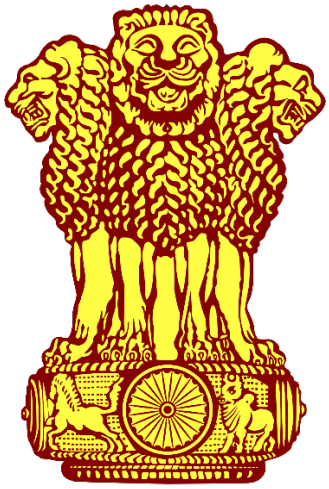
GUIDELINES OF THE SCHEME

"DEVELOPMENT OF TOOLS/ SUPPORT TO PREVENT OUTBREAKS & EPIDEMICS"

DURING 15TH FINANCE COMMISSION PERIOD



GOVERNMENT OF INDIA

MINISTRY OF HEALTH & FAMILY WELFARE

DEPARTMENT OF HEALTH RESEARCH

(June, 2021)

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DEVELOPMENT OF TOOLS/ SUPPORT TO PREVENT OUTBREAKS & EPIDEMICS

1. INTRODUCTION

1.1. At the time of formulation of the scheme for "Establishment of a Network of Labs for Managing Epidemics & Natural Calamities" during the 12th Plan, a provision for revolving fund of Rs. 85 crore for 5 years was separately proposed to facilitate rapid mobilization in the event of outbreak/disaster response to infectious disease outbreaks or natural/man-made disasters. The purpose of this component of the Scheme was to work in coordination with relevant departments of MoHFW and also agencies such as National Disaster Management Authority (NDMA), NCDC, NIV Pune, etc. To specially facilitate focused research to assist in dealing with emerging and re-emerging diseases, development of diagnostics kits, formulation of case management modules and

preventive strategies, to provide the labs with essential kits, diagnostics and training of the available staff in times of national crisis.

1.2. However, in the EFC meeting held on 20.3.2013 under the Chairmanship of Finance Secretary & Secretary (Expenditure, it was advised that the DHR may take action to establish a budget line (with a suitable fund allocation) to cater for the emergency action to facilitate rapid mobilization/disaster response in the event of an infectious disease outbreak instead of creating revolving fund.

2. OBJECTIVES OF THE SCHEME

2.1. The aim and objectives of the Scheme is to specially facilitate focused research to assist in dealing with emerging and re-emerging diseases, development of diagnostics kits, formulation of case management modules and preventive strategies, to provide the labs with essential kits, diagnostics and training of the available staff in times of National crisis. A Resource Centre is also established at National Institute of Virology (NIV), Pune which is envisaged to provide training, capacity building, and quality control and to ensure quality assurance of functional VRDLs.

2.2. The Scheme is completely need based and funds are sanctioned to various Medical Colleges / Institute to cater any outbreak situation. In order to fulfil this objective, following activities are proposed to be undertaken in the Scheme:

- To supply diagnostic kits and reagents
- To strengthen VRDLs as well as other ICMR/non-ICMR Medical Colleges / Institutions for diagnosing viral/non-viral agents.
- To establish surveillance for high risk pathogens for early detection, response and research in a prioritized way in different parts of the country.
- To strengthen laboratory quality systems in various laboratory networks across the country including the VRDLs.
- To create a trained workforce for handling infectious disease pathogens of public health importance.
- To conduct multi-centric research programs for Public Health Importance.
- To sustain and support the National resource centers for laboratory diagnosis and data capture: – ICMR-National Institute of Virology (NIV), Pune and ICMR-National Institute of Epidemiology (NIE), Chennai.
- To support technical, logistic, travel, transport, community engagement etc activities required during outbreaks/ elimination programmes.

3. ACTIVITIES AND FINANCIAL OUTLAY OF THE SCHEME

S. No.	Budget Head	Financial outlay for 5 years (Rs. In Lakhs)
1	Supply of diagnostic kits and reagents	750
2	Strengthening of infectious disease laboratories for diagnosis of non-viral etiological agents	929.6985
3	Surveillance	580
4	To improve quality of diagnosis	
4.1	External Quality Assessment (EQA)	500
4.2	Good Clinical Laboratory Practices (GCLP) for NABL preparation	194.54
4.3	Certification of BSL-3 labs	156.49
5	Multi-centric research programmes for Public Health Importance (Liabilites)	450
6	Training at Resource Centres	
6.1	ICMR - NIV Pune	1077.001
6.2	ICMR - NIE Chennai	333.394
7	Support for technical, logistic, travel, transport, community engagement etc activities required during outbreaks/ elimination programmes	100
	Total	5071

These activities are indicative and other need-based activities appropriate to the infectious disease outbreak management may also be undertaken as and when any such need arise with the approval of Secretary, DHR.

4. WHO CAN APPLY

State Government Medical Colleges, Central Government Medical/ Research Institutions

5. COMPONENTS ELIGIBLE FOR FUNDING

This scheme will be dedicated to ensure rapid response to outbreaks. This will involve preparedness and rapid mobilization in the event of an infectious disease outbreak. It will help in significantly augmenting laboratory capacities for diagnosis of pathogens. This will also serve as a useful tool for combating any infectious disease occurring throughout India. The Scheme is completely need based and funds can be sanctioned to Medical Colleges / Institute to cater any outbreak situation with the approval of Secretary, DHR in consultation with FA of the Department

A. Supply of diagnostic kits and reagents.

The recurrent epidemics of dengue, chikungunya, Japanese Encephalitis and Influenza over the past years have created a need for early detection, diagnosis and containment. In order to have uninterrupted facility for diagnosis of these infections, the scheme will provide funds for diagnostics kits and reagents to the labs across the country. To have better diagnostic kits across the country, funds can also be utilized for validation of kits by building consortium for validation of kits for viral pathogens.

B. Diagnosing of non-viral etiological agents.

Scheme will provide for holistic diagnosis of pathogens causing Acute Febrile Illness (AFI), including diagnosis of non-viral etiologies like scrub typhus and leptospirosis.

C. Establishing surveillance for high risk pathogens for early detection, response and research in a prioritized way in different parts of the country.

During the five years of the scheme, the VRDL network has provided diagnosis to 1500 disease clusters since March, 2014 till December, 2020 and thereby complemented IDSP in diagnosing the outbreaks early. This network provides a unique opportunity to set up an event based surveillance (EBS) for detecting unusual events. It is proposed to set up surveillance for early detection of high risk pathogens including Nipah virus, Kyasanur Forest Disease (KFD) virus, Filoviruses (Ebola and Marburg), Crimean Congo Hemorrhagic fever (CCHF) virus and others bacterial, fungal and parasitic infections as per need. Surveillance will include both hospital based and sentinel surveillance, molecular surveillance (Consortium for genomic sequencing) as well as Event Based Surveillance for early detection from the community. The scheme will provide for to establishment of EBS at selected sites to detect unusual events early.

This surveillance system will be helpful for (a) Early detection of predefined acute health events, (b) Ensure immediate communication of information suggestive of acute health events from Clinician to District/State Health Authorities and concerned Health Authorities at national level, (c) Documentation of the nature of the event e.g., investigation, characterization, etiological confirmation(d) Performing risk assessment to determine the level of risk posed by the detected event (e) Ensuring immediate alerting mechanisms at concerned levels – local, peripheral, national levels and (f) ensuring prompt investigation as necessary.

A sentinel and molecular surveillance system is used when high-quality data are needed about a particular disease that cannot be obtained through a passive system. Data collected in a well-designed sentinel system can be used to signal trends, identify outbreaks and monitor the burden of disease in a community, providing a rapid, economical alternative to other surveillance methods. Sentinel surveillance systems may enhance collaboration among health ministry services and health-care practitioners. Recently, as part of the country's preparedness program for control and spread of re-emerged viruses such as Zika, Nipah etc., surveillance of zika virus has been initiated with a network of 30 laboratories from the existing VRDLs in the country. These laboratories are situated in different geographical regions and offer comprehensive coverage of the north, south, east and western parts of the country. Therefore, in the 15th Finance Commission Period (2021-22 to 2025- 26), more surveillance networks shall be set up for important emerging and re- emerging viruses and viral diseases targeted for elimination like Nipah, Measles- Rubella, Arboviruses, Enteric viruses, Hepatitis viruses etc. Before initiating the surveillance, specific etiology based trainings will be provided to all the laboratories through the resource centres. All required consumables and contingencies will be released to identified sites for the time bound activity. Various infectious disease laboratories across the country will be involved.

D. Strengthening laboratory quality systems in various laboratory networks across the country including the VRDLs.

The Scheme will provide for developing and implementing laboratory quality systems for all important groups of viruses: respiratory viruses (Influenza and Respiratory Syncytial virus [RSV]), enteric viruses (Rotavirus, norovirus, astroviruses etc.), flaviviruses (dengue, chikungunya, zika, Japanese encephalitis, West Nile etc); Others like Measles, Rubella, etc. It will also provide for workshops on Good Clinical

& Laboratory Practices (GCLP) and subsequently NABL accreditation of VRDLs. Programs to strengthen quality of diagnosis for non-viral etiologies in VRDLs, ICMR/non-ICMR Institutes, Medical colleges etc. will also be launched as per need and feasibility. The following activities will be initiated:

a. *External Quality Assessment (EQA)* – To assess the quality of the VRDLs/Labs in terms of testing the samples.

b. *Good Clinical Laboratory Practices (GCLP)* - Good Clinical Laboratory Practice (GCLP) describes the principles and procedures which need to be followed by diagnostic laboratories involved in patient care and/or clinical research so as to provide results which are reliable, accurate and reproducible. GCLP will help to generate such quality results which can be reliably used for patient care and for performing quality research. These workshops may be accompanied with ISO 15189 training thereafter the infectious disease laboratories can opt for National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation on their own.

c. *Certification of BSL-3 laboratories* - Biosafety Level-3 containment laboratories for research and diagnosis are the difficult facility to design and operate. DHR-ICMR have come up with guidelines for designing a BSL-3 facility. There is an utmost need to have a government body to certify BSL-3 facilities, therefore, DHR is taking an initiative to certify BSL-3 containment facility through this scheme. A system will be devised through this scheme by which these laboratories shall be certified before initial operation followed by an annual schedule for certification. This will basically involve the systematic review of all components – Civil structure, administrative controls, safety controls and standard operating procedures. Therefore, through this scheme DHR will provide for a mechanism for certification of BSL-III Laboratories for the country.

E. To conduct multi-centric research studies of public health importance.

Over the past few decades, outbreaks of emerging and re-emerging infectious diseases have been increasing at an alarmingly high rate. Better surveillance and advanced technology development in diagnostics have contributed to the rise in diagnosis of emerging infections. Surge in prevalence is also due to a combination of factors such as expanded host range, alterations in the ecology of viral vectors and reservoirs, and changes in the dynamics of pathogen-host interactions. Epidemiological and sociological factors also play an important role due to global travel

and the increased human population density. All these factors facilitate the transmission and spread of infections globally.

Outbreaks generally provide research opportunities to address several research questions in a short span of time. Investigations provide opportunities to identify new agents and risk factors for infection or disease, define the clinical spectrum of disease, measure the effect of new control measures for clinical interventions, assess the usefulness of microbiologic or other biological markers, or evaluate the utility of new diagnostic tests.

Recent emergence/re-emergence of SARS-CoV-2, Zika, Ebola, Nipah, CCHF and highly-pathogenic influenza viruses are perfect examples of the hidden dangers to mankind and the need to deepen our knowledge about emerging viruses and develop methods to prevent and treat viral diseases. Inspite of years of prevention and control, recurrent epidemics of cholera and typhoid, malaria etc. pose a significant public health threat. Resurgence of Diptheria, cryptic fungal infections in hospital and ICU facilities are reported every now and then. Outbreaks of emerging known/ unknown infectious diseases requires immediate intervention by answering various research questions through different types of studies. The scheme will support to undertake such multi-centric studies

F. To sustain and support the National resource centers for laboratory diagnosis and data capture: – ICMR-National Institute of Virology (NIV), Pune and ICMR-National Institute of Epidemiology (NIE), Chennai.

Two resource centers at ICMR-NIV and ICMR-NIE for strengthening the infectious disease laboratories Network will be supported in terms of logistics and contractual engagement of manpower. The scheme will also additionally support other such centers as per need and feasibility.

G. Any other support for technical, logistic, travel, transport, community engagement etc activities required during outbreaks/ elimination programmes.

The Scheme is completely need based and funds can be sanctioned, with the approval of Secretary, DHR and in consultation with AS & FA, during any outbreak management to conduct field studies, hiring of manpower, advocacy in the community, transport of samples from the field, travel to manage the outbreak etc. In addition to this, Ministry of Health & Family Welfare and World Health Organization have come

up with various diseases elimination programmes for which various sites need to identified and supported.

6. FUNDING NORMS

Since the nature of outbreaks and pathogens is unpredictable, there shall be a flexibility of budget as per actual requirement/ need. Salary structure for the staff (if any) will be given as per DST norm or as per minimum wages in case of MTS, DEO and other no technical post etc. Costs for the kits/ reagents will be on actual basis. While submitting under any of the project, cost certificate should be accompanied.

7. IMPLEMENTING AGENCY

7.1. The scheme will be implemented through the ICMR and the DHR will exercise the overall managerial and supervisory control.

7.2. Funds would be released to the concerned institutes/organizations annually from DHR through ICMR on submission of UC in GFR 12- A and SoE for the previous year releases and utilization of 70% of available funds.

8. MONITORING MECHANISM

The system of monitoring and periodic evaluation of the projects will be undertaken by DHR annually after appropriate peer review/ Technical Review Committees with support from ICMR which will provide technical support. However, to approve funds for any activity under this scheme, the proposal has to be duly approved through approval committee which consist of following members:

1. Secretary, DHR
2. Joint Secretary, DHR
3. Technical Expert, ICMR

9. COMPONENTS OF THE PROJECT TO BE SUBMITTED

9.1. The proposal to be funded through this scheme should contain the background, introduction, objectives, Review of Literature, Methodology, timelines for accomplishment of objectives, detailed testing protocol, Budget for Staff salary, – (Staff structure may include – Scientist C, Scientist B, Staff nurse, Research assistant, Lab Technician, Data Entry Operator, Multi Task worker), Consumables, Contingency, Trainings, Travel; along with justification for each, Novelty and References.

9.2. Supporting documents – Institutional Ethical Clearance certificate, approval letter from scientific advisory committee of the Institute. The Institution (in case of a Research Project) where the study is being done should ensure that there is no financial conflict of interest by the investigators. The Institute/ Investigator should also furnish a declaration in the format given below:

Declaration & Attestation

1. I/We have read the terms and conditions for DHR Research Grant. All necessary Institutional facilities will be provided if the research project is approved for financial assistance.
2. I/We agree to submit within one month from the date of termination of the project the final report and a list of articles, both expendable and non-expendable, left on the closure of the project.
3. I/We agree to submit audited statement of accounts duly audited by the auditors as stipulated by the DHR.
4. It is certified that the equipment(s) is/are not available in the Institute/Department or these are available but cannot be spared for the project.
5. It is further certified that the equipment(s) required for the project have not been purchased from the funds provided by DHR for another projects(s) in the Institute.
6. I/We agree to submit (Online) all the raw data (along with descriptions) generated from the project along with annual report to the DHR within one month from the date of completion.

If any equipment already exists with the Department/Institute, the investigator should justify purchase of equipment.

Signature of the:

a) Principal Investigator _____

b) Co-Investigator(s) _____

c) Head of the Department _____

Date: Signature of the Head of the Institution with seal

10. AUDIT

The department would normally accept audited report from auditors as applicable to the concerned institution. Statement of accounts audited by Chartered Accountants approved by or registered with the CAG and /or Ministry of Health & Family Welfare would also be accepted. The necessary registration number should be provided for record.

11. ANNUAL UTILIZATION CERTIFICATE

The concerned Institutions/Medical College would be required to furnish the audited Utilization Certificate (UC) and Statement of Expenditure (SoE) in accordance with the provisions of the GFRs.

12. FINAL SETTLEMENT OF THE ACCOUNTS

The final settlement of the Accounts will be done only after the receipt of the following:

a. Final audited statement of expenditure
b. Final utilization certificate
c. List of equipments procured from the project along with their cost, date of purchase, and suggestions for disposal
d. The grant paid by the DHR shall be refunded by the institution as and when the investigator discontinues a scheme midway or does not follow the detailed technical programme as laid down and approved by the DHR.
e. All raw data (in all forms) should be made available/accessible to DHR.

13. PUBLICATION OF RESULTS/PRESENTATION OF PAPERS

The research papers and publications based on the results of the research project should acknowledge assistance by the DHR. Copies/reprints of papers published should be sent along with the progress/final report.

14. INTELLECTUAL PROPERTY RIGHTS

All new intellectual property rights viz., patents, designs etc. generated as part of the research supported by the DHR under the Scheme, would belong to the Department.

15. CONFLICT OF INTEREST

In order to maintain the objectivity in the conduct and reporting of research, it is imperative that the investigators should not have any financial or other interests that undermine scientific integrity while recording and reporting their data. Any research or other links of the investigators with industry are discouraged as such a link would compromise or likely to compromise unbiased reporting of research data. In addition, such a financial conflict of interest could lead to loss of public faith on the credibility of data being reported, especially in the light of recent reports of financial conflict of interest of investigators in drug and other clinical trials. All investigators, desirous of DHR support should declare financial conflict of interest, if any, before submitting the project for support. They should also ensure that during the conduct of the project, they would also observe the same code of conduct. If the Department comes to know of any unethical conduct on the part of investigator including improper/incomplete declaration, the project is liable to be terminated immediately with refund of cost.

CONTACT

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DHR website: dhr.gov.in
ICMR website: icmr.nic.in

16. THE FORMAT OF UTLIZATION CERTIFICATE & STATEMENT OF EXPENDITURE

GFR 12 – A

[(See Rule 238 (1)]

FORM OF UTILIZATION CERTIFICATE FOR AUTONOMOUS BODIES OF THE GRANTEE ORGANIZATION

UTILIZATION CERTIFICATE FOR THE PERIOD ……..…to ……..……
in respect of recurring/non-recurring
GRANTS-IN-AID/SALARIES/CREATION OF CAPITAL ASSETS

1. Name of the Scheme.....
2. Whether recurring or non-recurring grants.....
3. Grants position at the beginning of the Financial year
   (i) Cash in Hand/Bank
   (ii) Unadjusted advances
   (iii)Total

4. Details of grants received, expenditure incurred and closing balances: (Actual)

Unspent Balances of Grants received years [figure as at Sl. No. 3 (iii)]	**Interest Earned thereon**	**Interest deposited back to the Government**	**Grant received during the year**			**Total Available funds (1+2- 3+4)**	**Expenditure incurred**	**Closing Balances (5-6)**
1	2	3	4			5	6	7
			Sanction No. (i)	Date (ii)	Amount (iii)			

Component wise utilization of grants:

Grant-in-aid–general	Grant-in-aid–Salary	Grant-in-aid–creation of capital assets	Total

Details of grants position at the end of the year

(i) Cash in Hand/Bank
(ii) Unadjusted Advances
(iii) Total

Certified that I have satisfied myself that the conditions on which grants were sanctioned have been duly fulfilled/are being fulfilled and that I have exercised following checks to see that the money has been actually utilized for the purpose for which it was sanctioned:

(i) The main accounts and other subsidiary accounts and registers (including assets registers) are maintained as prescribed in the relevant Act/Rules/Standing instructions (mention the Act/Rules) and have been duly audited by designated auditors. The figures depicted above tally with the audited figures mentioned in financial statements/accounts.
(ii) There exist internal controls for safeguarding public funds/assets, watching outcomes and achievements of physical targets against the financial inputs, ensuring quality in asset creation etc. & the periodic evaluation of internal controls is exercised to ensure their effectiveness.
(iii) To the best of our knowledge and belief, no transactions have been entered that are in violation of relevant Act/Rules/standing instructions and scheme guidelines.
(iv) The responsibilities among the key functionaries for execution of the scheme have been assigned in clear terms and are not general in nature.
(v) The benefits were extended to the intended beneficiaries and only such areas/districts were covered where the scheme was intended to operate.
(vi) The expenditure on various components of the scheme was in the proportions authorized as per the scheme guidelines and terms and conditions of the grants-in-aid.
(vii) It has been ensured that the physical and financial performance under…….. (name of the scheme has been according to the requirements, as prescribed in the guidelines issued by Govt. of India and the performance/targets achieved statement for the year to which the utilization of the fund resulted in outcomes given at Annexure – I duly enclosed.
(viii) The utilization of the fund resulted in outcomes given at Annexure – II duly enclosed (to be formulated by the Ministry/Department concerned as per their requirements/specifications.)
(ix) Details of various schemes executed by the agency through grants-in-aid received from the same Ministry or from other Ministries is enclosed at Annexure –II (to be formulated by the Ministry/Department concerned as per their requirements/specifications).

Date:
Place:

Signature	**Signature**	**Signature**
Name.....	**Name.....**	**Name.....**
PrincipalInvestigator	**Head of the Finance**	**Head of the Organization**

Signature
Name.....
Chartered Accountant

(Strike out inapplicable terms)

STATEMENT OF EXPENDITURE

Showing grants received from the Department of Health Research (DHR), GoI and the expenditure incurred during the period from …… to ……

Heads	**Unspent balance brought forward from previous year**	**Grants received from the Department during the year**	**Total (2+3)**	**Actual expenditure incurred during the year**	**Balance (4-5)**	**Remarks, if any**
(1)	(2)	(3)	(4)	(5)	(6)	(7)

Signature
Name.....
Principal Investigator

Signature
Name.....
Head of the Finance

Signature
Name.....
Head of the Organization

Signature
Name.....
Statutory Auditor/Chartered Accountant