PETITION FORM FOR CONSENT IN THE DRUG CLINICAL DEVELOPMENT DOSSIER (DDCM) PROCESS – Version 2 of 12/19/2024

National Health Surveillance Agency
Petition Form for consent in the process of the Clinical Development Dossier of a Drug (DDCM)

Document Identification
(For use by the receiving agency)

Company Data

1	Applicant : CNPJ:	2	City/State/Country
3	The requesting company is classified as: ☐ Sponsor ☐ ORPC. In this case, inform: Sponsor Name: Sponsoring company: ( ) National – CNPJ:_____ ( ) Foreign		

Experimental Drug Data

4	Type of medicine: ☐ Synthetic or Semi-synthetic ☐ Phytotherapeutic ☐ Specific ☐ Dynamic ☐ Medical gas ☐ Biological ☐ Radiopharmaceutical ☐ Other: Specify
5	Product codes under development, if applicable:
6	Active Pharmaceutical Ingredient or active substance, if applicable:
7	Medicine approved in Brazil? ☐ No ☐ Yes Commercial name in Brazil: Registration No.:_____
8	Medicine approved in the world? ☐ No ☐ Yes Commercial name abroad: Countries where the drug is approved:
9	Manufacturer Name: Country:
10	Therapeutic Class / Product Category:

1 1	Is it a complex investigational product? (*according to item XI of Article 3 of IN 338/2024*) ☐ No ☐ Yes. It falls into the following category(ies): ☐ a. Active substances or complex active pharmaceutical ingredients, including monoclonal antibodies (mAbs), conjugated antibodies or antibody fractions, hormones, substances derived from recombinant DNA (rDNA) technology, mRNAs, blood coagulation factors, products originating from human tissues, polymeric compounds, complex mixtures of natural origin (phytotherapeutics), synthetic nucleotides, peptides or oligopeptides, high molecular weight synthetic substances, enzymatic products. ☐ b. Complex pharmaceutical forms, including liposomes, microspheres, nanocrystals, polymeric particles, nano-suspensions and nano-emulsions, injectable implants. ☐ c. Combining drugs with medical devices, such as injection pens, prefilled syringes, and other devices.

Disclaimer

We assume full civil and criminal responsibility for the information provided here, as well as for the quality of the experimental drug to be used in the clinical development presented.

_____ _____

Legal Representative Responsible Pharmacist
(Signature and Stamp) (Signature and Stamp)