to protect and promote

Kummissarju għall-Promozzjoni tad-Drittijiet ta' Persuni b'Diżordni Mentali

Commissioner for the Promotion of Rights of Persons with Mental Disorders

13th February 2023

To:
Chairpersons
Health Ethics Committees

Guidelines for clinical trials / medical or scientific research carried on persons with mental disorders

Having considered the provisions of the Mental Health Act, hereinafter called the Act, regarding clinical trials or other medical or scientific research, in particular articles 31 and 35 of the same Act;

And after having discussed the impact of the said Act on all research being conducted under the auspices of, inter alia, the University of Malta, and any other ethics committees in other higher educational institutions licensed under the Education Act and recognized by the Information and Data Protection Commissioner, research that is not only a cardinal function of the same University as established under Article 72 of the Education Act and for which purpose it is empowered by the same Act "*...to make such provisions for research .... as it may from time to time determine*" but is in general often beneficial for the same persons with mental disorders whose rights are promoted and safeguarded under the Act;

And after considering the rigorous internal mechanisms adopted by the University of Malta, including but not limited to, the two tier system of Research Ethics Committees whose services apply not only to research conducted under its auspices but may also be applied for by external researchers;

And after having duly considered the word and spirit of the Act providing that "... *persons with a mental disorder shall have the right to: (a)exercise all civil, political, economic, social, religious, educational and cultural rights*";

The Commissioner for Mental Health, in agreement with the University of Malta, is providing the following guidelines to be followed by those in charge and, or conducting such clinical trials or other medical or scientific research:

1) It shall be the duty of every person in charge and, or conducting such clinical trials or other medical or scientific research to comply with all legal, regulatory and ethical dispositions, including these guidelines. In particular, it shall be the duty of such person to ascertain that each and every person being interviewed has given their free and informed consent to participate in such research.

2) Clinical trials cannot be undertaken and, or commenced unless and until the Ethics Committee established by the Clinic Trial Regulations has issued a favourable opinion and the Licensing Authority referred to in the same Regulations has informed the responsible person that there are no grounds for non-acceptance.

3) Every person in charge of and, or conducting all medical and scientific research not falling under paragraph 2 above shall:

a) If the subject matter of the research concerns issues of mental health, inform the relevant Research Ethics Committee of the University of Malta accordingly, which Committee may consider requesting the favourable opinion of a Responsible Specialist and, or the Commissioner appointed under the Act, before authorizing such research.

b) Without prejudice to the generality of paragraph (a) above, if the person in charge of and, or conducting such research is made aware, or has reason to believe, that a person who it is intended will participate, or is participating, in the research, has a mental disorder in terms of the Act and is under the care of a Responsible Specialist, a certification from that Specialist that the person is capable to give free and informed consent and that the expected benefits of the research are likely to outweigh any potential harm, shall be obtained.

c) If the person who it is intended will participate, or is participating, in the research is not under the care of any Responsible Specialist, but the person in charge of and, or conducting such research is not satisfied that the participant, or potential participant, can give valid informed consent, a certification as provided for in paragraph (b) above, shall be obtained.

d) Without prejudice to paragraphs (b) and (c) above, if the person who it is intended will participate, or is participating, in the research, has been certified as lacking the mental capacity to give free and informed consent, a certification from 2 Specialists, one of whom shall preferably be the Responsible Specialist, that the expected benefits of the research are likely to outweigh any potential harm, shall be obtained. Moreover, in such cases, the approval of the responsible carer and of the Ethics Committee mentioned in paragraph (2) above, shall also be obtained.

e) Also without prejudice to paragraphs (b) and (c) above, if the person who it is intended will participate, or is participating, in the research is a minor suffering from a mental disorder and is under the care of a Responsible Specialist, a certification from 2 Specialists, one of whom shall be the Responsible Specialist who has clinical experience of working with minors, that the expected benefits of the research are likely to outweigh any potential harm, shall be obtained. Moreover, in such cases, the approval of the parent or legal guardian of the minor and of the Ethics Committee mentioned in paragraph (2) above, shall also be obtained.

4) Every Responsible Specialist being requested to certify a person with a mental disorder as provided for in these guidelines, shall be considered, *mutatis mutandis*, as having been appointed by the Commissioner to assess and certify the said person for this purpose.

5) For the avoidance of any doubt, it is being established that these guidelines shall apply, *mutatis mutandis*, to all other higher educational institutions licensed under the Education Act and recognized by the Information and Data Protection Commissioner, including, but not limited to, MCAST and IdeaMalta.

Dr. Denis Vella Baldacchino
Commissioner for the Promotion of Rights of Persons with Mental Disorders