GUIDE FOR THE PRESENTATION OF INFORMATION IN TECHNICAL-DESCRIPTIVE REPORTS

ÿ **OBJECTIVE:** To establish the requirements for the presentation of the information that the Partial Technical Report of the study should contain.

ÿ **SCOPE:** Any natural or legal person who intends to submit a Partial Technical Report of the study.

ÿ **RESPONSIBILITIES:** Sponsors, Contract Research Organizations, Research Centers and Principal Investigator.

ÿ **DESCRIPTION OF ACTIVITIES:** The submission of reports will be carried out through a "Free Writing", at no cost to the user.

PRESENTATION OF INFORMATION: It is a requirement established in NOM-012 for the purposes of monitoring the investigation to submit the Partial Technical Report of the study. The following form must be duly completed.

FORMAT FOR SUBMITTING THE PARTIAL TECHNICAL REPORT

Partial Technical Report

1. Study data

User's Business Name:

Sponsor:

Title of the Research Protocol:

Protocol Number:	Acronym (if applicable):

Study status: (Completed or in progress) According to the Technical-descriptive Report to be presented.

Number of subjects enrolled globally:	Number of subjects enrolled locally*: ***Note:** This number must match the totals enrolled in section 2.*
Date of first enlistment (locally):	Study cut-off date (locally):

2. Participating Research Center.

Center **	No. Authorization Letter	Company name of the research center	Name of Principal Investigator	Subjects		
				Recruited	Rolled up	They concluded
1						
2						
3						
4						
			Total subjects:			

***Place all the Research Centers Authorized for the Clinical Study.*

3. Amendments and Modifications during the development of the study.

Document, Version Number and Document Date	Authorization Letter Number	Authorization Date	Local implementation date

4. Material and methods (Summary of study procedures and/or Study schedule).

5. Summary of RAM and EA Reports.***

*** **Annex I.** Include the acknowledgment issued by the CNFV.

6. Result (Efficacy and Safety) and Conclusions. ****

Since the Study Results are not available due to the partial nature of the report, all relevant information indicating the progress of the research must be reported in this section.

**** **Note:** *The validity and/ or veracity, as well as the use of the results of the study recorded in this format for purposes that suit the user is the responsibility of the Center for Research and sponsor.*

7. Bibliographic References.*****

***** **Note:** *If there are no additional references to the protocol, only refer to the protocol version .*

8. Attachments.******

The following Annexes must be submitted: **- Annex**

I. Acknowledgement issued by the CNFV (Include in *section 5. Summary of RAM and EA Reports).*

- Annex II. Technical Sheet of the National Registry of Clinical Trials (RNEC).

- Annex III. Simple copy of the Letter of Delegation of Responsibilities signed by the Principal Investigator, which was submitted with the initial authorization procedure for conducting the Research Protocol and/or Inclusion of a Research Center. In the event that any modification has been made to the research team, a copy of the updated Letter of Delegation of Responsibilities must be attached.

-Annex IV. Include Patient Materials (documents that do not require authorization by COFEPRIS, which were approved by the Evaluation Committees).

- Other Annexes. ********According to section 7.4.1.6 of NOM-012, the "Annexes" that the researcher considers necessary to support the technical-descriptive report or those required by the institution or establishment where the research is carried out may be entered. In this section you must indicate which and how many annexes are being attached to this form.

ÿINTERNAL REVIEW OF YOUR APPLICATION:

Once the application has been submitted, the CIS will assign you an "entry number" with its corresponding printed form that you must keep for any follow-up and to collect your response **("ACKNOWLEDGEMENT OF RECEIPT"** OF THE INFORMATION SUBMITTED). The technical area that reviews your application is called Clinical Trials, by its acronym EC and belongs to the Health Authorization Commission. The acknowledgment of receipt of the submitted information should not be interpreted as an authorization.