**PIEC Application Form Annex G**

**– Research involving Minors (Individuals under the age of 21 years and who has never been married)**

**PROTOCOL TITLE:**

Text Field

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| --- |
| Please provide protocol specific information explaining how your proposed research project meets the following criteria. |

1. *Describe whether appropriate studies have been conducted on animals and adults first and the data available from such studies is available to assess risks to children participating in the research.*

Text Field

1. *Please justify the need to involve minors. Can the research question be answered through alternative means (e.g. involving adults only)?*

Text Field

*Please check all that apply. :*

*[ ]  Category 1 – Research that does not involve more than minimal risk.*

*[ ]  Category 2 – Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subject.*

 *The research must fulfill all of the following:*

 *[ ]  The risk is justified by the anticipated benefit to the subjects;*

 *Please justify:* Text Field

*[ ]  Category 3 – Research involving greater than minimal risk and no prospect of benefit to the individual subject.*

*The research must fulfill all of the following:*

 *[ ]  The risk of the research presents no more than a minor increase over minimal risk;*

 *Please justify:* Text Field

*[ ]  The intervention or procedure presents experiences to the subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations, and;*

*Please justify:* Text Field

*[ ]  The intervention or procedure is likely to yield generalizable knowledge about the subject’s disorder or condition which is of vital importance for the understanding or the amelioration of the disorder or condition;*

*Please justify:* Text Field

1. *Describe how the relation of potential benefits to risks is at least as favorable to the minors as that presented by alternative approaches.*

Text Field

1. *Provisions for obtaining consent or assent from minors (Tick all applicable):*

*[ ]  Consent/Assent will be obtained from all minors aged 6 years old and above. Parental Consent will be obtained.*

*[ ]  Assent Form (for minor subjects aged 6 – 12)*

 *Please submit the appropriate document. The assent form should be written using simple words which an average 6-12 year old is able to understand.*

*[ ]  Parental Consent Form (for minor subjects aged 6 – 12)*

 *Please submit the appropriate document.*

*[ ]  Consent Form (for minor subjects aged 13 – 20) with provision for legal representative to sign*

 *Please submit the appropriate document.*

*Note: For research approved under Category 3, parental consent must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonable available, or when only one parent has legal responsibility for the care and custody of the child.*

*[ ]  Consent /Assent will not be obtained from the minors. Only Parental Consent will be obtained.*

*Please justify:* Text Field

*Note: For research approved under Category 3, parental consent must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonable available, or when only one parent has legal responsibility for the care and custody of the child.*

*[ ]  Parental Consent will not be obtained from the parents. Only consent from minors will be obtained.*

*Please justify:* Text Field

*[ ]  Neither the child’s Assent nor Parental Consent will be obtained. Please also submit Annex E - Waiver of Informed Consent*

*Please justify:* Text Field

1. *To specify the process by which legal authority of surrogates will be verified by investigator/study team.*

*The following individuals are legal representatives under the Singapore law to consent on behalf of the minor in the following order of priority:*

*i. A deputy appointed under the Mental Capacity Act (if minor lacks mental capacity);*

*ii. Adult Parent, or if no parent (e.g. deceased);*

*iii. Legal Guardian.*

*a. A guardian appointed under the Guardianship of Infants Act.*

*b. A person to whom the care of a child is committed under the Children and Young Persons Act.*

Text Field

1. *Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable subjects.*

Text Field