REQUEST FOR EVALUATION OF *OBSERVATIONAL STUDIES WITH MEDICATION (OSM)*

REQUIREMENTS (essential documentation for evaluating OSM)

1. Cover letter in a format that allows information to be copied and requesting the evaluation, identifying the study with the data *on the following page*:

    - Protocol code
    - Title
    - Principal Investigator
    - Sponsor
    - Coordinating Investigator
    - Indicate whether is it prospective monitoring

2. Index of documentation submitted with version and date of documents that must be included in the resolution (protocol, PIS-IC); must be submitted in a format that allows information to be copied.

3. Delegation of representation Sponsor-CRO. If the applicant is not the sponsor, authorisation to act on behalf of the sponsor.

4. Protocol in Spanish (drafted according to Appendix I of Royal Decree 957/2020, dated 3 November). English will also be accepted provided it is accompanied by a summary in Spanish. **Indicate version and date.**

    Important information to be included:

    - Sponsor
    - Coordinating investigator
    - If prospective: indicate the reason for not changing common clinical practice.
    - Personal data pseudonymisation or anonymisation procedure.
    - Suspected Adverse Reactions – notification and person responsible

5. In the case of post-authorisation safety studies (PASS) imposed on the marketing authorisation holder (MAH) laboratory as a condition for authorising the medication and to be conducted in Spain:

    - Provide approval of the protocol by the relevant body.

6. Patient Information Sheet and Informed Consent (drafted according to Royal Decree 957/2020, dated 3 November). **Indicate version and date.**

7. Investigator's brochure or technical data sheet for the study investigational products.

8. Commitment of investigator and collaborators / Acceptance by departments involved from our site (form attached) signed by the Department heads of all departments involved in the trial, **including the study PI**, using the form attached at the end of the document. **Submit only for the PI from our site.**

9. Detailed economic report:

   Must include sources of funding for the study and planned compensation for participants and investigators.
   For non-commercial clinical research, the sponsor must submit a sworn statement signed by the sponsor and the coordinating investigator that the study complies with all terms and conditions.

10. For prospective monitoring observational medication studies that are "non-commercial clinical research":

    Sworn statement accrediting that the study complies with all terms and conditions referred to in Royal Decree 1090/2015(1) and in Royal Decree 957/2020(2).

11. Proof of CEIm fee payment: attach pdf document from the email sent to the foundation economic management department to the **email address** facturacion@vhir.org to request issue and including invoicing details. *Request for **exemption from fees***. In the case of an independent sponsor (academic sponsor, non-profit organisation, or investigators from HUVH or any of its Departments), *exemption from CEIm fees* may be requested (according to the document attached at the end of this document).

12. If aid/grant has been requested, you can submit a Temporary exemption from fees due to grant application (using the form on the last page of this document).

(1) "Non-commercial clinical research": Research conducted by investigators without participation by the pharmaceutical industry or on medical devices that meet all of the following characteristics:

1.º The sponsor is a university, hospital, public scientific organisation, non-profit organisation, patient organisation or individual investigator.

2.º Research data belong to the sponsor from the start of the study.

3.º There are no agreements between the sponsor and third parties to use data for regulatory uses or that generate industrial property.

4.º Design, completing, recruitment, data collection and notification of results of the research remain under the control of the sponsor.

5.º Due to their characteristics, these studies cannot be part of a development programme for a product marketing authorisation.

(2) Studies that meet the definition of "non-commercial clinical research" will benefit from exemption from any fees in accordance with Article 33.3 of Royal Decree 1090/2015, dated 4 December.

Clinical studies that meet the definition of "non-commercial clinical research" will benefit from exemption from fees or reduced fees in accordance with the provisions of the consolidated text of the Guarantee And Rational Use Of medications And medical Devices Act, approved by Royal Legislative Decree 1/2015, dated 24 July.

DOCUMENTATION FORMAT

1. Documentation must only be submitted **in digital format** by email to ceic@vhir.org.

2. It can be submitted any day of the month. Documents must be correctly identified by type of document, version and date.

RESOLUTION

1. The request will be included for evaluation once the complete, valid application has been received. The CEIm will have 10 calendar days for validation.

2. The mREC will issue resolution for the entire Spanish territory within 30 calendar days; this evaluation period will be interrupted if correction of documentation is requested.

Submission of response to clarifications to the CEIm (if requested):

- The sponsor will have 12 calendar days to respond to clarifications requested by the mREC. Can be submitted at any time of the month by **email** to ceic@vhir.org**.** Amended documents must be submitted along with a redlined version.

- A letter of response must be included with a description of the amended documents, and new versions and dates for inclusion in the final resolution.

If no response is received in the period indicated, the CEIm will issue an unfavourable resolution to the study.

Queries: Send any queries to:

mREC Support Unit: ceic@vhir.org / Telephone: +34 93 489 40 10