

## FEES OF THE ETHICS COMMITTEE - PARC DE SALUT MAR

### Clinical trials with medicines for human use (ECm)

Payment of fees must be made through the Spanish Agency for Medicines and Medical Device (AEMPS): <https://www.aemps.gob.es/la-aemps/tasas/>

- It is mandatory to download the payment document (model 317) which it has always to indicate (317xxxxxx) in the CONCEPT field of the wire transfer without letters or blank spaces. Once payment is made, it will be valid for 30 days.
- Exemption statement: non-commercial research may request exemption from fees.

#### Group II: Clinical Research (AEMPS + EC)

Description	Amount
Evaluation of a clinical trial of a medicinal product for human use not authorized in the EU.	5.741,27 €
Evaluation of a clinical trial of a medicinal product for human use authorized in the EU.	3.611,07 €
Substantial modification of a clinical trial of a medicinal product for human use (part I and II)	1.764,71 €
Substantial modification of a clinical trial of a medicinal product for human use (part II)	1.554,06 €

To pay fees, it is mandatory to access electronic payment, but there are two payment methods: by debiting an account – bank transfer – or paying with a credit or debit card – electronic payment. For more information consult the guide in AEMPS website: <https://www.aemps.gob.es/industria-farmaceutica/tasas/?lang=en>

### Clinical Research with medical devices (IC-PS)

Payment of fees must be requested to the Ethics Committee including the fiscal data in the cover letter:

Description	Commercial	Non-commercial *
Clinical Research with medical devices without CE mark	2.000 €	1.000 €
Clinical Research with medical devices with CE mark	1.500 €	1.000 €
Substantial Modification of a Clinical Research with medical devices (part I and II)	1.000 €	500 €
Substantial Modification of a Clinical Research with medical devices (part II)	500 €	250 €

### Non-clinical research with medicines for human use (EOM)

Payment of fees must be requested to the Ethics Committee including the fiscal data in the cover letter:

Description	Commercial	Non-commercial *
Initial	1.000 €	700 €
Substantial Modification (part I and II)	700 €	500 €
Substantial Modification (part II)	300 €	250 €

### Interventional clinical research and epidemiological (observational) studies

Payment of fees must be requested to the Ethics Committee including the fiscal data in the cover letter:

Description	Commercial	Non-commercial *
Initial	1.000 €	700 €
Substantial Modification (part I and II)	700 €	500 €
Substantial Modification (part II)	300 €	250 €
Approved by another EC	150 €	

#### NOTES:

- Fees applied to studies funded by non-commercial sponsors are detailed as \*Non-commercial.
- Non-commercial sponsors without financing may apply for tax exemption. The fee exemption request must be justified.
- Fees don't apply to ECm, EOM and IC-PS approved by another reference Ethics Committee in Spain.