

## CONTRACT PROCESSING REQUIREMENTS

To process a **Clinical Trial contract**:

- Contract model filled out in Spanish.
- Financial report.
- Approval by the AEMPS (Spanish Agency of Medicines and Medical Devices)\*.
- Approval by the CEIm (Medicinal Ethics Research Committee)\*.
- Clinical Trial protocol and its summary.
- Copy of the signatory's power of attorney.
- Document delegating functions/responsibilities (*legally authorised by notary public, or power of attorney to sign on behalf of the promoter, in the event that the CRO signs on behalf of the promoter*)
- Insurance policy certificate.
- List of participating centres.

*\*The contract can be negotiated without having obtained approval, but it must be submitted for the signed contract to be released.*

*\*\*The promoter will have to directly contact BIODONOSTIA to obtain the Document on Suitability of the Installations in order that the "Report on pertinence of the trial and extraordinary care burdens" required to process the contract can be studied internally at the centre.*

To process a **Post-Authorisation Study contract (PAS)**:

- Contract model filled out in Spanish.
- Financial report.
- Classification of the study by the AEMPS/Authorisation (PAS-Post approval commitments).
- Approval or notification report from the Basque Country CREC (Clinical Research Ethics Committee) and list of members\*.
- Favourable decision of the Basque Autonomous Community (General Office of Pharmaceutical Affairs (PAS-Prospective observational studies).
- Study protocol and its summary.
- Copy of the signatory's power of attorney.
- Document delegating functions/responsibilities (*if the CRO signs on behalf of the promoter*).
- List of participating centres.

*\*The contract can be negotiated without having obtained approval, but it must be submitted for the signed contract to be released.*

To process a **Non-Post-Authorisation Study contract (Non-PAS)**:

- Contract model filled out in Spanish
- Financial report.
- Classification of the study by the AEMPS.
- Favourable decision issued by the Basque Country CREC (Clinical Research Ethics Committee) and list of members\*.
- Study protocol and its summary.
- Copy of the signatory's power of attorney.
- Document delegating functions/responsibilities (*legally authorised by notary public, or power of attorney to sign on behalf of the promoter, in the event that the CRO signs on behalf of the promoter*)

- List of participating centres.

*\*The contract can be negotiated without having obtained approval, but it must be submitted for the signed contract to be released.*

## To process a **Health Product Post-Commercialisation Study contract**:

- Contract model filled out in Spanish.
- Financial report.
- Favourable decision issued by the Basque Country CREC (Clinical Research Ethics Committee) and list of members\*.
- Insurance policy certificate where appropriate.
- Study protocol and its summary.
- Copy of the signatory's power of attorney.
- Document delegating functions/responsibilities *(legally authorised by notary public, or power of attorney to sign on behalf of the promoter, in the event that the CRO signs on behalf of the promoter)*
- List of participating centres

*\*The contract can be negotiated without having obtained approval, but it must be submitted for the signed contract to be released.*

## To process a **Research Project contract**:

- Contract model filled out in Spanish.
- Financial report.
- Favourable decision issued by the Basque Country CREC (Clinical Research Ethics Committee) Euskadi and list of members\*.
- Insurance policy certificate where appropriate.
- Scientific report for the project.
- Copy of the signatory's power of attorney.
- Document delegating functions/responsibilities *(legally authorised by notary public, or power of attorney to sign on behalf of the promoter, in the event that the CRO signs on behalf of the promoter)*
- List of participating centres

*\*The contract can be negotiated without having obtained approval, but it must be submitted for the signed contract to be released.*

Generally speaking, three copies of the contract model will be signed unless otherwise expressly indicated.

Once all the documentation has been compiled, please send it to the email address: [leyre.curtoarzac@osakidetza.eus](mailto:leyre.curtoarzac@osakidetza.eus), where we will acknowledge its receipt.