ESTIMATION OF COSTS FOR THE CHARGE OF SERVICES AND OTHER EXPENSES PERFORMED AT THE INVESTIGATIONAL SETTING OF THE SUPPORT UNIT TO THE RESEARCH ETHIC COMMITTEES (REC) AND COORDINATION OF CLINICAL TRIALS

REGISTRY EXPENSES AND DOCUMENT MANAGEMENT*		
Type of project	**Evaluated by REC (HCSC)**	**Non evaluated by REC (HCSC)**
Clinical Trials**	1500€	700€
Non-interventional studies/Other**	800€	500€

EXPENSES OF FILE (25 years)	
Type of project	**All**
Clinical Trials**	700€
Non-interventional studies/Other**	300€

OTHER EXPENSES		
Type of projetc	**Evaluated by REC (HCSC)**	**Non evaluated by REC (HCSC)**
Clinical Trials Substantial Modifications**	600€	0€
Non-interventional studies/Other Substantial Modifications**	350€	0€
Agreement addendas	350€	350€

(*) The time of payment for "Registry and Document Management" will be when the registry has been made. This is considered done with the issue of suitability of the facilities. This document is the proof of the completion of the registration process.

(**) Those independent investigators, non profit organizations and scientific groups (societies) wishing to apply for exemption from expenses, may do it so provided they comply the requirements set out in the attached Annex I. This document must be given at the Office of Support Unit to the Clinical Trials Coordination

The amounts indicated do not include the VAT and are non-refundable.

This version entered into force February 15th, 2017

ANNEX I

Document of exemption from expenses

I, …….. as Representative **of Sponsor/Investigator** of Study entitled……
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DECLARES UNDER ITS SOLE RESPONSIBILITY

1) All criteria to be considered a **Study of Non-commercial Clinical Research** are fulfilled, because it is an investigation conducted by researchers without the participation of pharmaceutical or medical devices industry, which meets all of the following characteristics (according to *Royal Decree 1090 / 2015, Art. 2*):

a) The Sponsor is a university, hospital, public scientific group, non-profit organization, patients organization or individual researcher

b) The property of the research data belongs to the Sponsor from the outset of the study.

c) There are no agreements between the Sponsor and third parties that allow the use of research data for regulatory purposes or to generate an industrial property.

d) The design, conduction, participants recruitment, data collection and communication of research results are kept under the control of the Sponsor

e) By their characteristics, these studies cannot be part of a development program for a marketing authorization of a product

2) The Sponsor has not hired, or expected to do so, the services of an entity (for example a CRO) and/or professional for the development, implementation, coordination, study management or evaluation of the results.

3) The Sponsor does not have any funding from a public or private entity

4) The investigators will not receive any compensation, direct or indirect, for participation in the study.

If it does not meet any of the last three points, please you must specify and justify the reason

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In …….. at …… of…….. of 20.....

Signed: ……..