**PIEC Application Form Annex E**

**– Waiver of Informed Consent**

**PROTOCOL TITLE:**

Text Field

|  |
| --- |
| The PIEC may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent, if the PIEC finds that the study meets specific criteria. |

*Please select the type of request and complete all relevant sections under the selected requests.*

**A) Request for Waiver of Informed Consent:**

Please elaborate & justify if your study meets all of the following criteria:

1. *Does the research involve no more than minimal risk to the participants?*

Text Field

1. *Does the waiver of informed consent adversely affect the rights and welfare of the participants?*

Text Field

1. *Can the study be practicably carried out without the requested waiver or alteration of informed consent?*

Text Field

1. *Whenever appropriate, will the subjects or legally authorized representatives be provided with additional pertinent information after participation?*

Text Field

1. *Is the research subject to FDA / HSA regulations?*

Text Field

1. *Would the research be reasonably considered to contribute to the greater public good?*

Text Field

1. *Whenever appropriate, how would you justify that the process of obtaining consent will involve a disproportionate amount of effort and resources relative to the research requirements?*

Text Field

1. *Do you have any additional comments supporting the waiver of informed consent?*

Text Field

**B) Request for Alteration of Informed Consent:**

***Waiver of Documentation***

Please elaborate & justify if your study meets all of the following criteria:

1. *Is the consent document the only record linking the participant to the research?*

Text Field

1. *Is the principal risk of the research associated with potential harm resulting from a breach of confidentiality?*

Text Field

1. *Will each participant be asked whether he/she allows documentation linking them to the research, and the participants’ wishes will govern?*

Text Field

1. *Is the research subject to FDA regulations?*

Text Field

If the answer for Q4 is a ‘Yes’, please answer the following:

4.1) Does the research present no more than minimal harm to participants?

Text Field

4.2) Does the research involves any procedures for which written consent is normally required outside of the research context?

Text Field

1. *Will a written description regarding the research be provided to the participants for review? Please submit of a copy of the document.*

Text Field

***Emergency Situations***

Please elaborate & justify if your study meets all of the following criteria:

*Written certification by the Principal Investigator and 2 specialists not involved in the trial to*

*certify:*

*The potential subject is facing a life-threatening situation which necessitated*

*Intervention;*

*Comments:* Text Field

*That the person is unable to give his consent as a result of his medical condition;*

*Comments;* Text Field

*It is not feasible to request consent from that person or to contact the legally acceptable representative within the crucial period in which treatment must be administered*

*Comments:* Text Field

*Neither that person or his/her legally acceptable representative nor any members of that person’s family has informed the principal investigator of his/her objection to that person being used as a subject in a clinical trial*

*Comments:* Text Field

*The subject or subject’s legally acceptable representative will be informed about the research as*

*soon as possible and consent to continue will be requested for.*

*Comments:* Text Field