

 Institut d'Investigació Biomèdica de Girona Dr. Josep Trueta	PROCEDURE	CODE	DATE	REV.	APPROVAL
	Fees for clinical study contracts at the ICS/IAS center.	IDI-DOC-036	30/05/2024	02	
	Modification: Update of concepts and applicable fee.				Page: 1 de 1

Contract management fees for clinical studies linked to the Institut Català de la Salut (ICS) / Institut d'Assistència Sanitària (IAS) center.

The management of contracts for any clinical study (clinical trial, observational study, and clinical research project) conducted by IDIBGI, linked to the Institut Català de la Salut (ICS) - Dr. Josep Trueta Hospital in Girona, and Institut d'Assistència Sanitària (IAS) - Santa Caterina Hospital in Salt, are subject to the following minimum initial fees:

CONTRACT MANAGEMENT	
Clinical trials	
Administrative processing expenses of the file by IDIBGI, a one-time non-refundable payment invoiced at the time of contract signature.	500,00 €
Administrative start-up and monitoring expenses by the Clinical Studies Technical Office, a one-time non-refundable payment invoiced at the time of contract signature.	2.000,00 €
Expenses and management of contract amendment, in case of administrative changes (changes in payment details, CRO, policy, etc. This fee will not apply in case of change of Principal Investigator), a one-time non-refundable payment invoiced at the time of the amendment signature.	200,00 €
Expenses and management of contract amendment, other cases (changes in budget details, economic memorandum, etc. This fee will not apply in case of change of Principal Investigator), a one-time non-refundable payment invoiced at the time of the amendment signature.	300,00 €
Expenses and management of file and documentation custody at the center, a one-time non-refundable payment invoiced at the time of contract signature.	1.700,00 €
Observational studies	
Administrative processing expenses of the file by IDIBGI, a one-time non-refundable payment invoiced at the time of contract signature.	500,00 €
Administrative start-up and monitoring expenses by the Clinical Studies Technical Office, <i>only applicable for <u>observational studies with medication or medical device</u></i> , a one-time non-refundable payment invoiced at the time of contract signature	1.200,00 €
Expenses and management of contract amendment, in case of administrative changes (changes in payment details, CRO, policy, etc. This fee will not apply in case of change of Principal Investigator), a one-time non-refundable payment invoiced at the time of the amendment signature.	200,00 €
Expenses and management of contract amendment, other cases (changes in budget details, economic memorandum, etc. This fee will not apply in case of change of Principal Investigator), a one-time non-refundable payment invoiced at the time of the amendment signature.	300,00 €
Clinical research projects	
Administrative processing expenses of the file by IDIBGI, a one-time non-refundable payment invoiced at the time of contract signature.	500,00 €

* **Fee exemption:** In case the economic memory of the study lacks financial funding or the study's sponsor is a non-commercial entity, an exemption from fees and administrative costs may be requested. Consult and request approval from the IDIBGI management at the time of contract negotiation.