Informed Consent for Paediatric Clinical Trials in Europe 2015

Developed by the Working Group on Ethics

<table>
<thead>
<tr>
<th>Country</th>
<th>Legal age of consent</th>
<th>Mandatory / suggested age ranges defined for assent (or consent if assent not used)</th>
<th>Number of required signatories</th>
<th>Official language requirements</th>
<th>IC template(s) / guidelines / information sources</th>
</tr>
</thead>
</table>
| Austria¹  | 18 years             | 8-13 years  
EC may require younger assents                                                   | One parent                    | German                      | [http://www.medunigraz.at/ethikkommission/Forum/index.htm](http://www.medunigraz.at/ethikkommission/Forum/index.htm)  
[http://www.ethikkommissionen.at/](http://www.ethikkommissionen.at/)  
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.
<table>
<thead>
<tr>
<th>Country</th>
<th>Age Limits</th>
<th>Consent Requirements</th>
<th>Language(s)</th>
<th>EC Website Details</th>
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</thead>
</table>
| 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  
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 Republic²    | 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  
<table>
<thead>
<tr>
<th>Country</th>
<th>Minimum Age</th>
<th>Additional Age Range</th>
<th>Consent Process</th>
<th>Language</th>
<th>Relevant Documents</th>
</tr>
</thead>
</table>
| Denmark | 18 years    | 15-17 years proxy consent | Both parents | 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  
| 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 |
<table>
<thead>
<tr>
<th>Country</th>
<th>Age</th>
<th>Groups</th>
<th>Consent</th>
<th>Language</th>
<th>Website/Link</th>
</tr>
</thead>
</table>
| France    | 18 years | Based on EC – usually 2 or 3 age groups  
4-6 years  
7-12 years  
13-17 years  
| Germany³ | 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/  

³ Data for Germany were updated in November 2016
<table>
<thead>
<tr>
<th>Country</th>
<th>Age</th>
<th>Consent Details</th>
<th>Language</th>
<th>Legal References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iceland</td>
<td>18 years</td>
<td>Under 12 years: One parent – the EC can request both parents’ signature in some cases.</td>
<td>Icelandic or English. The study objective in Icelandic. Materials in Icelandic. (for studies involving groups of other ethnicity, an appropriate language is required)</td>
<td>The National Bioethics Committee <a href="http://www.vsn.is/en/node/189">http://www.vsn.is/en/node/189</a> The Parliament; <a href="http://www.althingi.is/english">http://www.althingi.is/english</a> -&gt; <a href="http://www.althingi.is/lagasafn/log-samthykkt-a-althingi/">http://www.althingi.is/lagasafn/log-samthykkt-a-althingi/</a> 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 <a href="http://www.althingi.is/lagas/nuna/2014044.html">http://www.althingi.is/lagas/nuna/2014044.html</a> Several laws and regulations on data protection, medicines, biobanks and health information collections (2014), etc.</td>
</tr>
<tr>
<td>Country</td>
<td>Age Requirements</td>
<td>Consent Process</td>
<td>Language</td>
<td>Resources</td>
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</table>
| 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/](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](http://www.molecularmedicineireland.ie/research_ethics)  
| Italy   | 18 years 6-10 years 11-14 years 15-17 years with own signature | Both parents | Italian | The Italian Medicines Agency [http://www.agenziafarmaco.gov.it/en/content/clinical-trials](http://www.agenziafarmaco.gov.it/en/content/clinical-trials)  
the Italian regulation on CTs include the following:  
<table>
<thead>
<tr>
<th>Country</th>
<th>Minimum Age</th>
<th>Maximum Age</th>
<th>Informed Consent</th>
<th>Language</th>
<th>Approval Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>Age</td>
<td>Consent Requirements</td>
<td>Language</td>
<td>Website</td>
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</table>
| Netherlands | 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.  
| 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 |

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4 Data for the Netherlands were updated in June 2017
<table>
<thead>
<tr>
<th>Country</th>
<th>Age</th>
<th>Years</th>
<th>Consent Clarification</th>
<th>Language</th>
<th>Country Regulations/Website</th>
</tr>
</thead>
</table>
| Portugal  | 18    | 0-8   | 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    | Under 6 | Both Parents        | Romanian  | National Ethics Committee of Romania  
http://www.adsm.ro/ro/comisia+nationala+de+biologia+a+medica+mentului+si+a+dispozitivelor+medicale#  
No information available in English |
| Scotland  | 16    | 0-5   | 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
<table>
<thead>
<tr>
<th>Country</th>
<th>Minimum Age for Consent</th>
<th>Minimum Age for Assent</th>
<th>Parental Involvement</th>
<th>Language</th>
<th>Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slovenia</td>
<td>18 years</td>
<td>9 years - assent</td>
<td>One parent</td>
<td>Slovenian</td>
<td>Republic of Slovenia National Medical Ethics Committee -&gt; <a href="http://kme-nmec.si/">Link</a> - only front page No additional information available.</td>
</tr>
</tbody>
</table>

6 Data for Spain were updated in January 2018
<table>
<thead>
<tr>
<th>Country</th>
<th>Age</th>
<th>Consent Process</th>
<th>Language</th>
<th>Consent Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweden</td>
<td>18 years</td>
<td>Written separate consent as soon as child is literate</td>
<td>Swedish</td>
<td>Both parents and the child when literate, need to sign the consent</td>
</tr>
<tr>
<td></td>
<td>6-10 years</td>
<td>11-14 years</td>
<td>15-17 years with own signature</td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>16 years</td>
<td>0-5 years</td>
<td>One parent</td>
<td>English</td>
</tr>
<tr>
<td></td>
<td>6-10 years</td>
<td>11-15 years</td>
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</tbody>
</table>

1 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.