European Network of Paediatric Research at the European Medicines Agency

23 October 2019

Informed Consent for Paediatric Clinical Trials in Europe 2015[i]

Developed by the Working Group on Ethics

	Consent / assent from child		Consent from parent(s) / guardian(s)	General informed consent information	
Country	**Legal age of consent**	**Mandatory / suggested age ranges defined for assent (or consent if assent not used)**	**Number of required signatories**	**Official language requirements**	**IC template(s) / guidelines / information sources**
Austria[1]	18 years	8-13 years EC may require younger assents	One parent	German	http://www.medunigraz.at/ethikkommission/Forum/index.htm http://www.ethikkommissionen.at/ http://www.uibk.ac.at/strafrecht/scheil/scheil-einfuehrung-in-die-arzneimittelpruefung-bei-kindern-und-jugendlichen---kks--kids-ip.pdf For clinical trials with an IMP: AMG §42 applies. Legal age of consent is 18. One parent has to sign ("Erziehungsberechtigter"). For clinical trials with an MD: MPG §51 applies. Legal age of consent is 18. One parent has to sign ("Erziehungsberechtigter").

[1] Data for Austria were updated in May 2016.

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Belgium	18 years	4-11 years (some sites do not use under 12 years) 12-14 years 14-17 years	One parent at recruitment, but both parents at some point for signatures	Dutch, French German at site request	http://www.fagg-afmps.be/en/human_use/medicines/medicines/research_development/ethic_committee/templates_informed_consent/ Do not have paediatric templates
Bulgaria	18 years	6-11 years 12-14 years 14-17 years – use own consent + parental signature also required	Both parents	Bulgarian	No national EC websites available in English Bulgarian Drug Agency -> clinical trials http://en.bda.bg/index.php?option=com_content&view=category&layout=blog&id=14&Itemid=34
Croatia	Nothing specified	Nothing specified	Nothing specified	Croatian	Agency for Medicinal Products and Medical Devices of Croatia -> Central Ethics Committee http://www.almp.hr/?ln=en&w=o_SEPu Information on clinical trials not available in English.
Czech Republic[2]	18 years	12-14 years 15-17 years	Both parents. Only by one parent if the other parent is not listed in the child's birth certificate, has died or is younger than 18 years.	Czech. Where the child's parents (or one of them) are foreign nationals, the information sheet shall be presented in bilingual format.	State Institute for Drug Control -> Details of clinical trials / Guidelines and Forms / KLH-22 version 4 http://www.sukl.eu/medicines/klh-22-version-4

[2] Data for the Czech Republic were updated in October 2019

Denmark	18 years	15-17 years- proxy consent	Both parents Exception - no parents if aged 15-17 and non-interventional no risk study (EC dispensation required)	Danish	The National Committee on Health Research Ethics -> Guidelines about Notification http://www.cvk.sum.dk/CVK/Home/English.aspx http://cvk.sum.dk/English/guidelinesaboutnotification.aspx -> 4.4. Medicinal product trials and clinical investigations of medicinal devices involving legally incompetent subjects; 4.4.1 Trials with children and young people under the age of 18 http://cvk.sum.dk/English/guidelinesaboutnotification.aspx#Afsnit%205.0 Act on Research Ethics Review of Health Research Projects
Estonia	18 years	0-7 years 7-17 years- mandatory	Both parents	Estonian	State Agency of Medicine -> Clinical Trials -> Conditions and Procedure for Conducting Clinical Trials of Medicinal Products http://www.ravimiamet.ee/en/clinical-trials-medicinal-products-estonia
Finland	15 years	Written separate consent as soon as child is literate; under 15 years own consent + parental consent. 15-17 years own consent + parental notification if minor can understand the significance of research + direct health benefit is expected	Parent or legal guardian and the child, when they are literate need to sign the consent. One parent by the law, but the other one can be informed (-both can sign if they want).	Finnish, Swedish	Medicines Research Act 488/1999 Medical Research Decree 986/1999 Additional info: FINPEDMED guidelines; legal and ethical regulation – templates for age groups 6-17 and parents. Regulatory requirements for clinical trials in Finland Picture Cards to support IC process

France	18 years	Based on EC – usually 2 or 3 age groups 4-6 years 7-12 years 13-17 years Picture ICFs for young children	Both Parents	French	Comité de Protection des Personnes Sud-Méditerranée II : http://www.cpp-sudmed2.fr/Information-et-autorisation-des?lang=fr National Consultative Ethics Committee for Health and Life Sciences: http://www.ccne-ethique.fr/en
Germany[3]	18 years	7-11 years 12-16 years 17 years own consent + parental consent required	Both Parents	German	Permanent Working Party of Research Ethics Committees (Arbeitskreis der Medizinischen Ethik-Kommissionen) German Ethics Council http://www.ethikrat.org/ - no information for Clinical Trials Landesärztekammer Brandenburg – information available ONLY in German. https://www.laekb.de/ ICF Guidance https://www.laekb.de/files/146A97FF999/AMG_Patienteninfo_Kinder_7bis11.pdf

[3] Data for Germany were updated in November 2016

Hungary	18 years	Under 6 years 6-10 years 11-14 years 15-17 years	One Parent	Hungarian	National Institute of Pharmacy and Nutrition -> Laws and regulations (only available in Hungarian) -> Miniszteri rendeletek http://ogyei.gov.hu/search/index.php?searchPhrase=decree&from=10 http://www.ogyei.gov.hu/magyar_jogszabalyok/ -> Decree 35/2005 (VIII. 26.) of the Minister of Health on the clinical trial and application of correct clinical practices of investigational medicinal products intended for use in humans 7§ Clinical trials conducted on minors http://net.jogtar.hu/jr/gen/getdoc.cgi?docid=A0500035.eum
Iceland	18 years	Under 12 years	One parent – the EC can request both parents' signature in some cases.	Icelandic or English. The study objective in Icelandic. Materials in Icelandic. (for studies involving groups of other ethnicity, an appropriate language is required)	The National Bioethics Committee (http://www.vsn.is/en/node/189) The Parliament; http://www.althingi.is/english -> http://www.althingi.is/lagasafn/log-samthykkt-a-althingi/ -> The Act of Law, No. 44/2014, on scientific research within the health sector defines the conditions for biomedical research and the role of the bioethics committees. http://www.althingi.is/lagas/nuna/2014044.html Several laws and regulations on data protection, medicines, biobanks and health information collections (2014), etc.

Ireland	16 years (Clinical trials) 18 years (all other research)	7 years, or according to capacity of child	One Parent	English	List of Research Ethics Committees for clinical trials of IMP: http://health.gov.ie/european-communities-clinical-trials-on-medicinal-products-for-human-use-regulations-2004/ Research Ethics Committee Standard Application Form: http://www.molecularmedicineireland.ie/research_ethics National Consent Policy: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/National_Consent_Policy/consenttrainerresource/trainerfiles/NationalConsentPolicyDOC.html Clinical Trial Regulation: S.I. No. 190/2004 - European Communities (Clinical Trials on Medicinal Products For Human Use) Regulations, 2004 http://www.irishstatutebook.ie/2004/en/si/0190.html
Italy	18 years	6-10 years 11-14 years 15-17 years with own signature No official mandatory age(s) for assent. Different age tailored assents are submitted voluntarily, and are evaluated by the ECs.	Both parents	Italian	The Italian Medicines Agency http://www.agenziafarmaco.gov.it/en/content/clinical-trials the Italian regulation on CTs include the following: D.lgs 211/2003 http://www.agenziafarmaco.gov.it/sites/default/files/decreto_24062003_inglese.pdf DM 21/12/07 https://www.agenziafarmaco.gov.it/ricclin/sites/default/files/files_wysiwyg/files/Normativa/MD_21_December_2007_CTAform_English.pdf

Latvia	18 years	0-7 years 7-17 years	One parent or legal representative	Latvian	State Agency of Medicines of the Republic of Latvia -> Clinical Trials and non-interventional trials -> legislation http://www.zva.gov.lv/?setlang=en -> http://www.zva.gov.lv/?id=396&sa=396&top=386 -> http://www.zva.gov.lv/index.php?id=381&sa=381&top=333&lang http://www.zva.gov.lv/doc_upl/MK_not_289_English_02062010.pdf
Lithuania	18 years	No set ages	Both parents	Lithuanian	The Lithuanian Bioethics Committee -> Biomedical Research -> favourable opinion on Clinical Drug Trial http://bioetika.sam.lt/index.php?3202747546 Informed Consent http://bioetika.sam.lt/index.php?3221858831 -> http://bioetika.sam.lt/index.php?577320631 – information available only in Lithuanian http://bioetika.sam.lt/index.php?3202747546
Malta	18 years	6-17 years	Parents or legal representative - Practice – both parents	One of the official languages of Malta (e.g. Maltese) or in a language understanda-ble to the clinical trial subject and, or his legal representative.	Malta Health Ethics Committee https://health.gov.mt/en/appbodies/hec/Pages/Links.aspx Maltese Clinical Trials Regulations 2004 (LN490 of 2004) MEDICINES ACT, 2003 (ACT NO. III OF 2003); http://justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=16860&l=1

Netherlands[4]	16 years	12-15 years with own signature (consent) is required	Both parents	Dutch	Central Committee on Research Involving Human Subjects (CCMO) -> Human Subject -> Informed Consent – information available only in Dutch. http://www.ccmo.nl/en/ -> http://www.ccmo.nl/en/minors
Norway	18 years	12-17 years with own signature is required.	Main rule: both parents sign the consent form if they have parental responsibility for the child.	Norwegian	The Norwegian National Research Ethics Committees -> Clinical Trials -> Regulations https://www.etikkom.no/en/ethical-guidelines-for-research/ http://www.legemiddelverket.no/English/Clinical_trials/Regulations/Documents/Norwegian%20regualtion%20for%20Clinical%20Trials.pdf National database for Laws and Acts -> Lov om medisinsk og helsefaglig forskning (helseforskningsloven) – information available only in Norwegian. https://lovdata.no/dokument/NL/lov/2008-06-20-44?q=helseforskning Act on medical and health research (Helseforsknings-loven) Guidance to Helseforsknings-loven (in Norwegian only) Additional info: Norwegian Medicines Agency: Website on clinical trials.
Poland	18 years	6-11 years 12-15 years 16-17 years	One parent Practice – both parents	Polish	http://www.eurecnet.org/information/poland.html No national EC websites available in English

[4] Data for the Netherlands were updated in June 2017

Portugal[5]	18 years	0-8 years 8-12 years 12-15 years 16-17 years use adult consent and LAR	Both Parents	Portuguese	http://www.eurecnet.org/information/portugal.html CEIC – National Ethics Committee for Clinical Research http://www.infarmed.pt/portal/page/portal/CEIC/English No national regulations/acts available in English Legislation relating to consenting in Portugal (in Portuguese) http://www.ceic.pt/documents/20727/57550/Documento+Orientador+CEIC+sobre+Consentimento+Informado+%28CI%29+para+participa%C3%A7%C3%A3o+em+ensaios+cl%C3%ADnicos+em+pediatria/15385b28-a792-4f2b-9a57-efc184f7951c
Romania	18 years	Under 6 years 6-10 years 11-14 years 15-18 years	Both Parents	Romanian	National Ethics Committee of Romania http://www.adsm.ro/ro/comisia+nationala+de+bioetica+a+medicamentului+si+a+dispozitivelor+medicale# No information available in English
Scotland	16 years	0-5 years 6-10 years 11- 15 years IC with own signature under 16 years, if they have capacity. Otherwise assent is taken	One parent	English	NRES Guidance http://www.hra-decisiontools.org.uk/consent/principles-children.html and http://www.ukctg.nihr.ac.uk/default.aspx

[5] Data for Portugal were updated in June 2018

Slovakia	n.a.	n.a.	n.a.	Slovakian	The State Institute for Drug Control (SIDC) -> Clinical Trials -> Instructions http://www.sukl.sk/en?page_id=256 -> http://www.sukl.sk/en/clinical-trials/instructions?page_id=2821 No national regulations/acts available in English
Slovenia	18 years	9 years - assent 15 years - with own signature	One parent	Slovenian	Republic of Slovenia National Medical Ethics Committee -> http://kme-nmec.si/ - only front page No additional information available.
Spain[6]	18 years	0-11 years 12-17 years with own signature	One Parent	Spanish	The Agencia Española de Medicamentos y Productos Sanitarios (AEMPS); A state agency within the Spanish Ministry of Health, Social Services and Equality -> Medicines for Human use - > Clinical Research with Medicines http://www.aemps.gob.es/en/investigacionClinica/medicamentos/home.htm The Ministry of Health, section about regulation of clinical trials: http://www.aemps.gob.es/en/legislacion/espana/investigacionClinica/ensayos.htm Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products, Ethics Committees for Investigation with medicinal products and the Spanish Clinical Studies Registry (English version)

[6] Data for Spain were updated in January 2018

Sweden	18 years	Written separate consent as soon as child is literate 6-10 years 11-14 years 15-17 years with own signature	Both parents and the child when literate, need to sign the consent	Swedish	The Central Ethical Review Board -> Documents -> Information for Research Participants http://www.epn.se/en/start/the-organisation/ -> http://www.epn.se/en/start/central-ethical-review-board-documents/ -Etikprövningslagen 2008. Regulatory requiement for clinical trials LVFS 2011:19 Läkemedelslagen - 1992 Biobank law- 2002 Personal Data Act 1998 National Medicines Agency -> Legislation -> Codes of Statutes -> 1996:17 Clinical trials of medicinal products https://lakemedelsverket.se/english/ -> https://lakemedelsverket.se/english/overview/Legislation/Codes-of-statutes/
UK	16 years	0-5 years 6-10 years 11- 15 years	One parent	English	NRES Guidance; http://www.hra-decisiontools.org.uk/consent/principles-children.html and http://www.ukctg.nihr.ac.uk/default.aspx

[i] The accuracy of this data cannot be guaranteed but it will be updated regularly on the basis of systematic review of comments received from all stakeholders and the ToolKit users. The reason for this possible non-accuracy is the non-uniform system of the official sources for this data, including language barriers and insufficient public availability of the requirements on public websites of national ethic committees and/or authorities.