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COMMITTEE ON BIOETHICS (DH-BIO)

Draft Additional Protocol concerning the protection of human rights and dignity of persons with regard to involuntary placement and involuntary treatment within mental healthcare services

as revised by the DH-BIO and finalised by the Secretariat in the light of Comments submitted by Delegations following the 17th plenary session (3 – 6 November 2020) (DH-BIO (2020) 25)

- Changes to the previous version (DH-BIO(2019)20REV3) appear **in bold letters** -

Delegations are invited to examine this draft in view of the final vote on the draft foreseen for the 18th plenary session of the DH-BIO (1-4 June 2021).

Preamble

The member States of the Council of Europe and the other signatories to this Additional Protocol to the Convention for the Protection of the Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (hereinafter referred to as "the Convention on Human Rights and Biomedicine", ETS No. 164),

Considering that the aim of the Council of Europe is the achievement of greater unity between its members and that one of the methods by which this aim is pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 (European Convention on Human Rights, ETS No.005) and in particular Articles 3, 5 and 8 thereof;

Taking into account the work carried out at international level on the protection of **the** dignity and rights of persons with disabilities, in particular the United Nations Convention on the Rights of Persons with Disabilities of 13 December 2006;

Considering that the aim of the Convention on Human Rights and Biomedicine, as defined in Article 1, is to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine;

Bearing in mind Recommendation Rec 2004 (10) of the Committee of Ministers to member States concerning the protection of the human rights and dignity of persons with mental disorder;

Acknowledging the importance of the work of the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT) and of the relevant Standards developed by that Committee;

Emphasising that any form of discrimination on grounds of mental health problems must be prohibited;

Recalling the importance of ensuring equitable access to mental health care services of ~~high~~ **appropriate** quality, taking into account health needs and available resources;

Emphasising the need to protect vulnerable persons with mental health problems;

Recalling that any intervention in the health field must be carried out in accordance with ~~relevant~~ professional obligations and standards;

Stressing the importance of adequate training of staff working within mental health care services;

Emphasising that human dignity requires persons to have access to support to exercise their autonomy;

Stressing the importance of persons being involved in decisions about their treatment and care;

Underlining the importance of the principle of free and informed consent to interventions in the health field;

Recognising that restrictions on the rights set out in the Convention on Human Rights and Biomedicine are permissible only if prescribed by law and necessary in a democratic society in the

interests of public safety, crime prevention, protection of public health or the protection of the rights and freedoms of others;

Taking into account national and international professional standards in the field of involuntary placement and involuntary treatment of persons within mental health care services and the previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field;

Considering that involuntary treatment on a person whose ability to decide on treatment is severely impaired must aim at enabling this person to regain such ability;

Emphasising the primary importance of developing appropriate mental health care measures carried out with the consent of the person concerned and aiming at avoiding recourse to involuntary placement and involuntary treatment;

Recognising that the use of involuntary placement and involuntary treatment has the potential to endanger human dignity and fundamental rights and freedoms and must therefore be minimised and only be used as a last resort;

Stressing the need of ensuring that, if such measures are used, the persons concerned are appropriately protected and can effectively exercise their rights;

Stressing the importance of appropriate monitoring of the use of such measures;

Resolving to take such measures as are necessary to safeguard human dignity and ensure respect for the human rights and fundamental freedoms **of the person** with regard to involuntary placement and involuntary treatment by clarifying the standards of protection applicable to the use of such measures,

Have agreed as follows:

Chapter I – Object and scope

Article 1 – Object

1. Parties to this Protocol shall protect the dignity and identity of all persons and guarantee, without discrimination, respect for their autonomy, their integrity and their other rights and fundamental freedoms with regard to involuntary placement and involuntary treatment within mental health care services**.**

2. The provisions of this Protocol do not limit or otherwise affect the possibility for a Party to grant a wider measure of protection than is stipulated in this Protocol.

Article 2 – Scope and definitions

Scope

1. The provisions of this Protocol apply to involuntary placement and involuntary treatment of persons with mental disorder.

2. The provisions of this Protocol do not apply to minors.

3. This Protocol does not apply to placement and treatment ordered in the context of a criminal law procedure.

Definitions

4. For the purpose of this Protocol, the term:

- "mental disorder" is defined in accordance with internationally accepted medical standards; a failure to adapt to society's moral, social, political, religious or other values may not be regarded as a mental disorder;

- "involuntary measure" refers to any placement and/or treatment of a person without that person's free and informed consent or against the will of the person;

- "therapeutic purpose" refers to controlling symptoms, slowing down the rate of deterioration, rehabilitation~~, recovery~~ and cure of the mental disorder **with a view to the recovery of the person**;

- "seclusion" refers to the involuntary keeping of a person alone in a room or designated area;

- "restraint" refers to the use of physical, mechanical or pharmaceutical means aiming at holding or immobilising a person or controlling his or her movements;

- "representative" means a person provided for by law to represent the interests of, and take decisions on behalf of, a person who does not have, according to law, the capacity to consent;

- "person of trust" refers to someone chosen by a person receiving mental health care, and who is expressly designated to assist and support him/her and who has accepted that role;

- "court" refers to a judicial body;

- "competent body" means an authority, or a person or body provided for by law to take a decision on an involuntary measure;

- “responsible authority” refers to the authority responsible for the facility in which the person is placed, or the authority with administrative responsibility for the physicians supervising the person’s medical care.

Chapter II – General Rule~~/Consent~~

Article 3 – General Rule

1. Measures in mental health care shall, as a general rule, only be carried out with the free and informed consent of the person concerned or, where, according to law, the person does not have the capacity to consent, respecting his or her wishes.

2. All available options respecting the provisions of paragraph 1 shall be considered and assessed before resorting to involuntary placement or involuntary treatment under the conditions provided for by this Protocol.

3. The existence of a mental disorder in itself shall, in no case, justify involuntary placement or involuntary treatment.

4. In all cases and to the extent possible, the person shall be involved in the planning of his or her mental health care and be treated in the environment in which he or she lives, with a view to his or her recovery.

Article 4 – Access to appropriate mental health care

Parties shall ensure that a range of services of appropriate quality, respecting the general rule laid down in Article 3, is provided to meet the individual mental health needs of persons in mental health care services.

Chapter III – General provisions

Article 5 – Legality

Involuntary measures shall only be applied in conformity with the provisions set out in the law, and in accordance with the safeguards established in this Protocol.

Article 6 – Proportionality and necessity

Involuntary measures shall only be used in accordance with the principle of proportionality and necessity. Persons subject to such measures shall be cared for in the least restrictive environment possible and with the least restrictive or intrusive treatment possible, taking into account their health needs and the need to protect them or other persons from harm.

Article 7 – Person of trust

In the context of a procedure concerning an involuntary measure, the person concerned shall have the right to choose a person of trust who would be expressly designated in accordance with the law.

Article 8 – Legal assistance

1. Persons subject to involuntary measures shall have the right to benefit effectively from legal assistance.

2. Subject to the conditions provided for by law, legal assistance shall be provided free of charge for all proceedings as referred to in Articles 12 and 16.

Article 9 – Professional standards

Persons subject to involuntary measures shall receive care delivered in accordance with professional obligations and standards by staff having the requisite competence and experience.

Article 10 – Appropriate environment

1. Parties to this Protocol shall take measures to ensure that any involuntary placement and any involuntary treatment take place in an appropriate environment respecting the person's dignity.

2. Any involuntary placement shall take place in a specific mental health care facility.

Chapter IV – Criteria for involuntary placement and for involuntary treatment

Article 11 – Criteria for involuntary placement and for involuntary treatment

Involuntary placement and/or involuntary treatment may only be used if the following criteria are met:

i. a) the person's current mental health condition represents a significant risk of serious harm to his or her health and his or her ability to decide on the measure is severely impaired or

b) the person's current mental health condition represents a significant risk of serious harm to others;

ii. the measure has a therapeutic purpose;

and

iii. any voluntary measure is insufficient to address the risk(s) referred to in paragraph i).

Chapter V – Procedures concerning involuntary placement and involuntary treatment

Article 12 – Standard procedures for taking decisions on involuntary placement and on involuntary treatment

1. The decision to subject a person to involuntary placement or to involuntary treatment shall ~~[, subject to paragraph 2,]~~ be taken by a court or another competent body. The court or other competent body shall:

i. act on the basis of an appropriate medical examination by at least one physician having the requisite competence and experience, in accordance with applicable professional obligations and standards;

ii. ensure that the criteria set out in Article 11 are met;

iii. act in accordance with procedures provided by law based on the principles that the person concerned shall be heard in person and with the support of his or her person of trust, if any;

iv. take into account the opinion of the person concerned, and any relevant previously expressed wishes made by that person; and

v. consult the representative of the person, if any.

~~[2. The law may provide that when a person is subject to involuntary placement, the decision to subject that person to involuntary treatment be taken by at least two physicians, one of whom is not involved in the person's care, each having the requisite competence and experience, after examination of the person concerned, and in accordance with the requirements set out in paragraph 1 ii, iii, iv and v.]~~

~~[3.]~~ **2.** The decision to subject a person to an involuntary measure shall specify the period of its validity and shall be documented.

~~[4.]~~ **3.** The law shall specify the maximum period of validity of any decision to subject a person to an involuntary measure and the arrangements for periodic review.

Article 13 – Procedures for taking decisions in emergency situations

1. When there is insufficient time to follow the procedures set out in Article 12 because of the imminent risk of serious harm, either to the health of the individual concerned, or to others, the decision to subject a person to involuntary placement and/or to involuntary treatment may be taken by a court or other competent body, under the following conditions:

i. involuntary placement and/or involuntary treatment shall only take place on the basis of a medical examination appropriate to the measure concerned;

ii. the criteria set out in Article 11 are met;

iii. paragraph 1 iii, iv and v of Article 12 shall be complied with as far as possible;

iv. decisions to subject a person to involuntary placement and/or involuntary treatment shall be documented.

2. The law shall specify the maximum period for which an emergency measure may be applied.

3. The duration of the emergency measure shall be as short as possible. It shall neither extend beyond the emergency situation nor the maximum period under paragraph 2, except where a procedure under Article 12 has been initiated.

Article 14 – Extension of an involuntary measure

The provisions of Article 12 shall also apply to procedures for taking decisions on the extension of an involuntary measure.

Article 15 – Termination of an involuntary measure

1. Involuntary placement or involuntary treatment shall be terminated if any of the criteria set out in Article 11 are no longer met.

2. The physician in charge of the person's care shall be responsible for assessing whether any of the relevant criteria set out in Article 11 is no longer met.

3. The responsible authority shall ensure that the measure's continuing conformity with the legal requirements is reviewed at regular intervals.

4. The physician in charge of the person's care or other health personnel designated by law, and the responsible authority, shall be entitled to take action on the basis of the assessment referred to in paragraphs 2 and 3, in order to terminate that measure, unless according to law, a court or another competent body shall be involved in the termination procedure.

Article 16 – Appeals and reviews concerning the lawfulness of involuntary measures

1. Parties shall ensure that persons subject to involuntary placement and/or involuntary treatment, with the support of their person of trust, if any, can effectively exercise the right:

i. to appeal to a court against the decision to subject them to the measure, and

ii. to request a review by a court that the measure or its continuing application conforms to the legal requirements.

An appeal may also be made and a review requested by the person's representative, if such a person has been designated.

2. Parties shall ensure that any person subject to an involuntary measure can effectively exercise the right to be heard in person, with the support of his or her person of trust, if any, or his or her representative, if such a person has been designated, at ~~such~~ reviews or appeals.

3. The person concerned, his or her representative**,** the person providing legal assistance in the court proceedings, and, according to law, ~~his or her~~ **the** person of trust shall have access to all the materials before the court subject to the protection of the confidentiality and safety of others according to law.

4. The court shall deliver its decision promptly, in accordance with the law.

Chapter VI – Restrictive and irreversible measures

Article 17 – Seclusion and restraint

1. Parties shall ensure the development of methods and programmes preventing the use of seclusion and restraint.

2. Seclusion and restraint shall only be used, subject to the protective conditions provided for by law, to prevent serious imminent harm to the person concerned or others. Seclusion and restraint shall always take place in an appropriate environment. In accordance with the principle of proportionality and necessity, seclusion and restraint shall only be used as a last resort and for a time limited to its strict necessity.

3. Any resort to seclusion or restraint shall be specifically and expressly ordered by a physician or immediately brought to the attention of a physician with a view to seeking the latter's approval. The nature of, reasons for, and duration of, every resort to seclusion or restraint shall be recorded in the person's medical file as well as specifically registered.

4. Persons subject to seclusion or mechanical restraint shall be continuously monitored by an appropriately trained member of staff.

5. Any use of seclusion or restraint may be subject to the complaint~~s~~ procedures provided in Article 22.

Article 18 – Treatment aiming at causing irreversible effects

Treatment aiming at causing irreversible physical effects shall not be used in the context of involuntary measures.

Chapter VII – Information and communication

Article 19 – Right to information

1. Appropriate information about their rights in respect to the involuntary measure(s) and of the remedies open to them shall be promptly given to persons subject to such measures, and to any person providing them with legal assistance, representative, and person of trust.

2. The persons concerned, any representative and any person providing them with legal assistance, shall be informed regularly and appropriately of the reasons for the measure and the criteria for its potential extension or termination and shall be provided with copies of all relevant decisions. The law may provide that the person of trust also receives this information.

3. The persons providing the persons concerned with legal assistance, the representative of the latter and their person of trust shall be informed promptly of any use of seclusion or restraint.

Article 20 – Right to communication

1. In the context of involuntary measures, the persons concerned have the right to communicate with any person providing them with legal assistance, representative, or official body charged with the protection of the rights of persons subject to involuntary measures, without restriction.

2. The persons concerned also have the right to communicate with their persons of trust and other persons and bodies than those referred to in paragraph 1. This right may only be restricted to the extent that is necessary to protect the health and personal security of the person concerned.

Chapter VIII – Record-keeping, complaint~~s~~ procedures and monitoring

Article 21 – Record-keeping

Comprehensive medical and administrative records shall be maintained for all persons subject to involuntary placement and/or involuntary treatment. The conditions governing access to and the period of storage of that information shall be specified by law.

Article 22 – Complaint procedures

Parties shall ensure that persons subject to an involuntary measure, with the support of their person of trust, if any, as well as any person providing them with legal assistance and ~~their~~ **any** representative have access to an effective complaints system, both within the responsible authority and to an independent outside body, regarding issues related to the implementation of involuntary measures, which are not covered by the procedures provided for in Article 16.

Article 23 – Monitoring

1. Parties shall ensure that compliance with the provisions of this Protocol is subject to appropriate independent monitoring.

2. Facilities used for the involuntary placement of persons within mental health care services shall be registered with an appropriate authority and shall be subject to independent and systematic inspections.

Chapter IX – Sanctions

Article 24 – Sanctions

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Protocol

Chapter X – Relation between this Protocol and other provisions and re-examination of the Protocol

Article 25 – Relation between this Protocol and the Convention

As between the Parties, the provisions of Articles 1 to 24 of this Protocol shall be regarded as additional articles to the Convention on Human Rights and Biomedicine, and all the provisions of the Convention shall apply accordingly.

Article 26 – Re-examination of the Protocol

In order to monitor scientific developments, the present Protocol shall be examined within the Committee referred to in Article 32 of the Convention on Human Rights and Biomedicine no later than five years from the entry into force of this Protocol and thereafter at such intervals as the Committee may determine.

Chapter XI – Final clauses

Article 27 – Signature and ratification

This Protocol shall be open for signature by Signatories to the Convention on Human Rights and Biomedicine. It is subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve this Protocol unless it has previously or simultaneously ratified, accepted or approved the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 28 – Entry into force

1. This Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Protocol in accordance with the provisions of Article 27.

2. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of the instrument of ratification, acceptance or approval.

Article 29 – Accession

1. After the entry into force of this Protocol, any State which has acceded to the Convention on Human Rights and Biomedicine may also accede to this Protocol.

2. Accession shall be effected by the deposit with the Secretary General of the Council of Europe of an instrument of accession which shall take effect on the first day of the month following the expiration of a period of three months after the date of its deposit.

Article 30 – Denunciation

1. Any Party may at any time denounce this Protocol by means of a notification addressed to the Secretary General of the Council of Europe.

2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 31 – Notification

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, the European Union, any Signatory, any Party and any other State which has been invited to accede to the Convention on Human Rights and Biomedicine of:

- **i. any signature;**
- **ii. the deposit of any instrument of ratification, acceptance, approval or accession;**
- **iii. any date of entry into force of this Protocol in accordance with Articles 29 and 30;**
- **iv. any other act, notification or communication relating to this Protocol.**