

Compensation for trial participants

This template may be used by sponsors of clinical trials as part of the application dossier to provide information on financial transactions and compensation provided for participation in the trial; including to persons supporting a subject to participate. This is not a mandatory form and different national arrangements may be in place, which should be confirmed by the sponsor prior to submission.

Please note that for trials, which involve incapacitated adults, minors or breast-feeding women, no incentive or financial inducement may be given to the subjects 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 (see also Q&A 9.1).

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. However, this template is also relevant under Directive 2001/20/EC and may be used in advance of the Regulation applying.

1.	Will compensation be offered? (select only one box) No <input type="checkbox"/> Please explain why not Click or tap here to enter text. Yes <input type="checkbox"/> Please complete sections 2 - 5																																												
2.	Who will compensation be offered to and in what format? (select all boxes that apply) <table border="1"> <thead> <tr> <th></th> <th>subjects</th> <th>parent/carer</th> <th>legal representatives</th> <th>Other individuals</th> </tr> </thead> <tbody> <tr> <td>travel expenses</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>accommodation expenses</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>meal expenses</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>loss of earnings</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>monetary payment</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>non-monetary payment</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>other</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </tbody> </table> <p>If this information is included in a different document in the application dossier (eg. Subject Information Sheet), a reference to this document is sufficient: Click or tap here to enter text.</p> <p>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.</p>						subjects	parent/carer	legal representatives	Other individuals	travel expenses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	accommodation expenses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	meal expenses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	loss of earnings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	monetary payment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	non-monetary payment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	subjects	parent/carer	legal representatives	Other individuals																																									
travel expenses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																									
accommodation expenses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																									
meal expenses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																									
loss of earnings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																									
monetary payment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																									
non-monetary payment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																									
other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																									

	<p>If loss of earnings is compensated, please explain how the amount is calculated with justification:</p> <p>If monetary payment is offered, please specify the amount with justification: Click or tap here to enter text.</p> <p>If non-monetary payment is offered, please specify the type and value of the benefit with justification: Click or tap here to enter text.</p>
3.	<p>Are there any conditions attached to the payment of compensation? (for example, where the full trial or stages of the trial must be completed)</p> <p>No <input type="checkbox"/> Yes <input type="checkbox"/> If yes please describe below</p> <p>Click or tap here to enter text.</p>