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                                                                      | One parent                    | German                        | http://www.medunigraz.at/ethikkommission/Forum/index.htm  
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</th>
<th>Consent Requirements</th>
<th>Language(s)</th>
<th>Websites</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>The general rule with respect to third parties acting in good faith: one parent</td>
<td></td>
<td>Do not have paediatric templates</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(is deemed to act with the agreement of the other parent)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>If there are indications of parental disagreement: both parents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulgaria</td>
<td>18 years</td>
<td>6-11 years</td>
<td>Bulgarian</td>
<td>No national EC websites available in English</td>
</tr>
<tr>
<td></td>
<td>18 years</td>
<td>12-14 years</td>
<td></td>
<td>Bulgarian Drug Agency -&gt; clinical trials</td>
</tr>
<tr>
<td>Croatia</td>
<td>Nothing specified</td>
<td>Nothing specified</td>
<td>Croatian</td>
<td>Agency for Medicinal Products and Medical Devices of Croatia -&gt; Central Ethics Committee</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><a href="http://www.almp.hr/?ln=en&amp;w=o_SEPu">http://www.almp.hr/?ln=en&amp;w=o_SEPu</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Information on clinical trials not available in English</td>
</tr>
</tbody>
</table>

---

2 Data for Belgium were updated in June 2023
<table>
<thead>
<tr>
<th>Country</th>
<th>Minimum Age</th>
<th>Maximum Age</th>
<th>Consent Process</th>
<th>Language</th>
<th>Ethics Committee</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Czech Republic</td>
<td>18 years</td>
<td>12-14 years</td>
<td>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.</td>
<td>Czech</td>
<td>State Institute for Drug Control -&gt; Details of clinical trials / Guidelines and Forms / KLH-22 version 4</td>
<td><a href="http://www.sukl.eu/medicines/klh-22-version-4">http://www.sukl.eu/medicines/klh-22-version-4</a></td>
</tr>
<tr>
<td>Czech</td>
<td>15-17 years</td>
<td></td>
<td>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.</td>
<td>Czech</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Denmark   | 18 years    | 15-17 years | 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   | 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 |
|           |             | 7-17 years  |                                             |             |                                                                                                          |                                                                                                 |
|           |             | mandatory   |                                             |             |                                                                                                          |                                                                                                 |

3 Data for the Czech Republic were updated in October 2019
<table>
<thead>
<tr>
<th>Country</th>
<th>Age</th>
<th>Consent Process</th>
<th>Language</th>
<th>Additional Info</th>
</tr>
</thead>
</table>
| 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 | 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  
<table>
<thead>
<tr>
<th>Country</th>
<th>Age Group</th>
<th>Consent Required</th>
<th>Parental Consent</th>
<th>Language</th>
<th>Information Source</th>
</tr>
</thead>
</table>

4 Data for Germany were updated in November 2016
<table>
<thead>
<tr>
<th>Country</th>
<th>Age Requirement</th>
<th>Age Requirement (Research)</th>
<th>Parental Consent</th>
<th>Material Language</th>
<th>Key Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>Age Range</td>
<td>Parental Involvement</td>
<td>Language</td>
<td>Website/Link</td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td>-----------</td>
<td>----------------------</td>
<td>----------</td>
<td>--------------</td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>18 years</td>
<td>6-10 years 11-14 years 15-17 years with own signature</td>
<td>Both parents</td>
<td>Italian</td>
<td>The Italian Medicines Agency <a href="http://www.agenziafarmaco.gov.it/en/content/clinical-trials">http://www.agenziafarmaco.gov.it/en/content/clinical-trials</a></td>
</tr>
<tr>
<td>Country</td>
<td>Age Range</td>
<td>Parental Consent</td>
<td>Language</td>
<td>Committee/Regulations</td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>-----------</td>
<td>------------------</td>
<td>----------</td>
<td>-----------------------</td>
<td></td>
</tr>
</tbody>
</table>

\(^5\) Data for the Netherlands were updated in June 2017
<table>
<thead>
<tr>
<th>Country</th>
<th>Age</th>
<th>Consent Requirements</th>
<th>Language</th>
<th>Additional Information</th>
</tr>
</thead>
</table>
| Norway | 18 years | 12-17 years with own signature is required. | 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=helseforskningsloven  
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 | Polish | http://www.eurecnet.org/information/poland.html  
No national EC websites available in English |
<table>
<thead>
<tr>
<th>Country</th>
<th>Age</th>
<th>Eligibility Details</th>
<th>Parents/Consent</th>
<th>Language</th>
<th>Website/Other Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portugal</td>
<td>18 y</td>
<td>0-8 years; 8-12 years; 12-15 years; 16-17 years use adult consent and LAR</td>
<td>Both Parents</td>
<td>Portuguese</td>
<td><a href="http://www.eurecnet.org/information/portugal.html">http://www.eurecnet.org/information/portugal.html</a> CEIC – National Ethics Committee for Clinical Research <a href="http://www.infarmed.pt/portal/page/portal/CEIC/English">http://www.infarmed.pt/portal/page/portal/CEIC/English</a> No national regulations/acts available in English Legislation relating to consenting in Portugal (in Portuguese) <a href="http://www.cec.pt/documents/20727/57550/Documento+Orientador+CEIC+sobre+Consentimento+para+participa%C3%A7%C3%A3o+em+ensaios+cl%C3%ADnicos+em+peditria/15385b28-a792-4f2b-9a57-efc184f7951c">http://www.cec.pt/documents/20727/57550/Documento+Orientador+CEIC+sobre+Consentimento+para+participa%C3%A7%C3%A3o+em+ensaios+cl%C3%ADnicos+em+peditria/15385b28-a792-4f2b-9a57-efc184f7951c</a></td>
</tr>
<tr>
<td>Romania</td>
<td>18 y</td>
<td>Under 6 years; 6-10 years; 11-14 years; 15-18 years</td>
<td>Both Parents</td>
<td>Romanian</td>
<td><a href="http://www.adsm.ro/ro/comisia+nationala+de+bioetica+a+medicina+mentului+si+a+dispozitivele+medicale">http://www.adsm.ro/ro/comisia+nationala+de+bioetica+a+medicina+mentului+si+a+dispozitivele+medicale</a> No information available in English</td>
</tr>
<tr>
<td>Scotland</td>
<td>16 y</td>
<td>0-5 years; 6-10 years; 11-15 years; IC with own signature under 16 years, if they have capacity. Otherwise assent is taken</td>
<td>One parent</td>
<td>English</td>
<td><a href="http://www.hra-decisiontools.org.uk/consent/principles-children.html">http://www.hra-decisiontools.org.uk/consent/principles-children.html</a> and <a href="http://www.ukctg.nihr.ac.uk/default.aspx">http://www.ukctg.nihr.ac.uk/default.aspx</a></td>
</tr>
</tbody>
</table>

---

6 Data for Portugal were updated in June 2018
<table>
<thead>
<tr>
<th>Country</th>
<th>Age Consenting</th>
<th>Age Assenting</th>
<th>Parental Involvement</th>
<th>Language</th>
<th>Key Contact/Website</th>
</tr>
</thead>
</table>
| Slovakia | n.a.           | n.a.          | n.a.                 | Slovakian | The State Institute for Drug Control (SIDC) -> Clinical Trials -> Instructions  
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. |
| Spain⁷ | 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  
The Ministry of Health, section about regulation of clinical trials:  
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) |

⁷ Data for Spain were updated in January 2018
<table>
<thead>
<tr>
<th>Country</th>
<th>Age Group</th>
<th>Consent Process</th>
<th>Language</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>16 years</td>
<td>0-5 years 6-10 years 11- 15 years</td>
<td>English</td>
<td>NRES Guidance; <a href="http://www.hra-decisiontools.org.uk/consent/principles-children.html">http://www.hra-decisiontools.org.uk/consent/principles-children.html</a> and <a href="http://www.ukctg.nihr.ac.uk/default.aspx">http://www.ukctg.nihr.ac.uk/default.aspx</a></td>
</tr>
</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.