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कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

No. E/252645/CD/2025 Dated: 09 December, 2025

Notification

This is to notify that due to inadequate number of responses received during the previous call for Expression of Interest (No. E/252645/CD/2025 dated 27/10/2025) published on the ICMR website with a closing date of 06.11.2025, the competent authority has decided to reopen the call for Expression of Interest for Joint collaboration for the **'Development and manufacturing of Monoclonal Antibodies against Nipah viral disease'**.

2. Details of EoI call for reopening-
   EoI No. E/252645/CD/2025
   Date of re-publication: 09.12.2025
   Closing date for submission: 17.12.2025

3. Interested eligible vaccine manufacturers/ pharma companies/ R&D Institutions are encouraged to submit their interest as per the instruction given in the EoI document.

4. Industries/companies which had already submitted the proposal/application during the previous call, need not submit again. Their earlier proposal shall be considered during the process of current evaluation.

9/12

(Ved Prakash)
Administrative Officer
Division of Communicable Disease

वी. रामलिंगस्वामी भवन, पोस्ट बॉक्स नं. 4911,
अंसारी नगर, नई दिल्ली - 110 029, भारत
V. Ramalingaswami Bhawan, P.O. Box No. 4911,
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EoI No. E/252645/CD/2025

Invitation for Expression of Interest (EoI)
For

Development and manufacturing of Monoclonal Antibodies against Nipah viral disease

By ICMR-Hqrs

Indian Council of Medical Research
(Department of Health Research, GoI)
V. Ramalingaswami Bhawan,
P.O. Box No. 4911, Ansari Nagar,
New Delhi - 110029, India

CONTENTS

Letter of Invitation

1. Invitation for Expression of Interest

Indian Council of Medical Research ((ICMR), New Delhi invites Expression of Interest (EoI) from the eligible organizations, companies, manufacturers for the **Development and manufacturing of Monoclonal Antibodies against Nipah viral disease**.

The EoI document containing the details of qualification criteria, submission details, brief objective & scope of work and evaluation criteria etc. can be downloaded from the ICMR website (https://www.icmr.gov.in).

Schedule for the Proponents is as under:

EoI Document Number	**EoI No. E/252645/CD/2025**
Date of first time Publication	**27/10/2025**
Date of republication	**09/12/2025**
Last date of submission	**17/12/2025**

Note:
Interested applicants may please send their proposals in a sealed envelope to the following address:

Dr. Jitendra Narayan
Scientist D
Communicable Disease Division
Indian Council of Medical Research,
V. Ramalingaswami Bhawan,
P.O. Box No. 4911,
Ansari Nagar, New Delhi - 110029, India

EoI Document No. EoI No. E/252645/CD/2025 along with the title of the EOI as "**EoI for Development and manufacturing of Monoclonal Antibodies against Nipah viral disease**" in **Bold** and complete address as above must be clearly mentioned on the sealed envelope.

ICMR reserves the right to cancel this EoI and/ or invite afresh with or without amendments, without liability or any obligation for such EoI and without assigning any reason. Information provided at this stage is indicative and ICMR reserves the right to amend/add any further details in the EoI, as may be desired by the Competent Authority ICMR and duly notified on its website.

2. Background

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. The ICMR has always attempted to address the growing demands of scientific advances in biomedical research on the one hand and the need of finding practical solutions to the health problems of the country, on the other.

Nipah virus (NiV) has emerged as one of the most important zoonotic threats for India, with repeated outbreaks recorded since 2001. The first recognized outbreak occurred in Siliguri, West Bengal, in 2001, where around 66 people were affected, primarily through hospital-based transmission. Another outbreak followed in 2007 in Nadia district, West Bengal, with a small but fatal cluster. After more than a decade of silence, the virus reappeared in 2018 in Kerala's Kozhikode and Malappuram districts, leading to 23 confirmed or probable cases with a very high case fatality rate of around 91 percent. Since then, Kerala has reported multiple episodes: a single case in 2019 in Ernakulam who recovered, a fatal case in Kozhikode in 2021, six confirmed cases with two deaths in 2023 again in Kozhikode, and fresh spillovers reported in 2024 in Malappuram with no secondary transmission. In 2025, Kerala reported four confirmed cases between April and July, including the first-ever cases in Palakkad, two of whom succumbed to the infection. These repeated spillovers highlight the persistence of Nipah risk in South India, particularly in Kerala, even as improved surveillance and rapid containment measures have limited large-scale transmission.

Nipah virus belongs to the family Paramyxoviridae, genus Henipavirus. It is a negative-sense RNA virus with fruit bats (Pteropus species) serving as its natural reservoir. Transmission to humans may occur directly from bats, through consumption of contaminated fruits or raw date palm sap, through an intermediate animal host such as pigs (as seen in Malaysia), or via human-to-human contact. Once in humans, the virus can cause a spectrum of illness ranging from mild symptoms to severe acute respiratory distress and fatal encephalitis. Case fatality rates range between 40 and 75 percent, depending on the level of clinical care available. In India and Bangladesh, the circulating strain is the Bangladesh clade (NiV-B), which is known to cause frequent person-to-person transmission and higher mortality.

Globally, research and development efforts are advancing but no licensed vaccine or antiviral is yet available. Several vaccine platforms are under investigation, including those supported by CEPI, with one candidate having progressed to mid-stage human trials with India identified as a key site. Similarly, research at other international institutes are ongoing for developing vaccine candidates. However, these are still years away from licensure. On the therapeutic front, monoclonal antibodies (mAbs) have emerged as the most promising option. The best studied candidate is m102.4, a fully human monoclonal antibody targeting the G glycoprotein of Nipah virus, which prevents viral entry by blocking its interaction with ephrin-B2/B3 receptors. m102.4 has shown strong protection in animal models and has been found safe in Phase 1 clinical trials. Though definitive human efficacy data are lacking, the antibody has been used under compassionate protocols in Australia and was also made

available to Kerala during recent outbreaks.

The importance of having monoclonal antibody stocks ready for deployment in India cannot be overstated. Given the very high case fatality and absence of licensed vaccines, mAbs represent the only currently feasible biomedical countermeasure. Their greatest value lies in post-exposure prophylaxis for high-risk contacts such as healthcare workers exposed without adequate protection, family members in close contact, or laboratory personnel with accidental exposure. Administered early, they can potentially prevent disease onset, as demonstrated convincingly in animal models. In addition, in patients presenting early during infection, monoclonal antibodies may offer a therapeutic benefit by reducing viral load and limiting progression, thereby complementing supportive critical care.

Maintaining ready access to such antibodies ensures that India can act swiftly during an outbreak. Pre-positioned stocks, streamlined regulatory and ethical approvals, and defined clinical protocols for prophylaxis and therapeutic use would allow immediate deployment without the delays that often occur when arrangements are attempted in the middle of an outbreak. This readiness, combined with continued strengthening of surveillance, infection control practices, and One Health investigations of bat reservoirs, will be critical for limiting the impact of Nipah virus outbreaks in the future.

Looking ahead, India needs to build its own indigenous medical countermeasures against Nipah virus, particularly monoclonal antibodies. The intent is to take this forward through active collaboration with Indian industry partners for developing an indigenous monoclonal antibody platform, and manufacturing the stock will not only ensure timely and reliable access during outbreaks but also strengthen national preparedness for emerging viral threats.

The ICMR-National Institute of Virology (ICMR-NIV), Pune, one of the constituent institutes of the Indian Council of Medical Research, has already initiated R&D in this direction, with experimental work at an advanced stage. The ICMR-NIV has state-of-art laboratory infrastructure including BSL-3 & BSL-4 facility and the team possesses expertise in outbreak investigations, surveillance, virological and molecular characterization, vaccine candidate development through virus inactivation and molecular methods, and conducting preclinical trials in suitable animal models. The institute also specializes in laboratory testing to evaluate antibody and immune responses in clinical trials at different phases I, II & III. The infrastructure and resources available at ICMR institutes, as indicated above at ICMR-NIV will be leveraged for joint R&D and preclinical studies.

3. Objective

To collaborate with eligible companies for the development and manufacturing of **Monoclonal Antibodies against Nipah viral disease**.

4. Scope of Work

i. ICMR is willing to collaborate with eligible organizations, companies, and manufacturers for the **'Development and manufacturing of Monoclonal Antibodies against Nipah viral disease'**

ii. The Company would be granted rights to undertake further development, manufacture, sell, and commercialize the Technology/Product '**Monoclonal Antibodies against Nipah viral disease'** or undertake further R&D and commercialize the end product(s)/technology.

iii. An Agreement (in case of joint development or licensing) following EoI is proposed to be executed on a "Exclusive/Non-Exclusive" basis with single/multiple companies to enable wider outreach of the **Monoclonal Antibodies against Nipah viral disease** (Technology/Product) for societal benefit and public health use. All the related issues shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.

iv. ICMR-NIV have expertise in various techniques, methods and information relating to aforesaid technology which could be used in **R&D for development of Monoclonal Antibodies against Nipah viral disease.**

Role of ICMR:

i. **ICMR and its Institutes** will provide expert guidance & technical support in **R&D for development of Monoclonal Antibodies against Nipah viral disease**, in all phases. Such technical oversight by **Scientist of ICMR** would accelerate the development of the Product and its commercialization.

ii. ICMR would provide technical support through its team of experienced scientists in study planning, product development, development of study protocol, results/data analysis, outcome assessment, safety & efficacy assessment, product improvement, etc., if deemed fit upon the mutual understanding between ICMR and collaborative company.

iii. ICMR through its Institutes would provide support and facilitation to conduct the R&D/clinical study of new technology/ product in India through its Affiliates/ Institutes, in collaboration with the company/institutions in a professional and mutually agreed-upon manner and timelines, which will be decided later under the Agreement.

iv. ICMR would provide financial support in development of product and manufacturing and will also facilitate the validation, if required, as per the terms & conditions of the Agreement.

Role of Company

i. The Company shall have valid provisions to provide all necessary infrastructure/ material/ manpower required for product development/ validation/ scale-up either directly or

otherwise.

ii. The Company shall have provisions to undertake the scale-up as required for the **Development and manufacturing of Monoclonal Antibodies against Nipah viral disease,** in a set milestone.

iii. The Company agrees to share the technical data with ICMR and participate in all discussions in a professional and mutually agreed-upon manner.

iv. The Company agrees to allow authorized personnel/scientist/team of ICMR to visit the designated lab/ production facility as and when required, as envisaged under this EoI and subsequent Agreement.

v. The Company shall be responsible for obtaining all the regulatory approvals required for commercialization or starting from R&D for product development to its commercialization

5. Intellectual Property Rights

Intellectual Property (IP) shall mean patents, rights to inventions, copyright and related rights, moral rights, rights in designs, rights in trademarks, rights to preserve the confidentiality of information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply for and be granted), divisional, continuations, continuations-in-part, reissues, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world regarding subject matter disclosed in Licensed patents.

ICMR legally possess the rights and authority to retain full or part of the 'Technology' by itself or to assign at its discretion full or part of the Technology including any patent(s) or intellectual property rights(s) or the invention(s), and/or ICMR is lawfully entitled to enter into any form of non-exclusive License Agreements with selected companies including transfer of the Technology through suitable Agreement(s).

In case of collaboration between ICMR and the Company for the Joint development of the Technology/ Product, Background Intellectual Property ("BGIP") shall always remain the sole and exclusive property of the Party generating the BGIP. Any IP, if generated during the course of collaboration, including any improvement thereof, shall be jointly owned by ICMR and the Company. All such provisions related to intellectual property rights shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.

6. Process involved in Partnership/Collaboration/Technology Transfer

Interested companies/manufacturers are invited to collaborate with ICMR for co-development/ further development & commercialization of the Technology/ Product(s). Under this EoI, the manufacturers/companies who are responsive and fulfilling all the technical need will be shortlisted based on their R&D plan, facilities and capabilities. Qualified companies/manufacturers will only be contacted for execution of MoA/MoU/Agreement for partnership/collaboration/technology transfer, etc. Subsequent to the execution of the Agreement such companies/manufacturers shall be responsible to pay

the Royalty @ 1% or 2% on Net sales, as applicable, according to the ICMR Guidelines for Technology Development Collaboration.

7. Publication

i. In case of Co-development, the Parties shall have equal rights on the manuscripts/scientific publications (joint publication/acknowledgment /other credits as applicable) and in accordance with guidelines of International Committee of Medical Journal Editors (ICMJE.org).
ii. Support of ICMR must be duly acknowledged in all publications by the Company.
iii. ICMR Scientists can be given due to advantage of authorships in the publications arising out of Licensing/co-development.

8. Data Rights

i. Data Rights will be exclusively with ICMR, if ICMR provide 100% funding.
ii. Data rights shall be jointly owned by ICMR and Licensee/Co-developer, in case of joint funding.
iii. Data rights in cases where Artificial Intelligence is involved shall be dealt separately.
iv. Licensee/ Company to ensure that data is anonymized, kept confidential and strictly abide by the provisions of Information Technology Act, 2000 while dealing with such data

9. Details of documents to be furnished

Proponents are requested to go through all pre-qualification requirements, scope of work for execution & requirements with respect to technical capabilities for submission of interest, subject for verification by ICMR.

Documents to be furnished are as follows:

i. Declaration - Expression of Interest (Format – 1)
ii. Authorization Letter (Format – 2)
iii. Undertaking with regard to Blacklisting (Format-3)
iv. Undertaking with regard to Non-Conviction (Format – 4)
v. EoI document with each page duly stamped and signed by the Authorized signatory.
vi. Undertaking with regard to laboratory facility (Format – 5)
vii. Production Capacity Undertaking (Format-6)
viii. Supporting documents, as mentioned in Format-1
ix. MSME Certificate (if applicable)
x. Undertaking regarding stockpiling of doses (As per format – 7)
xi. Supported evidence in form of research paper/articles published in peer reviewed journals, or detailed report containing Data pertaining to monoclonal antibodies developed
xii. Concept Proposal (Format-8)
xiii. Any other information which proponent may wish to provide to support the EoI.

ICMR reserves the right to call for any clarifications confined in the broad scope, wherever such a clarification become necessary for proper judgement in evaluation.

10. Rejection Criteria

The application is liable to be rejected if:

i. The proposal is not submitted as per the requirements indicated in the EoI.
ii. Not in the prescribed format.
iii. Not properly stamped and signed.
iv. Received after the expiry of due date and time.
v. All relevant supporting documents are not furnished with the Pre-Qualification Criteria (PQC).
vi. The proposal shall be substantially responsive without any material deviation, failing which the proposal shall be summarily rejected.
vii. Applications not fulfilling the terms of the document will be summarily rejected.
viii. Any other non-compliance.

11. Evaluation Methodology

Screening of EoIs shall be carried out as per Pre-Qualification criteria mentioned in the EoI document and based on verification of documents submitted.

12. Pre-Qualification Criteria (PQC)

The following will be the minimum Pre-Qualification Criteria (PQC). Responses not meeting the minimum PQC will be summarily rejected and will not be evaluated further:

Sl. No.	**Pre-Qualification Criteria**	**Supporting copy of documents required** (All documents must be self-attested by the authorized person of the proponent)
General Criteria		
1	The proponent shall be a legal entity, registered as Institution/Company/ LLP/ Society/ partnership firm/ proprietorship firm under respective acts in India and shall have more than 51% of Company stakes by promoters from India.	Registration of firm/ organization/ Company Incorporation Certificate from Registrar of Companies (ROC) /Partnership deed etc. whichever is applicable
2	The proponent must be registered in India with taxation and other Administrative authorities.	GST Registration or GST exemption certificate/ PAN Card

3	The proponent should have a manufacturing unit in India.	Registration copies/ factory license/ DSIR certificate, if have any.
	The proponent should have not been Blacklisted by any of the government funding agency/department.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format –3)
4	The proponent and its promoters should have not been convicted for any offence in India by any competent court or judicial body during the past 3 years.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format –4)
Specific Criteria (Based on the nature of the Proposal)		
5	The proponent should have functional laboratory to carryout R&D for the product development	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)
6	GMP/ quality certification (ISO or approved Indian certification) of manufacturing facility and GLP/ necessary certifications for R & D	Copies of Certificates
7	Proponents should have developed or have established proof of concept for development of monoclonal antibodies against Nipah Virus infection and have done preclinical studies part/full for safety and efficacy	Supported evidence in form of research paper/articles published in peer reviewed journals, or should submit detailed report containing Data of preclinical studies
8	Capacity to produce at least 1 lakhs doses per week	Undertaking (As per format – 6)
9	Commitment for stockpile monoclonal antibodies (400-500 doses) for emergency use once the regulator approves use.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory Undertaking (As per format – 7)

NOTE- For MSMEs and Start-ups, Start-Up-India, Make-in-India and other relevant guidelines of Government of India shall be applicable

13. Disclaimer

i. Technology rights will be owned by ICMR

ii. In case the agency/ company/ entity could not be able to continue the contract or wishes to break the contract, the technology rights will be given to any agency/ company/ entity that ICMR would specify.

iii. ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.

iv. ICMR reserves the right to cancel the call for EoI without assigning any reasons thereof.

v. ICMR may relax or waive any of the conditions stipulated in this document as deemed necessary in the best interest of the ICMR without assigning any reasons thereof.

vi. To include any other item in the Scope of work at any time after consultation with

proponents or otherwise.

vii. For International Clients, please note that EoI and other necessary correspondences shall be submitted in English only.

14. Arbitration

That any dispute and/ or any part of the dispute which couldn't be resolved through mutual consultation, the same shall be referred to the sole arbitrator as per the Arbitration & Conciliation Act, 1996 and any amendment thereafter. The Venue and Seat of the arbitration proceedings shall be New Delhi and the courts at New Delhi will have exclusive jurisdiction.

15. Contacts

In case of any clarification required, please contact:

For scientific issues-
Dr. Pragya Yadav
Scientist 'F'
Maximum Containment Facility
ICMR-NIV Pune
&
Director In-Charge
National Institute of One Health
Nagpur
Telephone No.: 020-26006390/290
E-mail: yadav.pragya@gov.in, director-nio@icmr.gov.in

Format-1

Expression of Interest

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research, Ansari Nagar, New Delhi.

Subject: Submission of Expression of Interest (EoI) for joint collaboration in **R&D for development of Monoclonal Antibodies against Nipah viral disease**

Ref: No. E/252645/CD/2025 dated 09 December, 2025

Sir,

The undersigned having read and examined in detail all the EoI documents pertaining to your transfer of technology, and do hereby express the interest to undertake the research & development/manufacture/ sale /commercialization of the product as mentioned in the EoI document. The details of the Company and contact person are given below:

Name of the Proponent	
Address	
Name, designation & address of the person (to whom all communications shall be made)	
Telephone No. (with STD code)	
Mobile No. of the contact person	
Email ID of the contact person	

The following documents are enclosed:

Sl. No.	Documents required	Type of document attached	Page No.
1	Authorization Letter	As per format – 2	
2	Company Incorporation Certificate from ROC/Partnership deed etc.		
3	GST Registration or GST exemption certificate/ PAN Card.		
4	DCGI/CDSCO license for the existing products available in the market		
5	Proof of a registered office and a manufacturing Unit in India		
6	DSIR certificate		

7	Undertaking regarding blacklisting	(As per format –3)	
8	Undertaking regarding non-conviction	(As per format –4)	
9	Undertaking regarding functional laboratory	(As per format – 5)	
10	GMP & GLP or ISO Certification	Copies of certificate	
11	Undertaking regarding production capacity	(As per format – 6)	
12	Undertaking regarding stockpiling of doses	(As per format – 7)	
13	Supported evidence in form of research paper/articles published regarding proof of concept or already developed product	Research paper or report on data	
14	Proposal for Development of Nipah Monoclonal Antibodies	(As per format – 8)	
15	MSME or recognized start-up	Certificate (if have any)	

I/we hereby declare that my/our EoI is made in good faith and the information contained is true and correct to the best of my/our knowledge and belief.

Thanking you,

Yours faithfully,
(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-2

Authorization Letter

(To be submitted on Company's Letter Head)

To,

The Director General
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Letter for Authorized Signatory
Ref: No. E/252645/CD/2025 dated 09 December, 2025

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for joint collaboration in **R&D for development of Monoclonal Antibodies against Nipah viral disease**.

Mr./Ms./Mrs./Dr…….is hereby authorized to submit the EoI documents and participate in the processing on behalf of M/s……. (Company Name)……., who's signature is below.

(Specimen Signature of Representative)

Date:

Place:

Yours faithfully,

(Signature of the Authorized signatory)
Name:……..
Designation:……..
Seal:……..

Format-3

Undertaking with regard to blacklisting

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research, Ansari Nagar, New Delhi.

Subject: Undertaking regarding Blacklisting / Non-Debarment.
Ref: No. E/252645/CD/2025 dated 09 December, 2025

Sir,

It is hereby confirmed and declared that M/s (Company Name) currently has not been blacklisted / debarred by any Government Department / Public Sector Undertaking / or any other company for which works/assignments/services have been executed / undertaken.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-4

Undertaking with regard to Non-Conviction

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research, Ansari Nagar, New Delhi.

Subject: Undertaking regarding Non-Conviction.
Ref: No. E/252645/CD/2025 dated 09 December, 2025

Sir,

It is hereby confirmed and declared that M/s….....(Company Name) and owner of the firm / board of directors, have not been convicted for any offence in India by any competent court or judicial body during the past 3 years.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-5

Undertaking with regard to laboratory facility

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding laboratory infrastructure.
Ref: No. E/252645/CD/2025 dated 09 December, 2025

Sir,

It is hereby confirmed and declared that M/s…….(Company Name)……. do have-

i. Adequate laboratory infrastructure (equipped laboratory facility). Please tick BSL-2/BSL- 3/ABSL-3/GMP/GLP/ Other* (if other please specify) and
ii. Adequate no. of experienced staff/skilled manpower to undertake R&D/ pre-clinical & clinical studies/manufacturing/commercialization of **Monoclonal Antibodies against Nipah viral disease**.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

*The Laboratory/ facility requirement will depend on the technology/ product

Format-6

Undertaking with regard to production capacity

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research, Ansari Nagar, New Delhi.

Subject: Undertaking with regard to production capacity.
Ref: No. E/252645/CD/2025 dated 09 December, 2025

Sir,

It is hereby confirmed and declared that at M/s…….(Company Name)……. does have the capacity in all mean (including infrastructure, fund, material, staff etc.) for manufacturing of **Monoclonal Antibodies against Nipah viral disease**, minimum …… (mention the quantity per week)……..

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-7

Undertaking with regard to stockpiling

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding stockpiling of product.
Ref: No. E/252645/CD/2025 dated 09 December, 2025

Sir,

It is hereby agreed and declared that M/s……(Company Name)….. will stockpile the …(No. of doses)…doses of the developed product i.e. Monoclonal antibodies against Nipah infection, for emergency use, once the regulator approves use.

It is also agreed that M/s…….(Company Name)…….will produced more doses, if requires or demanded by ICMR for the use in public health emergency, at the subsidized rate.

Yours faithfully,

(Signature of the Authorized signatory)

Name:
Designation:
Seal:
Place:

Format-8

Proposal on the Monoclonal Antibody against Nipah viral disease

A. About the Technology / Product / Process
   - Brief description of the monoclonal antibody candidate(s) (fully human, humanized, chimeric, or engineered formats).
   - Discovery platform employed (hybridoma, phage display, transgenic mice, single B-cell cloning, etc.).
   - Novel features such as antibody cocktails, Fc modifications, bispecifics, or long-acting formulations.

B. Work Done So Far
   - Preclinical in vitro studies (neutralization assays, binding affinity, epitope mapping).
   - In vivo studies in relevant animal models (hamster, ferret, non-human primates).
   - Toxicology/safety studies (GLP or pilot-level).
   - Scale-up or pilot GMP batch experience, if available.

C. Technology Readiness Level (TRL)
   - Current TRL of the product (with justification/data), preferably TRL-5 or above.
   - Supporting evidence of progression through proof-of-concept and preclinical evaluation stages.

D. Intellectual Property & Publications
   - Status of IP: patents filed/granted (national and international).
   - Freedom-to-operate (FTO) or any licensing arrangements.
   - List of publications in reputed journals related to Nipah or other monoclonal antibodies.

E. Company Profile & Experience
   - Track record in discovery, development, and commercialization of monoclonal antibodies.
   - Experience with infectious disease biologics or emergency response products.
   - Past collaborations with national or international health agencies (ICMR, DBT, WHO, CEPI, etc.).

F. Capacity and Infrastructure
   - GMP-compliant manufacturing facilities for upstream (cell culture) and downstream (purification) processes.
   - Manufacturing scale: pilot, clinical, and commercial.
   - Bioreactor capacity (single-use, stainless steel).
   - Analytical characterization facilities (ELISA, SPR/BLI, neutralization assays, stability).
   - Fill-finish, packaging, and cold chain logistics.
   - Access to BSL-3/4 laboratories or formal collaborations for Nipah-specific assays.

G. Preclinical & Analytical Capabilities
   - In-house or partnered capacity for virological assays (neutralization, cross-reactivity with Henipaviruses).
   - Availability of validated potency assays and bioanalytical methods.
   - PK/PD evaluation expertise.
   - Experience with animal challenge models (direct or via collaboration).

H. Regulatory & Compliance Readiness
   - Familiarity with WHO, DCGI, and ICH regulatory guidelines for mAb development.
   - IND/CTA filing experience for biologics.
   - Record of GMP certifications and regulatory inspections.
   - Ability to comply with accelerated regulatory timelines during outbreaks.

I. Timelines & Program Management
   - Development timelines (from current TRL to clinical readiness).
   - Availability of dedicated project management teams.
   - Risk mitigation strategies for expedited development.

J. Supply Chain & Resource Mobilization
   - Availability of critical raw materials and secure supply chains.
   - Cold storage and transport facilities for biologics.
   - Skilled manpower availability for round-the-clock execution.
   - Financial capacity to mobilize resources quickly.

K. Support Required from ICMR
   - R&D, Preclinical studies, access to the BSL-3 & BSL-4 laboratories for validation and trials.
   - Support for conducting Clinical Trial
   - Financial support etc.

L. Compliance & Declarations
   - We have gone through the complete EoI document No. …..dated and understood all the
   - terms & conditions fully.
   - We have also learnt about the purpose and objective of this EoI
   - We hereby declare that the information provided in the proposal are true & correct, and
   - we will not be deviated from the any of the commitment proposed in this proposal.
   - We agree to abide by the roles & responsibilities as outlined by ICMR in this EoI.
   - We accept that ICMR has the sole discretion of selection/rejection.

Authorized Signatory
(Name, Designation, Seal, Date)