MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de medicamentos y productos sanitarios

DEPARTMENT OF
MEDICINAL PRODUCTS
FOR HUMAN USE

Annex VI

Sponsor's commitment for non-commercial clinical trials Model

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Mr/Ms *<<NAME OF SPONSOR OR REPRESENTATIVE (if appropriate)>>*, on behalf of the Sponsor *<<NAME OF SPONSOR>>* with Tax ID Number *<<Tax ID number>>*, and business address at *<<ADDRESS OF SPONSOR>>*, by means of the present document.

HEREBY AGREES

1. To contract within the period stipulated in Art. 9.3 of Royal Decree 1090/2015 a Civil Liability Insurance policy in order to cover the damages that could be suffered by the subject as a result of his or her participation in the following clinical trial:

Protocol Code: *<<Protocol code>>*
Title: *<<Title of the clinical trial>>*
EudraCT: *<<EudraCT Number>>*
And which is to be conducted in the following sites and foundations:
Site: *<<Name of Site>>*
Address of Site: *<<Postal address of Site>>*
Foundation: *<<Name of Foundation>>*
Address of Foundation (if other): *<<Postal address of Foundation>>*
Principal investigator: *<<Name of Principal Investigator>>*

2. This policy also covers the liabilities which could be incurred by the sponsor, principal investigator and his/her research team, including contracted clinical investigators, and the hospital or site where the clinical trial is conducted, pursuant to article 61 of Royal Decree Law 1/2015, of 24 July, approving the consolidated text of the Act on guarantees and rational use of medicinal products and medical devices, and in the terms and risks defined in article 9 and article 10 of Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products, Ethics Committees for investigation with medicinal products and the Spanish Clinical Studies Registry.

3. Not to start the clinical trial until aforementioned policy has been contracted and is in effect and up to date in payment.

Witnesseth and for all relevant purposes, the present agreement is issued in *<<City>>* on *<<Day>>* of *<<Month>>* of *<<Year>>*

Signed: *<<NAME>>*

EMAIL

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