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**"From Law to Practice: Towards a roadmap to
strengthen children's rights in the era of biomedicine"**



Commissioned by the Committee on Bioethics (DH-BIO) of the Council of Europe

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Executive summary

Children today are increasingly impacted by the developments in biology and medicine (hereinafter: 'biomedicine'). As recipients of health care or as participants in biomedical research, children have benefitted greatly from the advances in biomedicine. Yet, the rapid developments in biomedicine also hold (potentially) adverse effects for children, and have far reaching implications for their rights and interests. International and European legal instruments and standards relating to biomedicine have recognised the vulnerable position of children (specifically, children not able to consent) and established some safeguards and limitation for their protection. Yet, significant gaps and challenges in the existing legal framework and practice exist, and these require careful consideration and a child rights-based evaluation.

This report, commissioned by the Council of Europe's Committee on Bioethics (DH-BIO), responds to this need. Its aim is two-fold; first, to assess whether and to what extent the existing body of international and European law provides adequate protection to the rights of children in relation to biomedicine and, second, to recommend actions ('roadmap') the Council of Europe could undertake to strengthen the rights of children in that regard. In doing so, the report relies on a previous report commissioned by the Committee on Bioethics (Uppsala University, 'The Rights of Children in Biomedicine: Challenges posed by Scientific Advances and Uncertainties', 2017) and it bases itself on the latter's identification of the main areas of concern in relation to children in biomedicine:

- Biomedical research
- Physical and mental health care;
- Preconceptional and prenatal interventions;
- Genetic techniques;
- Gender modification techniques;
- Transplantation care; and
- End of life decisions.

The report provides an extensive analysis of the relevant human rights of children, with particular attention on the UN Convention on the Rights of the Child (CRC) in relation to biomedical challenges (chapter 2). It then explores the relevant biomedical legal instruments, including soft law standards, offering a specific focus on the Council of Europe Convention on Human Rights and Biomedicine (CHRB, also known as the Oviedo Convention) and other relevant European instruments (chapter 3). Focusing on the abovementioned areas of concern, the report subsequently identifies the gaps and challenges for children's rights and proposes specific recommendations to the Council of Europe in order to better safeguard the rights and interests of children (chapter 4; Annex I). Among others, the report recommends the Council of Europe to provide specific guidance to States, notably its Member States, concerning domestic legislation and practices relating to biomedicine that are in accordance with children's rights, invest in awareness raising, education and trainings to ensure effective implementation of standards in practice, consider additional standard setting on specific themes, and conduct a mapping on legislative frameworks and practices of the 47 Council of Europe Member States in relation to children and biomedical issues.

The report concludes with a bird's-eye view and explores the over-arching and general observations in relation to children's rights and/in biomedical issues (chapter 5). The report finds that existing international and European standards in the field of biomedicine over-emphasise the child's right to

protection, and do not sufficiently recognise the principle of children's evolving capacities and their right to be heard and participate in decision-making related to their health and care. The conclusion concentrates on three over-arching themes. The first theme *consent, autonomy and legal representation of children by parents or others* pays particular attention to the special and complex relationship between children and parents in relation to health care, and also notes the important role of medical professionals in that regard. The report also reflects on the meaning of 'consent' and 'objection' to biomedical interventions and research, and their implications for children's (evolving) autonomy. The second theme is *child participation* and includes the right of children (also those not able to consent) to be heard and participate in decision-making relating to their lives, and have their views taken into account by parents as well as by medical professionals. In that regard, the report stresses, among others, the need for child-friendly health care and research, and adapted procedures and information for children, to enable their effective participation. Third, the theme *access to justice* ought to be recognised -more prominently – as an essential element of human rights protection and enforcement in the context of biomedicine. The report emphasises the need to better augment child-friendly justice and remedies and provide specific guidance to member states in this regard. The report concludes by referring to additional cross-cutting issues: *privacy and confidentiality*, *the role of medical professionals* and *the role of non-state actors*, such as pharmaceutical companies, insurance companies and research institutes, in relation to children's rights in biomedicine. In addition to the specific recommendations identified in chapter 4, the report concludes with five general recommendations for the Council of Europe towards establishing a roadmap for children's rights in biomedicine (Chapter 5, Annex II).

This report offers a comprehensive and extensive analysis of children's rights and biomedicine, from both an international and European perspective. It identifies and explores the main challenges and gaps in the existing legal framework and practices, and provides specific and general recommendations for establishing a roadmap by the Council of Europe to address the special position of children in biomedicine. Its recommendations, in particular, promote the view of children as rights holders and accommodate their rights and evolving capacities in relation to their health and care. Still, safeguarding children's rights and interests in biomedicine cannot be achieved by the Council of Europe alone, but requires careful consideration by other relevant actors, including legislators and policy makers, medical professionals, human rights institutions, the private sector and academia.

Résumé

Les évolutions que connaissent la biologie et la médecine (ci-après dénommées « biomédecine ») ont actuellement de plus en plus de conséquences pour les enfants. Que ce soit en tant que bénéficiaires de soins de santé ou participants à des études biomédicales, les enfants ont grandement bénéficié des progrès de la biomédecine. Cependant, les évolutions rapides dans ce domaine ont des effets (potentiellement) négatifs sur les enfants et de lourdes conséquences pour leurs droits et leurs intérêts. Des normes et instruments juridiques européens et internationaux relatifs à la biomédecine reconnaissent la situation de vulnérabilité dans laquelle se trouvent les enfants (en particulier les enfants qui ne peuvent pas donner leur consentement) et ont mis en place des limitations et des mesures de protection. Le cadre juridique et les pratiques en vigueur présentent des lacunes importantes et des défis de taille, qui doivent être pris soigneusement en considération et faire l'objet d'une analyse fondée sur les droits de l'enfant.

Le rapport, réalisé à la demande du Comité de bioéthique du Conseil de l'Europe (DH-BIO), répond à ce besoin. Son objectif est double : il s'agit, premièrement, d'examiner si et dans quelle mesure les textes législatifs européens et internationaux protègent de manière adéquate les droits de l'enfant dans le domaine de la biomédecine et, deuxièmement, de recommander des actions (dont l'élaboration d'une « feuille de route ») au Conseil de l'Europe pour renforcer les droits de l'enfant à cet égard. Pour ce faire, le rapport s'appuie sur un rapport antérieur réalisé à la demande du Comité de bioéthique (université d'Uppsala, « The Rights of Children in Biomedicine: Challenges posed by Scientific Advances and Uncertainties », 2017) et se base sur les principaux sujets de préoccupation en lien avec les enfants et la biomédecine que ce rapport a identifiés :

- recherche biomédicale ;
- soins de santé physique et mentale ;
- interventions avant la conception et avant la naissance ;
- techniques génétiques ;
- techniques de changement de sexe ;
- transplantation ;
- décisions de fin de vie.

Le rapport examine en profondeur les droits de l'enfant pertinents à cet égard et accorde une attention particulière à la Convention relative aux droits de l'enfant de l'ONU dans son analyse des défis biomédicaux (chapitre 2). Il examine ensuite les instruments juridiques biomédicaux, dont les normes non contraignantes, et met l'accent sur la Convention sur les Droits de l'Homme et la biomédecine du Conseil de l'Europe (ou « Convention d'Oviedo ») et d'autres instruments européens pertinents (chapitre 3). Le rapport identifie aussi les lacunes et défis liés aux droits de l'enfant en se concentrant sur les sujets de préoccupation susmentionnés et propose des recommandations spécifiques au Conseil de l'Europe afin de mieux protéger les droits et les intérêts des enfants (chapitre 4 ; annexe I). Le rapport recommande entre autres au Conseil de l'Europe de donner des conseils spécifiques aux États, en particulier à ses États membres, pour rendre la législation et les pratiques nationales relatives à la biomédecine conformes aux droits de l'enfant, d'investir dans la sensibilisation, l'éducation et la formation pour assurer une mise en pratique efficace des normes, d'envisager l'élaboration de normes supplémentaires sur certains thèmes spécifiques et de répertorier les pratiques et dispositions juridiques en rapport avec les enfants et la biomédecine dans les 47 États membres du Conseil de l'Europe.

Le rapport se conclut sur une vue d'ensemble et des observations générales relatives aux droits de l'enfant et aux questions biomédicales (chapitre 5). Il constate que les normes européennes et internationales existantes en matière de biomédecine donnent trop d'importance au droit de l'enfant à la protection et ne reconnaissent pas assez le principe d'évolution des capacités de l'enfant ni son droit d'être entendu et de participer à la prise de décisions en ce qui concerne sa santé et les soins qu'il reçoit. La conclusion se focalise sur trois grands thèmes. Le premier, intitulé *consentement, autonomie et représentation juridique des enfants par les parents ou d'autres personnes*, accorde une attention particulière à la relation spéciale et complexe entre enfants et parents par rapport à la santé, sans oublier le rôle important des professionnels de santé en la matière. Le rapport se penche également sur le sens des termes « consentement » et « objection » face à la recherche et aux interventions biomédicales et sur leurs conséquences sur l'autonomie (en évolution) des enfants. Le deuxième thème, à savoir la *participation de l'enfant*, englobe le droit, pour les enfants (y compris ceux qui sont incapables de consentir), d'être entendus et de participer à la prise de décisions quant à leur propre vie, et de voir leurs opinions prises en compte par leurs parents et les professionnels de santé. À cet égard, le rapport met entre autres l'accent sur la nécessité d'adapter les recherches, les soins de santé, les procédures et les informations aux enfants, afin de permettre leur participation effective. Troisièmement, le thème *accès à la justice* doit être – mieux – reconnu en tant qu'élément essentiel de protection et d'application des droits de l'homme dans le contexte de la biomédecine. Le rapport souligne la nécessité de mieux adapter aux enfants le système judiciaire et les voies de recours, et de donner aux États membres des conseils spécifiques en la matière. En conclusion, le rapport aborde d'autres questions transversales : *vie privée et confidentialité*, le *rôle des professionnels de santé* et le *rôle des acteurs non étatiques*, tels que les entreprises pharmaceutiques, les compagnies d'assurance et les instituts de recherche, en ce qui concerne les droits de l'enfant en biomédecine. Outre les recommandations spécifiques définies au chapitre 4, le rapport comporte cinq recommandations générales adressées au Conseil de l'Europe, qui visent l'élaboration d'une feuille de route relative aux droits de l'enfant en biomédecine (chapitre 5, annexe II).

Ce rapport offre une analyse complète et détaillée des droits de l'enfant et de la biomédecine, tant d'un point de vue européen qu'international. Il définit et examine les principaux défis et lacunes des pratiques et législations actuelles et formule des recommandations spécifiques et générales en vue de l'élaboration, par le Conseil de l'Europe, d'une feuille de route destinée à traiter la situation particulière des enfants en biomédecine. Ses recommandations soutiennent plus particulièrement l'idée que les enfants sont détenteurs de droits ; elles prennent en compte leurs droits et l'évolution de leurs capacités en ce qui concerne leur santé et les soins qu'ils reçoivent. Les droits et les intérêts des enfants en biomédecine ne peuvent toutefois pas être réellement protégés si seul le Conseil de l'Europe s'en charge. Ils doivent également être pris en considération par d'autres acteurs pertinents, dont les législateurs et responsables politiques, les professionnels de santé, les institutions de protection des droits de l'homme, le secteur privé et le milieu universitaire.

Acronyms

CCPR	Covenant on Civil and Political Rights (1966)
CEDAW	Committee/Convention on the Elimination of Discrimination against Women (1979)
CESCR	Covenant on Economic, Social and Cultural Rights (1966)
CFJ Guidelines	Guidelines on child-friendly justice (2010)
CFHC	Guidelines on child-friendly health care (2011)
CIOMS	Council for International Organizations of Medical Sciences
CHRB	Convention on Human Rights and Biomedicine (1997)
CJEU	Court of Justice of the European Union
CRC	Convention on the Rights of the Child (1989)
CRPD	Convention on the Rights of Persons with Disabilities (2006)
ECHR	European Convention on Human Rights (1950)
ECSR	European Committee of Social Rights
ECtHR	European Court of Human Rights
ESC	European Social Charter (1961, revised 1996)
EU	European Union
EU Charter	Charter of Fundamental Rights of the European Union (2000)
PACE	Parliamentary Assembly of the Council of Europe
UDBHR	Universal Declaration on Bioethics and Human Rights (2005)
UDHGHR	Universal Declaration on the Human Genome and Human Rights (1997)
UDHR	Universal Declaration of Human Rights (1948)
UN	United Nations
UNESCO	United Nations Educational, Scientific and Cultural Organization
WHO	World Health Organization
WMA	World Medical Association

Chapter 1: Introduction

This report describes and examines the existing body of international and European law relevant to children's rights in the field of biology and medicine (henceforth: biomedicine). This is a topical issue given the rapid developments in this area and the far-reaching implications biomedical research and new forms of treatment can have on the rights of children.¹ It is generally thought that the health and well-being of children – as well as others – can immensely benefit from the advances made in the domain of biomedicine, but at the same time there is considerable concern about its potential adverse effects on children and their rights.

The aim of this report is to answer the question whether the existing body of international and European law provides sufficient respect for and appropriate protection to children's rights with respect to biomedicine. In doing so, this report builds on the outcomes of the report *The Rights of Children in Biomedicine: Challenges posed by Scientific Advances and Uncertainties* (hereinafter: Uppsala Report),² notably the challenges identified by its authors in a limited number of areas, being:

- Biomedical research;³
- Physical and mental health care;
- Preconceptional and prenatal interventions;
- Genetic techniques;
- Gender modification techniques;
- Transplantation care; and
- End of life decisions.

The focus of the present report is on both the international and the European legal instruments, with special emphasis on the UN Convention on the Rights of the Child (CRC)⁴ and the Council of Europe Convention on Human Rights and Biomedicine (CHRB), also known as the Oviedo Convention, and its four additional protocols.⁵

Aim of the study

The ultimate aim of the present study is two-fold:

(1) To assess whether the existing body of international and European law provides adequate protection to the rights of children in the context of biomedicine;

¹ To guide its work on children's rights, the Council of Europe has adopted a strategy on the rights of the child; Council of Europe, 'Strategy for the Rights of the Child (2016-2021)', (2016). The strategy can also benefit actions related to biomedicine and children, see p. 19.

² Zillén, K., Garland J., and Slokenberga S., *The Rights of Children in Biomedicine: Challenges posed by Scientific Advances and Uncertainties*, Strasbourg: Council of Europe (2017) (hereinafter: '**Uppsala Report**').

³ This is referred to as 'Medical Science' in the Uppsala Report. See *Ibid*, p. 11.

⁴ UN General Assembly, Convention on the Rights of the Child, 20 November 1989, UN Treaty Series, vol 1577, p. 3 (hereinafter: '**CRC**').

⁵ Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997) (hereinafter: '**CHRB**'); Council of Europe, Additional Protocol on the Prohibition of Cloning Human Beings (1998) (hereinafter: '**Protocol concerning Cloning**'); Council of Europe, Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (2002) (hereinafter: '**Protocol concerning Transplantation**'); Council of Europe, Additional Protocol concerning Biomedical Research (2005) (hereinafter: '**Protocol concerning Biomedical Research**'); and Council of Europe, Additional Protocol concerning Genetic Testing for Health Purposes (2008) (hereinafter: '**Protocol concerning Genetic Testing**').

(2) To recommend actions (as part of a ‘roadmap’) the Council of Europe could undertake to strengthen the rights of children in light of the challenges identified in the biomedical field, using the existing body of international and European law.

Research methodology

This report is based on a study of legal instruments, case-law and relevant literature. The nature of the report is both descriptive and analytical. It does not restrict itself to describing international and European legal instruments, but also identifies which standards are relevant and appropriate for biomedical challenges in the field of research, health care and other related areas to be reviewed, and where these standards are missing or otherwise fall short in protecting the rights of children in biomedicine.

Stakeholders

In general, international and European human rights standards entail (negative and positive) obligations for States. States are the primary duty bearers and have the responsibility to implement international and European law relating to the individual’s human rights. This may imply regulating the relations between private persons, or protecting individuals against encroachments upon their rights by others. This is not different with regard to the human rights of children (i.e. children’s rights). However, the CRC as well as European human rights standards have specific implications for the position of parents (and other legal representatives as well as (extended) family) and the relationship between parents and children. In addition, the State has special responsibilities towards parents, among others, revolving around respect for the rights and responsibilities of parents for the upbringing of children and for the guidance of children in the enjoyment of their rights.⁶ It can thus be argued that parents have certain responsibilities towards children on the basis of international and European children’s rights standards, for example in relation to the child’s best interests and the right to be heard.⁷

In the context of biomedicine, there are additional stakeholders who play a role in respecting and ensuring the rights of children. Medical professionals, in particular, form an important group in that regard. Ensuring their professional autonomy, ethical standards, and adequate training and guidance is part of States’ responsibilities under international and European human rights law and serves as a crucial safeguard for children’s human rights in the area of research, health care and other related areas in the field of biomedicine. Issues relating to medical professionals as well as researchers will be briefly addressed, where necessary, throughout this report.

It should furthermore be noted that in the biomedical field other non-state actors are also involved (e.g. pharmaceutical industry, insurance companies and research institutions). This is of particular relevance in light of the growing interest in non-state actors’ (e.g. private sector, businesses, etc.) responsibilities concerning human rights.⁸ Due to the scope and aim of this report, the role and impact of these non-state actors will not be addressed; yet further exploration in this field by the

⁶ See Articles 5 and 18 CRC; see further in chapter 2 of this report.

⁷ See Articles 18(1), 12 CRC.

⁸ See UN OHCHR, Guiding Principles on Business and Human Rights: Implementing the United Nations ‘Protect, Respect and Remedy’ Framework, HR/PUB/11/04 (2011) (hereinafter: ‘**UN Guiding Principles on Business and Human Rights**’).

Council of Europe and its intergovernmental bodies is highly recommended and should in our view be included in the roadmap (see further chapter 5).

Terminology

The term ‘biomedicine’ is used in this report as a short-hand expression to refer to developments in the field of biology and medicine, notably biomedical research and health care (i.e. ‘therapy’ or ‘care’). The primary purpose of research concerning children is to develop or contribute to medical knowledge eventually with the aim to improve forms of treatment for all children. Research, thus described, may have therapeutic effects on individual children but this is not its prime goal. Therapy, or physical and mental health care, is aimed at treating a particular child and improving his or her health. As we will see, international and European legal standards commonly distinguish between research (with ‘research participants’) and therapy or care (with ‘patients’). We are, however, aware that in practice it is not always possible to make a sharp distinction between research and care,⁹ and do take this into account in this report. Moreover, it follows from the Uppsala Report that there are more areas of concern than biomedical research and physical and mental health care. These areas, even though closely related to research and care, raise their own legal and ethical questions when children are involved.

The term ‘legal’ is interpreted broadly in this report, not confined to legally binding instruments. Guidelines, recommendations or professional standards (i.e. ‘soft law’ instruments) play a significant role in the field of biomedicine. These measures, while not legally binding as such, often derive from and/or reflect legally binding norms and are traditionally taken into account in decision-making. The term ‘human rights’ is also interpreted broadly; in our report, human rights refer to the human rights of children, or children’s rights. These do not merely cover the internationally codified human rights but also the generally recognised human rights principles and interests underlying human rights.

The term ‘child’ is used to refer to persons from birth to the age of 18,¹⁰ even though we will sporadically also look into the legal aspects of biomedical research and health care in the prenatal and preconceptional stages.

Structure of the report

In chapter 2, we analyse the relevant human rights of children in relation to the challenges identified in the Uppsala Report. Subsequently, in chapter 3, we enumerate the relevant biomedical standards developed by the Council of Europe and other international and European organisations, and assess whether these have child specific provisions. In chapter 4, we compare the outcomes of chapters 2 and 3, and detect possible gaps for children’s human rights in light of the challenges identified by the Uppsala Report. The conclusions of this chapter are defined in terms of recommendations for the Council of Europe, suggesting measures the Council could take, at the intergovernmental level and as part of a Roadmap, to strengthen the rights of children in the biomedical field (chapter 5). The recommendations included in this report are not limited to the biomedical context, but also relate to other fields (e.g., data protection, access to justice).

⁹ Kass, N.E., Faden, R.R. Goodman, S.N. et al. (2013), The Research-Treatment Distinction: A Problematic Approach for Determining Which Activities Should Have Ethical Oversight, *Hastings Center Report* 43 (1), pp. S2–S44.

¹⁰ See also Article 1 of the CRC.

Chapter 2: Human rights of children

The aim of this chapter is to analyse relevant human rights in relation to the challenges identified in the Uppsala Report. We will study, what appear to be, the core human rights from a children's perspective (2.1), the general principles listed in the CRC (2.2), the special and complex relationship between the rights of the child and the rights of parents or other representatives prescribed by law (2.3), and other specific rights of children relevant in the context of biomedicine (2.4). This analysis builds on a large number of human rights instruments, with special attention on the CRC and Council of Europe documents, international and European case-law, and the discourse between human rights scholars. We will centre our analysis on the areas of heightened concern for the rights of the child as mapped out in the Uppsala Report.

2.1 Core human rights

Human rights are considered to be indivisible, interdependent and interrelated. By implication they are normatively equal. Even though there is no hierarchy among human rights, some rights are more fundamental than others when it comes to protecting basic values and norms in the context of biomedicine.

Human dignity

Human dignity is the basic principle underlying human rights law.¹¹ Or, in the words of the European Committee of Social Rights (ECSR), 'Human dignity is the fundamental value and indeed the core of positive European human rights law – whether under the European Social Charter or under the European Convention [of Human Rights]' adding that 'health care is prerequisite for the preservation of human dignity'.¹² Therefore, the concept of 'dignity', considered to be inherent to every human being,¹³ constitutes an essential value to be upheld both by the CRC and the CHRB.¹⁴ In fact, concerns about threats to human dignity as a result of 'misuse of biology and medicine' were an important motivation for the adoption of CHRB.¹⁵

Indeed, the precise meaning of human dignity is not always clear. According to the European Court of Human Rights (ECtHR), dignity concerns 'a particularly vague concept, and one subject to random interpretation'.¹⁶ It is at the same time undisputed that human dignity is 'an expression of the respect and value to be attributed to each human being on account of his or her humanity'.¹⁷ Respect for human dignity implies, among others, that individuals should be able to live their own lives and make their own choices, also with respect to biomedical research and care. The value attributed to human beings requires, at the same time, to offer protection, and ensure individuals are not exposed or subjected to humiliation and debasement. It follows that human dignity can be understood in two ways: as 'empowerment', thus reinforcing personal autonomy (see under autonomy), and as

¹¹ See ECtHR 9 March 2010, *Nilsen v. the UK* (dec), Appl. No. 36882/05.

¹² ECSR 7 November 2004, *International Federation of Human Rights Leagues (FIDH) v. France*, no. 14/2003, para. 31.

¹³ See the preambles of the UN, Charter of the United Nations, 24 October 1945, 1 UNTS XVI; preamble of the UN General Assembly, Universal Declaration of Human Rights, 10 December 1948, 217 A(III) (hereinafter: '**UDHR**').

¹⁴ See Council of Europe, Explanatory Report to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, ETS 164 (1997), para. 9 (hereinafter: '**Explanatory Report CHRB**').

¹⁵ Preamble of the CHRB.

¹⁶ ECtHR 26 July 2005, *Siliadin v. France*, Appl. No. 73316/01, para. 101.

¹⁷ Advocate General Stix-Hackl of the CJEU 18 March 2004, case C-36/02 (*Omega*), ECLI:EU:C:2004:162, para. 75.

'constraint', a term used to express that human dignity sometimes necessitates the taking of measures to protect the inviolability and integrity of human beings.¹⁸ As we will see, the inherent tension between 'empowerment' and 'constraint' is particularly topical with respect to children where it is felt that children should be prevented to make certain decisions autonomously to avoid (potential) harm. However, it is undisputed that children are entitled to respect for their right to dignity.¹⁹

Autonomy

In general, autonomy means that individuals are entitled to take actions based on their own values and beliefs, and to make their own choices. Thus, autonomy is a principle closely connected to human dignity as empowerment. In 2005, the ECtHR declared personal autonomy to be a *right*, particularly with respect to making choices about one's body (integrity),²⁰ notably with respect to biomedical questions such as artificial procreation,²¹ abortion,²² giving birth²³ and prenatal screening.²⁴ In the area of biomedical research and care, autonomy is primarily associated with free choice and informed consent, the latter as a guarantee for genuine free choice, fully aware of risks and uncertainties. But in case the sensible exercise of autonomy with respect to biomedical issues is in doubt and the person's competency is questioned, the State is entitled to take appropriate and proportionate measures (e.g., taking a child into care or appointment of a guardian²⁵).

Competence is commonly considered a prerequisite to exercise autonomy. By law individuals should have the mental capacity to exercise autonomy, notably in case of decisions that can have far reaching and irreversible consequences for their lives. This is why human rights law often seems to restrict the autonomy of children. This relates to the concept of the child's evolving capacities, holding that the extent to which children are considered competent depends on their age and maturity, and that it progresses with time and experience. This requires to recognise that children can be competent to make certain decisions in relation to their treatment and care, and that they should be allowed, empowered and encouraged to exercise their rights.

Integrity

Physical and mental integrity are important aspects of human dignity, and are directly relevant in case of research and care. According to human rights law, it is the individual itself who should freely decide on interferences with his or her integrity. Thus, individuals can consent to, for example, being subjected to genetic techniques, gender modification techniques and transplantation care, provided that they are well informed, including about the risks and burdens involved (informed consent). This

¹⁸ Byleveld, D. and Brownsword, R. (2001), *Human Dignity in Bioethics and Biolaw*, Oxford: Oxford University Press.

¹⁹ See preamble CRC.

²⁰ ECtHR 17 February 2005, *K.A. and A.D. v. Belgium*, Appl. No. 42758/98 and 45558/99.

²¹ ECtHR 7 March 2006, *Evans v. the UK*, Appl. No. 6339/05.

²² ECtHR 20 March 2007, *Tysiqc v. Poland*, Appl. No. 5410/03 and ECtHR 16 December 2010, *A., B. and C. v. Ireland (GC)*, Appl. No. 25579/05.

²³ ECtHR 14 December 2010, *Ternovszky v. Hungary*, Appl. No. 67545/09.

²⁴ ECtHR 26 May 2011, *R.R. v. Poland*, Appl. No. 27617/04.

²⁵ ECtHR 21 November 2006, *Roda and Bonfatti v. Italy*, Appl. No. 10427/02.

explains why integrity, in conjunction with personal autonomy, is a core right and why great importance is attached to informed consent in the area of biomedicine.²⁶

Human rights law offers additional protection to the integrity of children and others not (or less) able to consent by restricting, beforehand, a number of biomedical interventions such as participating in biomedical research, living organ donation and genetic testing.²⁷ Moreover, some interventions with the integrity of children have also been labelled as harmful and are therefore forbidden.²⁸

Torture, inhumane and degrading forms of treatment are considered flagrant violations of human dignity and integrity, and are absolutely prohibited under the Covenant on Civil and Political Rights (CCPR) and the European Convention on Human Rights (ECHR).²⁹ This is also important from a children's rights perspective since children have the right to protection from all forms of violence, including the most heinous forms amounting to 'torture or other forms of cruel, inhuman or degrading treatment'.³⁰ The ECtHR has in this respect emphasised that dignity and integrity require particular attention where a child is the victim of violence.³¹ At the same time, the ECtHR has repeatedly held that interventions to which a person is subjected against his or her will, which are of therapeutic necessity from the point of view of established principles of medicine, cannot in principle be regarded as inhuman and degrading.³² There is no corresponding exception with respect to research interventions or other non-therapeutic interventions, such as organ donations, from which the individual cannot directly benefit.

Equal treatment and non-discrimination

The right to equal treatment and the right to protection against discrimination figure dominantly in human rights instruments. These are built on the idea that all human beings are equal.

Under human rights law equal treatment and non-discrimination do not merely require the identical treatment of persons similarly situated, but also the different treatment of persons differently situated.³³ In other words, attention needs to be paid to the context in which people find themselves and for any relevant differences, such as the capacity to consent and personal views and needs, in order to advance equal outcomes. The Convention on the Rights of Persons with Disabilities (CRPD) is very explicit on this point and obligates States to ensure reasonable accommodations for persons with disabilities to secure the enjoyment of human rights on an equal basis.³⁴ The CRC also requires States to respect and ensure the rights of children without discrimination of any kind (see under

²⁶ See e.g. Chapter II of the CHR; Article 5 of the UNESCO, Universal Declaration on the Human Genome and Human Rights (1997) (hereinafter: 'UDHGHR').

²⁷ Article 14 Protocol concerning Transplantation; Article 15 Protocol concerning Biomedical Research; Article 10 Protocol concerning Genetic Testing.

²⁸ CRC Committee & CEDAW (2016), Joint general recommendation No. 31 of the Committee on the Elimination of Discrimination against Women/General Comment No. 18 of the Committee on the Rights of the Child on harmful practices.

²⁹ Article 3 Council of Europe, *European Convention for the Protection of Human Rights and Fundamental Freedoms*, November 1950 (hereinafter: 'ECHR'); See also ECtHR 15 November 1996, *Chahal v. the UK* (GC), Appl. No. 22414/93, para. 79; See also Article 7 UN General Assembly, *International Convention on Civil and Political Rights*, 16 December 1966, UN Treaty Series, vol. 999, p. 171 (hereinafter: 'CCPR') particularly prohibits the subjection to medical and scientific experiments in that regard.

³⁰ Article 37(a) CRC; see also Article 19 CRC.

³¹ ECtHR 15 March 2012, *C.A.S. and C.S. v. Romania*, Appl. No. 25951/07, para. 82.

³² ECtHR 24 September 1992, *Herczegfalvy v. Austria*, Appl. No. 10533/83, para. 82.

³³ ECtHR 6 April 2000, *Thlimmenos v. Greece* (GC), Appl. No. 34369/97, para. 44.

³⁴ Article 2 UN General Assembly, *Convention on the Rights of Persons with Disabilities*, 24 January 2007, A/RES/61/106 (hereinafter: 'CRPD').

general principles). European legal instruments further anchor a general prohibition of discrimination,³⁵ as well as in relation to specific children's rights and biomedical issues.³⁶

Access to justice

Access to justice and the availability of effective remedies are preconditions to ensure the enjoyment of human rights, and is therefore considered a core human right. The right to access to justice has also been recognised with respect to children.³⁷ This means that States should establish legal protection (i.e., legislation³⁸), set redress and complaints procedures for cases of the alleged violation of rights, and enable appropriate remedies – also for children. This requires that children, and their parents, are able to initiate judicial or administrative proceedings and seek appropriate remedies for infringements of the rights and protection afforded to them under the biomedical instruments (e.g., right to receive information in relation to transplantation³⁹ or protection of data derived from genetic testing).⁴⁰ As will be further discussed, in light of the complex and sensitive nature of conflicts in the field of biomedicine, the need for speedy resolutions, and the wish to enable a child-friendly procedure and decision-making, States should also invest in alternative dispute resolution mechanisms that allow parties to come to an agreement without resorting to litigation.

In practice, many children face barriers in accessing justice, while experiencing that contact with the justice system or other formal mechanisms are not always a pleasant and sometimes an intimidating experience.⁴¹ In response, the concept of child-friendly justice has emerged, and was laid down in the Council of Europe Guidelines on Child-Friendly justice (CFJ Guidelines). These Guidelines provide that proceedings should respect and protect the rights of children, and that justice shall be accessible, age-appropriate, speedy, diligent, and adapted to and focused on the needs and rights of children.⁴² Specifically, the CFJ Guidelines anchor the child's right to information, assistance, participation and protection, with due consideration of the child's level of maturity. They apply to judicial proceedings, as well as to proceedings before competent authorities, such as health care providers.⁴³ Thus, the CFJ Guidelines are relevant for children and/or parents that may require judicial or administrative proceedings in relation to biomedical research of care, or if they wish to file other related complaints.

³⁵ Article 14 ECHR; Article E (Revised) ESC, Article 21 of the EU, *Charter of Fundamental Rights of the European Union*, 26 October 2012, 2012/C/326/02 (hereinafter: '**EU Charter**'); Article 1 Protocol No. 12 of the ECHR.

³⁶ Council of Europe, *Guidelines of the Committee of Ministers of the Council of Europe on Child-Friendly Justice*, 17 November 2010, para. III(D)(1)-(2) (hereinafter: '**CFJ Guidelines**'); Article 1 Protocol concerning Biomedical Research; Council of Europe, Council of Europe Guidelines on *Child-Friendly Health Care*, (2011), para. III(A)(9), III(B)(10) (hereinafter: '**CFHC Guidelines**'); Council of Europe, *Recommendation CM/Rec(2012)2 of the Committee of Ministers to Member States on the participation of children and young people under the age of 18*, 28 March 2012, para. II (hereinafter: '**CoE Recommendation on the Participation of Children and Young People**').

³⁷ CRC Committee, General Comment No. 5 (2003) General measures of implementation of the Convention on the Rights of the Child (arts. 4, 42 and 44, para. 6), para. 24, 27 November 2003, CRC/C/GC/5 (hereinafter: '**CRC GC 5**'); See also Article 41 CRC; Article 2 para. 3 CCPR.

³⁸ CRC GC 5, *supra* note 37, para. 18.

³⁹ Article 12 of the Protocol concerning Transplantation.

⁴⁰ Article 16 of the Protocol concerning Genetic Testing.

⁴¹ See CFJ Guidelines, *supra* note 36, p. 7, and also para. I(3), IV(D)(5)(54), III(A)(1)

⁴² *Ibid.*, para II(c)

⁴³ *Ibid.*, para I(1)-(2)

2.2 General Principles of the CRC

The CRC Committee has identified four provisions of the CRC as ‘general principles’, which should be taken into account when implementing the CRC and when interpreting CRC provisions.⁴⁴

General Principle 1: Non-discrimination

Under the CRC, States are obliged to protect children against discrimination of any kind.⁴⁵ In addition, the CRC requires States to ensure the enjoyment of all rights laid down in the CRC on the basis of non-discrimination against them as well as against their parents, legal guardians, or family members. The CRC thus recognises that children can also become the victim of discrimination by association.⁴⁶

The prohibition of discrimination with respect to the child requires States to ensure, among others, that all children can equally access high quality health services and that they enjoy the same level of protection to their rights in care.⁴⁷ The CRC Committee, in particular, notes that children with disabilities are prone to discrimination in relation to their right to health, participation, protection and physical integrity. The CRC Committee requires that children with disabilities enjoy ‘full and decent life conditions’,⁴⁸ and that they should have a right to special care and assistance.⁴⁹ Yet, the CRC Committee has expressed concern that children with disabilities are discriminated against, noting the lack of early identification and medical treatment and rehabilitation of children with disabilities, and the increase of unnecessary and irreversible medical interventions (i.e., sterilization) on children with disabilities.⁵⁰

General Principle 2: Best interests of the child

The CRC holds that in all actions concerning children, the best interests of the child shall be ‘a primary consideration’.⁵¹ According to the CRC Committee, this general principle serves as a threefold concept: a substantive right, an interpretative legal principle, and a rule of procedure.⁵² The CRC Committee has interpreted this principle to ensure children the full and effective enjoyment of all rights, and to support the holistic and positive development of children.⁵³ Thus, the obligation to consider the best interests of the child as a primary consideration is not an obligation to merely prevent harm, but requires, according to the CRC Committee, States to ensure the interests are fulfilled for the child's optimal development.

⁴⁴ CRC GC 5, *supra note 37*. These principles are also of great importance for realising children’s right to health, according to the CRC Committee: CRC Committee General Comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health (art. 24), 17 April 2013, CRC/C/GC/15, para. 7-22 (hereinafter: ‘**CRC GC 15**’).

⁴⁵ Article 2 CRC.

⁴⁶ CJEU 17 July 2008, case C-303/06 (*Coleman*), ECLI:EU:C:2008:415 and Hendriks, A.C. (2010), ‘The UN Disability Convention and (Multiple) Discrimination: Should EU non-discrimination law be modelled accordingly?’ in: Waddington, L. and Quinn G. (eds.), *European Yearbook of Disability Law 2010*, Antwerp: Intersentia 2010, pp. 7-27.

⁴⁷ See CFHC Guidelines, *supra note 46*, para. III(A)(9), III(B)(10).

⁴⁸ CRC Committee General Comment No. 9 (2006) The rights of children with disabilities, 27 February 2007, CRC/C/GC/9, para. 11 (hereinafter: ‘**CRC GC 9**’).

⁴⁹ *Ibid.*, para. 12

⁵⁰ *Ibid.*, para. 60

⁵¹ Article 3(1) of the CRC.

⁵² CRC Committee General Comment No. 14 (2013) on the right of the child to have his or her best interests taken as a primary consideration (art. 3, para. 1), 29 May 2013, CRC/C/GC/14, para. 6 (hereinafter: ‘**CRC GC 14**’).

⁵³ *Ibid.*, para. 4.

The concept of the best interests of the child is also recognised in European legal systems.⁵⁴ The CHRB stipulates that the best interests of the person concerned should be a leading consideration.⁵⁵ This principle is equally upheld by the ECtHR⁵⁶, particularly with respect to such issues as paternity/the right to know one's parents⁵⁷ and recognition of a child.⁵⁸ The principle is of particular importance in the context of health: it should be reflected in all health-related policies, programmes and health-care systems, and it applies to institutions, services and facilities responsible for the care of children.⁵⁹ This principle requires that health-related decisions should include an evaluation on the child and that such an evaluation is taken into account in practice.⁶⁰ The concept of the best interests of the child is complex and should be determined on a case-by-case basis, taking into account the full range of the child's rights.⁶¹ This approach acknowledges that children are not a homogenous group; they differ not only in age and degree of maturity, but also in aspects relating to their socio-economic background, family situation, and health condition.⁶² The principle of best interests, then, requires States to conduct a child-specific evaluation, considering the child's specific needs and particular situation.

General Principle 3: Right to life, survival and development

The CRC holds that every child has an 'inherent right to life' and requires States to ensure to the maximum extent possible the survival and development of children.⁶³ The CRC Committee has interpreted 'development' in a broad and holistic sense, covering also the child's physical, mental, and psychological development and growth. This third general principle of the CRC is of particular significance in relation to health care⁶⁴ and to biomedicine as a whole.

The right to life obviously is one of the most fundamental rights of the child. In the context of biomedicine, the scope of the right to life is a matter of concern and the question is whether it extends to unborn children and to autonomously chosen end of life decisions – particularly given the concerns raised in the Uppsala Report. While there is no universal consensus on these issues, the CRC does state in its preamble that children require special safeguards and care, including appropriate legal protection, 'before as well as after birth'.⁶⁵ Still, due to the lack of international consensus, the

⁵⁴ See e.g. European Union Agency for Fundamental Rights (FRA) (2015), *Handbook on European Law relating to the Rights of the Child*, Luxembourg: Publications Office of the European Union (hereinafter: '**FRA (2015)**').

⁵⁵ Article 6 para. 5 of the CHRB.

⁵⁶ ECtHR 23 September 1994, *Hokkanen v. Finland*, Appl. No. 19823/92.

⁵⁷ ECtHR 7 February 2002, *Mikulic v. Croatia*, Appl. No. 53176/99; ECtHR 13 February 2003, *Odièvre v. France* (GC), Appl. No. 42326/98; ECtHR 17 July 2007, *Jevremović v. Serbia*, Appl. No.3150/05.

⁵⁸ In relation to article 8 ECHR. See Koffeman, N. (2015), *Morally Sensitive Issues and Cross-Border Movement in the EU*, Antwerp: Intersentia, p. 22 (hereinafter: '**Koffeman (2015)**'); ECtHR 5 November 2002, *Yousef v. the Netherlands*, Appl. No. 33711/96; Preamble of the Council of Europe, *European Convention on the Exercise of Children's Rights*, 25 January 1996, ETS 160.

⁵⁹ Article 3 para. 3 CRC; CESCR, General Comment No. 14 (2000): The Right to the Highest Attainable Standard of Health (Art. 12), 11 August 2000, E/C. 12/2000/4, para. 24.; CRC GC 14, *supra note 52*, p. 4-5; CFHC Guidelines, *supra note 36*, para. III(E)(15)

⁶⁰ Wade K., Melamed I. and Goldhagen J. (2016), 'Beyond Bioethics: A Child Rights-Based Approach to Complex Medical Decision-Making', *Perspect Biol Med* 58(3):332-40 (333) (hereinafter: '**Wade et al. (2016)**'); CRC GC 14, *supra note 52*, p. 2.

⁶¹ CRC GC 14, *supra note 52*, p. 5, 9.

⁶² Kil Kelly, U. (2015), 'Health and Children's Rights', in: W. Vandenhoele, E. Desmet, D. Reynaert and S. Lembrechts (eds), *Routledge Handbook on Children's Rights Studies*, London/New York: Routledge, pp. 216-233 (217) (hereinafter: '**Kil Kelly (2015)**').

⁶³ Article 6 para. 1 CRC.

⁶⁴ See Kil Kelly (2015), *supra note 62*.

⁶⁵ Preamble CRC; See also Detrick S., *A Commentary on the United Nations Convention on the Rights of the Child*, Martinus Nijhoff Publishers (1999).

CRC deliberately left open the question when life (and consequently childhood) 'begins'. In Europe, the ECtHR found that Article 2 of the ECHR, guaranteeing the right to life, does not apply similarly to unborn children and to embryos.⁶⁶ Also, the Council of Europe instruments relating to biomedicine either exclude embryos and fetuses from their scope, or provide them with limited protection.⁶⁷ Thus, fetuses and embryos may enjoy certain legal protection and status, depending on the particular context, and according to the margin of appreciation of States. This complex and sensitive issue raises questions on whether the right to life is applicable, what safeguards should be put in place, and how the conflicting interests should be weighted and resolved.

The same holds true with respect to end of life decisions that are nowadays increasingly seen as expressions of autonomy. In relation to children, the issue of end of life decisions also raises questions as to the role of parents, and to what extent parents can make irreversible decisions for their children (e.g. withholding consent for life-saving treatment or consent for active life-ending treatment).

General Principle 4: Right to be heard

The CRC holds that a child who is capable of forming his or her views has the right to express views 'in all matters affecting the child', and that the views should be given 'due weight in accordance with the age and maturity of the child'.⁶⁸ The right to be heard is also one of the general principles of the CRC and has been broadly interpreted as a right to participation. Under the Council of Europe Recommendation on the Participation of Children⁶⁹, participation is defined as the right, means, space and opportunity to express views freely, be heard, and be able to contribute to decision-making, with the views given due weight in accordance with the child's age and maturity. In this regard, the child's age and maturity should not be viewed as a limitation; there should be no age limit on the child's right to express views, but consideration should be given to children's age and evolving capacities and their opinions should be taken into account as an increasingly determining factor.⁷⁰

Child participation is pivotal in the context of biomedicine and the views of children, with respect to their evolving capacities, should be taken into account in relation to health services, and in decision making processes. Specifically, the organisation of health-care services needs to be informed by hearing children, and children should be actively consulted in relation to health care related plans, policies and legislation. To enable meaningful participation in relation to their own health, children and their parents need to be provided with all relevant information, and be offered support. Children, in particular, are entitled to receive child-friendly and age appropriate information, in an understandable language. In order to encourage children to effectively participate in health-care, professionals need to be trained on communication with children, and the process in which children are heard should be child-friendly, transparent, informative, voluntary and respectful of their rights, needs and interests.

It is important to distinguish between child participation and the ability of the child to provide consent to treatment. In relation to biomedical research and care, while the age of consent can differ

⁶⁶ Koffeman (2015), *supra note* 58 p. 21.

⁶⁷ Article 2 para. 1 and 2 Protocol concerning Biomedical Research; Article 18 CHRB.

⁶⁸ Article 12 CRC.

⁶⁹ CoE Recommendation on the Participation of Children and Young People, *supra note* 36.

⁷⁰ CRC Committee General Comment No. 12 (2009) on The right of the child to be heard, 20 July 2009, CRC/C/GC/12, para 20 (hereinafter: '**CRC GC 12**'); See also CFHC Guidelines, *supra note* 36, para IV(A)(23).

under national law, the views of the child, regardless of his or her legal ability to consent, should always be sought and taken into account as an increasingly determining factor, in accordance with his or her age and maturity.⁷¹

2.3 Rights of the child and rights of parents

Parental authority

Under human rights law, parents have the primary responsibility for the upbringing of their children and for guaranteeing their best interests (see under Stakeholders, Chapter 1).⁷² In addition, parents have the right and duty to provide guidance and direction to the child. As a corollary States are required to recognise parents' responsibilities, rights and duties.⁷³ This means that parents have an important role and responsibility in protecting, respecting and fulfilling children's rights, also in the field of health and biomedicine. But how to interpret these rights and duties, often referred to as 'parental authority'?

As the CRC views children as right holders, it requires that parents are guided in their decision making by the best interest of the child,⁷⁴ and that they take into account the interests and rights of children, as well as their evolving capacities and competences (see under evolving capacities).⁷⁵ Under the CHRB, parents can authorize and withhold consent to medical intervention, treatment and participation in research on behalf of their children,⁷⁶ and the ECtHR has identified the involvement of parents in medical decision-making under the protection of private and family life, according to Article 8 ECHR.⁷⁷ Yet, parental decision-making can be limited when it can infringe fundamental rights of children individually or as a group (e.g., right to life, right to preserve one's identity, protection from torture, right to equitable standard of health, etc.), in relation to public health considerations (e.g., child vaccinations), or when parental decision making can have irreversible results (e.g. organ donation).

Evolving capacities

It follows from the above that the way children can enjoy their rights in the domain of biomedicine is often determined by their parents (or other legal representatives as prescribed by law). This is notably because children are not always considered to be competent to consent or refuse to biomedical research and care.⁷⁸ The extent to which children are considered incompetent depends

⁷¹ See for example Article 14 para. 1(iv) Protocol concerning Biomedical Research"; CRC GC 12, *supra note* 70, para 30 holds that 'Maturity refers to the ability to understand and assess the implications of a particular matter, and must therefore be considered when determining the individual capacity of a child'. In the context of the right to be heard, the CRC Committee adds that '[t]he greater the impact of the outcome on the life of the child, the more relevant the appropriate assessment of the maturity of that child'.

⁷² Article 18 CRC.

⁷³ Article 23 CCPR; CRC Preamble and articles 5, 18(1). On the important role of parents in protecting and promoting the rights and best interests of children, see also the preamble of the European Convention on the Exercise of Children's Rights.

⁷⁴ Article 18 para. 1 CRC.

⁷⁵ Article 5 CRC.

⁷⁶ Article 6 para 2, 17 CHRB; Article 15 Protocol concerning Biomedical Research.

⁷⁷ See for example, ECtHR 9 March 2004, *Glass v. the UK*, Appl. No. 61827/00.

⁷⁸ Lepola, P., Needham, A., Mendum, A. et al. (2016), 'Informed consent for paediatric clinical trials in Europe', *Arch Dis Child* 0:1–9 (hereinafter: '**Lepola et al. (2016)**').

on their their age, maturity and their evolving capacities. Under the CRC parents are required to take into account their child's evolving capacities and best interests.⁷⁹

Thus, the role of parents in decision making relating to children should not be interpreted (only) as a parental right or as merely a protective measure for children. Rather, parental authority in decision making is also meant to reflect the interests of children, and assist them in exercising their own evolving autonomy, and safeguard their rights and interests.

2.4 Specific rights of children relevant to biomedicine

Three human rights, not listed above, are of particular relevance for children in the area of biomedicine and will be briefly addressed below.

Right to identity

Under the CRC States are required to respect the right of the child to preserve his or her identity, including nationality, name and family relations as recognised by law without unlawful interference.⁸⁰ Personal identity is closely connected with human dignity. The ECtHR acknowledged with respect to end of life decisions that forcing individuals to linger on in old age or in states of advanced physical or mental decrepitude may conflict with their ideas of personal identity.⁸¹ The meaning of the right to identity, however, is of relevance for more of the biomedical concerns identified by the Uppsala Report. Personal identity is, for example, also at stake when it comes to receiving information about one's descent, one's biological parents or the truth about paternity⁸² as well as respect for one's gender identity, according to the ECtHR 'one of the most intimate areas of a person's private life'.⁸³ The right to identity thus is also of importance for preconceptional and prenatal interventions as well as gender modification techniques.⁸⁴

Right to privacy and confidentiality

Like everybody else children are entitled to respect for their privacy.⁸⁵ The right to privacy, or 'private life' under Article 8 ECHR, is a broad concept, covering among other the physical and moral integrity of the person, including his or her sexual life.⁸⁶ In relation to biomedical interventions, children's right to privacy should also be taken into account, which among others implies that not all information is automatically shared with parents. The ECtHR also noted with respect to the right to private life that 'respecting the confidentiality of health data is a vital principle in the legal systems of all the Contracting Parties to the Convention'.⁸⁷ Both the right to privacy as well as the issue of confidentiality, bestowing a duty on groups of professionals not to share information about

⁷⁹ Kamchedzera, G. (2012), *A Commentary on the United Nations Convention on the Rights of the Child, Article 5: The Child's Right to Appropriate Direction and Guidance*, The Hague: Brill Nijhoff; Articles 5, 18 of the CRC.

⁸⁰ Article 8 para. 1 CRC.

⁸¹ ECtHR 29 April 2002, *Pretty v. the UK*, Appl. No. 2346/02, para. 65.

⁸² ECtHR 7 February 2002, *Mikulic v. Croatia*, nr. 53176/99; ECtHR 13 February 2003, *Odièvre v. France* (GC), Appl. No. 42326/98 and ECtHR 17 July 2007, *Jevremović v. Serbia*, Appl. No. 3150/05.

⁸³ ECtHR 12 June 2003, *Van Kück v. Germany*, Appl. No. 35968/97, para. 56

⁸⁴ ECtHR 10 March 2015, *Y.Y. v. Turkey*, Appl. No. 14793/08; ECtHR 6 April 2017, *A.P., Garçon and Nicot v. France*, Appl. No. 79885/12, 52471/13 and 52596/13; Also in relation to international surrogacy, the ECtHR confirmed that the right to identity of children should be considered as an element of the child's right to private life, see ECtHR 26 June 2014, *Mennesson v. France*, Appl. No. 65192/11; ECtHR 26 June 2014, *Labassee v. France*, Appl. No. 65941/11.

⁸⁵ Article 16 CRC.

⁸⁶ ECtHR 26 March 1985, *X and Y v. the Netherlands*, Appl. No. 8978/80, para. 22.

⁸⁷ ECtHR 25 February 1997, *Z. v. Finland*, Appl. No. 22009/93, para. 95.

individuals, has implications for, among others, data collection, access to medical files and information sharing in relation to medical care (e.g. between medical professionals and parents). There are also implications for the storage of biological material.

Right to health

The CRC recognises that each child has the right to the highest attainable standard of health and to health care.⁸⁸ The right to health is closely interconnected with other human rights.⁸⁹

International and European standards specifically anchor the right to health care and to health care services.⁹⁰ The right to health care entails the availability, accessibility, acceptability, and quality of such services for children.⁹¹ In instruments and documents elaborating the right to health care for children special emphasis has been placed on child-friendly health services, which regard children as rights holders, and position their rights, needs, voices and evolving capacities at the center of health-care policies and practices.⁹² The Council of Europe Guidelines for Child-Friendly Health Care (CFHC) specifically acknowledge the principles of participation, non-discrimination, dignity and the best interests of the child in the context of health-care, and emphasise that children should be treated with care, sensitivity, fairness and respect in any health-related intervention, with special attention to their personal situation and needs.⁹³

The right of the child to health is of imminent importance to biomedical research and care, and all the areas of concern identified by the Uppsala Report. Its realisation requires, in the field of biomedicine, specific measures to be taken matching the child's best interests and taking into account parental authority and the child's evolving capacities.

2.5 Conclusion

This chapter demonstrated that children have all the human rights other human beings have. In fact, some human rights primarily or exclusively seek to protect and respect the interests of children. This does not automatically provide a clear legal framework to address the challenges identified in the Uppsala Report. Correctly interpreting and applying these rights requires a deeper understanding of all relevant rights and child specific general principles, as well as the complex relationship between the rights of the child and the rights of parents.

⁸⁸ Article 24 CRC. This right was elaborated upon by the CRC Committee in its GC 15, see *supra note 44*. In this report, we will refer to the right to the highest attainable standard of health broadly as the right to lifehealth. See in relation, Toebes, B.C.A. (1999), *The Right to Health as a Human Right in International Law*, Antwerp/Oxford: Intersentia/Hart; Hendriks, A.C. (1998), 'The Right to Health in National and International Jurisprudence', *European Journal of Health Law* (5), pp. 389-408; Clapham, A. and Robinson, M. (eds) (2009), *Realizing the Right to Health*, Zurich: Rüffer & Rub; Toebes, B.C.A., Ferguson R., Markovic, M. and Nnamuchi, O. (eds) (2014), *The Right to Health - A Multi-Country Study of Law, Policy and Practice*, The Hague: T.M.C. Asser Press/Springer; David, É. (1985), 'Le droit à la santé comme droit de la personne humaine', *Revue Québécoise de Droit International*, pp. 63-115.

⁸⁹ San Giorgi, M. (2012), *The Human Right to Equal Access to Health Care*, Antwerp: Intersentia.

⁹⁰ Article 24 para. 1 CRC ; Article 3 CHRB; Article 35 EU Charter.

⁹¹ CRC GC 15, *supra note 44*, para. 25.

⁹² See CFHC Guidelines, *supra note 36*, para. I(1)-(2), II(3), III(A)(7).

⁹³ *Ibid.*, para. III(B)(10).

Chapter 3: Biomedical standards

This chapter contains a description of international and European legal standards relevant to the areas of concern and challenges identified in the Uppsala Report. We will particularly examine whether the existing biomedical standards have child specific provisions and, if so, what their meaning is.

3.1 International standards

On the international level, various standards emerged in response to developments in the fields of biomedical research and care, as well as in other areas of concern identified in the Uppsala Report.

There is a large number of international standards on **biomedical research** that seek to prevent that individuals participate in research programmes without strict criteria being met.⁹⁴ This approach can easily be understood given the way medical research was conducted in the recent past (not only in Nazi-Germany (Nuremberg Doctors' Trial), but also in Tuskegee (study of untreated syphilis in black males) and Willowbrook (study on the effects of gamma globulin to combat hepatitis with children with an intellectual disability). In response, it was considered essential to establish strict safeguards. At the same time, it is considered essential, and a right, that humanity can benefit from research.⁹⁵ More recent human rights documents, like the CRPD, emphasise both the importance of international cooperation in research and access to scientific and technical knowledge, while at the same time acknowledging the right of children to autonomy and express their views 'on matters affecting them' as well as the principle of the child's best interests.⁹⁶ To the extent that international documents on research do contain child specific provisions, like the CRPD, these provisions generally only seek to provide more protection to children – thus restricting the possibilities to serve as research participants – by enhancing the criteria that would allow their participation. As an example, reference should be made to the Declaration of Helsinki of the World Medical Association (WMA). This declaration, adopted in 1964, contains a set of ethical principles that should be adhered to when performing biomedical research with human beings. According to this declaration 'Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects'. When it comes, however, to involving 'vulnerable groups and individuals' such as children these should 'receive specifically considered protection'.⁹⁷

Reference should also be made to the International Ethical Guidelines for Biomedical Research Involving Human Subjects, adopted by the Council for International Organizations of Medical Sciences (CIOMS). These standards emphasise the ethical justification and scientific validity of biomedical research involving human subjects. Besides acknowledging the right to informed consent, the standards contain a guideline with respect to involving children as research participants, in an effort to optimally guarantee their rights and interests.⁹⁸

⁹⁴ For example, Article 7 CCPR stipulates that no one shall be subjected without his free consent to medical or scientific experimentation.

⁹⁵ According to Article 15 CESCR States are obliged to recognise everyone's right to enjoy the benefits of scientific progress and its applications.

⁹⁶ Article 7, 32 CRPD.

⁹⁷ Articles 17, 19 WMA, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, June 1964.

⁹⁸ Council for International Organizations of Medical Sciences (CIOMS) & World Health Organization (WHO), *The International Ethical Guidelines for Biomedical Research Involving Human Subjects*, 2002. See guideline 14; According to this Guideline an investigator is required, before undertaking research involving children, to ensure that:

A similar tension between potential benefits and threats is imminent with respect to international standards on **physical and mental health care**. Provisions on the right to health and health care, like Article 12 of the Covenant on Economic, Social and Cultural Rights (CESCR),⁹⁹ stress the importance of equal access to and the availability of health care, whereas other documents tend to protect individuals from unwanted health care interventions by emphasising consent and free choice. For example, Article 17 of the CCPR obligates States to offer legal protection against the ‘arbitrary or unlawful interference’ of a person’s privacy.¹⁰⁰ Similar concerns about potential abuse are particularly echoed by instruments seeking to prevent abuse of psychiatry.¹⁰¹ The CRC Committee also emphasises the range of measures States should take in order to attain the highest level of health.¹⁰² While the CRC is fully aware of the importance of such principles as non-discrimination, the child’s best interests and the right to be heard, the CRC is above all focused on achieving the preconditions in which children can live healthy. The CRC Committee recommends States to review and consider allowing children to consent to certain forms of medical treatments and interventions, giving the examples of HIV testing and sexual and reproductive health services. The CRC remains silent on particular issues that relate to consent, refusal and the limitation that should be placed on child participation in relation to medical treatment.¹⁰³ The World Medical Association (WMA) acknowledges in its Declaration on Child Care the importance of guaranteeing a full range of health facilities to children and performing research for its evidence-based continual improvement.¹⁰⁴

International standards on **preconceptional and prenatal interventions** mostly stress the importance of access to safe prenatal health care.¹⁰⁵ Safe prenatal health care is also seen as a means to improve the health of mothers and children.¹⁰⁶ Standards remain silent, however, on the precise meaning of prenatal health care, whether this extends to preconceptional interventions and how to assess whether these techniques are consistent with human dignity and the rights of the (future) child. In general, international standards urge for restraint and more research in case the implications of preconceptional and prenatal interventions, including their validity and ethical impacts, are not fully clear yet.¹⁰⁷

There are considerably more international standards on **genetic techniques**.¹⁰⁸ The drafting of these standards was mostly motivated by concern about the potential far reaching implications of genetic

-
- the research might not equally well be carried out with adults;
 - the purpose of the research is to obtain knowledge relevant to the health needs of children;
 - a parent or legal representative of each child has given permission;
 - the agreement (assent) of each child has been obtained to the extent of the child’s capabilities; and,
 - a child’s refusal to participate or continue in the research will be respected.

This list of requirements is accompanied by a commentary.

⁹⁹ Article 12 CESCR

¹⁰⁰ Article 17 CCPR.

¹⁰¹ World Psychiatric Association, Madrid Declaration on Ethical Standards for Psychiatric Practice (1996, reaffirmed 2011).

¹⁰² See CRC GC 15, *supra* note 44.

¹⁰³ Kil Kelly (2015), *supra* note 62, p. 221.

¹⁰⁴ WMA Declaration of Ottawa on Child Health (1998, reaffirmed in 2009).

¹⁰⁵ See for example Article 24 para 2 (d) CRC imposing a duty on States to ensure appropriate pre-natal and post-natal health care for mothers.

¹⁰⁶ UN (2015), Global Strategy for Women’s, Children’s and Adolescents’ Health (2016-2030)

¹⁰⁷ See for example the ISUOG consensus statement on the impact of non-invasive prenatal testing (NIPT) on prenatal ultrasound practice, published in *Ultrasound Obstet Gynecol* 2014; 44: pp. 122–123.

¹⁰⁸ See also Seon-Hee Yim and Yeun-Jun Chung (2013), ‘Introduction to International Ethical Standards Related to Genetics and Genomics’, *Genomics and Informatics* 11(4), pp. 218–223.

techniques, particularly when it comes to gene editing techniques¹⁰⁹, and their potential abuse. As an example reference should be made to the Universal Declaration on the Human Genome and Human Rights (UDHGHR) adopted by UNESCO (1997). According to this declaration 'Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law and (b) on the basis of the prior, free and informed consent of the person concerned.'¹¹⁰ This declaration thus clearly emphasises the rights to autonomy and to protection of (potential) research subjects. Similar values underlie UNESCO's Universal Declaration on Bioethics and Human Rights (UDBHR, 2005), a declaration that in general emphasises the importance of finding a proper balance between benefits and risks ('In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized').¹¹¹ In finding such a balance attention should be paid to relevant rights and interests, notably human dignity and human rights, autonomy and individual responsibility, consent and privacy and confidentiality.¹¹² These two documents do not specifically refer to children, but the UDBHR states that 'Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected'.¹¹³ There is particularly worldwide concern that children are subjected to genetic techniques at an age where they cannot yet consent themselves.¹¹⁴

When it comes to **gender modification techniques** international standards are still relatively silent. The CRC Committee recently urged States not to subject *intersex* individuals to unnecessary medical or surgical treatment during infancy or childhood, and to provide families with intersex children adequate counselling and support. The UN Special Rapporteur on Torture also recommended States to amend laws that fail to protect children from medically unnecessary gender-normalizing procedures.¹¹⁵ In addition, while the CRC Committee has emphasised the right of children, particularly adolescents, to respect for their physical and psychological integrity, gender identity and emerging autonomy,¹¹⁶ yet there are no sufficient international legal standards or guidance in relation to *transgender* children's access to gender modification techniques.

International standards on **transplantation care** express concern about the shortage of available organs, threatening the health and life of persons in need of a transplant organ. They equally stress the importance of ethical and legal procedures to increase supply with full respect for the human

¹⁰⁹ International Bioethics Committee (2015), Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights, Paris: UNESCO and Hinxton Group (2015), Statement on Genome Editing Technologies and Human Germline Genetic Modification.

¹¹⁰ Article 5 UDHGHR

¹¹¹ Article 4 UNESCO, *Universal Declaration on Bioethics and Human Rights*, (2005) (hereinafter: 'UDBHR').

¹¹² *Ibid.*, Articles 3, 5, 6, and 9, respectively.

¹¹³ *Ibid.*, Article 8.

¹¹⁴ E.g. The Canadian Paediatric Society and the Canadian College of Medical Geneticists, Guidelines for genetic testing of healthy children (2003 and as reaffirmed in 2017).

¹¹⁵ See in Garland, J. (2016), *On Science, Law, and Medicine. The case of gender-"normalizing" interventions on children who are diagnosed as different in sex development*, Lund: Lund University.

¹¹⁶ CRC Committee, General Comment No. 20 (2016) on the implementation of the rights of the child during adolescence, 6 December 2016, CRC/C/GC/20; See also WPATH (2011), Standards of Care: for the Health of Transsexual, Transgender, and Gender Nonconforming People, p. 10-21, 7th edition (hereinafter: 'WPATH (2011)').

dignity and autonomy of the potential donor.¹¹⁷ The WHO Guidelines ‘exclude vulnerable persons who are incapable of fulfilling the requirements for voluntary and knowledgeable consent’, such as children. The Guidelines also reflect concern about the increase in human organ tourism and trafficking.¹¹⁸

On an international level **end of life decisions** are still largely a taboo issue. For example, the World Medical Association unequivocally believes that euthanasia is in conflict with basic ethical principles of medical practice, and strongly encourages all National Medical Associations and physicians to refrain from participating in euthanasia, even if national law allows it or decriminalizes it under certain conditions.¹¹⁹ The UN Human Rights Committee, as well as the CRC Committee, expressed concern about the compatibility of the Dutch Law on the Termination of Life on Request and Assisted Suicide (Euthanasia Act).¹²⁰ Belgian law, that explicitly permits child euthanasia under strict conditions, also received worldwide critique.¹²¹

3.2 European standards

Concern about unethical forms of **biomedical research** that would be in contradiction with fundamental human rights and that would commodify human beings¹²² were a strong incentive in Europe to draft the CHRB.¹²³ In Europe a need was felt not only to regulate biomedical research with human beings¹²⁴ but also with human materials.¹²⁵

When it comes to involving children as research participants, European standards contain very strict criteria. According to CHRB five criteria should cumulatively be met before persons unable to consent can become a research participant.¹²⁶ Thus, according to these standards, involving children in biomedical research programmes is only permitted under exceptional circumstances. Yet, and as will be further discussed in chapter 4, the CHRB and its additional protocols regard children who are unable to consent. Children under this category are then provided with additional protection and safeguards, to ensure their rights and interests. However, the age of consent to medical treatment or research may vary among States, and children below the age of 18 can be able to make decisions relating to certain, or all, medical procedures. The focus of the CHRB, and its additional protocol, on ‘consent’ pose an over-arching challenge to children, as it fails to recognise that despite reaching the

¹¹⁷ WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation (2010), endorsed by the sixty-third World Health Assembly.

¹¹⁸ Declaration of Istanbul (2008), adopted by the participants in the International Summit on Transplant Tourism and Organ Trafficking convened by The Transplantation Society and International Society of Nephrology in Istanbul (April 30–May 2, 2008).

¹¹⁹ WMA resolution of euthanasia (2002, and reaffirmed in 2013).

¹²⁰ Concluding observations on the fourth periodic report of the Netherlands (2015), CRC/C/NL/CO/4, para. 29; Human Rights Committee (2009), Concluding observations of the Human Rights Committee, Netherlands, CCPR/C/NLD/CO/4, para. 7.

¹²¹ Coalition of Physicians for Social Justice, Belgian law for child euthanasia is in violation of the United Nations Convention of the Rights of the Child, <http://www.prnewswire.com/news-releases/belgian-law-for-child-euthanasia-is-in-violation-of-the-united-nations-convention-of-the-rights-of-the-child-245344051.html> (last accessed: 19.6.2017).

¹²² Cf Kantian ethics: ‘human beings should never be treated merely as a means to an end, but always also as ends in themselves’.

¹²³ Explanatory Report CHRB, *supra note* 14, para 21: ‘One of the important fields of application of this principle concerns research’, on the principle of the primacy of the human being.

¹²⁴ See Protocol concerning Biomedical Research.

¹²⁵ Council of Europe, Rec(2006)4 on Research on Biological Materials of Human Origin, 15 March 2006; Council of Europe, Rec(2016)6 of the Committee of Ministers to Member States on research on biological materials of human origin, 11 May 2016 (hereinafter: ‘**Rec(2016)6 on research on biological materials of human origin**’).

¹²⁶ Article 17 para. 1 CHRB; See also the Article 15 of the Protocol concerning Biomedical Research.

national age of consent, children can still require special assistance and support in the context of biomedicine. This may refer to issues such as child-friendly information and communications with medical professionals, access to justice and remedy, or parental support and assistance. The European Social Charter (ESC) is also of particular relevance with respect to the legal framework seeking to regulate the developments in the field of biomedicine. The Revised Charter reads as follows: ‘Children and young persons have the right to a special protection against the physical and moral hazards to which they are exposed.’¹²⁷ And the ESC further stipulates in general that ‘Children and young persons have the right to appropriate social, legal and economic protection’.¹²⁸ These obligations to protect are also of great importance when it comes to health and biomedical issues.

When it comes to **physical and mental health** care, European standards¹²⁹ seek to guarantee basic safeguards with respect to informed consent,¹³⁰ confidentiality,¹³¹ equal access,¹³² safety¹³³ and quality.¹³⁴ Also in Europe, there is special concern about the treatment of persons with a mental disorder.¹³⁵ When it comes to persons not able to consent, the CHR B stipulates that the best interests of the person concerned should be leading.¹³⁶

The ECtHR has interpreted the right to life as requiring States to make regulations compelling hospitals, whether public or private, to adopt appropriate measures for the protection of their patients’ lives.¹³⁷ It should also be mentioned in that regard that the ECtHR recognised the principle of the best interests of the child as one of its leading principles when interpreting rights protected by the ECHR and when weighing conflicting rights and interests.

According to ECSR, interpreting the ESC, States must take the necessary and appropriate measures to guarantee children receive the care and assistance they need and to protect them from any negligence, violence or exploitation, that pose a serious threat to the enjoyment of their basic rights, such as the rights to life, to psychological and physical integrity and to respect for human dignity.¹³⁸ States are required to guarantee the right of children to care and assistance, including medical assistance.¹³⁹ Also, the ECSR is aware of the importance to provide access to health care to children.¹⁴⁰ The Parliamentary Assembly of the Council of Europe (PACE) has in 2016 called upon all

¹²⁷ Article 7 para 10 Council of Europe, *European Social Charter (Revised)*, 3 May 1996, ETS 163 (hereinafter: ‘**Revised ESC**’).

¹²⁸ Article 17 Council of Europe, *European Social Charter*, 18 October 1961, ETS 35 (hereinafter: ‘**ESC**’).

¹²⁹ See also EU, Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare.

¹³⁰ ECtHR 9 March 2004, *Glass v. the UK*, Appl. No. 61827/00.

¹³¹ ECtHR 25 February 1997, *Z. v. Finland*, Appl. No. 22009/93.

¹³² Article 3 CHR B (‘equitable access’) and PACE, Resolution 1946 (2013) on ‘Equal access to health care’.

¹³³ ECtHR 13 November 2012, *Hristozov et al. v. Bulgaria*, Appl. No. 47039/11 and 358/12, and ECtHR 28 May 2014, *Durisotto v. Italy* (decision), Appl. No. 62804/13.

¹³⁴ Article 3 CHR B (‘appropriate health care’) and Article 4 (‘professional standards’); CJEU 12 July 2001, C-157/99 *Geraets-Smits and Peerbooms* [2001] ECR, I-5473, ECLI:EU:C:2001:404, § 92: ‘the state of international medical science and medical standards generally accepted at international level.’ See also Hendriks, A.C. (2016), ‘High-quality of Care throughout Europe — But Do We Speak the Same Language?’, *European Journal of Health Law* pp. 1-4.

¹³⁵ Council of Europe, Rec(2004)10 concerning the Protection of the Human Rights and Dignity of Persons with Mental Disorder (hereinafter: ‘**Rec(2004)10 concerning the Protection of the Human Rights and Dignity of Persons with Mental Disorder**’).

¹³⁶ Article 6 para. 5. CHR B.

¹³⁷ Article 2 ECHR; ECtHR 17 January 2002, *Calvelli and Ciglio v. Italy* (GC), Appl. No. 32967/96.

¹³⁸ ECSR 20 October 2009, *Defence for Children International (DCI) v. the Netherlands*, No. 47/2008.

¹³⁹ Article 17 ESC; ECSR 7 November 2004, *International Federation of Human Rights Leagues (FIDH) v. France*, No. 14/2003.

¹⁴⁰ See e.g. European Committee of Social Rights (ECSR) and Council of Europe, *Activity Report 2015*, p. 116.

to ensure access to health care for all children in Europe.¹⁴¹ And the Charter of Fundamental Rights of the European Union (EU Charter) states that ‘Children shall have the right to such protection and care as is necessary for their well-being...’. The second paragraph of this provision adds that ‘In all actions relating to children (...) the child’s best interests must be a primary consideration.’¹⁴²

On a European level, there is ample discussion on the regulation of **preconceptional and prenatal interventions**¹⁴³ but this is largely left to individual States in the absence of a European consensus. This also explains why this issue is not addressed by the CHRB, with the exception of human cloning.¹⁴⁴

On a European level a number of standards emerged in response to concerns about the ‘uncontrolled’ developments and application of **genetic techniques**.¹⁴⁵ In Europe there seems to be particular concern about the retrieval and use of sensitive information by genetic testing techniques.¹⁴⁶ This also holds true with respect to children¹⁴⁷ and other vulnerable groups. With respect to this category of persons, the Additional Protocol concerning Genetic Testing for Health Purposes proscribes that ‘a genetic test on this person shall be deferred until attainment of such capacity unless that delay would be detrimental to his or her health or well-being’ (Article 10).

European standards increasingly allow **gender modification techniques** provided that the rights of the persons concerned are fully respected.¹⁴⁸ PACE is also very concerned about discrimination against transgender persons in Europe.¹⁴⁹ Both the ECtHR and PACE call on States to abolish sterilisation and other compulsory medical treatment, as well as a mental health diagnosis, as a necessary legal requirement to recognise a person’s gender identity. Yet, such standards do not specifically relate to children.

Both the CHRB and its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (Protocol concerning Transplantation) contain standards with respect to **transplantation care**. The CHRB has two provisions on organ donations, with additional criteria to be met to allow for organ donation from a child or other vulnerable person.¹⁵⁰ These provisions have been elaborated upon in the Protocol concerning Transplantation, both for living and deceased donors.¹⁵¹ The Protocol holds that ‘No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 13 of this Protocol.’ The second paragraph does,

¹⁴¹ PACE, Resolution 2139 (2016) Ensuring access to health care for all children in Europe; See also Chauvin, P. et al. (2014), *Access to healthcare for the most vulnerable in a Europe in social crisis*, Médecins du monde, Paris: Clumic Arts Graphiques.

¹⁴² Article 24 para. 1 EU Charter

¹⁴³ See e.g. European Commission, Health & Consumer Protection Directorate-General (2006), *Report on regulation of reproductive cell donation in the European Union: results of a survey*, Brussels: Directorate C, Public Health and Risk Assessment C6, Health Measures.

¹⁴⁴ See Protocol concerning Cloning.

¹⁴⁵ Council of Europe, Rec(2003)10 on Xenotransplantation and its Explanatory Memorandum, 19 June 2003.

¹⁴⁶ Council of Europe, Rec(2016)8 on the processing of personal health-related data for insurance purposes, including data resulting from genetic tests, 26 October 2016; See also Protocol concerning Genetic Testing.

¹⁴⁷ British Society for Human Genetics (2010), *Report on the Genetic Testing of Children 2010*, Birmingham: British Society for Human Genetics. Clinical Genetics Unit, Birmingham Women’s Hospital, Edgbaston, Birmingham

¹⁴⁸ ECtHR 10 March 2015, *Y.Y. v. Turkey*, Appl. No. 14793/08; ECtHR 6 April 2017, *A.P., Garçon and Nicot v. France*, Appl. No. 79885/12, 52471/13 and 52596/13.

¹⁴⁹ PACE Resolution 2048 (2015) on Discrimination against transgender people in Europe.

¹⁵⁰ Articles 19 and 20 CHRB.

¹⁵¹ Articles 12-14 and Articles 15-19 Protocol concerning Transplantation.

however, list a few exceptions. It is however clear from these standards that, in general, children are not allowed to donate organs.¹⁵²

On a European level there is an ongoing discussion on **end of life decisions**.¹⁵³ In 2002 the ECtHR found that a 'right to die' cannot be derived from Article 2 ECHR.¹⁵⁴ At the same time the ECtHR held that patients have a right to refuse treatment, including life-saving treatment.¹⁵⁵ States that deny access to a lethal dose of a drug in order to commit suicide, where this is legal under national law, may violate the right to private life (individual autonomy) of a person.¹⁵⁶ As yet, however, there is no European consensus on these issues, let alone on the rights of children with respect to these forms of treatment.

3.3 Conclusion

Many international and European organisations have set standards in the areas of biomedical research and care, as well – but to a lesser extent – the other areas of concern identified in the Uppsala Report (see chapter 1). Above all, these standards seek to protect individuals from being subjected to or otherwise exposed to biomedical research and care without basic rights being respected. At the same time these standards acknowledge that research and care may be essential for others or the person himself or herself. Yet the existing standards predominantly establish criteria that should be met to justify these forms of treatment.

To the extent that standards are directly or indirectly applicable on children, their protective criteria are even stricter. In fact, children are in various instances not allowed to participate in research programmes, to donate organs or otherwise to engage in behaviour that may be seen as expressing solidarity unless very strict criteria are met. When it comes to health care, there are also additional protective mechanisms even though the parents, health care providers and others are increasingly expected to pay attention to the will of children as well as their best interests.

¹⁵² According to Article 14 para 1 of the Protocol concerning Transplantation.

¹⁵³ See e.g. European Parliament (2015), Written declaration, under Rule 136 of Parliament's Rules of Procedure, on dignity at the end of life.

¹⁵⁴ ECtHR 29 April 2002, *Pretty v. the UK*, Appl. No. 2346/02. See also Council of Europe, Guide on the decision-making process regarding medical treatment in end-of-life situations, May 2014.

¹⁵⁵ ECtHR 10 June 2010, *Jehovah's Witnesses of Moscow et al. v. Russia*, Appl. No. 302/02.

¹⁵⁶ ECtHR 14 May 2013, *Gross v. Switzerland*, Appl. No. 67810/10.

Chapter 4: Biomedical challenges and children's rights

4.1 International and European children's rights and biomedicine

The CHRБ and its Additional Protocols obligate States to ensure that human rights and fundamental freedoms are respected in the application of biomedicine, notably biomedical research and care. In this chapter, we will examine whether there are challenges and gaps in the framework of children's rights and biomedical standards, thus undermining the very aim of the CHRБ and its Additional Protocols. We will focus on the seven areas identified in the Uppsala Report, taking into account that law should, particularly in the area of biomedicine, be respectful of health professionals' autonomy, as well as allow flexibility for case-by-case decision-making.

4.2 Selected areas in biomedicine

4.2.1 Biomedical research

The CHRБ and its Additional Protocol concerning Biomedical Research (Protocol concerning Biomedical Research) strictly regulate biomedical research involving children who are unable to consent. While providing children with proven technologies, treatments and drugs require child-specific research, children should be prevented from being involved in studies that are disrespectful to human rights, notably children's rights. This requires that the study concerned has the potential to benefit the participant, that research of comparable effectiveness cannot be carried out on individuals capable of giving consent, that the participant is informed and does not object (the opinion of the child shall be considered as an increasingly determining factor), and that necessary authorization has been given. Research that does not have the potential to directly benefit the participants (e.g., research involving children as a 'control' group or 'basic research') can be conducted, if it can contribute to scientific understanding and to the ultimate attainment of results to benefit others in the same age category or afflicted with the same disorder, and if it entails minimal risk and burden.¹⁵⁷ The wording 'minimal risk and burden' reflects the balance between the potential collective benefit of research involving children, and the principle of the best interests of the child, and it enables a case-by-case evaluation for each research programme, which, among others, includes the intrusiveness of the research and the child's views. However, it should be noted that such research is not necessarily on strained terms with the best interests of the child principle.

Furthermore, the instruments set safeguards for research concerning pregnant or breastfeeding women,¹⁵⁸ and require that the research includes guarantees for children's privacy.¹⁵⁹ Thus, the CHRБ and the Protocol concerning Biomedical Research seek to strike a balance between protecting children on the one hand and ensuring that relevant research is indeed conducted to benefit the

¹⁵⁷ Article 6 para. 2 CHRБ; Articles 15, 17 Protocol concerning Biomedical Research; Council of Europe, Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, ETS 195 (2005), para 89 (hereinafter: '**Explanatory Report Protocol concerning Biomedical Research**'). In addition, similar conditions are set in relation to research on children's biological materials of human origin, see Article 12-21 para. 5 Rec(2016)6 on research on biological materials of human origin, *supra note* 125; Council of Europe, Recommendation CM/Rec(2016)6 of the Committee of Ministers to Members States on research on biological materials of human origin; Council of Europe, Explanatory Memorandum - Recommendation CM/Rec(2016)6 on research on biological materials of human origin, para. 57-65 (2016) (hereinafter: '**Rec(2016)6 on research on biological materials of human origin - Explanatory Report**').

¹⁵⁸ Article 18 para. 1-2 Protocol concerning Biomedical Research.

¹⁵⁹ Article 16 CRC; Article 10 CHRБ; Article 25 Protocol concerning Biomedical Research.

particular child and/or children as a group on the other. Yet, some challenges and gaps can be identified.

- 1. Children able to consent:** the safeguards concerning children under the Protocol concerning Biomedical Research can be found under the protection of ‘persons not able to consent’. As mentioned in chapter 3, basing the special safeguards on consent does not sufficiently address the fact that children below the age of 18 can be able, under national law and/or in practice, to consent to medical research and enjoy certain decision-making powers in that regard. Yet, despite being able to consent, children still require special assistance and safeguards in exercising their rights. It is unclear, however, what, if any, special measures of protection and assistance are available for such children in the context of biomedical research. **Therefore, it is recommended to undertake efforts to establish such measures and to make them available for all children participating in biomedical research.**
- 2. Participation:** the Protocol concerning Biomedical Research allows parents, or another body or authority as prescribed by law, to authorize a child’s participation in research, and holds that the opinion of the child should be taken into account as an increasingly determining factor, in accordance with his or her age and maturity.¹⁶⁰ The provision reflects the protective element of parental authority, while also requiring that in decision-making related to research, the opinion and wishes of the child are taken into account. Participation should be understood broadly as the obligation of decision-makers (e.g., parents, medical professionals) to hear and consider the views of the child throughout the research process, irrespective of the child’s legal capacity to independently consent or object. In addition, the child’s right to participate requires research bodies and/or medical professionals to ensure that that research procedures are designed in a child-sensitive manner, and that mechanisms are at place to allow and encourage children to effectively participate in decision-making processes. Yet, it is not clear from these standards how to ensure that children are effectively heard in relation to entering, refusing or withdrawing from research, as well as throughout the course of the research itself. Two additional elements closely connected with the broad concept of participation in that regard are ‘consent’ and ‘objection’ to biomedical research. The Protocol concerning Biomedical Research holds that a precondition to allow research on persons not able to consent is that they do not object.¹⁶¹ In relation to children, there is a need for a clear distinction between the legal ability of the child to consent and the ability to object to medical research.¹⁶² It is not clear how the CHRB or the Protocol concerning biomedical research distinguish between the right to participation (which is applicable to all children), and the elements of consent and objections to biomedical research. It is also not clear how to establish a child’s objection, and what weight should it be accorded when parents provide authorization and consent on behalf of the child. **This requires further guidance, as well as practical measures to enable children to exercise their right to be heard and to participate, and to ensure that medical professionals reach ethical and professional decisions in cases of children’s objection to biomedical research.**

¹⁶⁰ Article 14 para. 1(iv) Protocol concerning Biomedical Research.

¹⁶¹ Article 6 para. 2 - 17 para. 1(v) CHRB; Article 15(v) Protocol concerning Biomedical Research.

¹⁶² Article 13 para. 1 Protocol concerning Biomedical Research.

3. **Child-friendly information:** The CHRB and the Protocol concerning Biomedical Research require that children invited to participate in a research project, as well as their parents, receive full information about the project and their rights.¹⁶³ Such information shall be delivered ‘in a comprehensible form’. Yet, it is not sufficiently clear whether there is an obligation to provide children with child-friendly information, in an understandable language. **This requires to bridge between biomedical instruments and child-friendly standards, and guide States on how to implement those standards in the context of biomedical research.**
4. **Parental authority:** The CHRB and the Protocol concerning Biomedical Research recognise that parents, as legal representatives, can authorize the child’s participation in a research project.¹⁶⁴ Yet, this can raise tensions between parents and children; as well as between parents, children and medical professionals. A particular concern is that neither instruments explicitly refer to the principle of the best interests of the child as a criterion in decision-making. **Thus, guidance is required with regard to the discretion of medical professionals and parents in decision-making, and how States can support parents to ensure that their consent, refusal to consent or withdrawal from a research project is in accordance with the interests of the child, and that it respects the rights of children, including the right to be heard.**¹⁶⁵
- Another practical challenge in relation to parental authorization concerns the position of children who, during or following the research project, reach the age of consent, refuse or withdraw from a research project. **It is unclear whether the existing legal standards require to establish a ‘re-consent’ mechanism, and more guidance is required in this context.** In that regard, it is unclear whether a child, upon achieving legal capacity, has a right to decide on the continued storage or use of information or samples that were collected from him or her for biomedical research purposes, with the authorization of parents. **This requires additional guidance in relation to how to accommodate the child’s evolving age and maturity in biomedical research, and how to determine what mechanisms should be established that, on the one hand, recognise the child’s evolving capacities, and on the other, avoid the negative implications of withdrawing from research, and how to ensure that persons and organisations responsible for a research project enjoy stability in their research and procedures.**
5. **Access to justice and remedy:** the CHRB and the Protocol concerning Biomedical Research provide children with rights in the context of biomedical research (e.g. privacy, information), but are silent on the enforcement of these rights. To ensure that children’s rights in the context of biomedical research can be enforced, effective remedies must be available.¹⁶⁶ States should be required to establish available, accessible, and child-friendly redress and complaints mechanisms (see CFJ Guidelines), and ensure children and their parents are informed of their rights, the instruments available to seek remedy and mechanisms to review decisions. **It is therefore recommended to assist States in establishing legal protection, setting redress and complaints procedures, and providing appropriate remedies.**¹⁶⁷

¹⁶³ Article 13 para. 1-3, Article 14 para. 1, 16 Protocol concerning Biomedical Research.

¹⁶⁴ Article 15 para. 1(iv) Protocol concerning Biomedical Research; Article 6 para. 2, 17 CHRB.

¹⁶⁵ Wade et al. (2016), *supra note* 60, ‘p. 339(339).

¹⁶⁶ CRC GC 5, *supra note* 37, para. 24; See also Article 41 CRC; Article 2 para. 3 CCPR.

¹⁶⁷ See CoE Recommendation on the Participation of Children and Young People, *supra note* 36, para. III; CFJ Guidelines, *supra note* 36, para. IV(A)(1)(a)-(l).

6. Research on embryos and fetuses: the protection found in the CHRB and the Protocol concerning Biomedical Research in relation to embryos and fetuses is limited. Although the issue is increasingly debated, the CHRB prohibits the creation of human embryos for research purposes, and requires ‘adequate protection’ of embryos *in vitro* in research.¹⁶⁸ The Protocol, however, does not apply to embryos *in vitro* and holds that particular consideration shall be given to possible adverse impacts on the health of an embryo or fetus in research.¹⁶⁹ **It is recommended to address this apparent gap which can, in the absence of guidance and standards, have far reaching implications for (future) children and their rights, as well as for research purposes.**

4.2.2 Physical and mental health care

The right to equitable access to health care services is an important standard in relation to biomedicine.¹⁷⁰ It is recognised that proven technologies, including drugs, equipment and intervention, should be introduced to children, and that States have a positive obligation to take measures against health risks that relate to children.¹⁷¹ In particular, legal instruments relating to biomedicine anchor the principle of non-discrimination with respect to the application of biomedicine,¹⁷² conducting genetic testing,¹⁷³ transplantation,¹⁷⁴ and biomedical research.¹⁷⁵ In relation to the latter, it is specifically mentioned that persons, including children, who refuse to participate in research, or withdraw consent, shall not be subject to discrimination in medical care.¹⁷⁶

The child’s ability to consent or refuse medical treatment is a critical element in relation to the right to equitable health care. Generally, States enjoy a margin of appreciation, holding that when a child is able to consent under national law, medical intervention may be carried out only after he or she provides free and informed consent. If according to national law the child does not have a capacity to consent, his or her opinion shall be taken into account ‘as an increasingly determining factor’, in proportion to the child’s age and degree of maturity.¹⁷⁷ Concerning certain biomedical issues, objections of children should also be respected.¹⁷⁸ When children lack the capacity to consent, legal representatives (parents) or other authorities prescribed by law, can authorize medical intervention on their behalf.¹⁷⁹ Yet, some gaps can be identified in relation to children’s right to health care.

¹⁶⁸ Article 18 para. 1–2 CHRB.

¹⁶⁹ Article 22 para. 2 Protocol concerning Biomedical Research; Article 2 para. 2 CHRB.

¹⁷⁰ Article 3 CHRB.

¹⁷¹ CRC GC 15, *supra note 44*, para. 16; See also FRA (2015), *supra note 54*, p. 149.

¹⁷² Art 1 CHRB.

¹⁷³ Article 1 Protocol concerning Genetic Testing.

¹⁷⁴ Article 1 Protocol concerning Transplantation.

¹⁷⁵ Article 1 Protocol concerning Biomedical Research.

¹⁷⁶ Article 13 para. 3, 14 para. 2, 15 para. 3; Protocol concerning Biomedical Research.

¹⁷⁷ See for example: CFHC Guidelines, *supra note 36*, par III(C)(12)(i); Article 6 para. 2 CHRB; Article 29 para. 2 Rec(2004)10 concerning the Protection of the Human Rights and Dignity of Persons with Mental Disorder, *supra note 135*; Article 12 para. 4 Rec(2016)6 on research on biological materials of human origin, *supra note 125*; Rec(2016)6 on research on biological materials of human origin – Explanatory Report”, *supra note 157*, para 57-65; Article 12 para. 1 Protocol concerning Genetic Testing.

¹⁷⁸ Explanatory Report Protocol concerning Biomedical Research, *supra note 157*, para 86; Article 12 para. 4 Rec(2016)6 on research on biological materials of human origin, *supra note 125*; Rec(2016)6 on research on biological materials of human origin – Explanatory Report”, *supra note 157*, para. 57-65; Article 14 Protocol concerning Transplantation; CoE; *Guide on the Decision-Making Process regarding Medical Treatment in End-of-Life Situations*, 2014, p. 21.

¹⁷⁹ See for example, Article 12 para. 1 Protocol concerning Genetic Testing; Article 12 para. 1-2 Rec(2016)6 on research on biological materials of human origin, *supra note 125*.

1. **Children able to consent:** the CHRБ provides safeguards for children not able to consent.¹⁸⁰ As previously discussed, this does not sufficiently address the fact that children below the age of 18 can be able, under national law or in practice, to consent to treatment and enjoy certain decision-making powers in that regard. Yet, despite being able to consent, children still require special assistance and safeguards in exercising their rights, for example in relation to receiving information, access to justice, or other support. It is, however, unclear what, if any, special protection and assistance are available for such children in the context of biomedical treatment and care. **Therefore, it is recommended to undertake efforts to establish such measures and to make them available for all children undergoing health care.**

2. **Equitable health care:** from the existing provisions on the right to an equitable health care and non-discrimination it is not clear how these aims can be achieved in practice with respect to physical and mental health care. In that regard, it should be noted that the right to an equitable health care does not only require equal *availability*, but also concern accessibility, acceptability, and quality health care.¹⁸¹ **More detailed and concrete guidance is required to assist States in fully implementing these rights.**

3. **Participation:** As described in relation to biomedical research, participation should be understood broadly as the obligation of decision-makers (e.g., parents, medical professionals) to hear and consider the views of the child in health care, irrespective of the child's legal capacity to independently consent or object. In addition, the child's right to participate requires a child-friendly health care system, which includes mechanisms to allow and encourage children to effectively participate in decision-making processes. Yet, in practice, it is not clear from these standards how to ensure that children are effectively heard in relation to entering or refusing health care. Two additional elements closely connected with the broad concept of participation in that regard are 'consent' and 'objection' to health care. The instruments relating to biomedicine do not offer guidance relating to children's ability to give or refuse consent to proposed medical treatment, nor offer any guidance in relation to setting age limits for all or certain biomedical procedures. The same holds true for children's objections to forms of treatment. As previously discussed, the distinction between consent, objection and participation in decision-making requires further clarification. In particular, it is unclear what weight a child's objection should receive, what measures can be taken by medical professionals in such case, and how an objection relates to age of consent. In Europe, there are variations in relation to the age at which children are able to consent to medical treatment¹⁸² and, in practice, there are concerns that national laws do not recognise children's evolving capacities, and that their views are not effectively taken into account,¹⁸³ despite the fact that the CHRБ holds that the opinion of the child shall be taken into account, in accordance with his or her age and maturity.¹⁸⁴ **Thus, a**

¹⁸⁰ Article 6 para. 2 CHRБ.

¹⁸¹ See CRC GC 15, *supra* note 44, para VI(e)(2).

¹⁸² Lepola et al. (2016), *supra* note 78.

¹⁸³ See for example, CRC Committee, Concluding observations on the combined third and fourth periodic reports of Croatia, CRC/C/HRV/CO/3-4 (2014), para 24(E)-.

¹⁸⁴ See for example, CFHC Guidelines, *supra* note 36, par III(C)(12)(i); Article 6 para. 2 CHRБ; Article 29 para. 2 Rec(2004)10 concerning the Protection of the Human Rights and Dignity of Persons with Mental Disorder, *supra* note 135; Article 12 para. 4 Rec(2016)6 on research on biological materials of human origin, *supra* note 125; Para. 57-65 Rec(2016)6 on research on biological materials of human origin – Explanatory Report, *supra* note 157; Article 12 para. 1 Protocol concerning Genetic Testing.

mapping of the legal status (and related practices) of children in relation to consent, objections and participation in health care across national context can be beneficial and it is recommended that such mapping forms part of Council of Europe's roadmap.

4. **Child-friendly biomedical treatments:** child-friendliness of the health system should be adopted in all policies, services, practices and monitoring mechanisms.¹⁸⁵ Yet, the concept of child-friendly care is not addressed in the instruments relating to biomedicine. **There is a need, then, to identify, by way of a study, what elements in biomedicine require child-friendly adaptation.** For example, the CHRB requires that children and their parents are provided with 'appropriate information', but it does not specify whether such information is to be provided in a child-friendly manner and language for children. Nor does it address the importance of allocating appropriate resources and funds to ensure child-friendly care and procedures in practice.¹⁸⁶
5. **Parental authority:** as described, the CHRB recognises that parents, as legal representatives, can authorize health care interventions on behalf of the child, when the intervention is for the child's 'direct benefit'.¹⁸⁷ This, however, can raise tension between the best interests of the child and his or her views in this regard, parental autonomy, as well public health considerations. As described, the concept of the child's evolving capacities is reflected in the requirement that the opinion of the child shall be taken into consideration as an 'increasingly determining factor' in proportion to his or her age and degree of maturity,¹⁸⁸ but it remains unclear how to balance between the child's evolving capacities and views and the parental authority in decision making relating to care. **This requires additional guidance for States on how to balance between the interests and health of children, the concerns and wishes of parents, and public health and medical standards. Such guidance should be child-focused, emphasising the best interests of the child and the child's evolving capacities as primary considerations in decision making and policy design.**
6. **Access to justice and remedy:** the CHRB provides children with rights in the context of health care and biomedicine (e.g. non-discrimination). Yet, as previously discussed, the instrument does not include a provision relating to possible violations and access to justice and remedy. **More guidance is required on how States can establish available, accessible, and child-friendly redress and complaints mechanisms, including informal mechanisms and alternative dispute resolution measures, such as mediation, for children and their parents.**

4.2.3 Preconceptional and prenatal interventions

Preconceptional care concerns biomedical care and techniques prior to pregnancy, whereas prenatal care concerns biomedical care and techniques during pregnancy. Such interventions could hold consequences for the health of (future) children, and they also raise questions in relation to embryos and fetuses. As described in 4.2.1, the protection of embryos and fetuses is limited in the context of medical research.¹⁸⁹ The same holds true with respect to care. This is an issue of concern, now that

¹⁸⁵ CFHC Guidelines, *supra note* 36, para. VI(57), VI(58).

¹⁸⁶ Articles 5 and 6 para. 4 CHRB.

¹⁸⁷ Article 6 para 1 CHRB.

¹⁸⁸ Article 6 para 2 CHRB.

¹⁸⁹ See Article 18 para. 1–2 CHRB; Article 2 para. 2, Article 22 para. 2 Protocol concerning Biomedical Research.

we are at the doorstep of clinical applications to be introduced with respect to such techniques as genome editing with embryos. The Protocol concerning Transplantation and the Protocol concerning Genetic Testing do not apply to embryos or fetuses.¹⁹⁰ This may lead to uncertainty on how to act, particularly in case of a (potential) conflict between the rights and interest of (future) parents and their (future) children. Thus, various medical interventions conducted on embryos and fetuses can have implications for (future) children and their rights. It is clear that due to the sensitive nature of the issue, it is unlikely to reach consensus. Yet under the current situation, such medical interventions remain unregulated and specific guidance for States is lacking. **It is recommended to explore if the drafting of additional and legally binding standards in this regard is feasible or that further guidance should be provided through recommendations and/or guidelines to Council of Europe Member States.**

Another issue concerning preconceptional interventions is the use of surrogacy, as well as anonymous gamete (sperm or egg) donation. There is growing attention for the (future) child's right to know his or her origin, as part of the right to identity, protected under art. 7 and 8 CRC and art. 8 ECHR.¹⁹¹ The CHRB does not address the issue of donation of gametes, and this is also excluded from the Protocol concerning Transplantation (CHRB does forbid to choose sex of child).¹⁹² Yet, with the rise in assisted reproductive technology and biomedical advances, **this issue requires further guidance for States. It is recommended to provide guidance and best practices for States in relation to legal and other measures to ensure that children can receive reliable information on their origin and birth.**

4.2.4 Genetic techniques

The Protocol concerning Genetic Testing requires that genetic tests on persons who do not have the capacity to consent shall only be carried out for their 'direct benefit'.¹⁹³ It further holds that children's genetic testing shall be deferred until they can consent, unless such delay would negatively impact their health or well-being (i.e., in case the information allows a preventive measure or treatment).¹⁹⁴ In addition, the Protocol concerning Genetic Testing requires to weight privacy consideration in relation to the collection, saving, processing and communication of data derived from genetic testing,¹⁹⁵ and requires States to ensure the protection of such personal data.¹⁹⁶ Yet, gaps can be identified in relation to the protection of children's rights.

1. **Genetic testing of children:** Deferring genetic testing for children until they are able to consent reflects the concern that children may be screened for incurable diseases or life-threatening situations before they are psychologically and emotionally mature to understand the implications.¹⁹⁷ The provision reflects a protective approach and upholds the principle of the best interests of the child. Yet, in order to provide a more balanced approach between

¹⁹⁰ Article 3(b) Protocol concerning Transplantation; Article 2 para. 2(a) Protocol concerning Genetic Testing.

¹⁹¹ Article 7 CRC; See also in that regard ECtHR 26 June 2014, *Mennesson v. France*, para 99, Appl. No. 65192/11; ECtHR 26 June 2014, *Labassee v. France*, Appl. No. 65941/11; ECtHR 13 February 2003, *Odièvre v. France* (GC), Appl. No. 42326/98).

¹⁹² Article 14 CHRB; Article 2 para 3(a)-(b) Protocol concerning Transplantation; ECtHR 3 November 2011, *S.H. and Others v. Austria*, para 37-38, Appl. No. 57813/00.

¹⁹³ Article 10 Protocol concerning Genetic Testing.

¹⁹⁴ Article 10 Protocol concerning Genetic Testing; Council of Europe, Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes, ETS 203 (2008), para 90-91.

¹⁹⁵ Article 13(d) Protocol concerning Genetic Testing.

¹⁹⁶ Article 16 para. 1 Protocol concerning Genetic Testing.

¹⁹⁷ Alderson, P. (2017), 'Children's consent and the zone of parental discretion', *Clinical Ethics* 95, p. 209.

protection and recognising children’s evolving capacities and their right to autonomy and receive information on their health, **guidance regarding age of consent is required, as well as on the measures that can be taken in order to ensure that the age limits are respected in practice by those concerned within and outside the clinical setting.**¹⁹⁸ Such guidance should also allow for a child-specific evaluation, taking into account the particular child’s needs, maturity, and the type of the genetic test.

2. **Children able to consent:** under the Protocol concerning Genetic Testing it appears that children who are able to consent under national law enjoy the general safeguards and rights set under the Protocol. However, it can be argued that children, even if they are able to consent, still form a vulnerable group that requires additional safeguards and measures to ensure their rights and interests. For example, in relation to their effective participation, protection of privacy, etc. Yet it is unclear what, if any, special measures of protection and assistance are available for such children in the context of genetic testing. **Therefore, it is recommended to undertake efforts to establish such measures and to make them available for all children involved or affected.**
3. **Participation:** Genetic testing of children requires authorization from parents (or authority as prescribed by law), while the views of the child should be taken into consideration.¹⁹⁹ Yet, as previously discussed, **guidance is required, also for clinicians, on how States can implement the child’s right to be heard and what measures are required to ensure children’s opinions are taken into account in decision-making.**
4. **Child-friendly information:** the Protocol concerning Genetic Testing holds that everyone has the right to know the information collected and derived from his or her genetic testing, and that such information shall be ‘accessible to the persons concerned in a comprehensible form’.²⁰⁰ In addition, it prescribes that the persons tested shall be provided with prior appropriate information, covering the purpose and nature of the test, as well as the implications of results.²⁰¹ This again raises the issue of child-friendly information. **Guidance is required on the measures that should be put in place to ensure children are independently provided with child-friendly information.**

4.2.5 Gender modification techniques

Gender modification techniques (including decisions relating to conducting or refraining from treatment and surgical intervention), particularly relating to transgender and intersex children, can have irreversible and life-long consequences for the child.²⁰² This raises legal constraints between the wishes of parents, the assessment of the medical necessity by medical professionals and the rights, views and interests of children.²⁰³ These issues, however, are not adequately addressed in the current framework.

¹⁹⁸ Uppsala Report, *supra* note 2, p. 31-34.

¹⁹⁹ Article 12 para. 1 Protocol concerning Genetic Testing.

²⁰⁰ Article 16 para. 2 Additional Protocol concerning Genetic Testing.

²⁰¹ Article 8 para. 1 Additional Protocol concerning Genetic Testing.

²⁰² See European Union Agency for Fundamental Rights (FRA), *The Fundamental Rights Situation of Intersex People*, 04/2015, p. 5 (hereinafter: “**FRA (2015) on Intersex People**”).

²⁰³ Newbould, M. (2017), ‘When Parents Choose Gender: Intersex, Children and the Law’, *Medical Law Review* 24(4), p. 496; FRA (2015) on Intersex People, *supra* note 202, p. 7.

1. **Lack of specific guidance:** in relation to transgender and intersex children, there is no specific guidance on the issues these children are confronted with and on gender modification techniques in relation to children. Considering intersex children, the CHRБ holds that medical interventions for persons not able to consent may only be carried out for their ‘direct benefit’.²⁰⁴ Yet it is highly disputed whether gender modification techniques can be regarded as beneficial in the absence of a medical necessity. As long as clinicians themselves do not agree on the advantages and disadvantages of these interventions, particularly if performed at a young age, the concept ‘medical necessity’ does not provide much certainty either. The lack of concrete guidance on applying the CHRБ in the context of intersex children leaves the door open for medically unnecessary and irreversible gender modification procedures, with grave consequences for children’s rights and well-being, while others might argue that unnecessarily delaying such interventions is neither in the best interests of the child. Specifically In relation to transgender children, there is no specific guidance on when, and under what conditions, children can have access to hormonal treatment to suppress puberty and avoid developing permanent and unwanted characteristics of their biological sex, or even surgical interventions,²⁰⁵ and it is unclear if and to what extent the CHRБ can be applied in this context. **Therefore, more guidance is highly needed, as well as additional standard-setting in which the position of both transgender and intersex children is explicitly recognised. It is also recommended to explore if the drafting of additional and legally binding standards in this regard is feasible or that further guidance should be provided through recommendations and/or guidelines to Council of Europe Member States. The position of intersex and transgender children should also be explored as part of the recommended legal mapping across national contexts in the Council of Europe Member States.**

2. **Protection:** certain gender modification techniques on intersex and transgender children (e.g. sterilization, irreversible, involuntary and medically unnecessary procedures, etc.) can amount to a violation of a child’s right to protection and physical integrity. Gender is also recognised as a fundamental element in human identity, and such procedures can amount to a violation of the child’s right to preserve and maintain his or her identity.²⁰⁶ The responsibility of States to protect children also extends to health-related services, institutions and professionals working with and for children.²⁰⁷ **This requires guidance on how to implement and ensure the right of the child to protection in the context of gender modification techniques.**

3. **Participation:** gender modification techniques on intersex children are generally conducted before the child is able to provide consent. Authorization is provided by the parents who, even being well-intentioned, are often confused and under-informed. In relation to transgender children, it is unclear how their right to be heard is implemented in practice, and if it receives

²⁰⁴ Article 6 para. 1 CHRБ

²⁰⁵ Price-Minter, S. (2012), ‘Supporting Transgender Children: New Legal, Social and Medical Approaches’, *Journal of Homosexuality* 59, pp. 428-429; See also WPATH (2011), *supra note* 116, p. 18-21.

²⁰⁶ See Article 7 CRC.

²⁰⁷ CRC Committee, General Comment No. 8 (2006). The right of the child to protection from corporal punishment and other cruel or degrading forms of punishment (arts. 19; 28, para. 2; and 37, inter alia), 2 March 2007, CRC/C/GC/8; CRC Committee, General comment No. 13 (2011). The right of the child to freedom from all forms of violence, para. 52, 18 April 2011, CRC/C/GC/13; Recommendation CM/Rec(2009)10 of the Committee of Ministers. Council of Europe Policy guidelines on integrated national strategies for the protection of children from violence (2009).

adequate weight by parents and medical professionals. **States should therefore be encouraged to strictly regulate gender modification techniques applied on children (e.g. ethical committees), guided by the rights of the child and the general principles of the CRC. Again, the Council of Europe could facilitate this process by exploring the feasibility of the drafting of additional and legally binding standards in this regard and/or providing further guidance through recommendations and/or guidelines to Council of Europe Member States.**

4.2.6 Transplantation care

The Protocol concerning Transplantation holds as a general rule that removal of organs or tissues from a living person may be carried out only for the therapeutic benefit of the recipient, and in the absence of other therapeutic alternatives of comparable effectiveness.²⁰⁸ While this Protocol does not explicitly refer to children, it does provide safeguards for persons lacking the capacity to consent. Yet certain issues require additional guidance in relation to children's rights.

- 1. Children able to consent:** as described, the safeguards concerning children under the Protocol concerning Transplantation can be found under the protection of 'persons not able to consent', and it is unclear what, if any, special measures of protection and assistance are available for children who are able to consent and make decisions relating to transplantation care under national law. **Therefore, it is recommended to undertake efforts to establish such measures and to make them available for all children involved.**
- 2. Participation:** As previously discussed, participation in the context of transplantation care should be understood broadly, to include the child's ability to participate and be heard in decision making, as well as in relation to his or her (legal) possibility to consent or object to transplantation care. Along with other criteria, the Protocol concerning Transplantation holds that organs or tissues cannot be removed from persons unable to consent (e.g. children) if the donor objects to the transplantation.²⁰⁹ As previously discussed, additional guidance is required regarding the distinction between consent and objection of the child. **In particular, guidance is required on how to evaluate a child's objection, and what measures medical professionals can take in order to reach a professional and ethical decision, while taking into account children's participation rights and conditions under which children should be enabled to exercise these rights. Child participation and related practices with regards to transplantation care should also be explored as part of the recommended legal mapping across national contexts in the Council of Europe Member States.**
- 3. Autonomy:** The Protocol concerning Transplantation allows persons to donate organs for the benefit of a recipient with whom the donor has a close personal relationship as defined by law, or in the absence of such relationship, under conditions defined by law and subject to approval.²¹⁰ This reflects the person's right to physical autonomy in decisions relating to his or her body, with appropriate balance to other considerations such as protection from exploitation

²⁰⁸ Article 9 Protocol concerning Transplantation.

²⁰⁹ Article 14 para. 2 Protocol concerning Transplantation. This does not refer to cells whose removal implies minimal risk and burden for the donor: Article 15.

²¹⁰ Article 10 Protocol concerning Transplantation.

and human dignity.²¹¹ Yet, the concept of autonomy poses a problem in relation to children, and it is unclear if, and to what extent, children are able to exercise autonomy and make free and informed decisions on health matters, especially with regard to irreversible decisions, such as the donation of certain organs. **Further mapping is required regarding the age of consent to transplantation across national contexts and related practices, and how the principle of the child's evolving capacities is implemented in that regard.**

- 4. Child-friendly information:** The Protocol concerning Transplantation requires that the potential donor and, where appropriate, the person providing authorization, shall be provided with information on the procedure and its consequences and risks.²¹² **As previously discussed, guidance is required on how to ensure information is provided to children in a child-friendly manner and language.**

4.2.7 End of life decisions

The ECtHR has accepted that individuals may decide to refuse life-saving medical treatment²¹³ and by what means and at what point they would like to end their life, provided that they are 'capable of freely reaching a decision'.²¹⁴ Despite the CRC's recognition of children's evolving capacities, it is unlikely that children are thought to be capable of exercising these rights given the lack of European, let alone international consensus on such issues as euthanasia and the definition of futile treatment.²¹⁵ As a result, and given the sensitive nature of this issue, the ECtHR found that States should have a wide margin of appreciation.²¹⁶ In relation to children's rights and biomedicine, several challenges can be identified, in addition to the inherent tension with the children's evolving capacities.

- 1. Scope:** the CHRB includes that previously expressed wishes relating to medical intervention 'shall be taken into account'.²¹⁷ Yet it is unclear if and to what extent can CHRB refers to end of life decisions and whether such directives can or should be respected if expressed by a person who never reached the age of legal capacity. In any case, it remains unclear if the provisions related to children can and should be applied in this context **and further guidance should be provided.**
- 2. Right to be heard:** the issue of end of life decisions raises the issue of the child's right to be heard and have his or her views considered in the decision-making process, including in litigation or other professional or (semi) judicial mechanisms in which decisions regarding children's treatment are challenged (by the child or by others, including for example parents). In this regard, it can also be argued that the child's age should not be viewed as a limitation and

²¹¹ See Article 1, 21, 22 and preamble Protocol concerning Transplantation; ECtHR 26 March 1985, *X and Y v. the Netherlands*, Appl. No. 8978/80.

²¹² Article 12 Protocol concerning Transplantation.

²¹³ ECtHR 10 June 2010, *Jehovah's Witnesses of Moscow et al. v. Russia*, Appl. No. 302/02.

²¹⁴ ECtHR 20 January 2011, *Haas v. Switzerland*, Appl. No. 31322/07, para. 51.

²¹⁵ See ECtHR 19 July 2012, *Koch v. Germany*, Appl. No. 497/09, para. 70. For an overview, see ECtHR, 'End of Life and the European Convention on Human Rights', Factsheet, July 2015; For the CRC Committee's concern over euthanasia and children, see Concluding observations on the fourth periodic report of the Netherlands (2015), CRC/C/NDL/CO/4, para. 29; Human Rights Committee (2009).

²¹⁶ ECtHR 5 June 2015, *Lambert et al. v. France* (GC), Appl. No. 46043/14, para. 72-74, 144.

²¹⁷ Article 9 CHRB.

that his or her opinions should be taken into account as an increasingly determining factor, in accordance with his or her maturity and evolving capacities.²¹⁸ **This requires guidance at the European level, on how States should implement their margin of appreciation in the context of biomedical interventions and end of life decisions, while ensuring the rights of children comprehensively.**

²¹⁸ CRC GC 12, *supra note* 70, para. 20; See also CFHC Guidelines, *supra note* 36, para. IV(A)(23).

Chapter 5: Towards a roadmap for the Council of Europe

5.1 General findings and concluding observations

In this report, we have assessed whether the existing body of international and European law provides adequate protection to the human rights of children in the context of biomedicine. The aim of this report is to provide recommendations to the Council of Europe for an action plan at the intergovernmental level. We believe that there is a need for action, roughly in four different ways: 1) Providing guidance to States targeted at domestic legislation and practices; 2) Awareness raising, capacity building, education and training; 3) Additional standard-setting, among others with a particular focus on child-friendly systems; and 4) Further research, in particular the mapping of national legislative frameworks and practices in the Council of Europe Member States. Chapter 4 has provided specific recommendations in relation to the biomedical challenges identified in the Uppsala Report (see also Annex I). In addition, some general recommendations are made in paragraph 5.2 (see also Annex II).

In general, it can be concluded that the specific position of children has been acknowledged in international and European biomedical standards, even though these are primarily targeted at human beings in general. Children are often addressed as a different category of human beings, that is to say, as part of the group of vulnerable persons entitled to, or the object of, special consideration and protection. To the extent that there are child-specific biomedical standards these tend to lean towards protection of the rights and interests of children – particularly those who cannot consent – rather than recognising children’s evolving capacities and growing autonomy as well as their fundamental rights revolving around participation. In other words, the main body of international and European standards in the field of biomedicine reflects the view that children should above all be protected, thus building on the notion of dignity as a constraint, with (far) less importance being paid to the right and evolving capacities of children to make their own choices, or at least echo their will and views, thus acknowledging their dignity as empowerment. This has implications for all the biomedical areas of concerns identified in the Uppsala Report and themes addressed in this report, and relate to gaps and challenges concerning the following issues: 1) consent, autonomy and legal representation (by parents and others); 2) participation; and 3) access to justice and remedies. These cross-cutting issues, which are at the heart of international and European children’s rights, will be briefly presented below.

1) Consent, autonomy and legal representation by parents or other representatives

International and European biomedical standards are often not clear on issues regarding consent of children as such and/or the consent of parents (or others), which ultimately relates to children’s evolving autonomy. The particular complexity of the role of medical professionals in this regard is not carefully considered either. In addition, we found that international and European standards are not sufficiently clear on the precise meaning of consent and objection, and their implications for children’s autonomy. This has implications for all of the biomedical themes discussed in this report, although it should be acknowledged that in relation to some themes international and European standards do not recognise the specific position of children at all. This is true for gender modification techniques, research on embryos and foetuses, preconceptional and prenatal interventions and end of life decisions, and should be understood in light of the controversial nature and/or particular complexity of the matter and/or the inconclusiveness of international children’s rights standards.

Nevertheless, it is recommended to identify the child specific implications of human rights for these biomedical issues as well, at domestic and international level. The Council of Europe could facilitate this process by organising expert meetings, seminars or conferences on these matters. In addition, we recommend to assess the feasibility of developing additional legally binding standards to close the gaps in biomedical standards on the issues mentioned above. If considered not feasible, one could consider the development of recommendations or guidelines that reflect and elaborate upon legally binding norms laid down in the CRC and the case law of the European Court of Human Rights, among others.

It should be acknowledged that States have much discretion on how to regulate consent, autonomy of the child and legal representation. This implies that for a better understanding of the meaning of international and European standards for the protection of human rights of children in biomedicine, one has to look closely into domestic legislation (e.g. regarding age limits, medical decision making or biomedical research, position of parents and other legal representatives, role of medical professionals etc.) and practice. It is recommended that the Council of Europe provides more guidance on the balancing of autonomy and legal representation in specific biomedical arenas. This can be done by the development of guidelines similar to the Guidelines on child-friendly health care and child-friendly justice. However, one could also think of practical tools, including the drafting of models for laws/legislation, national strategies or professional guidelines. It also seems important to conduct or commission a mapping of the legislation within the 47 Council of Europe Member States to identify and better understand the realities on the ground. The mapping should cover the legal and practical aspects relating to all the biomedical areas explored in this report, particularly focusing on issues related to age limits, consent and objection, parental authority, child participation and related professional practices. Apart from this, the balancing of children's evolving capacities and related autonomy and children's representation requires knowledge and skills. Therefore, it is also recommended that the Council of Europe considers developing practical tools that can contribute to awareness among medical professionals and parents on the significance of considering children's evolving capacities and the implications for their position in the decision-making processes. This also relates to the second cross-cutting issue, participation.

2) Participation

The second issue that emerged in this study relates to the child's right to be heard and, broader, participation rights. The right to be heard and participate in decision-making must be ensured, and the child's views must be taken into account and given due weight in accordance with the child's age and maturity, and regardless of his or her legal ability to consent. Whether one is concerned with biomedical research, health care or end of life decisions, the views of all children must be taken into account, and age should not be a limiting factor in this regard. This is one of the most notable improvements of international children's rights instruments and has received prominent attention in European law and standards relating to children's issues. On the basis of our analysis, it can be argued that biomedical standards do not always (fully) recognise or regulate children's involvement in decision making affecting them. It is therefore strongly recommended that the Council of Europe expands its important (and leading) role in advocating for child-friendly health care and justice systems to all biomedical matters. Much guidance for States can be found in international and European standards (see e.g. the Council of Europe's child-friendly justice and health care instruments, which are grounded in, among others, the CRC and the case law of the European Court

of Human Rights), but these require adaptation to the specific context of the different biomedical issues. Participation assumes that each child is entitled to child-friendly information, assistance and empowerment in light of his or her age and maturity. In this regard, it is recommended to also invest in practical skills of medical professionals and other stakeholders, e.g. on communication with children (and their parents).

3) Access to justice

A third cross-cutting theme is access to justice, which is an essential element of human rights protection of individuals, including children, and the possibility to enforce human rights. International and European biomedical standards are limited in the way they recognise children's rights to access to justice and to an effective remedy, while these rights matter and ought to be given careful consideration. Given its general acceptance, the principle of access to justice does not require additional standard-setting. Rather, the Council of Europe should invest in awareness-raising, information/education and training for domestic legislators, policy makers, medical professionals and children and their families, as well as the promotion of accessible (formal and informal) procedures, including alternative dispute resolution and mediation mechanisms that allow parties to come to an agreement without resorting to (formal) litigation. In addition, it could facilitate the exchange of good practices among Council of Europe Member States.

4) Other overarching observations

There are a number of remaining overarching observations that deserve mentioning. First, we would like to highlight that existing legal standards tend to distinguish between (non-therapeutic) research and (therapeutic) care. In this report, it became clear that this binary approach does not do justice to the often complex dilemmas with respect to the rights of individuals and biomedicine, where it is not always clear whether an intervention pertains to the domain of research or treatment (i.e., certain forms of experimental treatment). Both research and care have potential benefits for the individual concerned and/or others. It is therefore argued that, particularly with respect to children, it were better, with respect to all the interventions falling within the realm of the seven areas of concern, to only make distinctions that are commensurate with risks and burdens of the persons concerned.

A second observation relates to the role of medical professionals, with respect to both biomedical research and care. We would like to underscore that the particular complexity of the role of the medical professionals in connection with the child-parent relationship and the role and responsibility of the State for children's and parents' rights requires ongoing attention and calls for supportive tools, such as an exchange of professional standards within the Council of Europe. This should be organised around specific biomedical themes and recognise the essential safeguarding role of medical professionals in relation to the protection of fundamental rights of individuals against unlawful interference by States. With regard to children, medical professionals also have a safeguarding role to play in light of the child-parent relationship and this requires specific education and training. In addition, one should take into account that law should, particularly in the area of biomedicine, be respectful of medical professional's autonomy, and allow flexibility for case-by-case decision-making.

Third, privacy and confidentiality should be recognised as important issues. Children have the right to privacy like any other human being. This has implications for the issue of confidentiality and the role

and responsibilities of parents. Providing parents with information about the health status of their children as well as the outcomes of predictive health tests may collide with the child's right to privacy and the professional's duty to confidentiality. In the absence of consensus, States enjoy a margin of appreciation how to balance the right of parents to be informed about the health status of their child and the child's right to privacy. However, privacy and confidentiality also have broader implications and concern issues such as data collection, access to medical files and the storage of biological material. It would be recommended to include all of these issues in the legal mapping suggested above.

Finally, we would like to reiterate the importance of recognising the role of non-state actors, including businesses, such as pharmaceutical companies and insurance companies, and research institutes. It is recommended that the Council of Europe further explores the meaning of the children's rights and business principles, based on the UN Guiding Principles on Business and Human Rights: Implementing the United Nations 'Protect, Respect and Remedy' Framework,²¹⁹ for the role of these non-state actors in respecting, promoting and fulfilling the rights of the child in relation to biomedical matters.

5.2 Recommendations

To conclude and in addition to the detailed recommendations included in chapter 4 (see also Annex I), we recommend the Council of Europe to develop a Roadmap to strengthen children's rights in the era of biomedicine that entails measures to:

1. Evaluate the child specific human rights implications for those areas of concern, as identified in the Uppsala Report, and identify groups of children that so far have not or hardly been the object of standard setting and assess the feasibility of additional standard-setting, either through legally binding instruments (such as additional protocols to the CHRB) or through recommendations or guidelines grounded in the broader international and European human rights framework relevant for children. In this respect, special attention also needs to be paid to the meaning of 'consent' and how this relates to the right to 'object' and to the specific relationship of the child with his or her parents (and guardian and/or extended family) and, where relevant, medical professionals. The child's right to be heard, participation rights and the right to access to justice should be given careful consideration as well.

2. Conduct or commission a mapping of the legislation within the 47 Council of Europe Member States related to biomedical issues, including legislation on health care and research, age limits, professional practices and issues related to privacy and confidentiality to identify and better understand domestic legal systems, realities on the ground and good practices. As an additional step, the Council of Europe could assist in developing model laws and/or model professional guidelines on the implementation of international and European standards relating to children's human rights and biomedicine.

²¹⁹ UN Guiding Principles on Business and Human Rights, *supra note 8*; UNICEF, UN Global Compact & Save the Children, "Children's Rights and Business Principles", (2010).

3. Promote the development of skills and knowledge with respect to the balancing of children's evolving capacities and related autonomy and children's representation. This may imply the development of practical tools that can contribute to awareness among medical professionals and parents on the significance of considering children's evolving capacities and the implications for their position in the decision-making processes.

4. Advocate for the introduction and application of child-friendly health care and child-friendly justice systems in all other areas of biomedicine, building on the existing standards and experience and emphasising children's right to participate effectively in decision-making affecting them, and their right to access justice and seek effective remedies.

5. Invest in awareness-raising, information/education and training for domestic legislators, policy makers, medical professionals and children and their families on access to justice in the context of biomedicine. This may imply facilitating the exchange of good practices among Council of Europe Member States.

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Annex I – List of specific recommendations (chapter 4)

Biomedical research

1. The Council of Europe is recommended to clarify what, if any, special measures of protection and assistance are available for children who are legally able to consent to biomedical research. It is recommended that such children receive special assistance and safeguards in exercising their right to consent and make decisions in the context of biomedical research. Therefore, the Council of Europe is recommended to undertake efforts to establish such measures and to make them available for all children participating in biomedical research.
2. The Council of Europe is recommended to publish clarifications in relation to the distinction between the right of the child to consent, object, and effectively participate in biomedical research. In that regard, participation should be understood broadly as the obligation of decision-makers (e.g., parents, medical professionals) to hear and consider the views of the child throughout the research process, irrespective of the child's legal capacity to independently consent or object. In addition, the child's right to participate requires research bodies and/or medical professionals to ensure that research procedures are designed in a child-sensitive manner, and that mechanisms are in place to encourage child participation. Special attention should be paid to the elements of 'consent' and 'objection' of the child to biomedical research. The Council of Europe is therefore recommended to provide further guidance, as well as practical measures, to enable children to exercise their right to participate and be heard, and to ensure that medical professionals reach ethical and professional decisions in cases of children's objection to biomedical research.
3. The Council of Europe is recommended to emphasise the obligation of States to deliver child-friendly information for child research participants and their parents. To that end, the Council of Europe is recommended to bridge between biomedical standards and child-friendly standards, and provide guidance to States on how to implement those standards in the context of biomedical research.
4. The Council of Europe is recommended to highlight the principle of the best interests of the child in the context decision-making by parents, or legal representatives, or medical professionals, in relation to child participation in research. This can be achieved by guiding States with regard to the discretion of medical professionals and parents in decision-making, and on how States can support parents to ensure that their consent, refusal to consent, or withdrawal from research project is in accordance with the interests of the child, and that it respects the rights of the child, including the right to be heard.
5. The Council of Europe is recommended to provide guidance in relation to the position of children, who have reached the legal age of consent, during or after participating in biomedical research. Such guidance should focus on the accommodation of the child's evolving age and maturity in biomedical research, and assist in determining what mechanisms should be established that, on the one hand, recognise the child's evolving capacities, and on the other, avoid the negative implications of withdrawing from research. The guidance should also focus on ensuring that persons and organisations responsible for a research project enjoy stability in their research and procedures.
6. The Council of Europe is recommended to assist States in establishing legal protection, setting redress and complaints procedure and providing appropriate remedies for children and their

parents in the context of biomedical research. Such guidance should ensure children's right to access justice and remedy and reflect the principles of child-friendly justice, as set by the Council of Europe (Guidelines on child-friendly justice, 2010).

7. The Council of Europe is recommended to consider the absence of sufficient standards in relation to research on embryos and fetuses. It is therefore recommended to address this apparent gap which can, in the absence of guidance and standards, have far reaching implications for (future) children and their rights, as well as for research purposes.

Physical and mental health care

8. The Council of Europe is recommended to clarify what, if any, special measures of protection and assistance are available for children who are legally able to consent to care and treatment. It is recommended that such children receive special assistance and safeguards in exercising their rights, for example in relation to receiving information, access to justice or other support. Therefore, the Council of Europe is recommended to stimulate and support States in establishing such measures and to make them available for all children undergoing health care.
9. The Council of Europe is recommended to assist States to fully implement the right to an equitable health care for all children by publishing detailed and concrete guidance. In that regard, it should be noted that the right to an equitable health care does not only require equal *availability*, but also concern *accessibility, acceptability and quality health care*.
10. The Council of Europe is recommended to clarify the distinction between the right of the child to consent, object, and effectively participate in biomedical care and treatment. In that regard, participation should be understood broadly as the obligation of decision-makers (e.g., parents, medical professionals) to hear and consider the views of the child in health care, irrespective of the child's legal capacity to independently consent or object. Special attention should be paid to the elements of 'consent' and 'objection' of the child to health care. To that end, the Council of Europe is recommended to conduct a mapping of the legal status (and related practices) of children in relation to consent, objections and participation in health care across national contexts, and it is recommended that such mapping forms part of the Council of Europe's roadmap.
11. The Council of Europe is recommended to identify, by way of a study, the elements relevant to biomedical treatment that require child-friendly adaptation in health-related policies, services, practices and monitoring mechanisms.
12. The Council of Europe is recommended to guide States on how to find appropriate balance between the best interests and health of children, the concerns and wishes of parents, and public health and medical standards. Such guidance should be child-focused, emphasising the best interests of the child and the child's evolving capacities as primary considerations in decision-making and policy design.
13. The Council of Europe is recommended to provide additional guidance for States on how to establish available, accessible and child-friendly redress and complaints mechanisms, and ensure the child's access to justice and remedy. Such guidance should also address informal mechanisms and alternative dispute resolution measures, such as mediation, for children and their parents

Preconceptional and prenatal interventions

14. The Council of Europe is recommended to explore the issue of preconceptional and prenatal interventions, including the appropriate protection of embryos and fetuses in relation to medical interventions, and balancing the (potential) conflicts between the rights and interests of (future) parents and their (future) children and their rights. It is recommended to explore if the drafting of additional and legally binding standards in this regard is feasible or that further guidance should be provided through recommendations and/or guidelines to Council of Europe Member States.
15. The Council of Europe is recommended to establish guidelines for States and identify best practices in relation to surrogacy and gamete donation that take into account the right of the child to identity and to receive reliable information on his or her origin and birth.

Genetic techniques

16. The Council of Europe is recommended to provide additional guidance or recommendations that take a balanced approach between protecting children and recognising children's evolving capacities and their right to autonomy and to receive information on their health in relation to genetic testing. Such guidance should address the age of consent for genetic testing, as well as the measures that can be taken to ensure that the age limits are respected in practice by those concerned within and outside the clinical setting. The guidance should also allow for a child-specific evaluation, taking into account the particular child's needs, maturity and the type of genetic test.
17. The Council of Europe is recommended clarify what, if any, special protection and assistance should be available for children who are legally able to consent to genetic testing. It is recommended that such children are recognised as vulnerable, and be provided with additional support and safeguards. Therefore, it is recommended that the Council of Europe undertakes efforts to establish such measures and make them available for all children involved or affected.
18. The Council of Europe is recommended to publish guidance for States and clinicians on how to implement the child's right to have his or her opinion taken into consideration in relation to genetic testing, and how to ensure children are heard when parents (or other authorities prescribed by law) provide authorization. Such guidance should also identify what measures are required to ensure children's opinions are indeed taken into account in decision making.
19. The Council of Europe is recommended to provide guidance on the measures that should be put in place to ensure children are provided with child-friendly information in relation to genetic testing.

Gender modification techniques

20. The Council of Europe is recommended to provide guidance, as well as additional standard-setting, for States in relation to gender modification techniques concerning intersex and transgender children. In relation to *intersex* children, guidance and standards should tackle, on the one hand, the medically unnecessary and irreversible gender modification procedures and their potential grave consequences for children's rights and well-being, and on the other, to recognise that delaying certain interventions can also negatively impact the best interests of children. For *transgender* children, guidance and standards are required to determine when, and under what conditions, children can have access to hormonal treatment and surgical interventions, and what role does the CHRB play in that regard. It is recommended to explore if

the drafting of additional and legally binding standards in this regard is feasible or that further guidance should be provided through recommendations and/or guidelines to Council of Europe Member States. The position of intersex and transgender children should also be explored as part of the abovementioned recommended legal mapping across national contexts in the Council of Europe Member States.

21. The Council of Europe is recommended to explore the practices relating to gender modification techniques on intersex or transgender children (e.g. sterilization, irreversible, involuntary and medically unnecessary procedures, etc.) and determine their implications in relation to the child's right to protection and to identity. In that regard, the Council of Europe is recommended to provide further guidance to States on how to implement and ensure the rights of intersex and transgender children to protection and identity in the context of gender modification techniques.
22. The Council of Europe is recommended to encourage States to strictly regulate gender modification techniques applied on children, and ensure that such regulative bodies and/or standards are guided by the rights of the child and the general principles of the CRC, and in particular the right of the child to be heard and participate in decision-making. Again, the Council of Europe could facilitate this process by exploring the feasibility of drafting of additional and legally binding standards in this regard and/or providing further guidance through recommendations and/or guidelines to Council of Europe Member States.

Transplantation care

23. The Council of Europe is recommended to clarify what, if any, special measures of protection and assistance are available for children who are legally able to consent to transplantation care. Such children should receive special assistance and safeguards in exercising their right to consent and make decisions in the context of transplantation care, and it is, therefore, recommended to undertake efforts to establish such measures and to make them available for all children involved.
24. The Council of Europe is recommended to provide clarification in relation to the distinction and relations between the child's right to consent, object and effectively participate in the context of transplantation care. In particular, guidance is required in relation to the evaluation of a child's objection, and the measures that can be taken by medical professionals to reach a professional and ethical decision, while taking into account children's participation rights and conditions under which children should be enabled to exercise these rights. Furthermore, child participation and related practices with regards to transplantation care should also be explored as part of the recommended legal mapping across national contexts in the Council of Europe Member States.
25. The Council of Europe is recommended to address the issue of autonomy in relation to children in the context of transplantation care. In particular, the extent of children's ability to exercise autonomy and make free and informed decisions on health matters, especially with regards to irreversible decisions such as donation of certain organs, should be addressed. Therefore, the Council of Europe is recommended to conduct legal mapping regarding the age of consent to transplantation care and related practices across national contexts, and how the principle of the child's evolving capacities is implemented in that regard.
26. The Council of Europe is recommended to provide guidance for States on how to ensure that potential donors and where appropriate, the person providing authorization (e.g. parents) are provided with child-friendly information, in an understandable manner and language.

End of life decisions

27. The Council of Europe is recommended to provide further guidance for States in relation to the applicability of the CHRB to the issue of end of life decisions of children.
28. The Council of Europe is recommended to develop guidance in relation to end of life decisions, and the child's right to be heard and have his or her views considered in decision-making processes, including in litigation or other professional or (semi) judicial mechanisms.
29. The Council of Europe is recommended to promote guidance at a European level for States in that regard, on how States should implement their margin of appreciation in the context of biomedical interventions and end of life decisions, while ensuring the rights of children comprehensively.

Annex II – List of general recommendations (chapter 5)

In addition to the detailed recommendations included in chapter 4 (see also Annex I), we recommend the Council of Europe to develop a roadmap to strengthen children's rights in the era of biomedicine that entails measures to:

1. Evaluate the child specific human rights implications for those areas of concern, as identified in the Uppsala Report, and identify groups of children that so far have not or hardly been the object of standard setting and assess the feasibility of additional standard-setting, either through legally binding instruments (such as additional protocols to the CHRB) or through recommendations or guidelines grounded in the broader international and European human rights framework relevant for children. In this respect, special attention also needs to be paid to the meaning of 'consent' and how this relates to the right to 'object' and to the specific relationship of the child with his or her parents (and guardian and/or extended family) and, where relevant, medical professionals. The child's right to be heard, participation rights and the right to access to justice should be given careful consideration as well.
2. Conduct or commission a mapping of the legislation within the 47 Council of Europe Member States related to biomedical issues, including legislation on health care and research, age limits, professional practices and issues related to privacy and confidentiality to identify and better understand domestic legal systems, realities on the ground and good practices. As an additional step, the Council of Europe could assist in developing model laws and/or model professional guidelines on the implementation of international and European standards relating to children's human rights and biomedicine.
3. Promote the development of skills and knowledge with respect to the balancing of children's evolving capacities and related autonomy and children's representation. This may imply the development of practical tools that can contribute to awareness among medical professionals and parents on the significance of considering children's evolving capacities and the implications for their position in the decision-making processes.
4. Advocate for the introduction and application of child-friendly health care and child-friendly justice systems in all other areas of biomedicine, building on the existing standards and experience and emphasising children's right to participate effectively in decision-making affecting them, and their right to access justice and seek effective remedies.
5. Invest in awareness-raising, information/education and training for domestic legislators, policy makers, medical professionals and children and their families on access to justice in the context of biomedicine. This may imply facilitating the exchange of good practices among Council of Europe Member States.