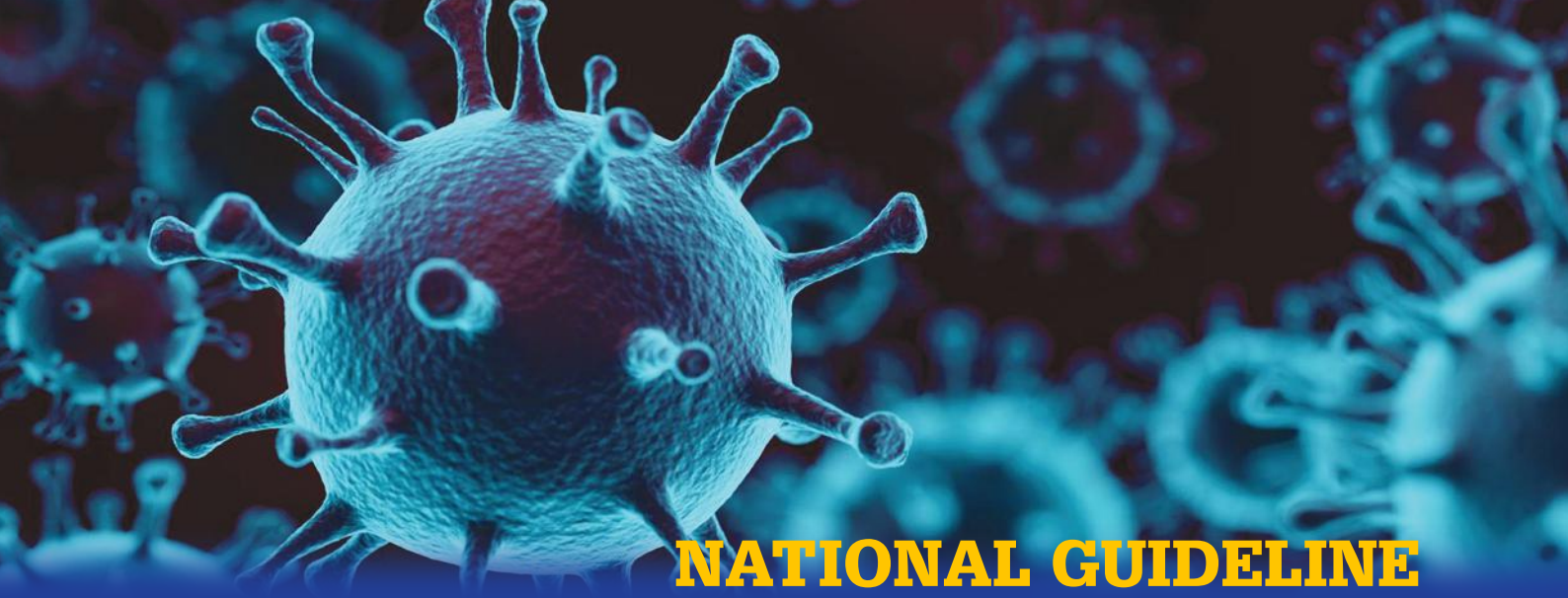

NATIONAL GUIDELINE

FOR STRENGTHENING EVIDENCE GENERATION ON COVID-19

Government of Nepal

Nepal Health Research Council

Ramshah Path, Kathmandu

NATIONAL GUIDELINE FOR STRENGTHENING EVIDENCE GENERATION ON COVID-19

June 2020

Government of Nepal
Nepal Health Research Council
Ramshah Path, Kathmandu

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Preface

The first case of COVID- 19 pandemic was reported in December 2019 in Wuhan, China, and until now it has affected over 12 million people worldwide and over half a million people died from it. In Nepal as well, there has been a steady rise in the number of cases, which has warranted an urgent and specific focus on research related to COVID in order to understand its pathogenicity, epidemiology, diagnosis and treatment measures in the national context. It is evident that the burden of COVID-19 may soon be unbearable to a developing nation like Nepal. Thus, country-specific evidences are warranted to effectively tackle the disease and mobilize resources available in the health-system. Recognizing the global and national threat of COVID-19, Nepal Health Research Council was requested to prepare a national guidelines regarding COVID-19 research and has been approved by Ministry of Health and Population.

The guideline will help to regulate, manage as well as facilitate research in the context of COVID-19. Current guidelines and arrangements set by NHRC can regulate, promote and facilitate the research activities in normal situations. In the context of COVID-19 emergency, there might be a requirement of additional provisions and arrangements to complement the existing ones. This guideline provides information regarding COVID-19 research methods, particularly related to questionnaire based studies, studies with biological samples, clinical trials, ethical consideration, quality assurance, capacity building and resource mapping as well as publication and dissemination of the results.

I would like to use this opportunity to extend my gratitude to all who have contributed to this guideline. My sincere appreciation goes to Nepal Health Research Council for their effort in successfully preparing and publishing the national guideline in the context of this global crisis. I sincerely hope that this guideline will be helpful for researchers and development partners for securing funds and implementation of research for timely generation of evidence for evidence based informed decision making in Nepal.

Laxman Aryal
Secretary

Government of Nepal
Nepal Health Research Council (NHRC)
Estd. 1991

Ref. No.: 2834

Acknowledgement

On behalf of Nepal Health Research Council (NHRC), I would like to express my sincere gratitude to the Ministry of Health and Population (MoHP) for requesting NHRC with the important task of developing national guidelines for COVID-19 research in Nepal. This guideline has been successfully developed with the contribution of several individuals.

First, I would like to thank, Incident Command System (ICS) Commander & Secretary, MOHP, Mr Laxman Aryal and Coordinator of ICS &Chief of Policy, Planning and Monitoring Division Dr Guna Raj Lohani for their cooperation and support, members of the ICS Research Pillar; Dr. Sharad Kumar Sharma, Mr. Paban Ghimire, Dr. Sujan Babu Marahatta, Dr. Rajendra Kumar BC and Dr. Krishna Kumar Aryal for their continued efforts and contributions towards the preparation of the Guidelines. Similarly, I am thankful to Dr Guna Niddhi Sharma, ICS Planning and budgetary Officer and Senior Public Health Administrator of Planning Section, MOHP for his valuable suggestion during the preparation of the guideline. I would also like to thank the support team including Prof. Dr. Prakash Ghimire, Dr. Meghnath Dhimal, Ms. Namita Ghimire, Mr. Bihungum Bista, Mr. Anil Poudyal, and Dr. Suman Pant for their contributions in reviewing and finalizing this guideline. Furthermore, I am grateful of Executive Committee of NHRC for timely endorsement of guidelines and MOHP for timely approval of Guidelines endorsed by NHRC Executive Committee of NHRC.

I hope these guidelines will help to promote, regulate and facilitate research in the context of COVID-19 in Nepal for generating country-specific evidences, which would help to support MoHP in tackling and containing this pandemic.

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List of Acronyms

COVID-19	Coronavirus Disease 2019
EDPs	External Development Partners
ERB	Ethical Review Board
HEOC	Health Emergency Operation Centre
ICS	Incident Command System
IPC	Infection Prevention and Control
IRC	Institutional Review Committee
KAP	Knowledge, Attitude and Practice
MoHP	Ministry of Health and Population
NHRC	Nepal Health Research Council
PPE	Personal Protective Equipment
RDT	Rapid Diagnostic Test
RT- PCR	Reverse Transcription - Polymerase Chain Reaction
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
VTM	Virus Transport Medium
WHO	World Health Organization

1. Introduction

1.1 Background

On 30th January, WHO declared the outbreak a Public Health Emergency of International Concern, due to COVID-19, initial infections detected in Wuhan in China On 11th March2020, WHO declared the COVID-19 outbreak as a "**pandemic**". As of 24th May 2020, around 5,429,185 diagnosed cases of COVID-19 with 344,444 deaths and 2,259,877 recoveries have been reported severely affecting United States of America (USA), Brazil, Russia, Spain and United Kingdom with few thousand cases and few deaths in other countries. In Nepal, the first case was reported on 23rd January 2020. The cases of COVID-19 have increased logarithmically in the last three weeks, with 1572 cases, 220 recoveries and eight deaths as of 31st May 2020. Scattered evidence on various aspects of the disease epidemiology, characteristics of the virus and its transmission, symptomatic case management has been developed globally, where there are very high mortality However, the morbidity and mortality due to COVID-19 in Nepal is slow and low in comparison, which demands country specific research developing evidences for policy and strategy planning for early containment and mitigation of the effects at the earliest.

Nepal Health Research Council, by the Act of parliament is mandated for conducting and regulating health research in the country. NHRC conducts research of national importance by itself through collaboration with other research and academic institutes in the country, while it has formed an independent Ethical Review Board (ERB) mandated for reviewing, approving and monitoring the research involving human participants. ERB meetings at NHRC are being organized every week facilitating approval of research related to COVID-19, maintaining basic principles of bio-ethics and in line with FERCAP accreditation received last year. NHRC is carrying out research on viral genomics, diagnostics, immunopathology of the COVID-19, pandemic preparedness & response, psycho-social effect of COVID-19 related lockdown and other actions in the country.

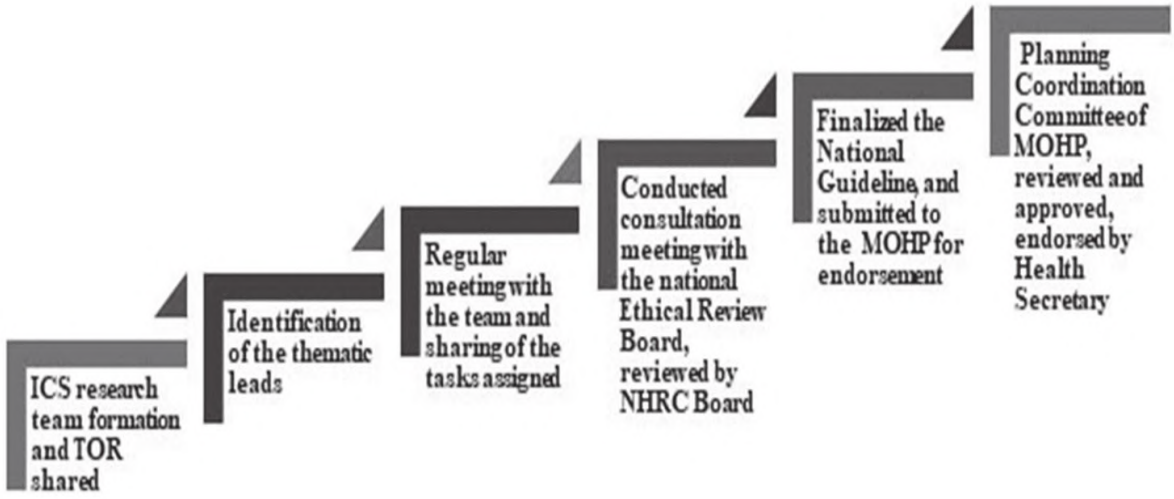
In addition to NHRC, there are other academic institutes, which are also involved in various aspects of COVID-19, including research of local and national importance. In order to streamline the research related to COVID-19, generating evidences for policy impact at the earliest possible timeline, this framework will be a supplementary guidance document for the researchers, without compromising basic principles of bio-ethics and in line with the requirements of ICH/GCP and Helsinki principles.

1.2 Rationale

Nepal Health Research Council (NHRC) is an apex body of the Government of Nepal which guides, regulates and promotes health research in Nepal through NHRC Act 1991 subjected to National Health Policy of Government of Nepal. NHRC has developed research strategy and prepared research priority list updated periodically and developed required infrastructure and co-ordination platforms for research conduction, monitoring, ethical clearances, publication and dissemination of research findings through appropriate channels and platforms.

In the context of COVID-19 pandemic, not only national, regional and global collaboration is required to combat the existing public health emergency but also focused approach is required for generating and using the evidence for response. Current guidelines and arrangements set by NHRC regulate, promote and facilitate the research activities in normal situations. In the context of COVID-19 emergency, there might be a requirement of additional provisions and arrangements to complement the existing ones. In order to address the urgency and capture opportunity for evidence generation, NHRC has already started expedited review of COVID-19 related research in Nepal.

1.3 National Guideline Development Process



2. COVID-19 Research Areas

Expansion of our knowledge base is a key challenge in national health and is achievable through appropriate research. For research to be used by decision makers to solve the problems they are facing currently or might face ahead, the research should focus on solving those and support decision-making process. Setting COVID-19 research priorities is an essential step towards increasing the efficiency and effectiveness of the Incident Command System (ICS) response to the emergency. Important links exist between COVID-19 research foresight and its research priority setting. COVID-19 research plans have to be flexible and subject to regular review.

2.1 Approach

Availability of evidence and gaps, dynamics of emergency, country capacity and availability of resources are important aspects for setting research priorities. Thus, various COVID-19 related documents existed in the MoHP, NHRC, World Health Organization (WHO), and elsewhere have rigorously been reviewed. After review, various COVID-19 research areas were discussed and finalized through ICS meeting. COVID-19 research areas have been grouped into 15 domains.

2.2 COVID-19 Research Areas

1 Emergency Preparedness and Response

2 Monitoring and Evaluation

3 Infection Prevention and Control (IPC) Practices

4 COVID-19 related Knowledge, Information and Data

5 COVID-19 related Fund and its Economic aspects

6 COVID-19 Epidemiology

7 Clinical Characterization, Presentation and Testing

8 Rapid learning about Immunity for Public Health Impact

9 Treatment and Rapid Impacts for COVID-19 Treatment

10 Non-pharmaceutical Intervention: Adherence and Mobility

11 Public Health Response

12 Genetics of COVID-19

13 Psycho-social dimension of COVID-19

14 Food and Nutrition during COVID-19 Pandemic

15 Risk Communication

Each of such areas contains specific research questions (Annex-I).

2.3 Identifying the Priorities for COVID-19 Research

COVID-19 research areas listed above and priority research questions as mentioned in the Annex I may further need updating based on: (1) diverse and changing risk population, and (ii) contextual and contemporary health problems. However, most accepted criteria for prioritization to be used in this process is basically grouped into seven areas namely; (1) Relevance, (2) Avoidance of duplication, (3) Urgency of data needed, (4) Social, political and economic acceptability, (5) Feasibility, (6) Application of results, and (7) Ethical acceptability. All of these specific criteria will be scored in a three-point rating scale in order to identify the priority of research areas/questions which may be grouped into low, medium and high priority research areas/questions depending upon the scores that it obtains. Format for priority score is given in Annex II. Any research planned around COVID-19 should be guided by and in line with the research priorities in COVID-19.

3. Guiding Principles for COVID-19 Research

Any attempts to health research response to this global challenge COVID-19 pandemic should be in line with the following key principles and considerations:

- The safety and well-being of the participants and their families, and health care professionals. Agreement for sharing the findings of the study at the earliest with NHRC and MOHP officials for policy implications.
- Agree to share benefits of the research outcome for the benefit of the research participants and for the nation, which may include sharing IPR (unlike virus and benefit sharing in case of research outcome leading to effective drug or vaccines)

3.1 Questionnaire based Study

The survey approach can employ a range of methods to answer the research question. Common survey methods include online questionnaires, face-to-face interviews, and telephone interviews. While the researchers may be using a wide range of topics to support building the evidence base for this rapidly evolving disease that has developed as a big public health threat in no time, each of the different types of research in one or the other form use some questionnaire or similar instruments to collect the data. The following general principles can be followed in any studies that involve use of questionnaire or similar data collection instruments:

- Where possible, researchers can use online methods of data collection using available best possible platforms.
- When required to carry out face to face interviews, researchers are to follow all possible public health and social measures with regards to preventing or supporting to prevent COVID-19 transmission as guided by national and international guidelines and strategies (universal preventing measures).
- An automated data editing and basic analysis system ensures immediate data analysis and provides fast access to the results.

3.2 Study with Biological Samples

Research involving human biological materials in relation to COVID-19 may include tissues, organs, blood, plasma, serum, Deoxyribonucleic acid, Ribonucleic acid, proteins, cells, urine, saliva, swab, or other bodily fluids. These biological materials may be collected expressly for a specific research purpose; from medical or diagnostic procedures In any case, these samples will have to be handled carefully so as to minimize the risk of transmission to the researchers and/or other people who might have the possibility of coming in contact with the sample. While handling such bio samples from COVID-19 patients, researchers are to follow all available national guidelines and protocols (and any other relevant guidelines from around the world if national guidelines and protocol are not developed). The following general principles are expected to guide studies that involve biological sample:

- When biological materials and related data are collected and stored, institutions must have a governance system to obtain authorization for future use of these materials in research.
- Researchers must not adversely affect the rights and welfare of individuals from whom the materials were collected.
- When specimens are collected for research purposes, consent procedures have to be guided by the National Ethical Guidelines and this will become more important in the COVID-19 context. Thus, either specific informed consent for a particular use or broad informed consent for unspecified future use must be obtained from the person from whom the material originally is obtained.
- When researchers seek to use stored materials collected for past research, clinical or other purposes without having obtained informed consent for their future use for research, the decision for the possibility of its use in any further research planned will have to be as per National Ethical Guidelines of Nepal.
- Similarly, following the National Ethical Guidelines, the custodians of biological materials must arrange to protect the confidentiality of the information linked to the material, by sharing only anonymized or coded data with researchers, and limiting access to the material of third parties. The key to the code must remain with the custodian of the biological materials.
- The transfer of biological materials must be as provisioned in the National Ethical Guidelines. In the COVID-19 context, researchers and research institutions must make sure that the biological materials and related data are only collected and stored in collaboration with respective health care institutions. The governance structure of such a collection should have representation of the original setting.
- Type of the samples to be collected for the COVID-19 research largely depends on the clinical presentation of the patients.
- All relevant guidelines regarding sample collection and handling to be followed using national guidelines and protocols and any relevant guidelines from around the world.
- All the biomedical waste should be disposed of in accordance with national guidelines in an environmental friendly way without any adverse effects to public health
- Sample is to be transported to the testing laboratory as per the requirement of temperature maintenance for respective biological samples, and following the protocol specified in a national (if any) guideline including packaging instructions.
- Ensure that the personnel who transport specimens are trained in safe handling practices and spill decontamination procedures.
- Follow IPC measures at all levels as guided by the relevant national guidelines.

3.3 Clinical Trials on COVID-19

Clinical trials are an important research area to discover and make available safe and effective treatments for COVID-19. International, regional, and national legal and methodological frameworks exist for clinical trials that also take into account ethical principles. In addition to using a particular appropriate framework for conducting clinical trials and other interventional studies in the COVID-19 context in Nepal, the following general principles are expected to guide such studies:

- Clinical trials in COVID-19 should be registered at or before the time of first patient enrolment and protocols possibly published in recognized registry. National clinical trial registry maintained at the NHRC should be the priority.
- Multi-center/multi-country studies with a high number of patients is encouraged to generate sound evidence on COVID-19 treatments. Collaborative trials, solidarity trial and multi-arm studies comparing different drugs are advisable.
- The ERB to provision a lawful fast track approval procedure of clinical trials in the current context while protecting individual rights.
- Protocols should follow standard criteria for data collection, stratification of the randomized population, type of intervention and comparator, a minimal set of primary outcome measures (e.g. SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials).
- Availability for timely publication of outcomes - even for negative and withdrawn studies - and for data sharing should be declared by investigators and sponsors at the time of study registration and included in the study documents (e.g. protocol, patient information sheet and consent form).
- The ERB facilitate compassionate use of approved repurposed drugs and establish a fast track for approval of all COVID-19 drugs. Adaptive study designs and post-authorization efficacy and safety studies after exceptional or conditional approval could be planned with sponsors in order to favor early access of severe patients to promising medicines.
- Adequate tools should be implemented for collection and analysis of reliable real-world data of drugs approved for the treatment of COVID-19.
- Data and trial documents should be made available for sharing. Individual participant data sharing should be based on explicit broad consent by trial participants (or if applicable by their legally authorized representatives) to the sharing and reuse of their data for scientific purposes, according to applicable law. Where real-world data are collected from patient registries or similar data sources not involving specific consent to participate, patients' privacy must be adequately protected being strictly guided by the National Ethical Guidelines. Data and trial documents should be transferred to a suitable and secure data repository to help ensure that the data are properly prepared, are available

  in the longer term, are stored securely, and are subject to rigorous governance. Existing repositories for e.g. that of the NHRC should be given a priority for sharing the data.

- For data sharing, clinical trial, data should always be associated with adequate and standardized metadata to improve discoverability.

4. Ethical Consideration

In the conduct of research during pandemic, it is essential to maintain the principles outlined in the National Ethical Guidelines for health research in Nepal. Conducting research in these situations raises important challenges such as the need to generate knowledge quickly, maintain public trust, and overcome practical obstacles to implementing research. These challenges need to be carefully balanced with the need to ensure the scientific validity of the research and uphold ethical principles in its conduct.

- Existing national and international ethical guidelines that govern research involving human participants apply to all research conducted during COVID-19 Emergency.
- The four basic principles (autonomy, beneficence/non-maleficence, justice and respect for environment) in any forms related to health research should be diligently followed.
- The ERB and respective IRCs must prioritize research review based on urgency and take needful steps to facilitate the review of new research and conduct ongoing research with necessary amendments as per need in the view of social distancing norms.

5. Quality Assurance

COVID-19 researchers and research institutions require the adoption of appropriate quality assurance mechanisms in the collection of data on any kind of research; collection, processing and storage of human biological samples; collection of information on studies including clinical trials. Standards for the collection, processing and storage of samples for research should be proportionate, practical, realistic and achievable. Researchers and/or research institutions are responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials/research are conducted, and data are generated, documented (recorded), and reported in compliance with the protocol, Good Clinical Practice (GCP) guidelines, and any other applicable regulatory requirements. Following general principles are expected to guide the overall quality assurance framework:

Relevance and Impact

- The proposed research should address pertinent question(s) about COVID-19 and follow the national COVID-19 research priorities and be able to address policy relevant issues with the greatest public health impact and potential to improve global health goals in line with COVID-19.
- The research problem should be well formulated, and the purpose of the study should be clear.
- Data and information should be easily available.

Excellence

- Researchers should conduct research that is excellent in technical quality and with the potential of maximum impact and generalizability both within and external to the study settings.
- Checklists those are appropriate to COVID-19 research design to be used to increase technical quality and ensure consistently high quality.
- Research approaches should be well designed and conducted.
- The implication and recommendations should be logical and supported by the finding and explained carefully with appropriate limitations.
- The research should be convincing, useful, and relevant to stakeholders and decision makers.

Integrity

- Researchers should comply with high standards of integrity and honesty in all steps of the research process, including proposal submission, data analysis and reporting.
- The research should include appropriate acknowledgment of one's contribution and the contribution of others and refraining from using the work of others without permission or acknowledgement and other infringement of intellectual property

Freedom from Conflict of Interest

- All investigators must disclose any conflicts of interest (CoI), including financial or other types of support for the research that may conflict with their work.

Adherence to Ethics Guidelines

- Researchers must adhere to guidelines as promulgated by the ERB and/or respective IRCs.

Monitoring

- The research institutions/laboratories and all other research settings should be monitored regularly to ensure research practice is in accordance with the protocol as well as current legislation and guidelines.

A quality assurance checklist is annexed in Annex - III, which can be contextualized and used for monitoring and ensuring quality of research.

6. Monitoring

Monitoring of the research activities are to be ensured both through an internal (researchers or research institutions) mechanism and also by the Ethical Review Board (ERB) and respective Institutional Review Committees (IRCs). The researchers or research institutions must provide relevant information to the committee to permit monitoring of research records, especially information about any Serious Adverse Events (SAEs) related to COVID-19 by the researchers and research institutions to ensure periodic and regular reporting of the study implementation as well as any other ad-hoc reporting of issues such as SAEs, deviation from the protocol, changes in plan etc. The ERB and respective IRCs also play their role in facilitating such processes. Existing Monitoring Committee of the NHRC is to play active role with enhanced monitoring. The committee can develop additional provisions and process for monitoring. Following the completion of study, researchers must submit a final report on monitoring and quality control mechanism and process adapted to the ERB and respective IRCs. There should be mandatory formation of Data Safety Monitoring Board (DSMB) in case of clinical trials on COVID19.

Selection of Research Team/Site

- Ensure that the researcher has adequate qualification and resources and remains adequate throughout the research period
- Research site has adequate research equipment and staff to safely and properly conduct the research
- Should ensure that the protocol and other research document and plans are up to date

Training/Coaching

- Ensure that researcher and staff are adequately informed about research
- The research is conducted as per protocol
- Only eligible subjects are enrolled in research

Onsite Control

- Ensure all quality assurance requirements are fulfilled
- Research tools and logistics
- Verify that the research tools and other logistics are stored on time and in good conditions and supply of required logistics are sufficient throughout the research period

Availability of Other Essential Documents

- Ensure that the researcher follows approved protocol
- Ensure that the written informed consent is taken before participation
- Ensure that the research documents are up- to- date not deviated from protocol
- Verify that source documents (data, records, checklists etc.) and other research records are accurate, complete and up –to- date

Adverse Event

- Ensure all adverse events are accurately recorded and reported

Management Issues

- Reporting of participation and recruitment rate
- Information about any recruitment error, omission and eligibility
- Communication of any deviation from protocol

7. Capacity Building and Resource Mapping on COVID-19 Research

7.1 Capacity Building Framework

Research capacity for COVID-19 is the ability to define problems, set objectives and priorities, conduct sound scientific research and identify solutions at national and sub-national level. It encompasses research capacity at the levels of individuals, research groups, institutions and of the country. Research capacity strengthening is the process by which individuals, communities and institutions develop abilities collectively – to perform research effectively, efficiently and in a sustainable manner to address the situation led by COVID-19.

The scientific community is facing the challenge to tackle the spread of COVID-19 and evidence-based healthcare information is an armor that can protect us and save lives. This has necessitated the need for evidence on more than one element/ factor to gauge and deal with the holistic impact of COVID-19. The disease is here to stay; and we need long-term planning for this. Hence, the need for national collaborative research efforts is imminent. The plan to develop a sustainable health research environment and harmonize national research efforts on COVID-19 has been presented.

i) Network strengthening, fostering exchanges between institutions and researchers (national and international) and communicate/share experiences

Collaboration between different stakeholders, and collaboration and communication go to the very core of research capacity strengthening for COVID 19. The engagement with various research stakeholders is essential. The research capacity strengthening efforts are part of a wider network. Governing bodies, the research community and the public are key partners in the effort to enhance evidence production and dissemination.

At this stage, network strengthening will involve collaborations and communications to discuss: (1) the overall need to strengthen COVID-19 related research in Nepal, (2) potential capacity mapping strategies that can be implemented at institutional, national and sub-national level, and (3) potential strategies for capacity building activities and their implementation.

ii) Capacity mapping/research mapping - Understanding different aspects of disease and existing research capacity of the institution to execute the researches

There is a need to engage all key stakeholders: researchers, policy-makers and communities to understand various aspects of disease. There is a need to understand the capacity and mapping of the ongoing research. A working knowledge of the capacity of health institutions in terms of facilities and human resources is essential to proceed the research activities. Meanwhile, supporting community research literacy is one of the challenges that must be prioritized to avoid incorrect health decision-making.

iii) Implementation of capacity building activities

Engagement with various research stakeholders is essential. Governing bodies, the research community and the public are key partners in the effort to enhance evidence. It's necessary to strengthen the processes surrounding the generation and implementation of high-quality evidence, preceded by a detailed process of research with methodological rigor and bioethical principles too. Moreover, facilitating the access to scientific data, enabling career developments in research, mobilizing resources to support scientific studies and generating lessons for future outbreaks, among other strategies which need to be focused.

The six dimensions of research capacity building in Cooke's framework (contextualized framework is in Annex - IV) are as follows (Cooke, 2005; Farmer & Weston, 2002):

1) Building skills and confidence

2) Ensuring research is close to practice

3) Developing partnerships and linkages

4) Supporting appropriate dissemination

5) Including elements of continuity and sustainability

6) Making investments in infrastructure to enhance research capacity building

7.2 Capacity Building Strategies

With a view to enhancing the COVID-19 related research capacity strategies, following activities will be put forth by the NHRC:

- Field epidemiology, epidemiological studies, diagnostic research and treatment modalities.
- Health research proposal, research management, data analysis, report and scientific manuscript writing training with a special focus on COVID-19.
- Providing the grant or scholarship to post-graduate students or researchers.
- Providing training on ethical aspects of health research including GCP.
- Enhancing diagnostic research capacity of clinical researchers.
- Enhancing interventional research capacity of researchers.
- Training on health policy and systems research as well as operational and implementation research.
- Establishing research centers for excellence for infectious diseases.

7.3 Monitoring and Evaluation of Capacity Building in COVID-19 Research

NHRC will upgrade its monitoring and evaluation framework considering following indicators but not limited to:

- Number of institutions initiating COVID-19 related research
- Number of research proposals submitted to the ERB and/or IRCs
- Number of research initiated/ completed
- Number of publications
- Implications to policy, planning and programme development (if any)
- Evaluation of evidence generation and use
- Resource mobilization and prediction for emergencies
- Training materials and manuals developed

7.4 Resource Mapping and Mobilization

Following dimensions of resources are considered here for COVID research in Nepal.

a) Financial resources

b) Infrastructure and Equipment

c) Consumable logistics

d) Human resources

e) Information and Documents

a) Financial Resources

NHRC explores the financial resources for COVID research within itself, MoHP and Departments, WHO, Academic Institutions, Health Research Institutions and EDPs. NHRC will also make estimation of required financial resources in lump sum for priority research areas and request to Government of Nepal, WHO and development partners for inventiveness on research on COVID-19. MoHP may facilitate the resource management in order to ensure key research and associated activities are implemented so as to meet the overall goal of strengthened national evidence base in COVID-19.

NHRC documents the financial resources available for COVID-19 research in all the related entities and co-ordinates for optimized use of that. NHRC would also make an arrangement for investment in research based on the financial resource prediction for conducting research in priority areas.

b) Infrastructure and Equipment

Shared use of lab facilities, clinics, information technology and other infrastructure needed for carrying out research in the emergency is rational. NHRC shall map out the frequently needed infrastructure and equipment in research and make the information public. MoHP and NHRC may facilitate shared use of those infrastructures and facilitate researchers to make use of such facilities and infrastructure.

c) Consumable Logistics

Procurement and acquisition of logistics is not easy during emergencies. MoHP and NHRC will help to manage the facilities for import, export, shipment, procurement and distribution of essential consumables for health research as essential health commodities.

d) Human Resources

Research activities demand experts from multiple disciplines ranging from field epidemiology, medical, public health, information management to socio-economic field. Pooling of these human resources (HR) and employing to facilitate the research activities for the timely evidence generation and use. NHRC prepares roasters of experts eligible, capable and willing for health researches during emergency and publicize them through NHRC website.

NHRC deploys the required HR critical for research management and system strengthening through fast track contract procedures. MoHP may encourage the health sector employees to engage in research activities following the existing regulation.

e) Information and Documents

Shared use of information is mandated by MoHP for research purposes. Existing fragmented and ignored information systems and distributed information products will be brought to the single platform at NHRC and ICS play crucial role on this. All the routine information systems, surveillance, research and studies related data will be pooled under the command of the responsible information manager within the framework of NHRC. A quality monitoring and data sharing mechanism will be set for easy access and use of those products for research and study purposes. Metadata will be maintained for all the data sets managed in the platform.

Several documents and research products related to COVID-19 are existing and emerging locally, regionally and globally on a continuous basis. NHRC may archive, procure and maintain the document separately in the NHRC library and NHRC website as well for easy public access. NHRC also prepare an inventory of all the documents available for public use and upload in its webpage. ICS will also facilitate for managing all the COVID-19 related guidelines, protocols and major public circulations in the Health Emergency Operation Centre (HEOC), MoHP and provide easy access to researchers.

8. Dissemination, Uptake and Utilization of evidence on COVID-19

Publication and dissemination of the research projects will be guided by National Health Research Strategy of Nepal and National Ethical Guidelines for Health Research in Nepal, 2019. Further consideration is made for research in COVID-19 context. Researchers have a duty to make sure the results of their health-related research on COVID-19 involving human beings are publicly available and are accountable for the completeness and accuracy of their reports. Due to its importance in early policy implications, a confidential early and preliminary report needs to be submitted to ERB/NHRC, as per the ethical approval requirement. The same will/need to be shared by the PI or NHRC to MoHP for utilizing as evidence for policy/strategy for early containment or mitigation of effects of the disease.

8.1 Publication and dissemination of the results of research

Following general guiding principles have to be followed in view of publishing and adequately disseminating the evidence generated from all COVID-19 research.

- Negative and inconclusive as well as positive results related to COVID-19 must be published or otherwise made publicly available.
- In journal publications, all involved parties must adhere to accepted guidelines, sources of funding; institutional affiliations and conflict of interest (CoI) must be disclosed in the publication.
- Reports of research that fail to comply with recognized publication and ethical guidelines must not be accepted for publication.
- Sponsors must not prevent researchers from publishing negative or statistically not significant findings that restrict their freedom of publication.
- As the persons directly responsible for their work, researchers must not enter into agreements that interfere unduly with their access to the data or their ability to analyse the data independently, prepare manuscripts, or publish them.
- Researchers must also communicate the results of their work to the lay public. Ideally, researchers should take steps to promote and enhance public discussion.
- Knowledge resulting from the research should be made accessible to the communities in which the research was conducted, either through publication in scientific journals or through other channels.
- Results can be made available to the media in order to support high quality and responsible reporting.

8.1.1 Publication

Research publications should be taken as key assets particularly produced in emergencies. The documentation, management and use of those would add value to build the evidence and consequent knowledge management in the emergency context. Since the public health emergency has also provided an opportunity to accelerate the research in innovative ways, the outcomes of the research as well as methods and techniques adopted are rare. Hence, the researchers and research institutions are encouraged to ensure sharing the publication from their research work to the MoHP and the NHRC. NHRC has to consider publishing special issue(s) of its journal – the Journal of Nepal Health Research Council incorporating manuscripts of high national importance arising from COVID-19 research. Furthermore, NHRC will develop a repository of all relevant COVID-19 research reports, manuscripts and other publications.

Researchers and research institutions implementing research with the approval from the ERB and respective IRCs should submit the report to the NHRC or respective IRCs. NHRC will manage dissemination of those reports submitted to NHRC, IRCs and other relevant stakeholders.

Ownership issues and responsibilities of data and publication of research manuscripts need to be carefully worked out well before data are collected and researchers should ensure clarity about data ownership, publication rights and obligations following data collection. Plans for manuscript publication and a common final report with contributors from the participating sites should be decided upon before initiation of the study. All COVID-19 related publications should be open access Journals or platforms and publication in commercial Journals should be avoided. Manuscript on COVID-19 should be provided first priority for publications in Nepalese Journals (e.g., listed in NEPMED).

Authorship

The researchers should follow the guidance of International Committee of Medical Journal Editors and National Ethical Guidelines for Health Research in Nepal regarding authorship. Researchers should be aware of potential stigmatization of the entire group and must explain ways to avoid the same during the conduct of research and publication of research results. Specific informed consent should be taken from concerned people (research participants) to publish pictures in the publication, and researchers will have to protect personal identification of the individuals while doing so. All the provisions regarding Intellectual Property Right must be followed according to National Ethical Guidelines for Health Research in Nepal.

8.1.2 Dissemination

Dissemination of the findings to the audience is the main way to materialize the research objectives. This is the pathway from where research outcomes are translated into action. Timely and quick dissemination of the research products are warranted mainly in the health emergencies. The dissemination tools may be of various forms based on research design and publication criteria set in priori; research reports, peer review papers, press releases, and policy briefs.

Mode of Dissemination

In view of the public health measures for prevention; social distancing, teleworking and limits in transportation, researchers and research institutions have to manage the various techniques of dissemination. Following dissemination channels would be adopted as appropriate.

- Virtual Meetings
- Interpersonal communication
- Local events
- Web sites
- Tele conferences
- Email messages
- Project team conference/meetings
- Policy briefs
- Dissemination workshops
- Technical reports
- Scientific seminars
- Mass media
- Online news
- Scientific publications

The digital media needs to be prioritized for disseminations as applicable.

Responsibility of Researchers:

The researchers should detail out the plan for dissemination from their side in the protocol submitted to the ERB of NHRC or respective IRCs for ethical approval. The research outcomes with a full report should be submitted to NHRC or respective IRCs immediately after preparation of the draft report. Researchers should participate in the dissemination events and provide clarification requested by audiences. NHRC may facilitate for online dissemination of research findings.

8.1.3 Governance framework for dissemination and utilization of research findings

In line with National Health Research Strategy of Nepal 2019, NHRC will play a key role in coordination with MoHP for dissemination and utilization of research findings from key studies of national importance. NHRC will provide factsheets and summary of findings to MoHP, HEOC,

concerned divisions of MoHP and relevant federal, provincial and local level governments and institutions for better response to COVID-19 pandemic. Similarly, NHRC will communicate the major research findings developing policy briefs to policy and decision makers to facilitate evidence-informed policy and program development for response.

8.1.4 Data Sharing

Given many unanswered questions on the reservoir, transmission, consequences and manifestations of COVID-19 infection and associated disease, all researchers are encouraged to be responsible for sharing their data as quickly and widely as possible to generate new hypotheses and scientific knowledge on COVID-19. When sharing data, researchers must respect the privacy and consent of study participants. Researchers can use any available data sharing platforms for e.g. the raw data sharing platform of the NHRC.

8.2 Uptake and Utilization of Evidence

The governance framework for dissemination and utilization of research findings will liaise with the Knowledge Cafe secretariat at the Policy, Planning and Monitoring Division, MoHP for bridging the uptake of evidence in policy and planning. Similar platforms need to be explored and made use of in the sub-national level for effective use of evidence in health decision making in respective levels. Evidence from both primary research and synthesis of evidence from other research at the national and global level are encouraged and promoted for its relevant use in health decision making.

8.2.1 Promoting uptake of evidence from primary research

Researchers need to produce plain language summaries of the findings so as to communicate them to the policy makers also considering them in Nepali language. To the extent possible, researchers and research institutions need to engage with the actors of the health care delivery system including the ministries, departments, divisions, directorates, health offices, and health sections at respective levels from the design phase of the research. And continue to do so till the results production phase and share the results in the form the respective agencies are comfortable with.

8.2.2 Promoting uptake of evidence from review and synthesis of evidence

The NHRC strengthens its Knowledge Management unit such that a review and synthesis of relevant local as well as global evidence is done on a regular basis. NHRC, in collaboration with relevant academia, research institutions, WHO and health EDPs will produce evidence summaries from such review and synthesis of evidence. NHRC will maintain a repository of synthesized evidence. Evidence synthesized by others in different forms of systematic reviews and meta-analysis also to be included in the repository. Such synthesis of evidence to be promoted for their use in policy, planning and decision making utilizing the existing platforms such as the Knowledge Cafe secretariat at the federal level and appropriate platforms in the sub-national level.

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Annexures

Annex – I. Research Areas/Questions on COVID-19

1. Emergency Preparedness and Response

- What is the situation of availability of Isolation Wards, and readiness of number of beds in various health facilities existed in Central, Provincial and Local Levels?
- What is the situation of availability of ventilators, oxygen support system, Intensive Care Unit (ICU), Patient Transport System (ambulances), Personal Protective Equipment (PPE) such as surgical face masks, surgical gloves, etc. at various levels?
- Where in the hospital and for which tasks are different levels of PPE sufficient?
- What is the situation of availability of general laboratory services along with RT-PCR Testing facilities at the Central and Provincial Levels?
- What is the situation of availability of Swab and blood sample collecting equipment, Swab sample transporting system (Virus Transport Medium, VTM), refrigerators (4 to 8 degree Celsius), freezers (-20 degree Celsius), etc.?
- What is the situation of availability of emergency medicines and related stuff in the health care facilities existed in various levels?
- What is the situation of availability of Human Resources for Health (HRH) [front line health workers (swab/blood collectors, clinicians, nurses, pharmacists, etc.), RT-PCR handler/RNA extractors, ambulance drivers, hospital waste handlers, medical recorders, etc..] by the type of health facility and targeted services?
- What specific types of health-care specialties are most needed in the regions with different types of comorbidities?
- What is the situation of the Quality of HRH [clinicians, nurses, laboratory personnel {sample (swab and blood) collectors, RT-PCR handler/RNA extractors, Samples (Swab, Serum and Extracted RNA) Keepers for storage}, Medical Recorders, etc.]?
- What is the status of Implementation of COVID-19 preventive strategies (for example, lockdown b, social distance, physical distance, self-quarantine, proper hand washing, proper use of appropriate mask in face, etc.) through public health friendly media mobilization?
- Is there any promotion of immune health through mostly available foods, body exercise, yoga/meditation, increasing positive vibes etc.?
- Is there any effective collaboration with private hospitals/laboratories and health related academic institutions for COVID-19 case investigation, treatment and management process?

- Are there any Embassies, Bi-lateral/Multi-lateral organizations, INGOs, NRN, NGOs, CBOs, Individuals (foreign or Nepalese) and related others' interested in preventing COVID-19 infection or supporting various aspects to fight against COVID-19?
- What is the situation of the availability of COVID-19 related guidelines, directives, guidance, SOP, Plan etc. to execute various specific aspects of COVID-19 related activities? How far these have been developed, endorsed and ready for implementation?
- Are there needs of any other policy/SOP related document or revising existing document?
- What is the availability of fund to tackle the upcoming or existing situation of COVID-19 infection (including its research aspects) in Central, provincial and Local Levels?
- Do we articulate and translate existing ethical principles and standards to salient issues in COVID-19?

2. Monitoring and Evaluation:

- How do we ensure that all the COVID-19 related guidelines, directives, guidance, SOP, Plan etc. have properly been followed and implemented?
- How do we ensure that there is an appropriate use of resources (human, test kits, PPE, Patient Transport vehicle, etc.)?
- How do we ensure that important human resources are maintaining their confidentiality, responsibility and accountability during their COVID-19 related work settings?
- How do we ensure that we are following standard criteria of purchasing quality RDT, RT-PCR kits, PCR machines, ventilator machines, PPE, etc. and guidelines for assessing the quality (validation) of such kits, machines and related equipment?
- How do we ensure that we are following proper Suspected Patients Dealing System?
- How do we ensure that all the Laboratory Investigation System for COVID-19 is being functioned as planned?
- How do we verify that we have figured out correct COVID-19 Infection Status of the Tested People?
- How do we ensure that Contact Tracing System for COVID-19 is being functioned as planned?
- How do we ensure that Suspected/Confirmed Case Management System (in hospital and quarantine centers) is being functioned as planned?
- How do we ensure that the COVID-19 patients have correctly been recovered?
- How do we ensure that all the Investigating pattern (lab and clinical sign & symptoms) of COVID-19 positive/negative patients (hospitalized), including RDT result and their record keeping status, are being done as planned?

- How do we ensure that all the Collected Swab Samples (both positive and negative) and extracted RNA have properly been stored with maintaining patient ID and its description including location, age and sex (for future genetic study and cross verification)?
- How do we ensure that all the laboratories (involved in swab storage process) are maintaining proper bio-security system for any sort of emerging threats in future?
- How do we ensure that all the serum samples (COVID-19) are properly stored in the laboratory with maintaining patient ID and its description including location, age and sex (for future antibody test and cross verification)?
- How do we ensure that Health facility based waste management system (collection, transportation, storage, dumping, etc.) is being functioned as planned?
- How do we ensure all the clinicians, laboratory personnel [sample (swab and blood) collectors, RT-PCR handler/RNA extractors, Samples (Swab, Serum and Extracted RNA) Keepers for storage], and Medical Recorders are competent for their job?
- How do we ensure that all ambulance/other similar drivers and health facility waste handlers are competent for their assigned task?
- How do we ensure that front line health workers and others are following Infection Prevention and Control prevention (IPC) practices at their work stations?
- How do we ensure that heath workers are properly maintaining the confidentiality of the record, accountability & responsibility, disease diagnosis result forwarding mechanism, etc.?
- How do we ensure that all the health workers are motivated enough to carry out their assigned task?
- How do we ensure that all health workers are perfectly fit in terms of their health condition?
- How do we ensure that the funds availability to tackle the COVID-19 related activities are sufficient enough to carry out its activity in Central, Province and Local Levels?

Infection Prevention and Control (IPC) Practices

- How frequently front line health workers are using PPE, Surgical Masks, Surgical Gloves into their work settings?
- How frequently variety of population are using surgical masks and doing hand washing with soap?
- What is the situation of IPC practices among general public?

3. COVID-19 related knowledge, Information and data

- What is the situation, level and adequacy of public health counseling related to COVID-19?
- What is the situation of COVID-19 Knowledge Flow and Co-ordination between Different Government Levels?
- What is the situation of COVID-19 related news (national and international) surveillance?
- Are there COVID-19 related Information available in Central, provincial and Local Levels?
- What is the situation of Interoperability and Uninterrupted COVID-19 data recording and reporting at each level of government (E-recording and reporting)?
- What is the situation of COVID-19 related logistics (RT-PCR, PCR Kits, RDT Kits, VTM, Cold Chain boxes, PPE, Surgical Face Masks, Surgical Gloves, etc.) management information system?
- Is there any Information gap in COVID-19 related data and record keeping system?

4. COVID-19 related Fund and its Economic aspects

- What is the situation of the public sector health care expenditure for COVID-19 [cost of COVID-19 diagnoses (before treatment), cost for its treatment {general laboratory, bed (general/cabin), X-ray, ICU, life support system (ventilator/oxygen), COVID-19 test (after treatment), etc.}, cost for contact tracing, food cost in quarantine and isolation centers, cost of patient transport system, etc.]?
- What is the situation of private sector health expenditure (including out of pocket expenditure) for COVID-19?

5. COVID-19 Disease Epidemiology

- What is the Etiology of COVID-19 among Nepalese population and its risk factors?
- What is the situation of vulnerable population who are at most risk of developing the COVID-19 infection?
- What do we understand by susceptibility of populations?
- What is the likelihood of infection upon exposure?
- What is the prevalence and incidence of COVID-19 disease in Central, Provincial and Local Levels?
- What do we know about the transmission dynamics of the COVID-19, including the basic reproductive number (Ro), incubation period, serial interval, modes of transmission and environmental factors?

- What is the COVID-19 disease transmission rate in Central, Provincial and Local (Community) Levels?
- What is the rate of asymptomatic spread and how does this contribute to transmission?
- What is Attack rate and infection rate?
- What is the risk of mother to child transmission and sexual transmission of the COVID-19?
- How is the disease transmitted in different settings?
- Is the disease being spread in different settings such as quarantine, isolation and other health care settings?
- What is the rate of asymptomatic or pre-symptomatic spread and its contribution to COVID-19 disease transmission at various levels?

6. Clinical Characterization, Presentation and Testing

- How do we define the natural history of disease to inform clinical care, health interventions, infection prevention control, transmission, and clinical trials?
- How do we develop a core clinical outcome set to maximize usability at data across a range of trials?
- How does disease severity affect the duration of an individual's infectiousness?
- How many cases are asymptomatic and subclinical?
- How detectable is COVID-19 in syndromic surveillance data?
- What is the most effective use of diagnostic and serological testing, given low detection?
- How long does natural immunity last for those who have recovered?
- How does disease progression differ for different types of comorbidities?
- What is the mechanism by which some co-morbidities, e.g. obesity, increase disease severity?
- Why is different age, sexes and ethnic groups affected differently by COVID-19?
- What is Recovery Rate, Survival Rate, Case Fatality Rate due to COVID-19 in Central, Provincial and Local Levels?
- What explains differences in case fatality rate by province?
- What is the age specific mortality and morbidity among Nepalese population?
- What are the rates and mechanisms of re-infection and/or relapse with COVID-19?
- Is there any active infection outside of the respiratory system?

- How can we reliably test whether COVID-19 patients remain infectious?
- How do we define the severity of disease, including risk of fatality among symptomatic hospitalized patients, and high-risk patient groups?
- How do we develop a core clinical outcome set to maximize usability of data across a range of trials?

7. Rapid Learning about Immunity for Public Health Impact

- What, if any, antibody properties confer protection against the virus, and what proportion of antibody responses are protective?
- What is the sero-prevalence of COVID-19 antibodies?
- What proportion of individuals mount either an antibody, or a cellular response or both after infection?
- How can laboratory-based antibody tests ensure that are not confounded by cross-reactivity to other Coronavirus?
- What proportion of infected individuals mount a protective immune response?
- How long is natural and vaccine immune protection likely to last?
- What immunological factors correlate with protection to COVID-19 by vaccine, and how effective are vaccines in protecting older people?
- What is the role of immuno-genetics in COVID-19 infection, and what can this tell us about potential therapeutic targets?
- What is the roe of immuno-genetics in the immune response, disease susceptibility and severity?

8. Treatment and Rapid Impacts for COVID-19 Treatment

- What are the various Allopathic treatment modality existed in various countries?
- What are the various Ayurveda and related treatment modality existed in the country and elsewhere?
- When, in the disease process, should specific type of treatment (name) be started?
- What treatments (Allopathic/Ayurveda/others) are most successful for different types of patients and how can those be applied in practice?
- What would be the potential therapeutic targets for COVID-19?
- What is the efficacy of FDA emergency use approved Ramdesivir drug in treating COVID-19 Nepalese patients?

- What is the efficacy of recently launched COVID-19 vaccine in protecting Nepali population from COVID-19 infection?
- What is the efficacy of Ayurveda medicine in treating for COVID-19 patients?
- What is the efficacy of Ayurveda medicine in protecting vulnerable population from COVID-19 infection?
- How do we determine adjunctive and supportive interventions that can improve the clinical outcomes of infected patients (e.g. steroids, high flow oxygen)?
- Can we isolate COVID-19 specific neutralizing antibodies from recovered patients with protective immunity, and use these to develop monoclonal antibodies for disease treatment, or prophylaxis (prevention) in groups who may not be able to produce protective immunity?
- How can we use convalescent plasma for the treatment of patient with COVID-19?
- What is the case management modality in treatment?
- What is the full immunopathology of COVID-19 in the lung and other organs?
- What are the biomarkers predictive of sever disease?
- What can immunological markers tell us about clinical prognosis, and how to treat hospitalized patients?
- Which biomarkers tell us about the disease and how to treat it?
- What is the potential role for antiviral and immunomodulation therapies in COVID-19 treatment?

9. Non-pharmaceutical Intervention: Adherence and Mobility

What is the effectiveness of different types of non-pharmaceutical interventions and what makes them successful (e.g., population density, percentage of people who comply, or degree to which they comply)?

- What are effective strategies to promote acceptance and adherence to public health measures aimed at limiting COVID-19 human-to-human transmission, e.g. isolation, social distancing, quarantine, public health prevention advice etc.?
- What are effective strategies to promote acceptance and adherence to infection prevention and control measures in community settings?
- How can rapid investigation of social drivers of transmission contribute most effectively to public health response measures?
- How can we rapidly identify secondary impacts of the outbreak and outbreak control measures, and deliver effective strategies to mitigate potential harms?

- To what degree does disease spread appear to be driven by air travel versus other types of travel?
- What percentage of a community do we need to test to be able to shift back to contact tracing and to lift non-pharmaceutical interventions?

10. Public Health Response:

- What is the systems' ability to contact trace and identify exposures?
- How can we know whether hospitalized patients are still infectious?
- How do we use the asymptomatic rate to inform when and how we deploy vaccines?
- What do we know about post-infection immunity, and what can tell this about herd immunity?
- How can we tell whether a person has encountered the virus and mounted an immune response?
- To what extent do antibodies, or other elements of the immune response, provide future protection?
- What are the important aspects for using antibody tests (RDT)?
- How long might immunity last and what do we know about re-infection?
- At what level of herd immunity can we safely reopen schools?
- In what ways contact tracing will be accelerated?
- In what way social distancing will be accelerated?
- What do we know about patients who have comorbidities?
- What do we know about 'early warning system' for the detection of new epidemics of COVID-19?
- What is the impact of disinfection agents used in the body?
- What are the local barriers and enablers for the uptake and adherence to public health measures for prevention and control?
- How do we know the food Items (particularly, chicken, eggs, meat, fish, vegetables, fruits, milk, curd, etc.) that people are purchasing are safe and consumable? And If not safe, how will they consume during COVID-19 pandemic?
- What are the preventive measures that need to be adopted during opening of (i) Schools/ Colleges, (ii) General Shops or Barber Shops, Beauty Parlor, Physical Fitness Centers, Cinema Hall, Shopping Mall, Party Palaces, Banks, Religious Places, etc., (ii) Vehicles (big buses, mini buses, Tempos, Rickshaws, Jeeps, etc.)?

- What is the Impact of COVID-19 pandemic in various (i) ongoing health researches in Nepal, (ii) health care services (maternal health, child health, nutritional rehabilitation, eye, dental, TB, HIV, etc.) including Universal Health Coverage (UHC), (iii) health related SDG indicators, etc.
- What is the impact of different levels of 'lock-down' for informing decision makers and public on what works for both disease and social/economic impact?

11. Genetics of COVID-19:

- What do we know about complete genomic sequence of COVID-19 strain isolated from various positive Nepalese cases returning from different countries?
- What can viral gene sequencing tell us about the functional significance of different viral genotypes in the disease process and immune evasion?

12. Psycho-social Dimension of COVID-19:

- What are the mental health conditions among general and vulnerable population (elderly, people living with chronic illness, pregnant women, recently delivered women, immune-compromised people, etc.) due to COVID-19 lockdown?
- Are they suffering from any kind of stress, anxiety and depression during COVID-19 pandemic situation?
- What is the situation of mental condition of those people who are put under quarantine or isolation ward?
- What is the situation of mental condition of health workers involved in front line health activities?
- What is the impact of social isolation among the family members of health workers who are involved in front line heath activities?
- What sort of social stigma that the COVID-19 positive cases are facing within and outside of their family circle?
- What sort of social stigma that the front line health workers are facing within and outside of their family circle?
- What is the situation of Psychological distress (depression and anxiety) among fever clinic attendants with and without COVID-19 symptoms in the health care facilities existed in central and provincial levels?
- What is the situation of Psychological distress among COVID-19 positive cases who are put under treatment in the health care facilities existed in central and provincial levels?

- What is the situation of Psychological distress among front line health care providers during COVID-19 pandemic and their attitudes towards patient care in various settings?
- Is there any social violence during lockdown due to COVD-19 pandemic?
- What are the socio-cultural dimensions of the epidemic such as examining how individuals and communities understand and react to the disease, including special attention to vulnerable groups?

13. Food and Nutrition during COVID-19 Pandemic:

- What types of food, vegetables and herbs are being consumed by variety of population during COVID-19 pandemic? And its association with COVID-19 infection pattern?
- What sort of foods being provided to COVID-19 patients in the various types of health facilities existed in central and provincial levels?
- How frequently general people are conscious about immune health through consumption of micronutrients rich diets? And its association with COVID-19 infection pattern?
- What is the situation of the availability of food items, and its supply chain system during lockdown due to COVID-19 pandemic?
- What is the situation of the nutritional status of the vulnerable population during COVID-19 pandemic?

14. Social Media and Communication:

- How are people using social media to access information?
- What is the impact of mass and social media on developing people's attitude and behaviors towards COVID-19 disease?
- What drives deliberate circulation of conspiracy misinformation, stigmatizing and xenophobic messaging, and conspiracy regarding COVID-19?
- What are the underlying drivers of fear, anxiety and stigma that fuel misinformation and rumor, particularly through social media?

Annex – II. Priority Setting Tool

Format for Priority Scoring

Research Area/Question:

Score

Scoring Criteria

(Please select only one option and write its corresponding numeric value in the box)

Relevance 1 = Not relevant
2 = Relevant
3 = Very Relevant

Avoidance of Duplication 1 = Sufficient information already available
2 = Some information available but major issues not covered
3 = No sound information available on which to base problem-solving

A. **Urgency**
1 = Information not urgently needed
2 = Information could be used right away but a delay of some months would be acceptable
3 = Data very urgently needed for decision-making

Political Acceptability1 = Topic not acceptable to high level policymakers
2 = Topic more or less acceptable
3 = Topic fully acceptable

Feasibility1 = Study not feasible, considering available resources
2 = Study feasible, considering available resources
3 = Study very feasible, considering available resources

1 **Applicability of Results** = No chance of recommendations being implemented
2 = Some chance of recommendations being implemented
3 = Good chance of recommendations being implemented

B. **Ethical Acceptability**
1 = Major ethical problems
2 = Minor ethical problems
3 = No ethical problems

Total Score

Annex – III. Research Quality Assessment Checklist

SN	Criteria	Yes	No	NA
1	Is the research problem well formulated and the purpose of the research was clear?			
2	Is the research approach well designed and executed?			
3	Is there adequate evidence that the researchers have a clear understanding of related research?			
4	Is there adequate evidence that best available data and information are included in the research?			
5	Are the assumptions explicit and justified?			
6	Do the research findings advance knowledge and provide important policy recommendations?			
7	Are the implications and recommendations logical, justified by the findings, and explained thoroughly, with appropriate limitations?			
8	Are the documentations accurate, understandable and clearly structured?			
9	Is the research finding convincing, useful, and relevant to stakeholders and decision makers?			
10	Is the research neutral, independent, and balanced?			
Total Score				

Note: *Yes=1, No=0, NA=Not Applicable*

Annex – IV. Capacity Building Framework

Dimensions	Definition	Interventions	Indicators
Building skills and confidence	Training, mentoring and supervision, sharing of skills and expertise as well as providing opportunities to apply acquired skills	Conducting training related with research (proposal writing, data analysis and scientific writing.) Orientating researcher about the dissemination strategies.	Number of trainings /workshops conducted Number of trained manpower
Research applicability	Importance of making research relevant to the priorities and challenges of countries, organizations, institutions and key stakeholders.	Supporting in development of research priorities by every level (federal, Provincial and local level)	Development of health research priorities mainly in federal and provincial level
Linkage partnerships and collaboration	Establishing relationships among diverse groups (professional associations, practitioners and academics, novice and expert researchers, service users, researchers and policy-makers) is the basis for information exchange and collaboration that ultimately provides the required evidence to tackle complex health problems.	Identifying and developing common platform that can coordinate with professional associations, practitioners and academic. Defining the proper channel to link academic/research institutions to policy makers.	Establishment of defined proper academic /research institutions channel.

Empowerment	Researchers and research users the power to prioritize context-relevant approaches to capacity building, and to use and mobilize fully their skills, influence, networks and resources to get things done.	Empowering new researcher to research networks Empowering relevant stakeholder about the proper utilization of research findings. Developing a research methodology curriculum.	Number training or workshops conducted about proper utilization of research findings. Providing scholarship and grants for conducting research for researchers. Number of universities developing curriculum.
Leadership	At the individual and team level to enable senior researchers to support junior researchers and to champion the development of institutional supports for research (including protected time for research) and essential technical and human infrastructure, such as research space and information technology, financial and administrative policies and procedures, ethics review processes, and experienced research staff. In organizational level, fundraising; Managing teams; developing institutional strategic research priorities that are mirrored in the recruitment of faculty, graduate students and postdoctoral fellows; and engaging with national and international research networks and decision-makers	Encouraging and advocating research institutions/ academia's leadership to set up research related requirements. Encouraging the university/ academia/ institutions for developing institution's research strategy and priorities Engaging research institutions' leaders in establishing international and national research networks.	

Dissemination and knowledge translation	A range of dissemination techniques including peer-reviewed publications and conference presentations; the development of protocols of care, lay publications, and fact sheets; and using the media.	Developing push and pull strategies to maximize the uptake and impact of research in practice, programmes, and policies. Developing common platform for dissemination of national level and important health issues.	Number of researches translated in policies/ guidelines etc. Number of trainees published scientific papers.
Continuity and Sustainability	Establishing essential research structures and by providing opportunities to apply and extend knowledge and skills gained into practice. This also indicates that establishing mentoring relationships in which experienced researchers work with novice researchers is key to sustaining capacity.	Assuring a regular budget for research via unified centre. Advocating need of research activities on academic institutions.	Amount of budget released to different research centre /universities/ academia.
Infrastructure	Involving both academic and management staff to supervise and manage projects, providing protected time for research, creating research positions, and enhancing knowledge about and access to research funding opportunities.	Encouraging universities/academia to establish a research department	Number of university/academia establishing research department.

Annex – V. Approval of Guideline from MoHP

नेपाल सरकार
स्वास्थ्य तथा जनसङ्ख्या मन्त्रालय
नीति, योजना तथा अन्तर्राष्ट्रिय समन्वय महाशाखा
रामशाहपथ, काठमाडौं

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प.स. ७६/७७
च.नं. 9902

मिति :- २०७७।०३।१७

श्री नेपाल स्वास्थ्य अनुसन्धान परिषद्
रामशाहपथ, काठमाडौं।

दर्ता नं. 9690
मिति: 2077/12/05

विषय :- National Guideline for Strengthening Evidence Generation on COVID-19 स्वीकृत सम्बन्धमा।

प्रस्तुत विषयमा नेपाल स्वास्थ्य अनुसन्धान परिषद्को मिति २०७७।०२।२३ गतेको १८८ औं कार्यकारी समितिको बैठकद्वारा अनुमोदन गरी स्वास्थ्य तथा जनसंख्या मन्त्रालयको स्वीकृतिका लागि मिति २०७७।०३।०१ गते पेश हुन आएको **"National Guideline for Strengthening Evidence Generation on COVID-19"** श्रीमान् सचिवज्यूको अध्यक्षतामा मिति २०७७।०३।११ को PCC बैठकमा विस्तृत छलफल भई नेपाल सरकार (सचिवस्तर) मिति २०७७।०३।१५ गतेको निर्णयानुसार स्वीकृत भएको व्यहोरा अनुरोध छ।

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चित्रा खनाल
बरिष्ठ नर्सिङ अधिकृत

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