**GUIDANCE FOR RESEARCH INVOLVING PSYCHIATRIC PATIENTS**

Dear Sir,

When registering research involving psychiatric patients,please take note of the following instructions which may be found in the Act on Protection of Persons with Mental Disorders (OG 76/14):

Chapter IV: **SPECIAL MEDICAL PROCEDURES AND BIOMEDICAL RESEARCH**

**Article 19**

(1) Biomedical research may be conducted in relation to persons with mental disorders, if:

1. the Commission for protection of persons with mental disorders (hereinafter: the Commission) has approved the biomedical research project, after examining its scientific significance, the importance of its aim, and the ethics of the research.

2. The ethical committee has given a positive opinion regarding the ethical acceptability of including persons with mental disorders in the research.

3. The person with a mental disorder has been informed in a precise and comprehensible manner of the importance of the research, and its purpose, nature, consequences, benefits and risks.

4. The person with a mental disorder has given written consent, which may be revoked at any time, and if their capacity to give consent to biomedical research has been confirmed by another psychiatrist who is not an employee of the psychiatric institution where the research is being conducted, as designated by the Commission.

5. It may be justifiably expected that the results of the research will be useful for the health of that person, and without harmful side effects, about which the ward doctor shall give an opinion.

(2) The decision to include a person with a mental disorder in biomedical research is rendered by the head of the psychiatric institution after obtaining all the documents referred to in paragraph 1, points 1 to 5 of this Article.

(3) The psychiatric institution is obliged to inform the Commission that it is conducting the biomedical research.

**Article 20**

(1) Notes on the use of special medical procedures and notes on the conduct of biomedical research, and all the documents prescribed in Articles 18 and 19 of this Act must be included in the medical documentation.

(2) Consent to the special medical procedure and the biomedical research may not be given by a legal representative or any person of confidence in place of the person with a mental disorder.

(3) A member of the ethical committee must be exempted from decision making if he or she is the ward doctor of a person with a mental disorder included in the special medical procedure or biomedical research.