GUIDE for Promoters and CROs

How to carry out the economic-administrative procedures
of the clinical studies in
the Public Healthcare System of Extremadura

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Fundación para la Formación e Investigación de los Profesionales de la Salud de Extremadura (FundeSalud)
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1. INTRODUCTION

On January 13, 2016, the new Royal Decree 1090/2015, of December 4th, came into force. It regulates the clinical trials with medicines, the Ethics Committee of Research with Medicines and the Spanish Registry of Clinical Studies. Clinical trials, post-authorization studies and clinical research with medical devices must have a contract signed by the promoter, the center and the managing entity before the start of the study. The contract establishes the responsibilities of the parties in its development and reflects its economic aspects.

FundeSalud developed this guide with the aim of providing a unified and homogeneous procedure, thus facilitating the contact, the collaboration and the participation of the promoters/CROs, who wishes to carry out clinical studies in centers of the Extremadura Healthcare Service (SES).

2. SERVICES FOR THE CLINICAL TRIAL PROMOTER

The SES, has the support of the Foundation for Training and Research of Healthcare Professionals of Extremadura (FundeSalud).

At the level of the Autonomous Community of Extremadura, FundeSalud promotes relations between the Promoter, the Principal Investigator and the SES for the subscription of Contracts for clinical trials with drugs and medical devices, in compliance with Decree 57/2010, of March 5th, and Decree 6/2015, of January 27th. It also takes over the financial and administrative management of the funds intended for the clinical trials with medicines and medical devices. The SES is structured into 8 Healthcare Areas:

Badajoz, Mérida, Don Benito-Vva. de la Serena, Llerena-Zafra, Cáceres, Plasencia, Coria and Navalmoral de la Mata.

For further information and contacts of the centers of the Extremadura Public Health Service consult the following link:

https://saludextremadura.ses.es/web/Directories

3. CONTRACTS MANAGEMENT AND ADMINISTRATION

3.1 Dialogue and communication

The management and administration of contracts for clinical trials will be carried out through FundeSalud, which provides the following email address:

Investigacionclinica@fundesalud.es

The procedure may begin when the promoter deems it appropriate. It is possible to require, at once, the document on the suitability of the facilities, in case of clinical trials involving medicinal products, and the start of the processing of the contract.

The facility suitability document will be processed directly between the promoter/CRO and the center, through the Principal Investigator and the corresponding service manager, in order to obtain the signature from the SES Health Area Management or a person delegated.

3.2 Contract templates

According to the regulations in force, the Promoter of the trial (or the CRO that represents it) must sign a contract with FundeSalud and the SES, in accordance with the procedure established in Decree 6/2015, which modifies Decree 57/2010, of March 5th, that regulates the procedure for carrying out clinical trials with medicines and medical devices, in the Public Health System of the Autonomous Community of Extremadura, and approves the contract template to be signed and the observational one about post-authorization studies.

The following contract templates are available in Spanish and bilingual (Spanish / English):

- ✓ Model Contract for a Clinical Trial with Drugs
- ✓ Model Contract for a Clinical Trial with Medical Devices
- ✓ Model Contract for a Post-authorisation safety study
- ✓ Model Contract for Research
- ✓ Contract Addendum Template

You can download the file from:

- http://www.fundesalud.es/web/ensayos-clinicos
- http://www.fundesalud.es/web/estudios-observacionales

3.3 Contracts Administration and Negotiation

The Promoter/CRO will send the Request for Contract Review to Investigacionclinica@fundesalud.es the contract template must be completed with the study data and accompanied by the following documentation:

- Protocol in English or in Spanish (and synopsis in Spanish in case of protocol in English).
- Information about the study authorization process. If already available, attach the authorizations from the Ethical Committee and/or the Medicine Agency (FDA, EMA or AEMPS) or appropriate Classification, respectively. In case of starting the contract management before obtaining the corresponding authorizations, the Promoter/CRO must commit to send the authorizations to FundeSalud, once available. The contract is conditioned upon authorization.
- Insurance Certificate (if applicable[1]).
- Economic Report by the Promoter.
- Relevant documentation in case the promoter delegates in CRO the trial.

3.4 Approval and signing process

Each center applies the internal procedure considered appropriate for the approval of the contract as well as the conditions associated with it.

Once the content has been agreed by all the parties involved, FundeSalud will inform the Promoter / CRO by email, attaching the PDF with the final version of the contract.

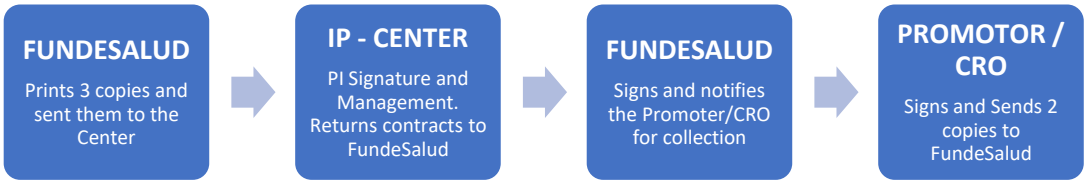
FundeSalud will be responsible for printing the copies of the contract and sending them to the corresponding center, in order to initiate the signature process with the agreement of the Principal Investigator and the signature of the Health Area Management. The center will return the signed contracts to FundeSalud to continue with the process and finally, FundeSalud will notify the Promoter/CRO to collect the contracts and incorporate their signatures.

Once signed, the Promoter / CRO will return 2 signed original copies to FundeSalud at the following address:

Fundación para la Formación e Investigación de los
Profesionales de la Salud de Extremadura (FUNDESALUD)
C/ Pio Baroja, nº10
06800 Mérida

[1] Only when the clinical trial involves any intervention to the patient. Low-level of intervention trials may not require any insurance.

Summary of the process:



The contract is conditioned upon authorization, if it is NOT available during signature.

4. MONITORING AND BILLING

The promoter will inform FundeSalud about the recruitment of patients and the realization of extraordinary tests and will send via e-mail the invoice request indicating the pertinent data according to the financial report signed in the study contract.

5. MODIFICATIONS AND FINALIZATION OF THE STUDY

In case of modifications affecting the contract stipulations and/or the conditions for conducting the study at the Center, the parties must formalize the corresponding “Amendment” to the contract. The latter will follow the same process initially established for the contract.

Written notification by the Promoter/CRO of the study end in the centre is required, within a maximum period of 3 months after its completion.