

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

10 October 2022

BIO-ENF/CP (2022)1 REV2

BIO/ENF-CP

**Drafting group on developing a guide for the participation of children
in decision-making process regarding their health**

**DRAFT GUIDE TO THE PARTICIPATION OF CHILDREN
IN DECISION-MAKING PROCESSES
REGARDING THEIR HEALTH**

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I. Introduction

Children, defined as any person under the age of 18 years¹, have a **right to participate** in decisions about their lives concerning relevant issues that affect them, including but not limited to their health, education, social and democratic life, and the environment. This is enshrined in Article 12 of the United Nations Convention on the Rights of Child (UNCRC, 1989), which requires that:

- ▶ all children capable of forming their own views, have the right to express their views freely in all matters affecting them
- ▶ that children's views be given due weight in accordance with their age and maturity.

The recognition of this, along with greater acknowledgement of children's evolving capabilities, has led to an increasing awareness that children's views must be given value in European and national policies.

The *Committee of Ministers Recommendation (2012)2 on the participation of children and young people under the age of 18*² establishes guidelines on the implementation of active and meaningful child participation. Importantly, it defines child participation as "a process where children and young people have the right, the means, the space, the opportunity and, where necessary, the support to freely express their views, to be heard and to contribute to decision-making on matters affecting them, their views being given due weight in accordance with their age and maturity".

The right to participate is important [not only as a right and a general principle but also] because taking children's views into account in decisions and actions that affect them brings significant immediate and long-term benefits for them. Children have unique knowledge about their lives, needs and concerns. Using this knowledge, their ideas and views can lead to improved individual decisions for children, and enhanced fulfilment of children's rights. Children are entitled to choose whether or not to express their views or participate in decision making on issues that affect them.

In **the health field**, when considering the participation of children in decision-making processes relevant to them, a distinction needs to be made between participation of a child in an *individual* health-care decision and children's *collective* involvement in the development of health policies and services³.

The provisions of the Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention, 1997), namely in its Article 6, are consistent with Article 12 of the UNCRC⁴ about the participation of a child in a decision-making process regarding an intervention to be carried out on him or her. In accordance with Article 6 of the Oviedo Convention, the opinion of a child, who according to law is considered not able to consent, shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

¹ This definition is in line with the provisions of Article 1 of the UNCRC. Article 6 (2) of the Convention on Human Rights and Biomedicine, refers to the term "minor". For the purposes of this guide, the term "child" is used, unless direct reference is made to provisions using different terminology.

² Council of Europe CM Recommendation (2012)2 on the participation of children and young people under the age of 18.

³ General comment N° 12 (2009), UN Committee on the Rights of the Child, Paragraphs 98-103

⁴ Explanatory Report to the Oviedo Convention par; 45

The participation of children in their own health care is essential for ensuring children's access to health care and optimal health outcomes.⁵ Children's rights, needs and resources should be placed at the centre of relevant healthcare activities, taking into account their family and social environment. Policies to deliver child-oriented services, based on child-specific developmental needs and evolving capacities are to be promoted, ensuring children's participation at every level of decision making, in accordance with their age and degree of maturity.

Through the Strategy for the Rights of the Child⁶ and the Strategic Action Plan on Human Rights and Technologies in Biomedicine, the Council of Europe is promoting such child-friendly health care and research approach, rooted in the UNCRC, the European Convention for Human Rights and the Oviedo Convention⁷ and its Additional Protocols.

a. Scope and aim of the guide

This Guide is intended to provide a practical tool based on concrete examples of good practices. It is primarily targeted at health professionals and others working with or for children in healthcare. It will also contribute to increasing the awareness of parents and children's legal representatives, and other relevant stakeholders (e.g. members of ethics committees).

It aims to support those concerned in engaging with children in individual decision-making processes, including those that, in accordance with domestic legislation, have the right to give their own consent to treatment and interventions. The guide will also consider how children's opinions may be used to facilitate and improve such processes.

While acknowledging the importance of promoting the participation of children in the development of health policies and services, it will focus on **individual health-care decision making**.

Specifically, the objectives of the Guide are:

- ▶ To highlight relevant international frameworks and standards
- ▶ To provide examples of national legislation and good practices
- ▶ To provide guidance on how professionals can improve their practices when involving children in individual decision-making processes affecting their health
- ▶ To identify other measures that healthcare and other relevant institutions may apply to advance and facilitate such involvement

This guide was developed through a multi-step research process involving a review of international and European standards relevant to the field of the study, a literature review, consultations with experts and key stakeholders and a series of surveys and questionnaires administered by the Council of Europe. Children have also provided their views on the content of this guide.

⁵ Council of Europe guidelines on child-friendly health care (2011) <https://rm.coe.int/guidelines-of-the-committee-of-ministers-of-the-council-of-europe-on-c/16808c3a9f>

⁶ <https://rm.coe.int/council-of-europe-strategy-for-the-rights-of-the-child-2022-2027-child/1680a5ef27>

⁷ Council of Europe guidelines on child-friendly health care (2011) <https://rm.coe.int/guidelines-of-the-Committee-of-Ministers-of-the-council-of-europe-on-c/16808c3a9f>

b. The importance of participation of children in individual health decision-making processes

Giving children a voice and involving them in individual health decision-making processes is *every child's right*. But enabling the participation of children is not only a right, it also has significant immediate and long-term benefits.

Children who participate in individual decision-making processes on issues relevant to their health are likely to be more informed, feel more prepared, to learn how to better manage their condition and treatments on their own and experience **less anxiety** about the unknown.

Allowing children to participate in decisions regarding their health may help them develop competence, confidence, self-efficacy and responsibility, leading to their **empowerment** and greater participation in their own lives. In turn, this contributes to fostering their self-esteem, developing self-caring and participation skills that are necessary for long-term self-management as well as to promoting health-seeking behaviour, satisfaction, health-related quality of life and overall welfare⁸.

Participating in medical decision-making processes can instil children with a sense of control, which results in increased **cooperation** with procedures, **better** adjustment to and **compliance** with treatment, which helps to reduce conflicts that may arise during these processes.

Overall, such participation contributes to improving practices by developing more effective **partnerships with healthcare professionals**.

Effective communication and meaningful participation, responding to children and families' needs and preferences, are also considered a key standard to be implemented in national standards of care and protocols, organizing, and planning for services and resources to achieve high-quality care for children in health facilities⁹.

⁸ Coyne I (2006) Consultation with children in hospital: children, parents' and nurses' perspectives. *Journal of Clinical Nursing* 15; 61–71.

⁹ WHO, Standards for improving the quality of care for children and young adolescents in health facilities, Report 2018, <https://www.who.int/publications/i/item/9789241565554>

Figure 1. Benefits of children's participation in health decision-making processes



Children's participation is not a one-off event. Participation is a rolling process and does not stop with children's views being expressed, it also involves adults and children co-producing decisions. Understanding participation in this way encourages children and adults to work together for meaningful participation. Furthermore, the right to participation does not contradict the right to protection. Indeed, active participation of children is beneficial for their protection¹⁰.

Benefits for children with chronic and long-term illnesses, when involved in their own health

Involving children in decision-making processes, starting with providing them appropriate information about their condition, is particularly important for those who live with chronic or other long-term conditions. In such situations, the involvement of children in their care will have concrete and long-term benefits in helping them to understand and cope with their condition in daily life and in the future. For critically ill children, uncertainty regarding diagnosis and prognosis may make it harder for all stakeholders to decide which treatment option is in the child's best interest. In case of rare diseases, delays in diagnosis and difficulties in early therapeutic management may also have to be faced. These challenges are especially relevant for children with ethnicities or demographic characteristics that are disproportionately at risk of being affected by acute, chronic or rare diseases.

c. Challenges concerning children's participation

Although children's right to participation in the health decision-making process relevant to them is enshrined in legislation and policies, there are a number of challenges that may hinder the effective implementation of this right and children's experiences in decision-making processes, such as:

¹⁰ "Listen – Act- Change, Council of Europe Handbook on children participation for professionals working for and with children" (2021) <https://rm.coe.int/publication-handbook-on-children-s-participation-eng/1680a14539>.

- 145 ► Children may be listened to only when the issue is trivial. The more serious the
146 situation, the less likely that the child's view are considered if it is different from the
147 view of adults.
- 148 ► There is a discrepancy between applicable legislations, relevant policies, knowledge
149 and practice of professionals, as well as the experiences of children and of their
150 parents concerning the implementation of the right to informed consent.¹¹
- 151 ► Lack of training on children's rights in health care and research settings is noted, in
152 particular how these translate into practice. Specific training could include, for
153 example, how to understand and respect the individuality of children and families, but
154 also culture-specific parenting beliefs and expectations; how to effectively
155 communicate with children, in accordance with their evolving capacities; and how to
156 enable children to make informed choices in relation to their lifestyle, among other.
- 157 ► The complexity of a decision-making process, in particular, when difficult decisions
158 need to be made may lead to conflict between parents and children or parents, children
159 and health professionals.
- 160 ► In some population groups or communities involving children in decision-making
161 process, may be more difficult.
- 162 ► Some children face additional challenges or barriers to being included in decision-
163 making processes, for example some children with a disability or a specific health
164 condition, young children, as well as some children from marginalized groups.
- 165 ► How healthcare professionals involve parents in decision-making is dependent on
166 many factors such as lack of resources, time constraints and organizational
167 shortcomings as well as health professionals' attitudes and thinking towards the
168 parental role and their own professional role¹².
- 169 ► Implementing and enabling child participation in decision making processes may face
170 new challenges with the further evolution of existing health and biomedical research
171 practices including emerging technologies, advanced therapies and genetic
172 techniques, that may have future or long-term implications for children and also imply
173 the collection and sharing of genomic and health data. These, as well as pandemics,
174 such as COVID-19, raise new questions relating to the risk of fundamental rights
175 infringements (e.g., to autonomy, privacy, discrimination...) and possible harm to
176 future generations. They imply a change in societal perceptions of how to balance the
177 protection of and the respect for autonomy of children with the increased recognition
178 of their decision-making capacities and their rights.

¹¹ Machado *et al.* (2019) [*Informed Consent - Vision and Perspectives of Adolescents, Parents and Professionals: Multicentric Study in Six Hospitals*](#). *Acta Med Port* 2019 Jan;32(1):61-69

¹² Aarhun, A., & Akerjordet, K. (2014). Parent participation in decision-making in health-care services for children: An integrative review. *Journal of Nursing Management*, 22, 177–191. 10.1111/j.1365-2834.2012.01457.x

II. Background

a. Principles governing children's participation

The UNCRC has identified four guiding principles for the implementation of all rights of the Convention:

Guiding principles of the UNCRC

Article 2. The obligation to respect and ensure the rights to each child without discrimination of any kind.

Article 3(1): the best interests of the child as a primary consideration in all actions concerning children.

Article 6. the child's inherent right to life and the obligation to ensure to the maximum extent possible the survival and development of the child.

Article 12. the child's right to express his or her views freely in "all matters affecting the child", those views being given due weight.

In simple terms, this means that all children have the right to participate in the decision-making process regardless of age or other characteristics, taking into account their best interests and what is necessary for their well-being and development. This means that decision-making processes must be a balance between what the child wants, what is needed to secure the child's health (including their survival, life and development), what other stakeholders want (parents and health professionals) and what is *genuinely* in the best interests of each child. In the context of health practices, this also includes consideration of the negative effects of not enabling participation. For example, non-compliance with treatment, inability of a child to identify alert symptoms in case of a chronic illness, or other.

United Kingdom: Assessing a child's best interests during health care decision-making processes

"An assessment of best interests will include what is clinically indicated in a particular case. You should also consider:

- a. the views of the child or young person, so far as they can express them, including any previously expressed preferences
- b. the views of parents
- c. the views of others close to the child or young person
- d. the cultural, religious or other beliefs and values of the child or parents⁴
- e. the views of other healthcare professionals involved in providing care to the child or young person, and of any other professionals who have an interest in their welfare
- f. which choice, if there is more than one, will least restrict the child or young person's future options.

This list is not exhaustive. The weight you attach to each point will depend on the circumstances, and you should consider any other relevant information. You should not make unjustified assumptions about a child or young person's best interests based on irrelevant or discriminatory factors, such as their behaviour, appearance or disability."

In UK General Medical Council. Guidance for practitioners, available at: [Assessing best interests - GMC \(gmc-uk.org\)](https://www.gmc-uk.org/guidance/assessing_best_interests.aspx)

Mexico: Determining the best interests of the child in health sector

Ten premises to guide the child best interests in the right to health:

1. Ensuring health means ensuring the enjoyment of all other rights.
2. Predict scenarios that mitigate social disparities in all health decision-making.
3. Ensure that the health of children and adolescents is not hindered by discrimination of any kind.
4. Privilege children and adolescents with violated rights individually and collectively, as well as those in underserved areas.
5. Encourage mechanisms for children and adolescents to express their views and be given due consideration, according to their age and maturity, on health-related issues, including: what services are needed, where they are best provided, barriers to accessing services, the quality of services, and the attitudes of health professionals, among others.
6. To substantiate with child best interests' criteria that contribute to resource allocation decisions.
7. Build policies aimed at protecting the physical and social **environments** in which children and adolescents live, grow and develop, as well as those that favour the life, survival, growth and development of children and adolescents.
8. Establish procedures and criteria to guide health workers in determining child best interests in health care.
9. To have information disaggregated by age, sex, relative disability status, socio-economic status, socio-cultural aspects and geographic location in terms of health.
10. Supporting all treatment decisions through the child best interests.

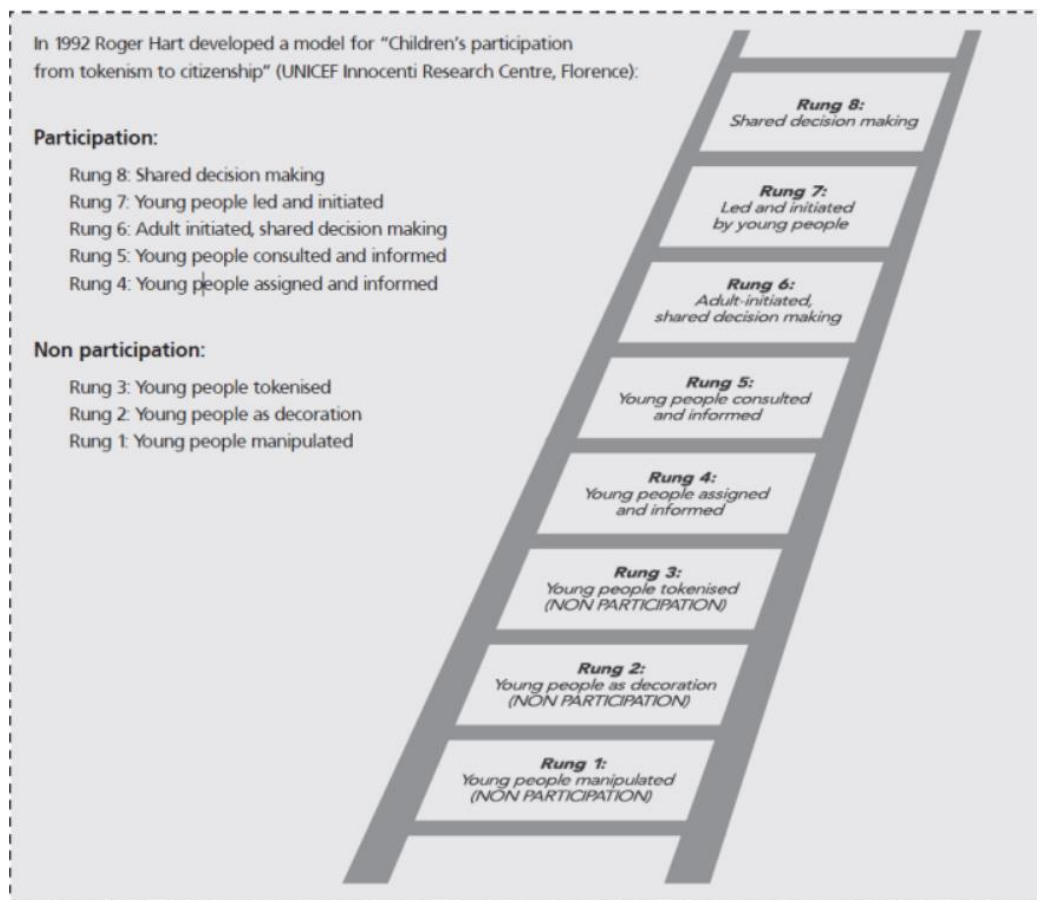
Own elaboration based on General Comment 15 of the UN Committee on the Rights of the Child.

In Ricardo Antonio Bucio Mújica, La determinación del interés superior de la niñez en la salud, Available at : <https://archivos.juridicas.unam.mx/www/bjv/libros/11/5276/13.pdf>

Different children at different times might prefer to have varying degrees of involvement or responsibility. All efforts should be done to maximize the opportunity for any child to choose to participate in decision regarding their health if they choose, at the highest level of his/her ability.

The confidence and competence to be involved must be gradually acquired through practice. For this reason, increasing opportunities for children to participate in decision-making processes in health should be created both by health institutions and professionals.

The Ladder of Participation diagram as a beginning typology for thinking about children's participation



The ladder of participation should not be considered as a simple measuring stick of the quality activities and programmes.

<https://www.coe.int/en/web/compass/on-the-ladder>

Finally, it important to underline that child's autonomy has to be conceptualised as "the child's right to an open future". This means that they have the right to have future options kept open until they are self-determining adult capable of deciding and that they have to be protected against being engaged in certain irreversible choices. It is crucial to enable children to build their own informed opinion on practices which have future or long-term implications for them, fostering the inclusion of children in decision processes in new and challenging contexts (healthcare and research using emerging technologies, advanced therapies, genetic tests...). Specific initiatives should be promoted, with a participatory methodology, to develop policies and practices reflecting children needs, expectations and priorities while fostering their involvement in decisions regarding their health.

b. International frameworks setting standards on children's participation in health

In 1989, with the adoption of the UNCRC, a fundamental value underpinning children's rights was put forward: the vision that children must be agents in their own lives, in particular, through Article 12, which sets out that children's views must be taken into account and given due

weight in a manner consistent with their evolving capacities. This article later became known
as “children’s right to participation”.

216 The respect for the child's right to express his or her views and to participate applies to
217 individual health-care decisions, as well as to children's involvement in the development of
218 health policy and services aimed at promoting the healthy development and well-being of
219 children.

Conditions for the effective implementation of the “children rights to participation” according to the General Comment 12¹³

- ✓ Children should be provided with information about proposed treatments and their effects and outcomes, including in formats appropriate and accessible to children with disabilities
- ✓ Physicians and health-care facilities should also provide clear and accessible information to children on their rights concerning their participation in paediatric research and clinical trials
- ✓ Where fixed age at which the right to consent transfers to the child is established, children above this age have an entitlement to give consent without the requirement for any individual professional assessment of capacity after consultation with an independent and competent expert
- ✓ Where a younger child can demonstrate capacity to express an informed view on her or his treatment, this view is given due weight
- ✓ Access to confidential medical counselling and advice without parental authorisation should be ensured, irrespective of the child's age, where this is needed for the child's safety or well-being
- ✓ Measures enabling children to contribute their views and experiences to the planning and programming of services for their health and development should also be introduced.

At the European level, the Oviedo Convention¹⁴, the only international legally binding instrument on the protection of human rights in the biomedical field, lays down the general rule that an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given clear and understandable information as to the purpose and nature of the intervention as well as its consequences and risks. Furthermore, consent may be freely withdrawn at any time (art.5). The respect for the child's right to express his or her views clarifying conditions to implement this right is reaffirmed in art.6.

Relevant Oviedo Convention provisions

Chapter II – Consent

Article 5 – General rule: An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.

Article 6 – Protection of persons not able to consent

¹³ UNCRC Committee (2009) General Comment No 12 The right of the child to be heard. Paragraphs 98-103 ; available at <https://www2.ohchr.org/english/bodies/crc/docs/advanceversions/crc-c-gc-12.pdf>.

¹⁴ CETS no. 164, [Full list \(coe.int\)](http://coe.int)

(...) 2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

228 It also clarifies that situations should take account of the nature and seriousness of the
229 intervention as well as the child's age and ability to understand, and that the child's opinion
230 should increasingly carry more weight in the final decision. This could even lead to the
231 conclusion that the consent of a child should be necessary, or at least sufficient for some
232 interventions¹⁵.

233 While the UNCRC and the Oviedo Convention provide the basis for children's right to
234 participation in decision-making processes on matters relevant to their health, legislation,
235 policies and practices have evolved significantly beyond, including European legislation on
236 biomedical research, including clinical trials and national legislation on children's right to
237 informed consent.

Relevant provisions of the COE Additional Protocol on biomedical research

At the European level, in the context of biomedical research, the Additional Protocol to the Convention on Human Rights and Biomedicine (CETS No. 195), which came into force in 2007, establishes that research on a person without the capacity to consent to research may be undertaken only if, among others, all the following specific conditions are met:

- the person undergoing research has been informed of his or her rights and the safeguards prescribed by law for his or her protection, unless this person is not in a state to receive the information
- the necessary authorisation has been given specifically and in writing by the legal representative or an authority, person or body provided for by law, and after having received the information required by Article 16, taking into account the person's previously expressed wishes or objections
- the person concerned does not object

The opinion of a minor shall be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity.

Objection to participation, refusal to give authorisation or the withdrawal of authorisation to participate in research shall not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care (art.15).

Relevant provisions of the EU Regulation on clinical trials

At European level, in the context of clinical trials, the EU Regulation 536/2014 on clinical trials, which came into force on 31 January 2022, establishes that a clinical trial on minors may be conducted only if the "informed consent of their legally designated representative" has been obtained. Nevertheless, a child who is capable of forming an opinion and assessing the information given to him or her, should himself or herself assent in order to participate in a clinical trial. The relevant provisions of the EU Regulation on clinical trials include:

¹⁵ Para. 45 of the Explanatory Report to the Oviedo Convention, <https://rm.coe.int/16800ccde5>

- The minor shall take part in the “informed consent procedure” in a way adapted to his or her age and mental maturity
- The explicit wish of a minor who is capable of forming an opinion and assessing the information, to refuse participation in, or to withdraw from, the clinical trial at any time, is respected by the investigator
- If during a clinical trial the minor reaches the age of legal competence to give informed consent as defined in the law of the Member State concerned, his or her express informed consent shall be obtained before that subject can continue to participate in the clinical trial (art.32)

238 In emergency situations, health professionals may be faced with a conflict of duties between
 239 their obligations to provide care and to seek the patient's consent. Art. 8 and 9 of the Oviedo
 240 Convention allows the practitioner to act immediately in such situations without the consent of
 241 the patient.

Relevant provisions of the Oviedo convention on emergency situations

- This possibility to act without the authorisation of the legal representative is restricted to emergencies which prevent the practitioner from obtaining the appropriate consent and is limited solely to medically necessary interventions which cannot be delayed
- Interventions for which a delay is acceptable are excluded
- The intervention must be carried out for the immediate benefit of the individual concerned
- In emergency situations health care professionals must make every reasonable effort to determine what the patient would want
- When persons have previously expressed their wishes, these shall be taken into account Nevertheless, taking previously expressed wishes into account does not mean that they should necessarily be followed
- These provisions apply both to persons who are capable and to persons who are unable either *de jure* or *de facto* to give consent

242

Relevant provisions of the EU Regulation on clinical trials for trials in emergency situations

The EU regulation provides for specific rules concerning informed consent in emergency situations (art.35). Where, due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the clinical trial, and it is not possible to obtain informed consent prior to the intervention, patients may be enrolled in the clinical trial under the following conditions:

- the clinical trial should relate directly to the medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative
- there are scientific grounds to expect that participation of the subject in the clinical trial will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement
- the clinical trial poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition
- any previously expressed objection by the patient should be respected, and informed consent from the subject or from his/her legally designated representative

should be sought without undue delay and the information shall be given as soon as possible to the subject and to his/her legally designated representative

c. National legislation concerning children's participation in health

The right for children to participate in treatment and research decisions is recognised at national level, but substantial differences exist among national laws. Across Europe, the statutory age at which a child is considered able to consent varies from 12 years to 18 years.

- ▶ In some countries, the legal age for consent to a medical intervention corresponds to the age of legal majority, and children under this age require authorisation from their legal representatives before an intervention can be carried out. However, some national laws recognise the need for informing children and taking their will into account, according to their cognitive capacity.
- ▶ In other countries, children younger than the age of legal majority can give consent without their parents' or carers' authorisation, *either* according to their maturity and competence in relation to the nature of the health issues concerned *or* from a fixed age.¹⁶

In Belgium, France, Finland, Germany, Hungary, Italy, Monaco and Switzerland

The right to receive information and/or to express his/her will, is recognised on the basis of evolving capacities / (*the evaluation of the degree of maturity / or of the capacities / or of the level of development of the child*)

In Austria, Bulgaria, Ireland, Italy, the Netherlands, Norway, Portugal, Spain and Ukraine

The exercise of the right to receive information or to express his/her will is recognised once the child reaches the minimum age set by legislators. The age ranges vary from 7 to 16 years and are combined with different conditions and legal consequences

Children's competency: The notion of children's competency was first discussed in a case brought to court in the UK in 1986¹⁷. The so-called *Gillick competency* grew in importance and is increasingly recognised as a determining factor for giving children the right to consent to treatment. For example, the Scottish Age of Legal Capacity Act (1991) states that:

"a person under the age of 16 years shall have legal capacity to consent on his own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending him, he is capable of understanding the nature and possible consequences of the procedure or treatment."¹⁸

It is important to know legislation applicable in your own setting and validated tools to reliably assess children's competency or capacity to be implemented in your practice.

¹⁶ Altavilla A, Halila R, Kostopoulou M-A, Lwoff L, Uerpmann K, Strengthening children's participation in their health: the new initiative of the Council of Europe, *Lancet Child Adolesc Health* 2021 Feb 10. Doi: 10.1016/S2352-4642(21)00019-5

¹⁷ The so-called Gillick competency derives from the *Gillick v West Norfolk and Wisbech AHA Case* (1986), where the court's ruling stated that "whether or not a child is capable of giving the necessary consent will depend on the child's maturity and understanding and the nature of the consent required. The child must be capable of making a reasonable assessment of the advantages and disadvantages of the treatment proposed, so the consent, if given, can be properly and fairly described as true consent." (*In Hastings AM & Redsell S Listening to Children and Young People in Healthcare Consultations* (2010))

¹⁸ Guerreiro AIF and Fløtten K (2016) [Article 12: The Translation into Practice of Children's Right to Participation in Health Care](#); in Liefgaard T and Sloth-Nielsen J (eds) *Conference Book, The United Nations Convention on the Rights of the Child: Taking Stock after 25 Years and Looking Ahead*, Leiden University

d. The roles of parents, children and healthcare professionals

1. The role of Parents

Parents and other holders of parental responsibility are natural and essential partners in any process concerning children's health, well-being and development. The experiences of parents and the influence they may have on their child's health care varies across countries. Parenting culture, that is the way parents include their children in matters of daily life, as well as patient's health literacy are important factor affecting parental knowledge and understanding of their child's condition and health care having an influence on the nature and extent of children participation. Some parents are not involved or listened to and thus may feel powerless and uncertain about their child's health care. This heightens parent's and children's stress in an already demanding situation and can limit parent's coping strategies and their ability to support their child^{19,20}. Parents need appropriate information about their child's health problem, disease and the different options for treatment in order to be able to participate in decisions related to their child's health care^{21,22}.

Parents are dependent on *if, how* and *when* healthcare professionals involve them in decision making about their child's health.

Tips for addressing parents

- ✓ Speak in a language and way that parents understand and avoid medical jargon
- ✓ Provide the same information at different times and stages
- ✓ Complement oral information with written where possible and appropriate
- ✓ Coordinate with other health professionals to avoid that parents and children receive contradictory information
- ✓ Advise and guide parents on how they can support their children's participatory efforts
- ✓ Take time to encourage parents to ask questions and provide explanation

Information to parents should always include:

- ✓ The purpose and duration of the procedures involved
- ✓ The extent and duration of the procedures involved
- ✓ Available preventive, diagnostic and therapeutic procedures and alternatives
- ✓ Any information collected about children's health
- ✓ Arrangements to ensure respect for private life and ensure the confidentiality of personal data
- ✓ Any foreseen potential further uses, including commercial uses, of personal data or biological materials

¹⁹ Tallon M.M., Kendall G. E., Snider P. D. (2015). Development of a measure for maternal confidence in knowledge and understanding and examination of psychosocial influences at the time of a child's heart surgery. *Journal for Specialist in Pediatric Nursing*, 20, 36–48. 10.1111/jspn.12096

²⁰ Edwards, M. , Davies, M. , & Edwards, A. (2009). What are the external influences on information exchange and shared decision-making in healthcare consultations: A meta-synthesis of the literature. *Patient Education and Counseling*, 75, 37–52. 10.1016/j.pec.2008.09.025

²¹ Jackson C., Cheater F. M., Reid I. (2008). A systematic review of decision support needs of parents making child health decisions. *Health Expectations*, 11, 232–251. 10.1111/j.1369-7625.2008.00496.x

²² Uhl T., Fisher K., Docherty S. L., Brandon, D. H. (2013). Insights into patient and family-centered care through the hospital experiences of parents. *Journal of Obstetric, Gynecologic & Neonatal Nursing*, 42, 121–131. 10.1111/1552-6909.12001

In the case of research it should also include :

- ✓ The arrangements for responding to adverse events or the concerns of research participants
- ✓ The source of funding of the research project
- ✓ The arrangements for fair compensation in the case of harm
- ✓ The arrangements for access to information relevant to the participant arising from the research and to its overall results

It is important to recognise the value of the parents' role and guidance, and to respect the wishes of those children who wish their parents to be involved in the decisions.

However, parental duties and responsibilities to provide "appropriate direction and guidance" for the care, protection and well-being of the child change in the light of the child's evolving capacities.

2. The role of children

Children are recognised as rights-holders and not merely as persons in need of protection. They are the key agent also in the health care partnership. Children's views should be obtained and respected as much as possible prior to decisions. Children's right to express their views "is not dependent upon their capacity to express a mature view; it is dependent only on their ability to form a view, mature or not" on the basis of the appropriate information received. Children should be provided with adequate and appropriate information in order to understand the situation and all the relevant aspects in relation to their interests, and be allowed, when possible, to give their consent and express their views in an informed manner. There is no minimum age to benefit from the right to express one's views. A child's degree of maturity does not determine the existence of his/her rights, but rather what weight is given to the child's view. The fact that the child is very young or in a vulnerable situation neither deprives him or her of the right to express his or her views, nor reduces the weight given to his or her views.

Specific and appropriate support should be provided on a case-by-case basis, to enable the equal exercise of children's right to participate in decision-making processes, and to ensure their full participation in the assessment of his/her best interests.

Children often express that they want the opportunity to provide input and want to feel heard but do not want the burden of having to make the final decision. Sometimes, adults may have a final say in making decisions and they would and could overrule their choices on the condition to have included children in the decision process. Being asked to express one's views also implies a greater responsibility for the child, which not all children would like or feel ready for. Therefore, deciding to leave the adults to make the major decisions is also participation in decision-making.

The level of involvement can differ from child to child and between circumstances. Information-sharing involving the child requires that the child is included, and duly guided by adults, while giving due weight to the child's perspective²³.

²³ Coyne, I., Hallstrom, I., & Soderback, M. (2016). Reframing the focus from a family-centred to a child-centred care approach for children's healthcare. *Journal of Child Health Care*, 20(4), 494–502. <https://doi.org/10.1177/1367493516642744>

How to effectively implement children's right to participation

- Adequately inform children about the possibility for participating in decision-making about health care interventions
- Support children and invite them to talk about to what extent they wish to participate, in what way and when
- Increase children's understanding of their own health situation

3. The role of healthcare professionals

Healthcare professionals have a central role in advocating and ensuring that all children have opportunities and spaces for participation and, additionally, in creating security for children in uncomfortable situations and in empowering them to take more control of their own health²⁴.

Healthcare professionals also have an essential role in providing patients and other persons involved in the decision-making process with the necessary information. Also, to facilitate parents' active involvement in children's health care decisions, once verified whether and to what extent the child is capable of understanding the information and form a personal view. Healthcare professional may contribute to strengthen both children's and parent's sense of coherence and in improving their ability to cope with the situation they are experiencing. These processes in turn help to increase parents' and children's competencies and engagement in children's care and ensure the quality and provision of child-friendly health care.

Continuous training for healthcare professionals

- ✓ Professionals in direct contact with children should be trained in communicating with children of all ages and stages of development, and with children in situations of particular vulnerability
- ✓ Training should include an increased awareness of children's individual needs, capacities, and preferences and learning about strategies to involve them according to these abilities and wishes
- ✓ Training should focus on professionals' attitudes and practices, aiming at the improvement of communication with parents and children
- ✓ Training may be especially challenging within diseases or other circumstances where families feel that standardised protocols leave them little room for choice²⁵
- ✓ Regular refresher training should be held to equip professionals with new skills and to share experiences

[Please, provide reference for further reading and examples of training and specific curricula]

The presence of especially trained can be a valuable resource to advocate for and support children and increase/enhance the skills of other health workers. However, the presence of involvement of such specialized workers should not and does not reduce the responsibilities and needs for all healthcare professionals working with children, to advocate for and provide appropriate support for children role in decision making.

²⁴ Sjöberg C, Amhliden H, Nygren J M, Arvidsson S, Svedberg P, (2015) The perspective of children on factors influencing their participation in perioperative care, Journal of Clinical Nursing, 24, 2945–2953, doi: 10.1111/jocn.12911

²⁵ Coyne I, Amory A, Kiernan G, Gibson F (2014) Children's participation in shared decision-making: children, adolescents, parents and healthcare professionals' perspectives and experiences. Eur J Oncol Nurs 18:273–280

Child life Specialists and services

Child Life Specialists (already existing in Germany, Spain, UK and United States) are experts in child development who advocates for children rights in healthcare, providing interventions to ensure that children's voices are heard, and needs responded to in a developmentally appropriate way. Certified Child Life Specialists are educated and clinically trained in the developmental impact of acute and chronic illness, injury, trauma and disability. In healthcare, research and community settings, their role helps improve patient and family care, satisfaction, and overall experience. Infants, children and youth confront a wide variety of stressful and potentially traumatic events that can impact their ability to cope.

There may be organisational aspects, such as available resources, the allocation of time to communicate with children and parents and other possible constraints that influence the quality and effectiveness of decision-making processes. These constraints should be identified and addressed by both institutions and professionals.

[Please provide reference for further reading and examples of organisational policies, and specific resources devoted to enhancing participation of children in decision regarding their health.]

III. Fulfilling children's right to participation in health care

The involvement of children in their care should be seen as a progressive process according to their evolving capacities and involving, where appropriate, four levels of participation: (1) being informed, (2) expressing a view, (3) influencing a decision, and (4) being the main decision-maker, for example, giving consent to a treatment or intervention.²⁶ In turn, children's level of participation should be informed by both their abilities and preferences²⁷.

a. Informing children

Appropriate and accessible information in accordance with the child's evolving capacities and degree of maturity is an important pre-requisite for the ability to speak out, express views and discuss decisions. Adults have a responsibility to find ways in which to enable children to communicate their views, concerns or ideas.

Providing children, according to their individual capacities, with information regarding treatments (including the accompanying risks and benefits, diseases' characteristics or research practices) aids children's understanding of the process and implications²⁸. A lack of information increases children's fears and anxiety surrounding treatments, causing them to feel unprepared for procedures and reduces self-esteem²⁹.

Tips for effectively informing children

²⁶ Alderson P and Montgomery J *Health Care Choices: Making Decisions with Children* (1996) Institute for Public Policy Research, London

²⁷ McCabe MA (1996) Involving children and adolescents in medical decision making: developmental and clinical considerations. *J Pediatr Psychol* 21:505–516.

²⁸ Coyne I, O'Mathúna DP, Gibson F, Shields L, Sheaf G.(2013) Interventions for promoting participation in shared decision-making for children with cancer. *Cochrane Database of Systematic Reviews*, Issue 6. Art. No.: CD008970. DOI:10.1002/14651858.CD008970.pub2.

²⁹ Coyne IT, Hayes E, Gallagher P, Regan G. (2006) Giving children a voice: investigation of children's experiences of participation in consultation and decision-making in Irish hospitals. *Giving Children a Voice: Investigation of Children's Experiences of Participation in Consultation and Decision-Making in Irish Hospitals*. Dublin: Office of the Minister for Children.

- ✓ information must be sufficiently clear and suitably worded, for example, avoid medical language and include terms that the child can understand
- ✓ enable the child to understand how to weigh the aim and methods, the necessity or usefulness of the intervention against its risks and the discomfort or pain it will cause³⁰
- ✓ tell the child he/she can ask questions at any time
- ✓ adequately answer children's requests for additional information, also according to circumstances

Child-friendly information material about relevant topics should be prepared and made available to children to complement the communication of information between healthcare providers and children. Information materials that may be useful may include, among other:

- ▶ Rights relevant for the health sector (e.g. data protection, prohibition of discrimination, equitable access to treatment, right to be informed ...);
- ▶ Children's right to participation in decision-making processes in the health sector;
- ▶ Information related to specific categories of diseases (e.g. oncology, mental health conditions, rare diseases);
- ▶ Other, as appropriate.

This information material shall be developed with a participatory methodology.

Child-friendly information material helps to support the communication and mutual understanding of children and service providers. It also helps children to reflect on the information they received orally and to identify questions for a follow-up conversation with the healthcare professionals. Medical conditions and the diversity of the groups are important aspects to be taken into account in developing materials.

Possible formats of child-friendly information material

- ✓ Brochures and leaflets
- ✓ Videos
- ✓ Information accessible through social media, specific websites or applications
- ✓ Games
- ✓ Other

Video of the Council of Europe on “Children participation in decision making process in health”

The video was developed by TEDDY Network and TEDDY Kids with a participatory methodology by a group of children aged between 12 and 18 years, coming from Italy, France, Greece and Albania, and which included young patients and healthy children. It targets children of a similar age group.

The first step was to train the children involved about child rights and in particular the right to participation. The script was developed on the basis of the most documents (article of Oviedo Convention, UN Declaration of the Rights of the Child), further discussed with the secretariats of the CDBIO and CDENF and TEDDY kids and modified accordingly. Brainstorming sessions were organised to collect ideas and raise consensus on the scenario, the format, the animations, the animated characters etc.

³⁰ Oviedo Convention Explanatory Report <https://rm.coe.int/16800ccde5>

The main objective was to use appropriate language and an exciting and interesting scenario. In this perspective, a mixed format, including animated characters and real adolescents, to be closer to the real life, was adopted. A square format to be easily read and used on mobile phones was preferred.

<https://www.coe.int/fr/web/bioethics/guide-to-good-practice-concerning-the-participation-of-children>

[Add examples of child-friendly informative materials and existing brochures or Charters on Children's rights in health care]

Health education should be an important component of the treatment plan for children, including learning about their rights and how to get their needs met. Information, communication and education, combining approaches and methods that enable children, families to play active roles in achieving, protecting and sustaining their own health, should be promoted.

Playing can help children to acquire knowledge and increase their awareness of different aspects related to healthcare and research settings. Play in the clinical setting also helps to address children's unique needs on the basis of their developmental level, medical condition and physical abilities, psychosocial vulnerabilities, while reducing emotional distress and helping children cope with healthcare experiences.

Examples of information, communication approaches developed with a participatory methodology

- ✓ Interpersonal communication (such as counselling sessions or group discussions, meetings and events)
- ✓ Live, interactive programming using closed-circuit television systems aimed at engaging paediatric patients restricted to their rooms for infection-control or medical reasons
- ✓ Other interactive technology such as video conferencing, aimed at helping patients engage with people outside the hospital, including their peers, the community, and their schools
- ✓ Age-appropriate learning and training activities

Paediatric "expert patients" training workshops

Paediatric "expert patients" training workshops were organised, within the framework of the European Joint Programme on Rare Diseases (EJPRD), by TEDDY (European Network of Excellence for Paediatric Research) in collaboration with EURORDIS and the Sant Joan de Déu Research Foundation. The workshops were for patients with chronic rare diseases (around 15 participants each year, aged from 12 to 18) interested in the themes of health, biomedical research, healthcare, and children rights. They aimed to prepare young patients to actively participate in scientific research and play an important role in improving research and healthcare services for all patients by contributing their own specific experience. Ice-breakings activities and role-plays were carried out and child-friendly education materials were developed. The training plans, approved by a dedicated Programme Committee and a Young Programme Committee, were prepared with a participatory methodology designed to enable the contribution from the young people.

Within the workshop, assent forms were developed for processing and sharing health data for research within the European Reference Networks - virtual networks connecting healthcare professionals engaged in the diagnosis and care of patients with rare diseases. Before developing the assent form, an education session about data protection principles and child rights was organised to increase the participants' awareness. A questionnaire was developed and given to child participants to collect their feedback. A practical activity was organised with specific instructions for children to highlight in different colours the words and concepts that were easily understandable, not clear, or to be improved.
<https://www.ejprarediseases.org/event/first-paediatric-expert-patients-training-workshop/>

Serious games

“My Clinical Trial Center” is a digital game with an educational purpose. It aims to explain to children in a fun way what clinical trials are, how they work and why they are so important to developing medicines suitable for children.

The game is extremely informative: game-players will learn about clinical trials, study protocols, informed consent and assent in children, phases and procedures of clinical trials, data collection, and pharmacovigilance. It can be downloaded in Play Store and Apple Store. The game is currently in English. The game was developed with a participatory methodology by the TEDDY KIDS (KIDS Bari and Albania young) members and received approval of the International Children's Advisory Network (iCAN).

<https://www.teddynetwork.net/2021/06/29/4676/>

“Silver” is a science-based, serious game. It teaches new 'serious' issues in a playful way. The game focuses on strengthening mental resilience in young people aged 12 to 16. Silver is based on elements from cognitive behavioural psychology and was studied among more than 1,000 pupils from ten Flemish schools.

“Do you sometimes wonder what goes on in other people’s heads? Are you curious about why others react in a certain way? Would you like to know more about the connection between thoughts, feelings and behaviour?”

If so, Silver is for you. You will follow four young people during their day at the Silver Festival. They regularly find themselves in difficult situations. Depending on your choices, the day of the characters will take a different turn every time. You determine their adventure.

Silver is a serious game for children aged 12 to 16.”

<https://www.silvergame.be>

389 b. Expressing a view

390 A trusting relationship with healthcare professionals is a prerequisite for increasing children's
 391 opportunities to be pro-active in the care given to them. The rights of children should be
 392 reflected in the entire health care process, from the moment they call to make an appointment,
 393 to the built environment where they access care, to the interactions with all staff, including

394 clinicians, to the treatment plan, and finally to any follow-up care. By empowering children at
395 every stage in this process and by giving children a voice in the design and implementation of
396 these processes, healthcare professionals can create a collaborative process that improves
397 outcomes³¹. Parents should also be involved in this process to be able to provide full support
398 to their children.

The ability of children to express their views and opinions is influenced by:

- ✓ Their age and maturity
- ✓ Their decision-making capacities
- ✓ Prior experience of participation either in health care or other relevant decision-making processes (at home, school or other)
- ✓ The extent to which they understand their situation (illness, consequences of the treatment or long-term illness, etc)
- ✓ How comfortable and engaged they feel within the decision-making process
- ✓ Cultural background and health literacy

399 To help children express their views, healthcare professionals need to remain alert to their
400 changing health care needs. They need to follow children closely, constantly assessing,
401 reflecting, learning, and innovating, always with the children at the centre. Sensitivity, humane
402 approaches to care, transparency and honesty in the exchange of information, helps to
403 generate trust, supporting both parties to better achieve their common goal: providing the child
404 with the best possible care³².

405
406 Privacy is an important issue when working with children, especially when sharing or
407 discussing information concerning their own health. It is critical to discuss confidentiality issues
408 with children, at the outset and allow them time to ask questions. It is also important to have
409 time alone with the child and/or with the parents, where necessary, to provide space for
410 children to discuss whatever matters to them.³³

411
412 Healthcare professionals and institutions also need to consider whether their physical space
413 is one that both encourages children to feel welcome and empowered to exercise their right
414 to be heard and that enables clinicians and staff to respond to children in a way that makes
415 youth participation meaningful.

How to help children express their views

- ✓ Have time alone with the child to provide space for him or her to discuss whatever matters to them
- ✓ Play with the child while talking to help reducing the stress of discussing difficult topics and to be able to express him/herself more freely
- ✓ Both active questioning and active listening are essential.
- ✓ Avoid making judgements in all interactions
- ✓ Check that the child understands the information that has been given

³¹ Wallerstein N. (2002) Empowerment to reduce health disparities. Scand J Public Health 2002;30:72–7.

³² Gómez-Zúñiga B, Moyano RP, Pousada Fernández M, García Oliva A, Armayones Ruiz M (2019) The experience of parents of children with rare diseases when communicating with healthcare professionals: towards an integrative theory of trust, Orphanet J Rare Dis. 14: 159. doi: 10.1186/s13023-019-1134-1

³³ McKee MD, Rubin SE, Campos G, O'Sullivan LF. (2011) Challenges of providing confidential care to adolescents in urban primary care: clinician perspectives. Ann Fam Med vol;9:37–43.

- ✓ Ask the child what he or she think, as this gives the child permission to express. Don't assume a child will share his/her thoughts voluntarily.
- ✓ Allow more time for a child to think, if he or she wants and needs it
- ✓ Reassure the child that his/her opinions and thoughts are important – whether those are about big things or small things (sometimes small things can be very important)

416 Environments, both physical (office, rooms, furniture...) and psychological (privacy, safety...) are important to enhance a child's participation and sense of control within healthcare and research, and to speak freely about his or her health status and concerns. Developing environments and practices better suited to meeting children's needs (reading, playing, discussing,...) makes children feel more welcome, reduces fears and anxiety and empowers children to exercise their right to be heard. Children should contribute to developing these environments, tailored and engageable for both children and families.

Child-friendly and family-friendly hospital environments:

Azienda Ospedaliero-Universitaria Meyer (AOU Meyer) University Hospital in Florence, Italy

In the hospital, children have the right to maintain the maximum continuity of daily life, playing, studying and participating in moments of animation and socialization. Thanks to the support of the Meyer Foundation, there are many welcoming activities and projects reserved for children and young people and their families. They have grown over the years and are articulated and offered based on the disease, age and specific needs of patients and their families. There is space for play, in the ward or in a dedicated place such as playroom, pet therapy, music, clowns and school support.

Family members with specific needs related to being away from home and the child's pathology can count on a hospitality service, psychological support and company social services. The social service is also a point of reference for the activities carried out by voluntary associations and parents' associations and foundations to help families during the child's hospitalization period.

To improve communication with children and families who come from distant countries, a linguistic-cultural mediation service is available on-site for Arabic, Chinese and Albanian languages. There is also telephone interpreting for emergencies available in all languages. In the basement of the hospital there is a space, open to all, dedicated to meditation and prayer. For religious support from the respective ministers of worship, the social service provides users with reference contacts.

<https://www.meyer.it/index.php/en/ospedale/accoglienza-bambini-e-famiglie>

Sant Joan de Déu Children's Hospital in Barcelona, Spain

SJD Barcelona Children's Hospital has started using a new magnetic resonance device that help in reducing the duration of anaesthesia, which some patients need for these procedures, as well as an improved and safe experience for the patient and the family members who accompany them. The hospital has also made the most of the new installation to analyse the experience of patients and their families in terms of use of space and to make some changes. At the entrance to the new magnetic resonance area there is a hall that channels patients towards different anterooms (the reanimation and preparation area) to improve the experience of the patients and their families in terms of

comfort and privacy. The magnetic resonance facility has also been made more child-friendly, with themed decoration based on the planets, outer space and magnetic fields. This means that children will find a spaceship with an astronaut and information about gravity, the planets and the distance between objects and planet Earth, as well as the friendly dog Laika. This theme-based decoration has been used around the entire Diagnostic Imaging Area, creating a much brighter and more orderly ambiance.

<https://www.sjdhospitalbarcelona.org/en/diagnostic-imaging-department-ground-breaking-initiative-europe-implementation-new-15t-resonance>

[Please provide more examples from Children's Hospitals/institutions]

c. Influencing a decision

When, according to national legislation, children are not able to give their consent to a treatment or intervention, their views and opinions should nevertheless genuinely influence a decision. This means that their views and opinions should be taken seriously and given due weight in the final decision. It should be properly explained to children why a decision was taken, especially when the final decision does not reflect their wishes.

Children should be able to influence a decision in accordance with their **evolving capacities**. The "evolving capacities" of the child is a key concept to be taken into account when working with and for children. It recognises children's developmental characteristics and needs, their competencies and emerging personal autonomy.³⁴ This means that, as children grow, they should be more involved in decisions. Children's age, maturity, but also their life experiences should be taken into account when enabling a child to participate.

Secondly, the principle of the **best interests of the child** is crucial in any decision that concerns children. This principle, closely linked to the evolving capacities principle, places children at the centre of the decision-making process, looking at what is best for each single child, taking into account their age, maturity, personal characteristics, but also the short, medium and long-term consequences of a given treatment and intervention to the life of that particular child. Assessment of the child's best interests must also include consideration of the child's safety, protection and care to be considered in relation to the comprehensive ideal of ensuring the child's development and well-being, including his/her basic material, physical, educational, and emotional needs, as well as needs for affection³⁵ and other important dimensions of the child's life, including culture and religion. All these aspects should be given due weight and help professionals arrive at the best possible decision for the child.

Childhood is not a single, fixed, universal experience. At different stages in their lives, children require different degrees of protection, provision, prevention, information and participation. Children's wishes should be considered seriously, most of all in relation to health care and biomedical research.

³⁴ Lansdown, Gerison (2005) The evolving capacities of the child. UNICEF Innocenti Research Centre

³⁵ UNCRC 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)

451 d. Giving consent to treatment

452 Giving consent to treatment is the final stage in the individual process of decision-making.
453 Informed consent is the decision, taken freely after being duly informed of the nature,
454 significance, implications and risks of an intervention (including all medical acts and
455 interventions performed for the purpose of prevention, diagnosis, treatment, rehabilitation or
456 research) by any child capable of giving consent. This would equally apply to the authorisation
457 given by the child's legal representative, when according to national legislation, the child is not
458 able of giving consent. Children can be called, according to national legislation to provide their
459 assent or to express their dissent.

Assent and Dissent

The terms assent and dissent generally describe when children give their agreement or disagreement to a treatment, especially in cases where they do not yet have a right to give their consent to treatment, in accordance to the law. If a child is considered capable of assent/dissent, their assent/dissent should be sought/respected in addition to parental permission. The notion of assent was introduced by the Declaration of Helsinki* and mentioned in the WHO-CIOMS and ICH-E11 guidelines**, as well as in the COE Guide for Research Ethics Committee Members***. These concepts are implemented differently in national legislations. In most European countries, the written consent (authorisation) of both parents in addition to the child's own assent or consent (where applicable) is required according to different conditions.

Giving children the possibility to assent and dissent to treatment is important because it involves children more directly in the decision-making process and prepares them for taking responsibility in similar processes in the future.

Furthermore, in case the child disagrees, such conflict should be addressed, and attempts should be made to resolve it together with the patient.

*<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

**https://www.who.int/docs/default-source/ethics/web-cioms-ethicalguidelines.pdf?sfvrsn=f62ee074_0

***[https://www.coe.int/t/dg3/healthbioethic/source/INF\(2011\)_en.pdf](https://www.coe.int/t/dg3/healthbioethic/source/INF(2011)_en.pdf)

Examples of Guidelines

- ✓ Ethical Considerations for Clinical trials on medicinal products conducted with minors – Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use

https://health.ec.europa.eu/system/files/2018-02/2017_09_18_ethical_considerations_with_minors_0.pdf

- ✓ Guidelines developed by the EMPREMA Working Group on Ethics intended as an overview tool of the contents for assent/informed consent forms for all stakeholders (such as patients, sponsors and investigators) to support the conduct of high quality paediatric clinical trials in the EU across all paediatric age groups from birth to less than 18 years of age

https://www.ema.europa.eu/en/documents/other/assent/informed-consent-guidance-paediatric-clinical-trials-medicinal-products-europe_en.pdf

460 It is important to verify the national legislation and guidelines applicable in your own setting
461 regarding the need to obtain assent or consent from children and/or authorisation from
462 parents.

In order to ensure that children can exercise their right to consent, hospitals and other health services should put in place different measures, including:

- Adopting a hospital or health service consent policy, reflecting national legislation
- Ensuring that health professionals are aware of this policy
- Promoting capacity building of professionals to ensure they have the knowledge and competencies to engage and involve children in the decision-making process in a meaningful way and that they ask for their consent to treatment whenever it is required
- Engaging with children regularly to assess existing policies and practices, as a way to improve these and also children's experiences of care.

[Example of a hospital information/assent/consent policies concerning children]

IV. Engaging with children as a means to improve individual decision-making processes

International child rights standards emphasise that children's right to participation in health care includes both their participation in decisions affecting their own health, but also their participation in the development, assessment and improvement of healthcare services. The latter may be described as *collective or group participation*. Similar to the elements identified for the individual processes, children participating in collective decision-making processes need to be empowered adequately to be able to fully participate.³⁶

Children may participate collectively to improve the policies of healthcare institutions and practices of professionals on a number of issues.³⁷ In the specific case of the participation of children in individual decision-making processes, children may help to:

- ▶ Assess current practices by professionals in a given healthcare service, for example, the extent to which they are able to provide information in an effective manner;
- ▶ Identifying ways to improve existing policies and practices in hospitals and health services;
- ▶ Design specific information and materials targeting children;
- ▶ Help designing more adequate policies on individual participation of children in individual decision-making processes.

Engaging children in an evaluation of existing processes can identify opportunities to further improve current practices.

Collective actions to be undertaken with a participatory methodology to improve of individual decision-making processes:

- ✓ Developing adequate policies
- ✓ Routine inclusion of children in assessment of experience and quality of care
- ✓ Creating appropriate environment, spaces and opportunities
- ✓ Building staff capacity and training health professionals/families

³⁶ Treseder P (1997) in Creative Commons *Participation Models: A Chase through the Maze* 2 ed (2012)

³⁷ In addition to the improvement of policies and practices concerning decision-making processes, children may participate as a group to: Inform the design of a new paediatric hospital or department; Assess current services provided by a healthcare service; Contribute to identifying measures to improve existing hospitals and health services; Design specific information and assent materials targeting children; Help designing research protocols providing their feedbacks on methods and tools; Raise awareness of specific issues linked to healthcare and biomedical research; and Influence strategic priorities, planning and resource allocation.

- ✓ Supporting advisory groups, consultative bodies and collective self-advocacy initiatives
- ✓ Promoting age-tailored information, training and “play to learn” activities
- ✓ Promoting awareness campaigns, survey, debates and research projects
- ✓ Developing evaluation mechanisms
- ✓ Setting up child friendly complaints

495 Children may provide their views on services through different ways, for example, “experience
 496 of care” feedback or satisfaction questions, surveys or research studies. Children’s collective
 497 or group participation may also be institutionalised in hospitals or other health services, for
 498 example, by setting up children’s councils, advisory groups or promoting other initiatives
 499 (forums, networks, summits...).

Awareness campaigns with children on Rare Diseases

On Rare Disease Day (February the 28th), TEDDY Kids and other Advisory Groups participated in the “Global Chain of Lights and Share Your Colours” campaign (<https://www.rarediseaseday.org/downloads/lightupforrare/>) aimed at raising awareness and taking action to support children with rare diseases. Participants were asked to take multiple photos with their cell phones while they were illuminated by the coloured screen of their computer provided by the site www.rarediseaseday.org. The final video was then developed and finalized by the TEDDY team in collaboration with the KIDS Bari young members and is available at this link: Children also prepared several slogans (“My being special has lighted me up”, “They are not their disease”, “They are not numbers... they are amazing and stunning teens in love with life and passionate about science! Aren't they amazing? Their smiles are our hope for a better future!”).
<https://www.facebook.com/149882855953928/videos/3097720380505087>.

Young Persons Advisory Groups (YPAGs) role and activities having an impact on individual decision-making process

YPAGs have already been set up across Europe and at international level to underpin clinical trials. The YPAGs include young people aged between 8-19 years (although some groups have older young adults up to the age of 21) who are patients, regular attenders at hospital, and/or healthy youths having an interest in science and healthcare. YPAGs are predominantly facilitated by a professional involved in a clinical research facility, children’s hospital, or academic institution. They are recruited by means of schools, associations, hospitals and the patients’ and families associations, and were selected according to their motivation and interest in being involved in this kind of empowerment activities. YPAGs provide a platform for children and young people to have a voice, share their opinions, and apply their experience to a variety of issues relevant for biomedical research

[Further examples from Sweden kids, Kids Barcelona, Kids France, EYPAG, iCan, TEDDY Kids and iCAN summit]

Consultative initiatives

Consulting young children on the quality of services In Ireland, throughout 2017, the Children and Young People's Services Committee of Roscommon ran consultation sessions with groups of children aged 3 ½ - 4 years in the county to improve their services. The theme of the consultation was 'What do young children in Roscommon think would help them to live healthier, happier and more active lives?' The consultation involved preparation with children, families and professionals and was carried out through games and interactive activities. Some of children's demands included opportunities to play outside, 'hugs and cuddles' from important adults, enough sleep and water, and they are reminded and helped to brush their teeth. The results were synthesized through the metaphor of a volcano representing the things children said they needed every day, often, and sometimes. The 'Happy & Healthy Volcano' was used to inform the Early Years' Health and Well-being Plan for Roscommon and was shared with all the county's early childhood services.

Research project on eHealth as an aid for facilitating and supporting self-management for children in Sweden

The multidisciplinary research project on eHealth as an aid for facilitating and supporting self-management for children with long-term childhood illness. The overall aim of the project is to 1) Evaluate, advance and implement models of eHealth to improve self-management for children and adolescents with or at risk for long-term illness and their families for better allocation of family-, healthcare- and societal resources; 2) Increase the knowledge of cultural factors, implementation strategies and models to successfully implement eHealth in paediatric care; 3) Enhance the integration of research findings into care services and society by supporting healthcare professionals provide evidence-based care and better communicating research results.

The project focus is on the needs of children and families and how they participate in care and decisions when a child is ill, focusing on transitions in paediatric care, for example to home care and how the family can be supported with the help of various e-health interventions. It also focuses on preventive for improved family health such as obesity and physical activity.

The research generates knowledge about the short and long-term impacts of chronic childhood illness on the whole family, and how care and treatment affect the family's daily life.

Child and young person's (CYP) patient involvement in customisation improvements within a network of paediatric hospitals in Sweden

The network aims at improving quality of paediatric care, with the involvement of young patients, parents and staff. It has its foundation in a set of quality criteria derived from law, professional standards, knowledge of care environment, and the expressed opinions of CYPs (children from primary and high schools) from Patient Reported Experience Measure (PREM) surveys and young adviser groups (YPAGs).

The health facility self-evaluates its practices and includes CYPs and families in the process. The evaluation reports are developed by receiving feedback from CYP and families, and are exchanged with a similar clinic to do a thorough mutual collegial examination. When the final reports have been exchanged the clinics have a clear idea of what to improve, including improvements to be done with CYP. In terms of methodology, routines for how staff involve CYP patients in planning their care, communicating their opinions and preparing for medical measures or interventions are required. The clinic

carrying out the evaluation on its practice has to demonstrate how the staff has these skills. Every clinic member of the network is encouraged to develop their own methods of participation for CYP, based on resources, size, and previous experience in the area. The network offers advice and sample questions to be used, for example in PREM surveys, and methods for involving CYP in care environment surveys.

VI. Terminology / definitions

For the purpose of the present guide:

- **“Child”** refers to any person under the age of 18 years
- **“Participation”** is about individuals and groups of individuals having the right, the means, the space, the opportunity and, where necessary, the support to freely express their views, to be heard and to contribute to decision making on matters affecting them, their views being given due weight in accordance with their age and maturity. Participation is also *an ongoing process of children’s expression and active involvement in decision-making at different levels in matters that concern them. It requires information-sharing and dialogue between children and adults based on mutual respect*³⁸
- **“Parent”** is understood as an “individual biologically and/or emotionally linked to the child”, which typically includes “the provision of care, concern and affection”. For the purpose of this guide, the term “parent” is used in relation to the “legal parent”, i.e. the person holding parental responsibility, unless stated otherwise. Where a parent does not or no longer hold parental responsibility, the term may need to be defined specifically in terms of biological or social and affective parenthood.
- **“Holder of parental responsibility”** refers to parents and other persons or bodies entitled to exercise some or all parental responsibilities, according to national law.
- **Parental responsibility** refers to all rights and duties relating to the person or the property of a child, which are given to a natural or legal person by a decision, by law or by an agreement having legal effect, including the right and duty to complement the limited legal capacity of the child and rights of access³⁹.
- **“Informed Consent”** is a process enabling a person able to consent to take an informed decision on an intervention after being duly informed of its nature, significance, implications and risks. With regard to consent to certain interventions, additional elements are required. For example, informed consent to participate in a research project has to be given expressly, specifically and be written, dated and signed; if the person concerned is unable to write oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation.

Where the person concerned is, according to national law, not capable of giving consent, the **authorisation** of his or her legal representative, or of the authority, the person or body designated by law, is required for any intervention on the person concerned.

³⁸ UNICEF, Every Childs Right to be Heard, Report 2011, <https://resourcecentre.savethechildren.net/node/5259/pdf/5259.pdf>

³⁹ Council of Europe (2021) Feasibility study of a legal instrument on the protection of the best interests of the child in domestic law proceedings by public authorities to limit parental responsibilities or place a child in care <https://rm.coe.int/cj-enf-ise-2021-08b-feasibility-study-best-interests-care-proceedings-/1680a342d3>

536 The legal representative, the authority, the person or body concerned shall be given
537 the **relevant information**, meaning information that enables him/her to exercise his or
538 her rights fully unless the provision of such information were contrary to the [best
539 interests] of the child.⁴⁰

540 ▪ **To empower** is to help children exercise their rights and develop and voice their
541 opinions.⁴¹

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⁴⁰ Council of Europe, European Convention on the Exercise of Children's Rights, European (1996) Treaty Series No. 160, Strasbourg, 25 January 1996, Article 2.d. Text in brackets added by the author

⁴¹ Sale E, Bellamy N, Springer JF, Wang MQ. (2008) Quality of provider-participant relationships and enhancement of adolescent social skills. J Prim Prev vol.29:263–78.