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The expression of objection by people with mental disabilities in the context of the WMO

A code of conduct for physicians involved in the assessment of expressions of objection by people with mental disabilities

On the basis of the parameters set out in the Medical Research Involving Human Subjects Act, with particular regard to incapacitated subjects, the following points may be made regarding people with mental disabilities.

- 1 Among the mentally disabled, both inter-individual and intra-individual differences exist in terms of competence to make decisions of various kinds. The wishes of a prospective subject should be determined as far as possible. However, it will in most cases be necessary to involve third parties in any decision regarding participation in medical research. These third parties will be needed not only to assess the prospective subject's competence, but also to interpret his or her behaviour. The third parties concerned will include both professional supervisors and lay individuals with an interest in the case (legal representatives). The basis for their decision-making should be the duty of care or representation that they have towards the prospective subject. When considering whether a prospective subject should be permitted to participate in a study, it is necessary to weigh up the direct interest that the individual has in non-participation against any potential long-term interest he or she may have in the outcome of the proposed research.
- 2 In most cases, it will be necessary to deduce objection from the subject's behaviour; this will entail the interpretation of the subject's actual behaviour at the time of the (proposed) research in order to decide whether it constitutes objection. The interpretation and assessment of behaviour should in principle be made by a multidisciplinary team including at least a care expert/group supervisor, a behavioural scientist and a physician. Non-professional interested parties should also play a role.
- 3 The (prospective) subject may express objection by both verbal and non-verbal means. In many cases, it will be necessary for third parties to interpret behaviour in order to determine whether a given action or utterance constitutes an expression of objection to the particular research in its particular form. If it is concluded that certain behaviour does constitute an expression of objection, or if the observers are not in agreement regarding its significance, the subject should not participate. In this context, anticipated behaviour, i.e. behaviour that is expected from a subject when confronted by the prospect of a particular research procedure, has the same significance as actual behaviour. In other words, if on the basis of the third parties' knowledge of the subject it is expected that he or she will object, the individual in question should not be involved in the research.
- 4 From point 3 it may be inferred that familiarity with the behaviour of the individual subject is important in determining whether an objection has been expressed. In this sense, the situation with regard to people with mental disabilities differs from the situation with regard to other incapacitated subjects, insofar as a mentally disabled person's life history provides pointers to the interpretation of his or her behaviour even though the subject may not explicitly give or may never have explicitly given expression to that behaviour. Knowledge of a (potential) subject's life history may be gleaned from various sources: family members, treatment providers (physicians, educationists, psychologists), group supervisors (personal and other supervisors), and entries in the person's care/treatment plan or medical record.

- 5 The signs that should generally be regarded as expressions of objection may be verbal or non-verbal. Some of these signs are set out below, although the list is by no means exhaustive:
- *verbal*:
 - things subject says to people from his/her own environment;
 - use of phrases such as ‘don’t want’, ‘no, don’t’, ‘ouch, ouch’;
 - *non-verbal*:
 - pushing investigator or investigator’s arm away, throwing away research material, walking away, turning head away, curling up, keeping mouth tightly shut, groaning, nervous behaviour (agitation, physical tension, flapping about).
- Resistant behaviour will need to be assessed in the context of the developmental age of the subject; it is possible that, in a given instance, behaviour normal for a person of the subject’s developmental age should not be interpreted as objection. Any behaviour which differs in nature or degree from that typically displayed by the subject in situations not encountered on an everyday basis should always be interpreted as an expression of objection. Furthermore, it is appropriate to consider excluding from a study individuals who perceive routine care procedures to be unpleasant. A prospective subject’s behaviour should be interpreted by third parties who are familiar with the individual in question.
- 6 The preceding paragraphs make repeated reference to the interpretation of behavioural signs. Such interpretation is necessary because a particular form of behaviour may mean different things when exhibited by different individuals. One must be familiar with the individual in question in order to attribute a meaning to a particular form of behaviour. The behaviour that it is anticipated a (prospective) subject will display at the prospect of or in response to the discomfort of a proposed procedure must be interpreted on a similar basis. The interpretations attached to a subject’s behaviour should be noted in his or her medical records and in the research file. With a view to facilitating review, the considerations on which these interpretations are based should also be noted, along with details of the parties involved in making the interpretations. A (prospective) subject’s behaviour should be assessed not only prior to or at the commencement of the research, but also continuously throughout the research. If an initially cooperative subject expresses objection at a later stage of the research, the subject’s participation should be ended.
- 7 The research protocol that is to involve mentally disabled subjects should explicitly state what is to be done if subjects object to (continued) participation. The medical ethics review committee responsible for the review of such a research should satisfy itself that this requirement has been complied with. Medical research can certainly serve the general or immediate interests of a person with a mental disability. Hence, it will generally be necessary for a reviewing committee to weigh up the discomfort and inconvenience associated with participation against the benefits that the research may have for the target group.