it may entail**, and any other relevant aspects of the study.

- The potential participant **must be informed on the right to refuse to participate** in the study **or to withdraw consent** to participate at any time **without reprisal**. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing.
- Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have the duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. **Negative and inconclusive as well as positive results should be published or otherwise made publicly available.**
- At the end of a study, the **patients** entered into the study **are entitled to be informed about the outcome of the study** and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

If you decide to take part

It is important to remember to make sure you understand the project – why is it done and exactly what it will require from you if you decide to take part. The researcher should be able to answer any questions you may have, and inform you about all relevant aspects of the project.

If the project is a medical project, a member of staff will explain in detail what it will involve for you. If the project is non-medical, for instance a psychology project involving a questionnaire, the researcher will explain the project, or you will be given an information sheet from the researcher to read. This information letter is important to keep and refer back to for information about the study or the contact details of the researcher/s.

The researcher should be able to give you an idea about when the project is due to finish and the result of the study should be given to you if you wish to know.

Tourettes Action will do its best to disseminate the findings of research studies we fund or otherwise support. We do this through our newsletter and by publicising the results on our website www.tourettes-action.org.uk.

If you have any questions about any research studies taking place that are supported by Tourettes Action, contact Research Manager Linnea Larsson on linnea@tourettes-action.org.

¹ The Nuremberg Trials were a series of trials, or tribunals, most notable for the prosecution of prominent members of the political, military, and economic leadership of Nazi Germany after its defeat in World War II. The trials were held in the city of Nuremberg, Germany, from 1945 to 1946, at the Palace of Justice.

² World Medical Association's Declaration of Helsinki; Ethical Principles for Medical Research Involving Human Subjects (<http://www.wma.net/e/policy/b3.htm>).