

POST-AUTHORIZATION SAFETY STUDY (PASS-LA)

- **CONTRACT** and **BUDGET TEMPLATES** completed in Spanish (may also be signed in English, but the Spanish signature is required)
- Protocol
- Favourable opinion of the **Ethic Committee (ECRmp)**
- Authorization of the study by **AEMPS** (Spanish Medications and Healthcare Products Agency)
- **APPROVAL BY THE CENTRE MANAGEMENT.** - Issued by our **Ethic Committee (ECRmp)**. This document will include the **HULP CODE**. You must contact with:

sol.gracia@salud.madrid.org

maribel.arribas@salud.madrid.org

- **NOTARIZED DOCUMENTATION OR WITH HAGUE APOSTILLE of:**

WHO SIGNS THE AGREEMENT?	REQUIRED DOCUMENTATION
Sponsor signs in his own name and representation	Powers of Sponsor's legal representative
CRO signs on behalf of Sponsor	Powers of legal representative of the CRO
	Sponsor's letter of delegation to the CRO

POST-AUTHORIZATION SAFETY STUDY (PASS-SP)

- **CONTRACT** and **BUDGET TEMPLATES** completed in Spanish (may also be signed in English, but the Spanish signature is required)
- Protocol
- Favourable opinion of the **Ethic Committee (ECRmp)**
- Authorization of the study by **COMMUNITY OF MADRID**
- **APPROVAL BY THE CENTRE MANAGEMENT.** - Issued by our **Ethic Committee (ECRmp)**. This document will include the **HULP CODE**. You must contact with:

sol.gracia@salud.madrid.org

maribel.arribas@salud.madrid.org

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	Sponsor's letter of delegation to the CRO

POST-AUTHORIZATION SAFETY STUDY (PASS-OD)

- **CONTRACT** and **BUDGET TEMPLATES** completed in Spanish (may also be signed in English, but the Spanish signature is required)
- Protocol
- Favourable opinion of the **Ethic Committee (ECRmp)**
- Qualification of the study by **AEMPS** (Spanish Medications and Healthcare Products Agency)
- Notification of the study to **COMMUNITY OF MADRID**
- **APPROVAL BY THE CENTRE MANAGEMENT.** - Issued by our **Ethic Committee (ECRmp)**. This document will include the **HULP CODE**. You must contact:

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CRO signs on behalf of Sponsor	Powers of legal representative of the CRO
	Sponsor's letter of delegation to the CRO

POST-AUTHORIZATION SAFETY PROMOTED WITH PUBLIC FUNDS (PASS PUBLICS)

- **CONTRACT** and **BUDGET TEMPLATES** completed in Spanish (may also be signed in English, but the Spanish signature is required)
- Protocol
- Favourable opinion of the **Ethic Committee (ECRmp)**
- Qualification of the study by **AEMPS** (Spanish Medications and Healthcare Products Agency). Only if the study collects drugs data
- Notification of the study to the Coordinating Committee PASS Secretary (**AEMPS**)
- **APPROVAL BY THE CENTRE MANAGEMENT.** - Issued by our **Ethic Committee (ECRmp)**. This document will include the **HULP CODE**. You must contact:

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CRO signs on behalf of Sponsor	Powers of legal representative of the CRO
	Sponsor's letter of delegation to the CRO