National Research Ethics Committee for Clinical Trials (NREC-CT)

Compensation for trial participants

**This template should be completed by sponsors of clinical trials and submitted through the Clinical Trial Information System, for any Part II submission where Ireland is the Member State concerned. This document provides information on the financial transactions and compensation provided for participants and those supporting participants in the trial.**

Please note that for trials, which involve incapacitated adults, minors or breast-feeding women, no incentive or financial inducement may be given to the participants or their legally designated representatives except for compensation of expenses or loss of earnings directly related to the participation in the trial. A small token of appreciation is not considered an incentive but needs to be explicitly evaluated and approved by the ethics committee. (Reference EMA Q&A Q9.1)

This template has been developed and endorsed by the EU Clinical Trials Expert Group to comply with Regulation (EU) No. 536/2014 Clinical Trials on Medicinal Products for Human Use and adapted by the National Office for Research Ethics Committees.

|  |  |
| --- | --- |
| 1. Will compensation be offered? (select one box) | |
| Yes | Please complete sections 2 & 3 |
| No | Please explain why not:  Click or tap here to enter text. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 2. Who will be offered compensation and in what form? (Select all boxes that apply) | | | | |
|  | Participants | Parent / Carer | Legal representative | Other individuals |
| Travel expenses |  |  |  |  |
| Accommodation expenses |  |  |  |  |
| Meal expenses |  |  |  |  |
| Loss of earnings |  |  |  |  |
| Monetary payment |  |  |  |  |
| Non-monetary payment |  |  |  |  |
| Other |  |  |  |  |
| If you enter “other individuals”, please specify who will be the recipient of the compensation or the type of compensation: | | | Click or tap here to enter text. | |
| If loss of earnings is compensated, please explain how the amount is calculated with justification: | | | Click or tap here to enter text. | |
| If monetary payment is offered, please specify the amount with justification: | | | Click or tap here to enter text. | |
| If non-monetary payment is offered, please specify the type and value of the benefit with justification: | | | Click or tap here to enter text. | |

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| 3. Are there any conditions attached to the payment of compensation? (for example, where the full trial or stages of the trial must be completed) | |
| Yes | If Yes, please describe below:  Click or tap here to enter text. |
| No |  |