

"REIMBURSEMENTS AND ALLOWANCES FOR TRIAL PARTICIPANTS"

(EU REGULATION no. 536/2014, ART. 30,31,32 ANNEX I, SECTION P, PARAGRAPH 70)

Each Member State, for each clinical trial, will have to evaluate the aspects related to Part II of the Regulation, among which there is also the possible "**Compensation for trial participants**". Sponsors should include in the application dossier all information relating to allowance or reimbursement to be devolved to subjects involved in clinical trials. This model has been developed and approved by the Coordination Centre starting from the model elaborated by the EU Clinical Trials Expert Group in accordance with Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use. However, this model is also relevant under Directive 2001/20/EC.

No incentives or financial benefits may be granted to¹ the subjects or their legally designated representatives, with the exception of allowances for lost earnings directly related to the participation in the clinical trial, which shall be properly documented.

Requests for allowance and their motivation must be evaluated and approved by the responsible Ethics Committee. The allowances shall not be used to compensate for the violation of the rights and safety of participants and shall not lead to undue influence.

Reimbursements directly incurred for participation in the study such as, for example, accommodation expenses and food, are not considered financial incentives. These refunds can also be granted to a caregiver in the case of people who are unable to travel independently. The refunds and their motivation must be evaluated and approved by the competent Ethics Committee.

Title of the study:

Study code:

No. EU clinical trial (EU CT number):

Clinical Center:

Principal investigator:

¹ Please refer to what is indicated in the Contract for the conduct of clinical trials approved by the Coordination Center, that can be consulted in the current version at the following link: <https://www.aifa.gov.it/centro-coordinamento-comitati-etici>

1.	Will an allowance be offered? (check only one box) No <input type="checkbox"/> Explain the reason Click or tap here to enter the text. Yes <input type="checkbox"/> Complete sections 2 – 5																		
2.	Will a refund be recognized? (check only one box) No <input type="checkbox"/> Explain the reason Click or tap here to enter the text. Yes <input type="checkbox"/> Complete sections 4																		
2.	Who will be offered the allowance and how? (check all relevant boxes) <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 25%;"></th> <th style="width: 15%;">Subjects involved</th> <th style="width: 20%;">Spouse, cohabitant, civil partner, caregiver</th> <th style="width: 20%;">Legal representatives (e.g. parent, guardian...)</th> <th style="width: 20%;">Other subjects</th> </tr> </thead> <tbody> <tr> <td>loss of earnings</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Other expenses directly associated with the trial</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table> <p style="margin-top: 10px;">If this information is included in a different document within the application dossier (e.g. Subject Information Sheet), a reference to this document is sufficient: Click or tap here to enter the text.</p> <p>If you enter "other subjects" (e.g. those assisting patients unable to travel alone), specify the recipient of the allowance or the type of allowance: Click or tap here to enter your text.</p> <p>In case of compensation due to lost earnings, explain how the amount is calculated with a motivation: Click or tap here to enter the text.</p>					Subjects involved	Spouse, cohabitant, civil partner, caregiver	Legal representatives (e.g. parent, guardian...)	Other subjects	loss of earnings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other expenses directly associated with the trial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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3.	Are there any conditions applying for the payment of the allowance? (for example, the conclusion of the trial/part of the trial) No <input type="checkbox"/> Yes <input type="checkbox"/> If Yes please describe below Click or tap here to enter the text.																		
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Food expenses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Sponsor

Qualification (name and surname)

Date: