Annex VB

Additional Responsibility Commitment in relation to coverage of clinical trial insurance

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In accordance with current legislation, the sponsor of a clinical trial is responsible for contracting an insurance to cover the damages suffered as a result of the trial, as well as the responsibilities that may be incurred by the sponsor, the principal investigator and their collaborators, including the clinical investigators hired, and the hospital or center *(Foundation / Institute)* where the trial is conducted. However, it is not required to take out any insurance for "low-level of intervention clinical trials" if the damage and harm to the subject of study that might result were covered by the individual or collective professional civil liability insurance of the health center where the clinical trial is being performed.

This insurance is intended to compensate all expenses arising from the impairment of the health or physical condition of the person subjected to the clinical trial, as well as the economic damage that may arise directly from said impairment, provided that this is not inherent to the pathology object of study or the evolution of their illness as a result of the ineffectiveness of the treatment (article 10.2 of Royal Decree 1090/2015, of December 4, which regulates clinical trials with drugs, the Drug Research Ethics Committees and the Spanish Registry of Clinical Studies).

The Drug Research Ethics Committees (hereinafter, CEIm) must verify that the insurance is in accordance with current legislation and that it does not contain any exclusion clause except those indicated in the legislation, but bearing in mind that many of the insurance policies are international, since most of the clinical trials carried out in Spain are international, sometimes there are exclusion clauses that if accepted may be questionable with respect to the coverage legally required in Spain.

For these cases of policies that contain exclusion clauses of doubtful acceptance regarding the insurance coverage legally required in Spain, given the possible difficulty of modifying these clauses and as an exceptional solution to this situation, the CEIm may assess the acceptance of an additional commitment of the sponsor's responsibility by which the sponsor undertakes to indemnify the damages and losses suffered as a result of the trial that may not be covered by said policies. The decision to accept this additional commitment from the sponsor in these cases is left to the criterion of each CEIm.

The attached document of commitment of responsibility has been agreed upon by the CEIm Working Group on clinical trial insurances, composed by Francisco Abad Santos, María Luisa Albelda de la Haza, Iciar Alfonso Farnós, Milagros Alonso Martínez, Cristina Avendaño Solá, Filiberto Chuliá Fernández, María del Puerto Conejero Montero, Josep Corbella, Maria C de la Cruz, Maite Espina, Txema González

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ANNEX

ADDITIONAL RESPONSIBILITY COMMITMENT

[sponsor institution], with registered offices at [**complete**] and NIF [**complete**], represented by Mr./Mrs. **[complete]** in his capacity as [**complete**],

DECLARES

That it undertakes to indemnify the subjects participating in the clinical trial with the title "**[to complete]**", protocol code **[to complete]** and EudraCT **[to complete]**, for the damages and losses suffered as a result thereof, and also to cover the responsibilities of the investigator and his collaborators, including the clinical investigators hired, and of the hospital or center where the study is carried out, in what might not be covered by the hired insurance policy and by which [sponsor institution], as Sponsor of the study, must respond legally in accordance with the provisions of Royal Decree 1090/2015, of December 4, which regulates clinical trials with drugs, clinical trials with drugs, the Drug Research Ethics Committees and the Spanish Registry of Clinical Studies, Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials of medicinal products for human use and other legislation that is applicable.

In witness whereof, this document is issued in **[city]**, **[day]** of **[month]** of **[year]**.

[sponsor institution]
P.P.

Mr./Mrs. **[complete]**