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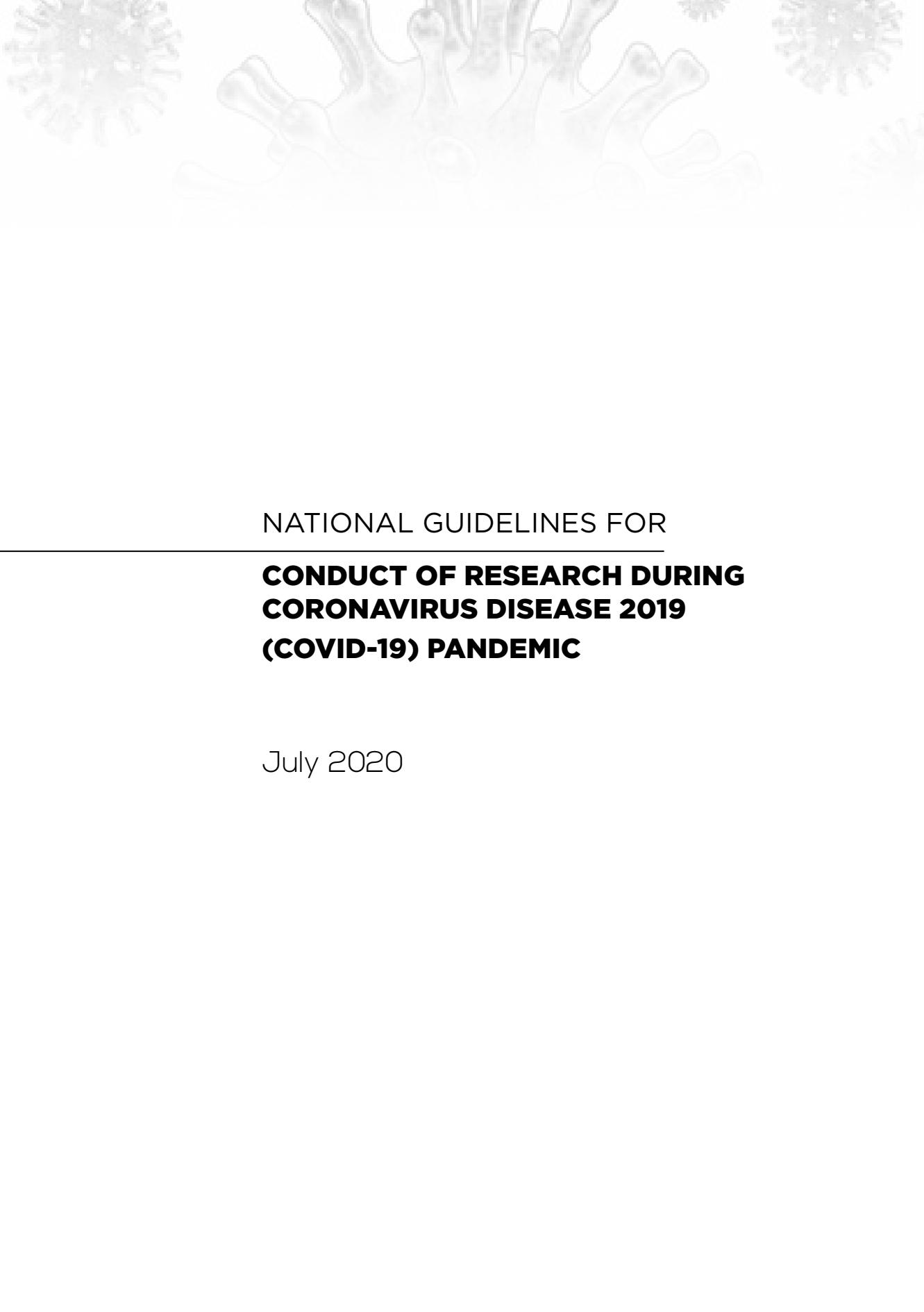
THE REPUBLIC OF UGANDA

NATIONAL GUIDELINES FOR **CONDUCT OF RESEARCH DURING CORONAVIRUS DISEASE 2019 (COVID-19) PANDEMIC**

July 2020



Safe Drugs Save Lives



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**CONDUCT OF RESEARCH DURING
CORONAVIRUS DISEASE 2019
(COVID-19) PANDEMIC**

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ACKNOWLEDGEMENTS

The Uganda National Council for Science and Technology (UNCST), would like to acknowledge the contribution of the Uganda National Health Research Organization (UNHRO) and the National Drug Authority (NDA) in preparing these guidelines. UNCST also appreciates the valuable technical support, commitment and dedication of members of the Taskforce: Dr. Frederick Nelson Nakwagala (Chair) from Mulago National Referral Hospital, Prof. Peter Olupot-Olupot from Mbale Clinical Research Institute, Mbale Regional Referral Hospital, Dr. Sam Okware and Dr. Harriet Nabudere from Uganda National Health Research Organization, Dr. Tom Lutalo from Uganda Virus Research Institute, Dr. Racheal Kyeyune from National Drug Authority, Ms. Hellen Opolot (Secretary), Ms. Beth Mutumba and Ms. Winfred Badanga Nazziwa from Uganda National Council for Science and Technology. These Guidelines are designed to complement existing National Research Guidelines.

DOCUMENT ERRORS

Readers who detect errors of omission or commission are invited to send corrections and suggestions to UNCST by email at info@uncst.go.ug.

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PREFACE

The World Health Organization (WHO) declared Corona Virus Disease 2019 (COVID-19) a pandemic on 11th March 2020. The highly infectious novel virus transmitted mainly by respiratory droplets remains without effective cure or vaccine to date, though research on development of the same are underway. Therefore, support to research activities in the country amidst the pandemic is paramount. These Guidelines have been prepared by the National Research Regulatory Agencies namely the Uganda National Council for Science and Technology (UNCST), Uganda National Health Research Organization (UNHRO) and National Drug Authority (NDA) with expertise from the Forum for Research Ethics Committees of Uganda (FRECU). The purpose of these guidelines is to streamline conduct of research during the COVID-19 pandemic and in harmony with guidelines by the Government of Uganda, Ministry of Health and International Development Agencies for the prevention and management of COVID-19. They uphold the rights, welfare and safety for both the research participants and research teams. They allude to the standard operating procedures for the conduct of research amidst COVID -19.

This is a dynamic document; updates will be made as more information, evidence and data become available. On behalf of UNCST, UNHRO, NDA and FRECU, we are pleased to have these guidelines launched to guide research during the COVID-19 pandemic in Uganda.



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**Executive Secretary, Uganda
National Council for Science and
Technology**



Dr. SAMUEL OKWARE

**Director General, Uganda National Health
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LIST OF ACRONYMS

AVAREF	African Vaccines Regulatory Forum
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease 2019
CTA	Clinical Trials Applications
FRECU	Forum for Research Ethics Committees of Uganda
IMST	Incident Management and Support Team
MHPSS	Mental Health and Psychosocial Support
MOH	Ministry of Health
NDA	National Drug Authority
PI	Principal Investigator
PPE	Personal Protective Equipment
REC	Research Ethics Committee
R&D	Research and Development
RMPs	Risk Management Plans
UNCST	Uganda National Council for Science and Technology
UNHRO	Uganda National Health Research Organization
WHO	World Health Organization

1.0 INTRODUCTION

Coronavirus Disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It was first identified in December 2019 in Wuhan, China, and has resulted in an ongoing pandemic. Common symptoms of COVID-19 include fever, cough, fatigue, shortness of breath and loss of smell and taste. While the majority of cases result in mild symptoms, some progress to Acute Respiratory Distress Syndromes (ARDS) likely precipitated by a cytokine storm, multi-organ failure, septic shock, and blood clotting. The time from exposure to onset of symptoms is typically around five (5) days but may range from two (2) to fourteen (14) days. The virus is primarily spread between people during close contact, most often via small droplets produced by coughing, sneezing, singing and talking. The droplets usually fall to the ground or onto surfaces rather than travelling through air over long distances. The WHO declared the COVID19 outbreak a public health emergency of international concern (PHEIC) on 30 January 2020 and a pandemic on 11 March 2020.

Recommended measures to prevent infection include frequent hand washing and sanitising, maintaining physical distances from others (especially from those with symptoms), quarantine (especially for those with symptoms), and keeping unwashed hands away from the face. The use of cloth face coverings such as masks, a scarf or a bandana is recommended in public settings to minimise the risk of transmissions, with some authorities requiring their use. Medical grade facemasks such as N95 masks should only be used by healthcare workers, first responders and those who care for infected individuals. According to the World Health Organisation (WHO), there are no specific vaccines nor specific antiviral treatments for COVID-19, but trials on these are ongoing in various settings. Management involves the treatment of symptoms, supportive care, isolation and experimental measures.

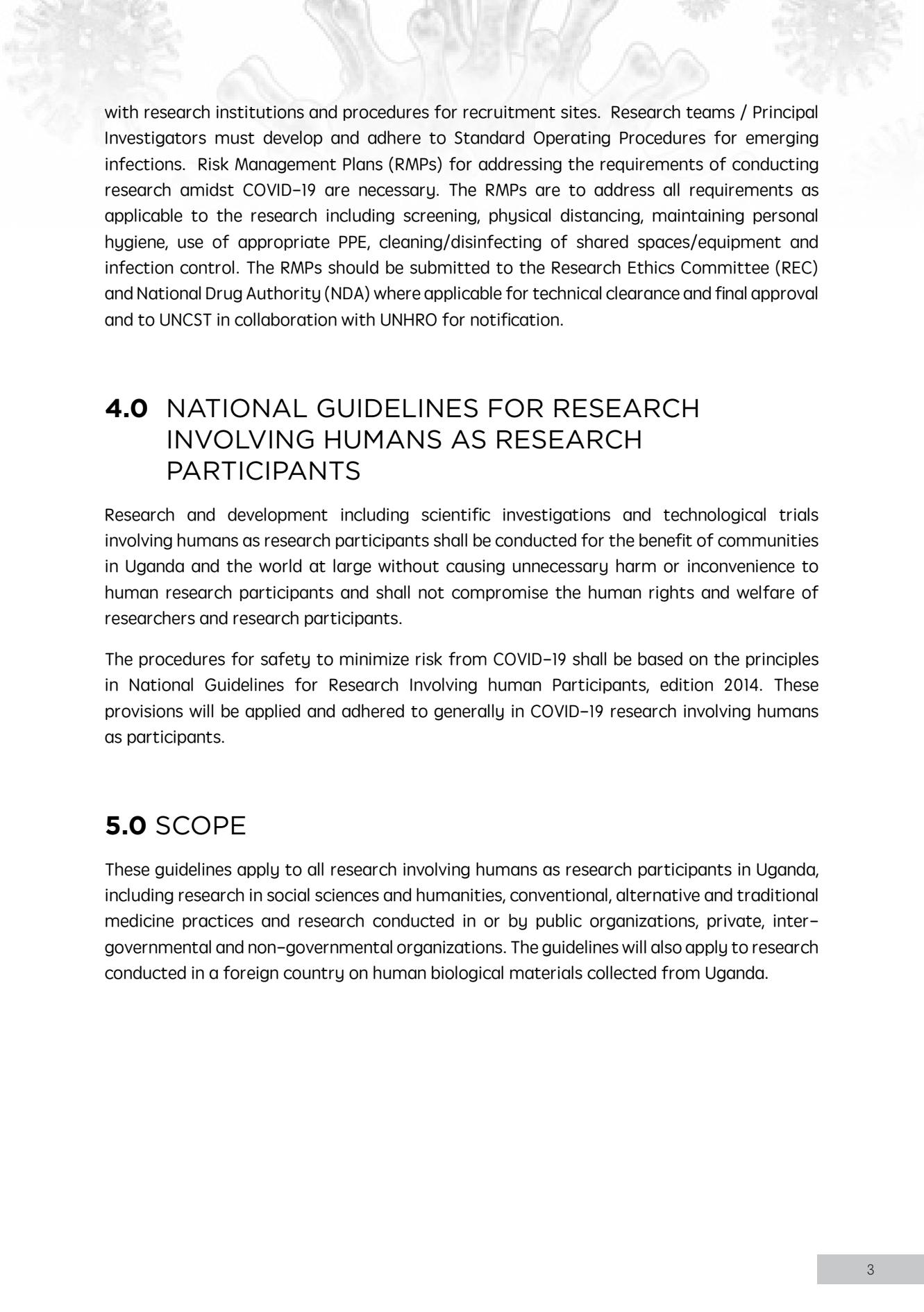
The WHO recommends 1 metre (3 ft) of social distance; the U.S. Centres for Disease Control and Prevention (CDC) recommends 2 metres (6 ft). People can transmit the virus without showing symptoms, but it is unclear how often this happens. People are most infectious when they show symptoms (even mild or non-specific symptoms), but maybe infectious for up to two days before symptoms appear (pre-symptomatic transmission). They remain infectious an estimated seven (7) to twelve (12) days in moderate cases and an average of two weeks in severe cases. When the contaminated droplets fall to floors or surfaces, they can, though less commonly, remain infectious if people touch contaminated surfaces and then their eyes, nose or mouth with unwashed hands. On surfaces, the amount of active virus decreases over time until it can no longer cause infection, and surfaces are thought not to be the main way the virus spreads. Surfaces can be decontaminated with alcohol-based household disinfectants that kill the virus outside the human body or on the hands. These perceptions and mode of spread are still being debated. COVID has led to total lockdown throughout the world and resulted in cessation of trade and socio-economic activity. Unprecedented human traffic and world commerce stagnated. Community socioeconomic endeavours were seriously impacted leading to severe loss of income, productivity and self-sustenance at household levels.

2.0 JUSTIFICATION

The current prevention strategies have been adopted variably, and their effectiveness may vary from one setting to another. More evidence is urgently required to refine these prevention guidelines in Uganda. COVID-19 is a novel emergent, fast-evolving infectious disease. Many research and disease control gaps remain, resulting in a dearth in understanding effective prevention and control measures. For instance, despite rapid research on the disease, knowledge gaps persist in its etiology, epidemiology, ecology, modes of transmission, prevention and treatment. There is also a lack of clarity on dynamics in the perceived aerosol routes. The current prevention methods and strategies equally need evaluation to determine what works effectively. There is yet no cure nor vaccines. The potential of traditional medicine and remedies have been mentioned, but the advancement of research on these treatments is still lagging. There is an urgent need for clinical trials to specifically refine case management and inform the re-integration of life in the community. Simpler and rapid diagnostics tools for early detection and diagnosis is required. The impact on society and mental health has been reported on the increase especially during the lockdown but remains poorly described. The socio-economic ramifications of the lockdown and travel advisories on the economy and the population is herculean and unprecedented. The coping mechanisms by communities to mitigate these challenges are yet to be determined at individual, community and national levels. Research is required to determine vital aspects that will support timely and effective prevention and control of the pandemic in a sustainable and integrated approach. The WHO regional office for Africa has established the Incident Management and Support Teams (IMST) to oversee and coordinate the conduct of research as part of its response to COVID-19 support for research in countries. The team will also identify research priorities in the Region.

3.0 PURPOSE AND GUIDANCE

Research is a key aspect of response to public health emergencies. WHO Joint External Evaluation in 2017 of Uganda's progress on International Health Regulation (IHR 2005), indicated that the country had progressed in 11 out of the 19 key milestones on responding to emerging public health threats(1). Rapid response to disease outbreak remains essential. As the situation with COVID-19 continues to evolve, having information and facts about COVID-19 will help diminish fears and anxieties around the disease and support the ability to cope with any secondary impacts in the lives of those who have been affected. It is important to remember that COVID-19 does not differentiate between borders, ethnicities, disability status, age or gender. The purpose of this document, therefore, is to guide how best research can be conducted in the country in line with the Ministry of Health (MOH) guidelines for the prevention and management of COVID-19, without compromising the rights, welfare and safety for both the research participants and research teams. It provides actionable guidance for safe operations through the prevention, early detection and isolation, management and control of COVID-19 for research teams working directly with communities, teams working



with research institutions and procedures for recruitment sites. Research teams / Principal Investigators must develop and adhere to Standard Operating Procedures for emerging infections. Risk Management Plans (RMPs) for addressing the requirements of conducting research amidst COVID-19 are necessary. The RMPs are to address all requirements as applicable to the research including screening, physical distancing, maintaining personal hygiene, use of appropriate PPE, cleaning/disinfecting of shared spaces/equipment and infection control. The RMPs should be submitted to the Research Ethics Committee (REC) and National Drug Authority (NDA) where applicable for technical clearance and final approval and to UNCST in collaboration with UNHRO for notification.

4.0 NATIONAL GUIDELINES FOR RESEARCH INVOLVING HUMANS AS RESEARCH PARTICIPANTS

Research and development including scientific investigations and technological trials involving humans as research participants shall be conducted for the benefit of communities in Uganda and the world at large without causing unnecessary harm or inconvenience to human research participants and shall not compromise the human rights and welfare of researchers and research participants.

The procedures for safety to minimize risk from COVID-19 shall be based on the principles in National Guidelines for Research Involving human Participants, edition 2014. These provisions will be applied and adhered to generally in COVID-19 research involving humans as participants.

5.0 SCOPE

These guidelines apply to all research involving humans as research participants in Uganda, including research in social sciences and humanities, conventional, alternative and traditional medicine practices and research conducted in or by public organizations, private, inter-governmental and non-governmental organizations. The guidelines will also apply to research conducted in a foreign country on human biological materials collected from Uganda.

6.0 OBJECTIVES OF COVID-19 RESEARCH

The major role of researchers and research institutions during this period is to create knowledge for the effective prevention, control and management of COVID-19 pandemic in Uganda. In particular, researchers shall promote the following:

- a. Conduct research that is community responsive and aligned to national priorities
- b. Ensure that such research is carried out with the highest ethical standards consistent with respect of personal autonomy, beneficence to maximize benefit, non-maleficence to minimize harm and fair distribution of benefits and burdens.
- c. Share information about research findings and reviews of existing knowledge
- d. Develop a Cure and a vaccine through the conduct of clinical studies on care and management, prevention, and control of the pandemic
- e. Undertake clinical trials on traditional and complementary medicine
- f. Evaluate laboratory tools to improve quality assurance and simplify easy use
- g. Undertake operational and implementation research to determine the best practices and strategies for containment.

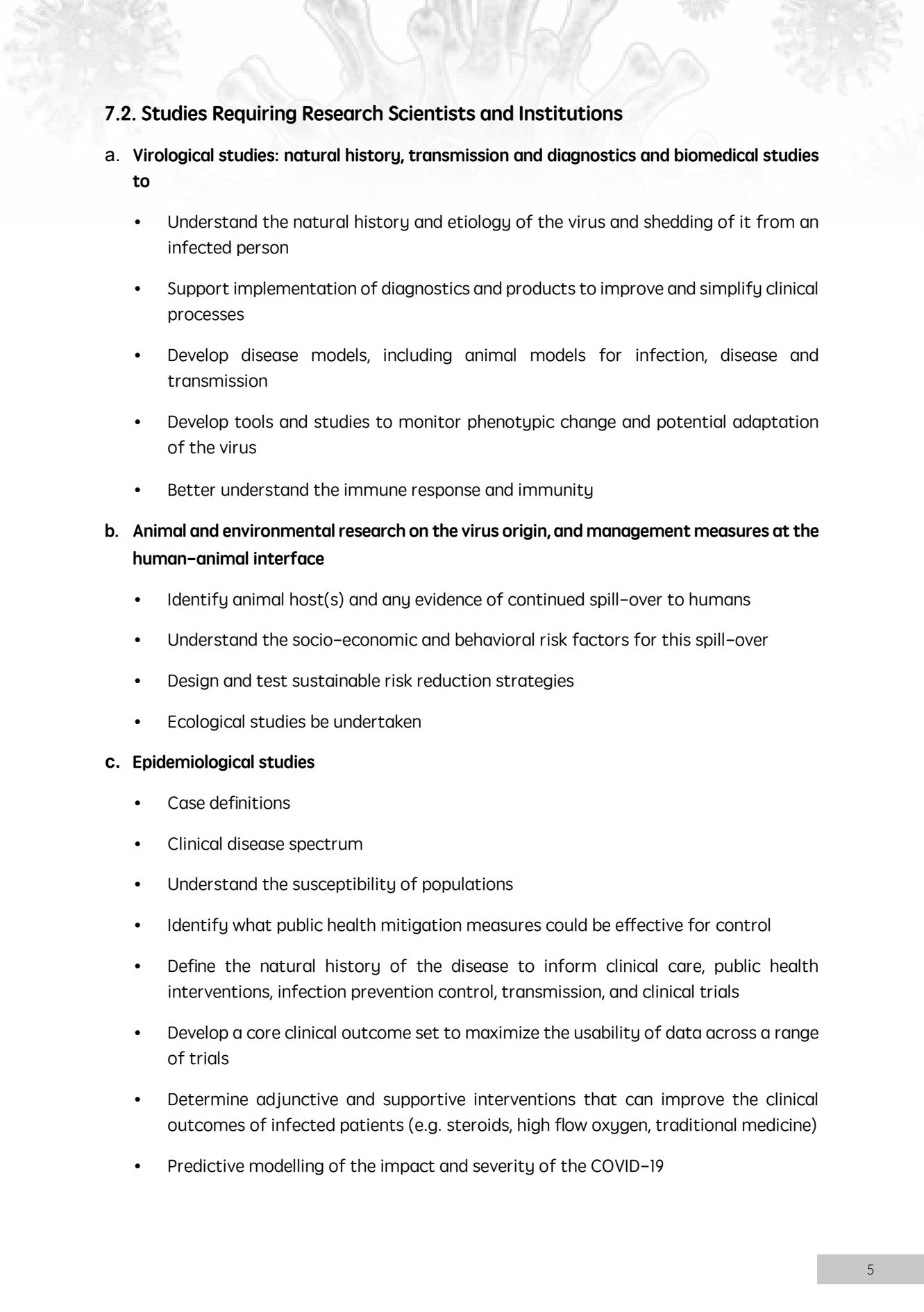
7.0 PRIORITIES FOR COVID-19 RESEARCH

COVID-19 is a novel emergent, fast-evolving infectious disease. Many research and disease control gaps remain, resulting in limited understanding for effective prevention and control measures. For instance, despite rapid research on the disease, knowledge gaps persist in its etiology, epidemiology, ecology, modes of transmission, prevention and treatment. Research is required to determine vital aspects that will support timely and effective prevention and control of the pandemic in a sustainable and integrated approach. Therefore, the following priorities should be considered as key areas of research:

7.1. Rapid Assessment Special Studies

Early investigation involves the rapid assessment of the outbreak

- Index cases studies
- Households transmission studies
- Risk factors assessment for Health Workers (HW)
- Environmental sampling and
- Population-based age-stratified sero-epidemiological surveys

A faint watermark of a COVID-19 virus particle is visible in the background of the page.

7.2. Studies Requiring Research Scientists and Institutions

a. Virological studies: natural history, transmission and diagnostics and biomedical studies to

- Understand the natural history and etiology of the virus and shedding of it from an infected person
- Support implementation of diagnostics and products to improve and simplify clinical processes
- Develop disease models, including animal models for infection, disease and transmission
- Develop tools and studies to monitor phenotypic change and potential adaptation of the virus
- Better understand the immune response and immunity

b. Animal and environmental research on the virus origin, and management measures at the human-animal interface

- Identify animal host(s) and any evidence of continued spill-over to humans
- Understand the socio-economic and behavioral risk factors for this spill-over
- Design and test sustainable risk reduction strategies
- Ecological studies be undertaken

c. Epidemiological studies

- Case definitions
- Clinical disease spectrum
- Understand the susceptibility of populations
- Identify what public health mitigation measures could be effective for control
- Define the natural history of the disease to inform clinical care, public health interventions, infection prevention control, transmission, and clinical trials
- Develop a core clinical outcome set to maximize the usability of data across a range of trials
- Determine adjunctive and supportive interventions that can improve the clinical outcomes of infected patients (e.g. steroids, high flow oxygen, traditional medicine)
- Predictive modelling of the impact and severity of the COVID-19

- Evaluation or predictive modelling of the impact of health interventions on the spread of coronavirus i.e. how health interventions or their lack of affect the spread.
- Development and evaluation of models for future prediction of similar outbreaks and their impact
- Impact of COVID-19 on Health Systems and Services
- Transmission of COVID-19 infections from asymptomatic contacts

d. Infection prevention and control, including health care workers' protection

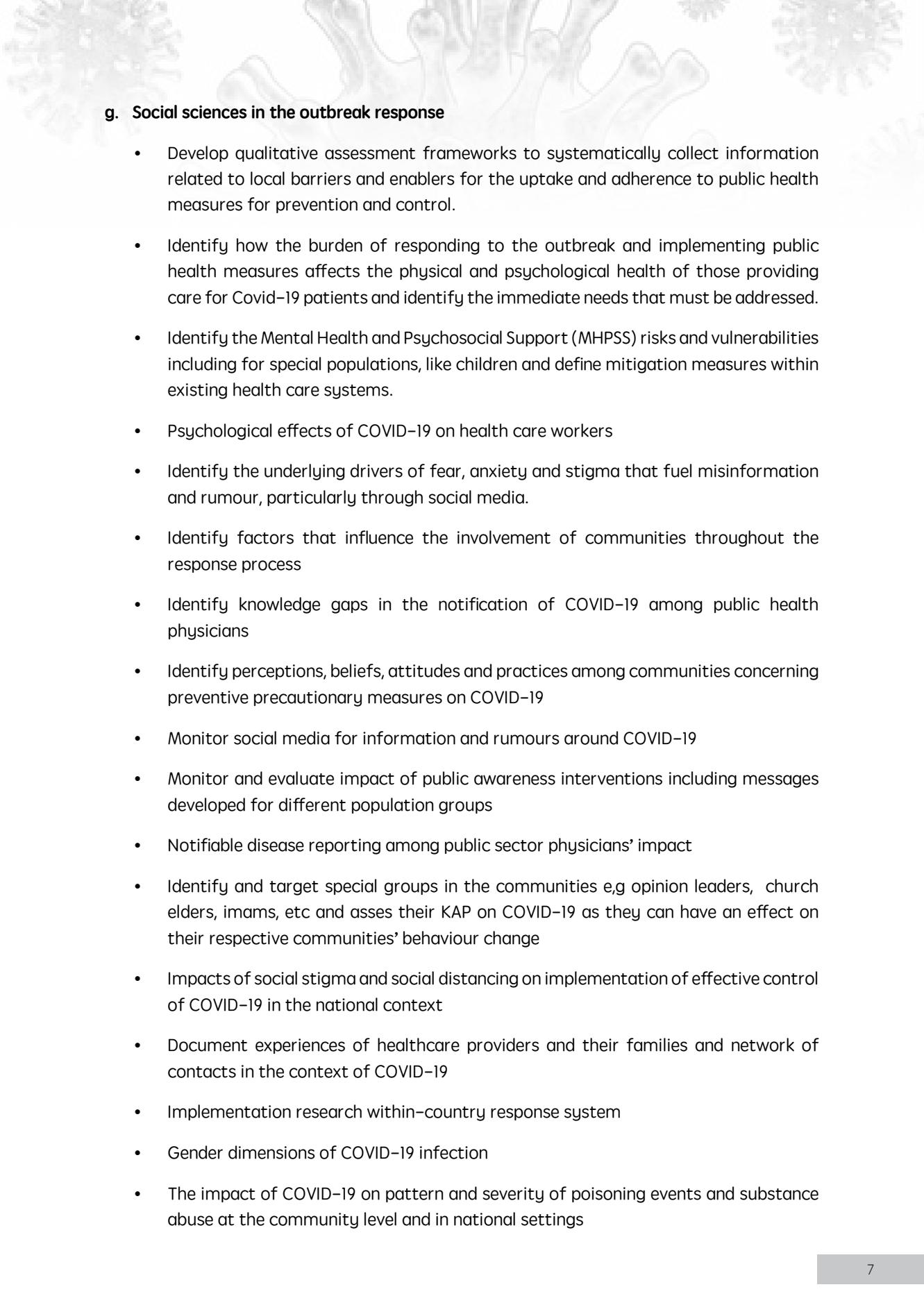
- Understand the effectiveness of movement control strategies to prevent secondary transmission in health care and community settings
- Optimize the effectiveness of personal protective equipment (PPE) and its usefulness to reduce risk of transmission in health care and community settings
- Examine the role of workload on adherence to IPC guidelines by frontline health workers
- Minimize the role of the environment in transmission
- Self-risk of exposure assessment using clinical reflection among health workers
- Documentation on PPE production
- Understand the risks of infections to COVID-19 for sanitation workers carrying out environmental cleaning within health care facilities and for those managing faecal sludge (onsite sewage systems emptying) at the community level.

e. Candidate therapeutics R&D

- Develop animal models and standardize challenge studies
- Develop prophylaxis clinical studies and prioritize in healthcare workers
- Ensure adequate supply of investigational therapeutics showing efficacy (address cost/affordability, equitable access, production capacity and technology transfer)
- Traditional medicine and complementary medicine assessment and clinical trials.

f. Candidate vaccines R&D

- Optimize clinical trial design, including for all Phases, prioritized candidates for testing
- Understand approaches to evaluate the risk for enhanced disease after vaccination
- Develop assays to evaluate vaccine immune response and process development for vaccines, alongside suitable animal models



g. Social sciences in the outbreak response

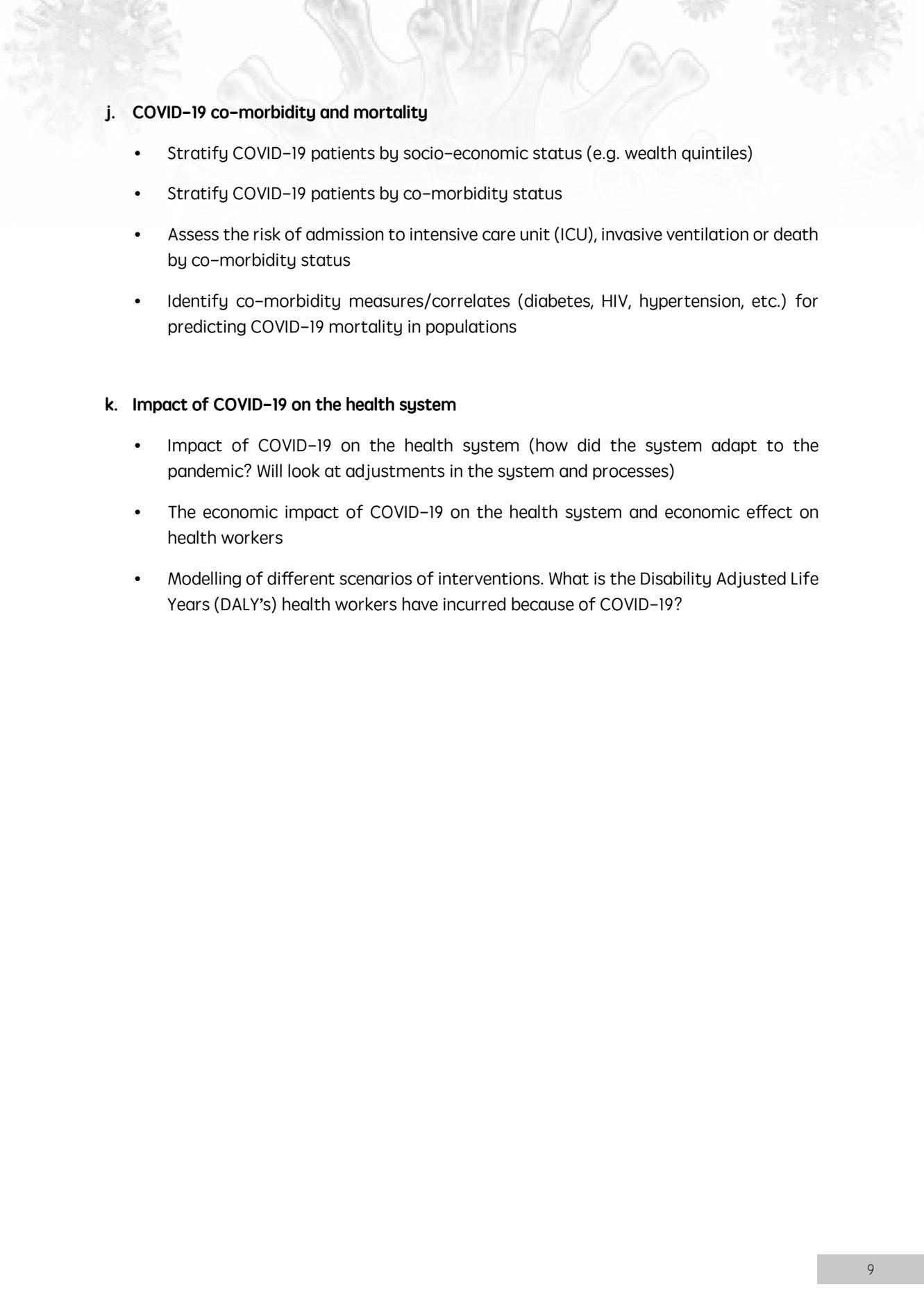
- Develop qualitative assessment frameworks to systematically collect information related to local barriers and enablers for the uptake and adherence to public health measures for prevention and control.
- Identify how the burden of responding to the outbreak and implementing public health measures affects the physical and psychological health of those providing care for Covid-19 patients and identify the immediate needs that must be addressed.
- Identify the Mental Health and Psychosocial Support (MHPSS) risks and vulnerabilities including for special populations, like children and define mitigation measures within existing health care systems.
- Psychological effects of COVID-19 on health care workers
- Identify the underlying drivers of fear, anxiety and stigma that fuel misinformation and rumour, particularly through social media.
- Identify factors that influence the involvement of communities throughout the response process
- Identify knowledge gaps in the notification of COVID-19 among public health physicians
- Identify perceptions, beliefs, attitudes and practices among communities concerning preventive precautionary measures on COVID-19
- Monitor social media for information and rumours around COVID-19
- Monitor and evaluate impact of public awareness interventions including messages developed for different population groups
- Notifiable disease reporting among public sector physicians' impact
- Identify and target special groups in the communities e,g opinion leaders, church elders, imams, etc and asses their KAP on COVID-19 as they can have an effect on their respective communities' behaviour change
- Impacts of social stigma and social distancing on implementation of effective control of COVID-19 in the national context
- Document experiences of healthcare providers and their families and network of contacts in the context of COVID-19
- Implementation research within-country response system
- Gender dimensions of COVID-19 infection
- The impact of COVID-19 on pattern and severity of poisoning events and substance abuse at the community level and in national settings

h. Innovation for the outbreak response

- Use of innovative technologies to enhance screening especially persons with abnormal body temperatures
- Innovation techniques for detecting asymptomatic cases
- Use of innovative technologies in tracking individuals on self-isolation
- Innovative ways of enhancing social distance
- Innovative ways of enforcing social distance principles in the populations
- Innovative techniques for warning health workers without adequate protection
- Implementation research for adaption of innovations
- Innovative ways of procuring and making accessible PPEs and IEC materials to both workers and the populations
- Use of technology to manage COVID-19 for climate change affected populations (settlements, water conservation, water quality, sanitization...)

i. COVID-19 impact on existing health services

- Routine immunization service
- Access to essential medicines and health products
- HIV/AIDS, Malaria control and TB
- Measles, rubella, hepatitis B elimination
- Elimination of yellow fever epidemics
- Maternal tetanus elimination
- Polio eradication
- Neglected tropical diseases
- Meningitis control
- Traditional Medicine use
- Maternal and child health
- Others

The background of the slide features a faint, watermark-like illustration of the COVID-19 virus, showing several spherical particles with prominent spikes.

j. COVID-19 co-morbidity and mortality

- Stratify COVID-19 patients by socio-economic status (e.g. wealth quintiles)
- Stratify COVID-19 patients by co-morbidity status
- Assess the risk of admission to intensive care unit (ICU), invasive ventilation or death by co-morbidity status
- Identify co-morbidity measures/correlates (diabetes, HIV, hypertension, etc.) for predicting COVID-19 mortality in populations

k. Impact of COVID-19 on the health system

- Impact of COVID-19 on the health system (how did the system adapt to the pandemic? Will look at adjustments in the system and processes)
- The economic impact of COVID-19 on the health system and economic effect on health workers
- Modelling of different scenarios of interventions. What is the Disability Adjusted Life Years (DALY's) health workers have incurred because of COVID-19?

8.0 INFORMED CONSENT

The consenting of research participants during the COVID-19 pandemic must follow principals set out in the National Guidelines for Research Involving Human participants (2014). Research participants must be allowed to make informed choices about what should be done to them. There must be exchange of adequate information between the researcher and research participants on the whole research process. The information provided must be comprehensible to research participants with decision-making capacity who voluntarily decide whether to participate or not. In addition to informing the research participants about the whole study research processes, the researcher should also inform them or enhance their knowledge about the COVID-19 pandemic.

The participants need to be informed about best practices for the prevention of COVID-19 infection (to both the research participant and the researcher) as detailed in the Risk Management Plans. Research activities will be carried out among COVID-19 confirmed cases, suspected cases and other members of the community. How the researcher plans to interact with any of the three groups must be laid out in the Risk Management Plan (RMP) approved by the Research Ethics Committee and NDA where applicable and submitted to the UNCST for acknowledgment. The requirements for providing information and seeking consent will be consistent with the current provisions in the National Guidelines for Research involving Human Participants (2014). Although COVID-19 research is taking place as part of a public health emergency, that does not mean all studies are classified as emergency research and Institutional RECs will have to decide on this as they review the individual protocol applications.

The method or medium used by the researcher to inform and consent the research participant must be for the safety of both the researcher and the research participant. The research must be clearly explained to the research participant, replicable, easy to monitor and must have been approved by REC and UNCST and where applicable the NDA. It is paramount that the methods used should be protective of research participants, researchers and communities from exposure to SARS-Cov-2 the virus that causes COVID-19. The researcher should provide information to participants about the research using a format that is best suited to supporting the consent process and enhancing safety. Apart from text-based information on paper, which is most often used for informing participants, alternative formats, such as using images, diagrams, audio (e.g. pre-recorded or read out to the potential participant) may be more appropriate during this COVID-19 epidemic.

With COVID-19 research, using these alternative formats for providing information makes it easier to convey information and/or reduce risk of infection (e.g. if the information is provided via an electronic device or via a laminated summary sheet that can be cleaned). One can use electronic methods for seeking, confirming and documenting informed consent in research studies. This may be particularly helpful in facilitating COVID-19 research where the consent process may be completed without any contact (e.g. electronic recording of the process) or with minimal contact using surfaces that are more readily cleaned (e.g. a handheld electronic device is used to give information and record consent).

For sample collection, storage and future use, the requirements will be consistent with the current provisions in the National Guidelines for Research involving Human Participants (2014). Documented proof of adequate informed consent for biological material and data donation shall be provided. This shall include: a separate consent document for storage for future use and separate consent document for genetic research where applicable. All biological materials/data obtained during the research, clinical care, public health interventions and surveillance require evidence of documented informed consent from the sample donor or their representative.

Where there is planned use of a Biobank, documentation of the informed consent status for each bio-specimen will be required. Additionally, procedures for obtaining informed consent and protecting the privacy of identifiable human research participants and confidentiality of data and procedures to follow in the case of withdrawal of consent shall be clearly described.

During the clinical care process, public health interventions and surveillance, the researcher will document the process of having obtained informed consent from the sample donors. The laboratory request form should have adequate basic information for the participant to make a decision for sample storage. For clinical care, the laboratory form should be in triplicate with copies given to the sample donor, laboratory and custodians of the Biobank. The biobank custodian shall ensure that there are available policies, protocols and procedures in place on the collection/reception, labelling, registration, processing, storage, tracking, retrieval, dissemination, use, auditing, sharing and certified safe destruction of samples and/or data.

9.0 COMPENSATION

9.1. Introducing Hazard Pay

The provision of compensation to study participants must follow guidelines set out in the UNCST guidelines National Research Guidelines (2014). However, where the study involves confirmed COVID-19 cases and the use of frontline workers at isolation centres (not primary study staff who would follow guidelines set out in the RMP), the researchers should consider providing hazard pay to these workers. This is in recognition of the high risk of infection to the frontline workers and to their families for performing a job now deemed “essential” for society. A fair and equitable system for hazard pay should compensate essential, frontline workers who face significant exposure to COVID-19 through their jobs.

9.2. Insurance

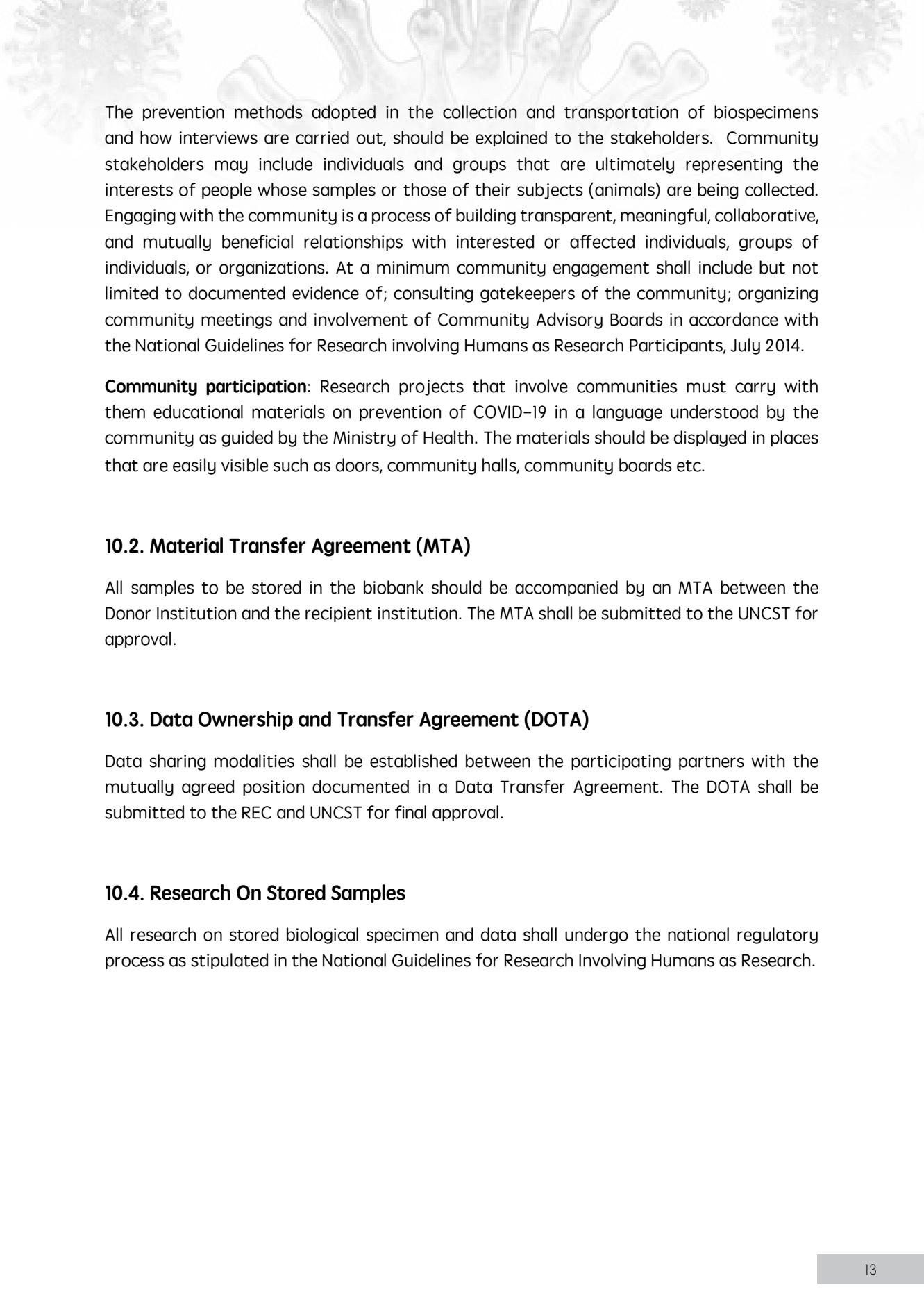
All clinical research related to COVID-19 should be comprehensively insured. The sponsor shall put in place a mechanism for compensating injury arising from research related to COVID-19 infection prior to commencement of a study. The mechanism, which may include, *inter alia*, insurance and medical care, should be documented in the protocol and acceptable to the REC and NDA for clinical trials. Drug-related clinical trials will require as part of the application, the submission of an insurance policy and certificate that has been issued by a locally licensed insurance company (The National Drug Policy and Authority Conduct of Clinical Trials Regulations, 2014). COVID-19 devices and technology shall also be subjected to similar requirements. The participant in liaison with the REC may initiate the compensation process

10.0 SAMPLE COLLECTION

Before obtaining biological materials from sample sources the following should be obtained or be in place:

10.1. Community Engagement and Participation

Experience has demonstrated that the best way to respond to pandemics is to build trust in communities and services, understand community perspectives, share information and work with communities to determine how to keep people safe. Reasonable effort must be made by researchers to engage communities during the COVID-19 outbreak responses, including how to support an integrated response as well as outbreak prevention. To reduce the risk of infection to communities and researchers, changes must be made in the way researchers interact with communities. Access to communities will become limited due to the restrictive measures put in place. There is a need for researchers to get contact details of relevant stakeholders for the different groups of interest, discuss with them key perceptions, risks and challenges and determine their solutions.



The prevention methods adopted in the collection and transportation of biospecimens and how interviews are carried out, should be explained to the stakeholders. Community stakeholders may include individuals and groups that are ultimately representing the interests of people whose samples or those of their subjects (animals) are being collected. Engaging with the community is a process of building transparent, meaningful, collaborative, and mutually beneficial relationships with interested or affected individuals, groups of individuals, or organizations. At a minimum community engagement shall include but not limited to documented evidence of; consulting gatekeepers of the community; organizing community meetings and involvement of Community Advisory Boards in accordance with the National Guidelines for Research involving Humans as Research Participants, July 2014.

Community participation: Research projects that involve communities must carry with them educational materials on prevention of COVID-19 in a language understood by the community as guided by the Ministry of Health. The materials should be displayed in places that are easily visible such as doors, community halls, community boards etc.

10.2. Material Transfer Agreement (MTA)

All samples to be stored in the biobank should be accompanied by an MTA between the Donor Institution and the recipient institution. The MTA shall be submitted to the UNCST for approval.

10.3. Data Ownership and Transfer Agreement (DOTA)

Data sharing modalities shall be established between the participating partners with the mutually agreed position documented in a Data Transfer Agreement. The DOTA shall be submitted to the REC and UNCST for final approval.

10.4. Research On Stored Samples

All research on stored biological specimen and data shall undergo the national regulatory process as stipulated in the National Guidelines for Research Involving Humans as Research.

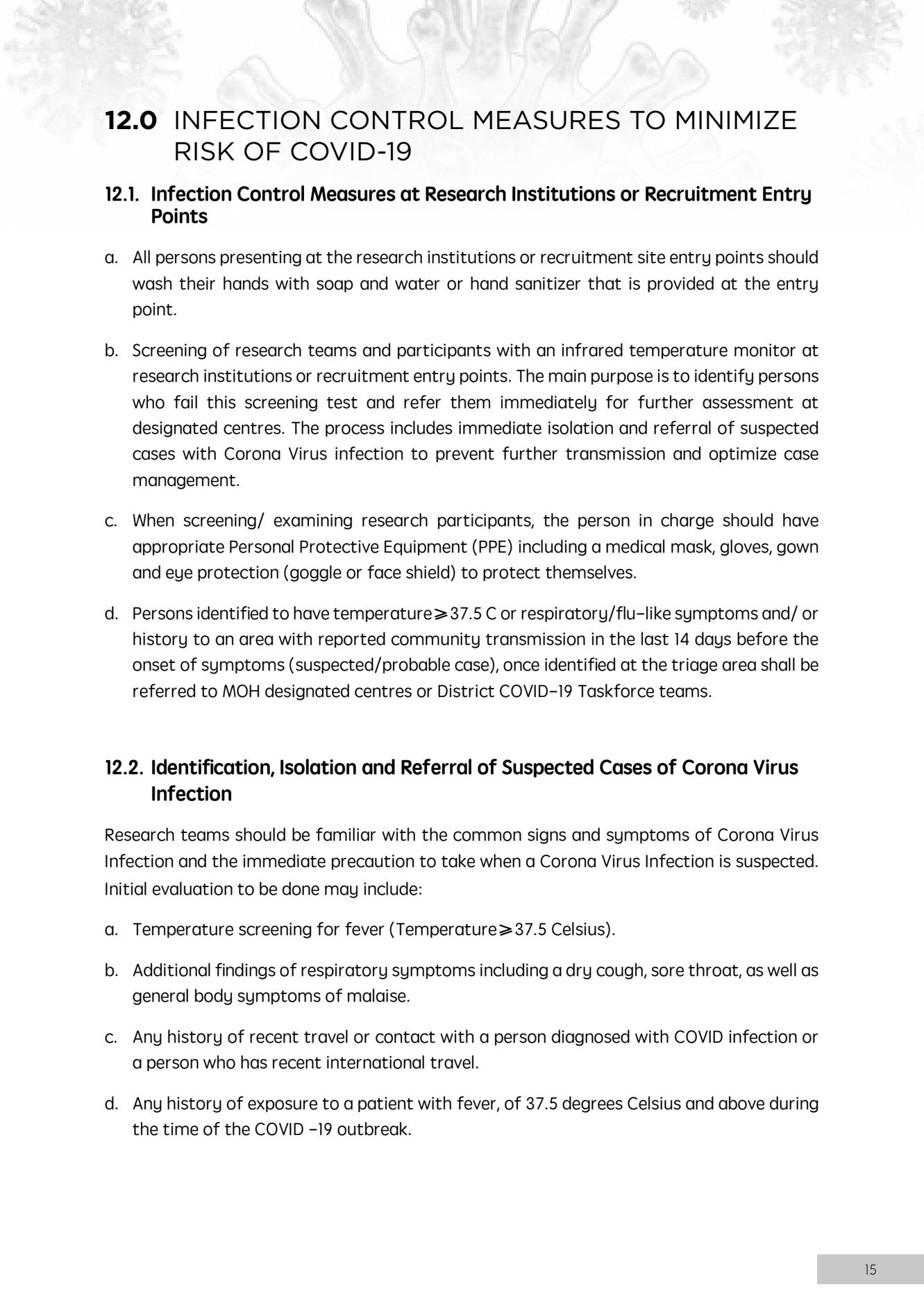
11.0 ESTABLISHMENT OF BIOSAFETY COMMITTEE

Research institutions or recruitment sites shall be required to set up a Biosafety Committee comprising of the relevant expertise at the institution to support RECs. A researcher shall notify and provide the Institutional Biosafety Committee (IBC) with the research proposal involving potentially hazardous substances of a physical, chemical, biological, or any other nature. The IBC's function is to minimize potential human and environmental harm that may be associated with research on or with potentially hazardous substances such as pathogens, select agents, radioactive material and applications of biotechnology, especially recombinant DNA techniques and processes. The researcher shall submit his/her proposal to the IBC before submission to the REC. The decision of the IBC shall inform the decision of the Research Ethics Committee.

11.1. Establishment of an Advisory Committee

For investigators whose institutions do not have Biosafety Committees it will be necessary to set up an advisory committee to perform the following functions:

- a. Updating on emerging scientific data and information from the Ministry of Health about COVID-19 epidemiology, prevention and management;
- b. Advising management on best practices and evidence-based recommendations about COVID-19 to promote both research teams and research participants' safety;
- c. Reviewing strategies for public education and mobilization. Sensitizing and educating staff about COVID -19 disease and management at research institutions or recruitment sites;
- d. Maintaining effective online and direct communication of new knowledge, findings, literature, strategies and developments (policies, SoPs, politics) with stakeholders and researchers, and the National Scientific Task Force of the MoH
- e. Supporting the implementation of health-related precautions at the research institutions or recruitment areas for both the research teams and research participants during the COVID -19 outbreak;



12.0 INFECTION CONTROL MEASURES TO MINIMIZE RISK OF COVID-19

12.1. Infection Control Measures at Research Institutions or Recruitment Entry Points

- a. All persons presenting at the research institutions or recruitment site entry points should wash their hands with soap and water or hand sanitizer that is provided at the entry point.
- b. Screening of research teams and participants with an infrared temperature monitor at research institutions or recruitment entry points. The main purpose is to identify persons who fail this screening test and refer them immediately for further assessment at designated centres. The process includes immediate isolation and referral of suspected cases with Corona Virus infection to prevent further transmission and optimize case management.
- c. When screening/ examining research participants, the person in charge should have appropriate Personal Protective Equipment (PPE) including a medical mask, gloves, gown and eye protection (goggle or face shield) to protect themselves.
- d. Persons identified to have temperature ≥ 37.5 C or respiratory/flu-like symptoms and/ or history to an area with reported community transmission in the last 14 days before the onset of symptoms (suspected/probable case), once identified at the triage area shall be referred to MOH designated centres or District COVID-19 Taskforce teams.

12.2. Identification, Isolation and Referral of Suspected Cases of Corona Virus Infection

Research teams should be familiar with the common signs and symptoms of Corona Virus Infection and the immediate precaution to take when a Corona Virus Infection is suspected. Initial evaluation to be done may include:

- a. Temperature screening for fever (Temperature ≥ 37.5 Celsius).
- b. Additional findings of respiratory symptoms including a dry cough, sore throat, as well as general body symptoms of malaise.
- c. Any history of recent travel or contact with a person diagnosed with COVID infection or a person who has recent international travel.
- d. Any history of exposure to a patient with fever, of 37.5 degrees Celsius and above during the time of the COVID -19 outbreak.

12.3. Physical Distancing

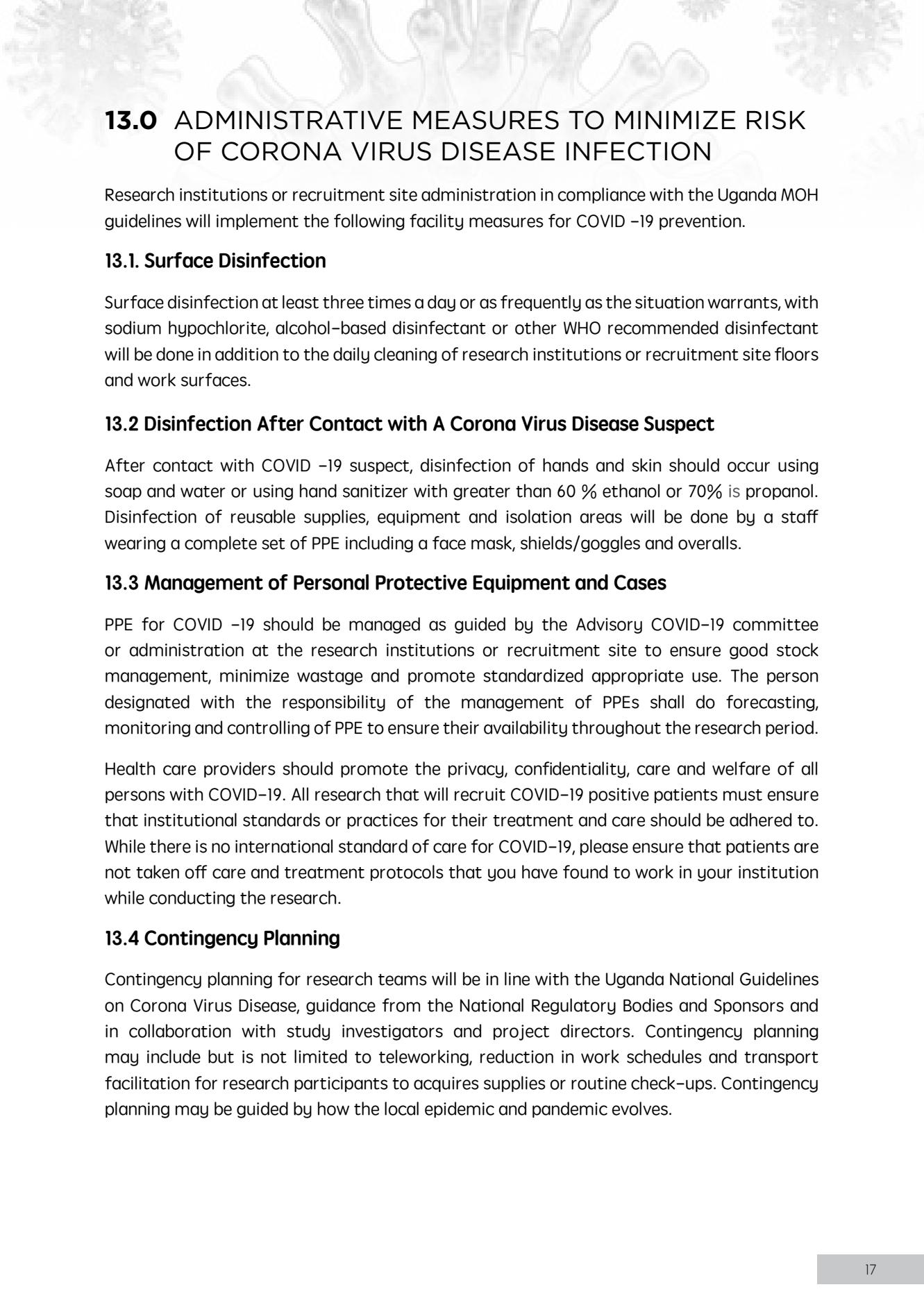
- a. A distance of a minimum of two (2) meters should be ensured during research procedures and activities such as consenting, focus Group discussions and training to prevent person- to- person spread of the Corona Virus while conducting research activities. Online discussion is the preferred mode of interaction.
- b. No more than ten (10) people should converge in one place to undertake research procedures. It is recommended that research teams ensure at least two (2) square meters for each person. Research teams should avoid hand-shakes and hugging at all times.

12.4. Handwashing and Disinfection

Hand washing is the most important precaution for the prevention of infections. Research teams and participants should consistently wash their hands with soap and water or use a hand sanitizer throughout the day when at the research institutions or recruitment sites until when they are ready to leave.

12.5. Use of Personal Protective Equipment for Corona Virus Disease Prevention

Personal Protective Equipment should be made available to all members of the research team that require it for their duties at the research sites. PPE for Coronavirus disease include gloves, medical/ surgical masks, goggles or face shield, gowns, aprons and medical grade gumboots. In addition, for specific procedures, respirators (i.e. N95 or FFP2 standard or equivalent) will be required. The use of PPE in the respective situations or risk categories will be tailored to the current guidelines of Ministry of Health.



13.0 ADMINISTRATIVE MEASURES TO MINIMIZE RISK OF CORONA VIRUS DISEASE INFECTION

Research institutions or recruitment site administration in compliance with the Uganda MOH guidelines will implement the following facility measures for COVID -19 prevention.

13.1. Surface Disinfection

Surface disinfection at least three times a day or as frequently as the situation warrants, with sodium hypochlorite, alcohol-based disinfectant or other WHO recommended disinfectant will be done in addition to the daily cleaning of research institutions or recruitment site floors and work surfaces.

13.2 Disinfection After Contact with A Corona Virus Disease Suspect

After contact with COVID -19 suspect, disinfection of hands and skin should occur using soap and water or using hand sanitizer with greater than 60 % ethanol or 70% is propanol. Disinfection of reusable supplies, equipment and isolation areas will be done by a staff wearing a complete set of PPE including a face mask, shields/goggles and overalls.

13.3 Management of Personal Protective Equipment and Cases

PPE for COVID -19 should be managed as guided by the Advisory COVID-19 committee or administration at the research institutions or recruitment site to ensure good stock management, minimize wastage and promote standardized appropriate use. The person designated with the responsibility of the management of PPEs shall do forecasting, monitoring and controlling of PPE to ensure their availability throughout the research period.

Health care providers should promote the privacy, confidentiality, care and welfare of all persons with COVID-19. All research that will recruit COVID-19 positive patients must ensure that institutional standards or practices for their treatment and care should be adhered to. While there is no international standard of care for COVID-19, please ensure that patients are not taken off care and treatment protocols that you have found to work in your institution while conducting the research.

13.4 Contingency Planning

Contingency planning for research teams will be in line with the Uganda National Guidelines on Corona Virus Disease, guidance from the National Regulatory Bodies and Sponsors and in collaboration with study investigators and project directors. Contingency planning may include but is not limited to teleworking, reduction in work schedules and transport facilitation for research participants to acquire supplies or routine check-ups. Contingency planning may be guided by how the local epidemic and pandemic evolves.

13.5 Communications

Research institutions or recruitment sites should make information about COVID-19 available online and in places that are easily visible to research teams and participants for safety precaution and adherence to set precautionary measures. On the other hand, research projects that involve community engagement must carry with them educational materials on prevention of COVID-19 in a language understood by the community as guided by the Ministry of Health. The materials should be displayed in places that are easily visible such as notice boards and doors, etc.

14.0 CONDUCT OF CLINICAL TRIALS DURING COVID-19

The COVID-19 pandemic has disrupted the conduct and management of ongoing clinical trials for instance inability to complete study visits as scheduled leading to protocol deviations and potential implications on the scientific conclusions that will be made in the context of missing data, treatment disruptions and has also led to the possibility of having to extend the trial duration as a consequence of the pause in trial activities during the lockdown. The need to initiate new trials has also been curtailed by the additional burden presented of minimizing the risk of transmission/infection with COVID-19 to both trial staff and potential participants.

Sponsors together with Investigators therefore, need to undertake a thorough Risk Assessment of the impact of COVID-19 related measures on the trial integrity and interpretability. This impact analysis should be done as independently as possible (by the Independent Data Monitoring Committee) with the aim of documenting follow-up actions and recommendations.

The following considerations for the conduct of clinical trials, especially those that are ongoing should be made:

- a. Proper documentation of pandemic-related protocol deviations and the reasons for these deviations. This should distinguish data that were affected and those that were not and the potential impact on the trial outcomes.
- b. Investigators should consider which information is critical for the interpretation of the trial outcomes and prioritize these visits as well as consider alternative methods of data collection should the protocol-defined methods become impossible to employ.
- c. Following the risk assessment, the Sponsor should consider establishing an Independent Data Monitoring Committee for trials deemed to have been affected by the pandemic. This committee will ensure that the trial integrity is preserved and will also guide on follow-up actions such as the need to adjust the trial sample size, how to deal with potential bias such as from missing data, additional measures on how to complete the trial, how to pause or stop the trial etc.

- c. Any resulting substantial changes to the design and conduct of the trial should receive prior review and approval by the Ethics Committee and the National Regulatory Agencies unless these changes are considered urgent safety measures to ensure safety of the participants.
- d. The Sponsor should define the critical data points and trial processes and develop a risk-based approach to trial monitoring. In consideration of the capacity of the site in terms of staffing, equipment and other resources, the Sponsor may consider adjusting the requirement for on-site monitoring and adopt additional mechanisms such as off-site monitoring and in exceptional circumstances, remote source data verification. It is the Sponsors responsibility to determine the nature and extent of remote source data verification.
- e. Sponsors working together with Investigators are required to submit the Risk Management Plans for the trial sites prior to re-starting a trial and the RMP should be updated as and when important information may become available such as from the report of the IDMC.

Clinical Trials Applications (CTAs) in relation to COVID-19 to be conducted in Uganda, shall be reviewed through a Joint Scientific and Ethical review mechanism involving UNCST/FRECU, UNHRO, NDA and a subject matter expert when necessary. The joint review is intended to optimize the turnaround time for review and approval of the application.

14.1. Role of the National Regulatory Agencies

Three regulatory agencies have specific mandates for the regulation of health research in the country: The specific clauses relevant to their clinical trials operations are described as follows:

- a. The National Drug Authority under the NDA Act 2016 mandates it “to issue a certificate of approval to any person for the purpose of carrying out clinical trials in respect of a drug that may be specified in the certificate). No person may carry out any clinical trial in respect of any drug unless he or she has a certificate issued (Art 40).
- b. The Uganda National Health Research Organization (UNHRO) is mandated to “appraise scientifically and ethically and give approval to all research protocols related to health, before the commencement of any biomedical or other health-related research” (UNHRO Act 2011 –Art 6(e); 16(k); … and in so doing “it shall cooperate with the Uganda National Council for Science and Technology” (UNHRO Act (art 6 (2)). For expediency, this process will jointly be processed at the UNCST secretariat as discussed below through a joint mechanism by regulatory Agencies.
- c. The Uganda National Council of Science and Technology is mandated under Sections 4 and 5 of the UNCST Act (CAP 209) to “act as a clearinghouse for information on research and experimental development taking place in scientific institutions, centres and other enterprises and on the potential applications of their results; and to work in close cooperation with and co-ordinate all scientific and technological activities of persons, institutions, sectors and organizations”.

14.2. Approval Process

The procedure for joint scientific and ethical review requires submission of a CTA request by a Principal Investigator (PI) to the UNCST secretariat. The CTA is pre-screened for completeness and appointment of reviewers from the REC, NRAs and experts in a given field is done in one (1) day. A high-level joint review meeting is held after five (5) working days by the selected reviewers. It is at this meeting that the PI and the selected members of the research team are provided with comments and recommendations for improvement of their application. The PI is required to address the comments and recommendations in two (2) days and thereafter, officially submit to the local REC for review and approval. The PI will then send the approved protocol from the REC to UNCST for final clearance in collaboration with UNHRO and registration within at least one (1) day and then proceed to NDA for issuance of a clinical trial certificate within at least one (1) day.

15.0 COLLABORATION AND PARTNERSHIPS

The COVID-19 pandemic has underscored the crucial need for international scientific collaboration in both the public and private sectors to develop diagnostics, vaccines and treatments to tackle health emergencies. This collaboration requires an open exchange of and rapid access to samples and information. Open and timely access to genome sequences of the emerging coronavirus enabled global collaboration in the scientific community and an early start to develop diagnostics, vaccines and treatments against COVID-19. Therefore, all local researchers conducting or collaborating with international partners to conduct COVID-19 related research should ensure that all COVID-19 related research seeks ethics clearance before commencement as stipulated in the National Guidelines for Research involving Humans as Research Participants, July 2014.

At the regional level, the East African Health Research Commission (EAHRC) is making regional initiatives to coordinate the support for COVID-19 research. The WHO/AFRO Regional Office for Africa has established the Incident Management and Support Teams (IMST) in Brazzaville to oversee and coordinate the conduct of research as part of the countries' response to COVID pandemic. At national level, the private sector has the potential to provide support and transform the research findings into innovations and new tools for prevention and control of the pandemic and ultimately the commercialization of innovations by industry.

16.0 CONCLUSION

The COVID-19 pandemic is a crisis and a human tragedy but it is also an opportunity to recognize and address the deeper shortcomings of our current health systems, and its interface with society at all levels since knowledge about the biological pathways through which COVID-19 attacks the body is still evolving.

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APPENDIX: DOCUMENT CONTROL

DOCUMENT INFORMATION			
DOCUMENT TITLE	National Guidelines for Conduct of Research During Coronavirus Disease 2019 (COVID-19) Pandemic		
DOCUMENT REFERENCE	VERSION	DATE	
National Guidelines for Conduct of Research During Coronavirus Disease 2019 (COVID-19) Pandemic	1.0	28.07.2020	
DOCUMENT ORIGINS	NAME	DATE	
	UNCST	22.06.2020	
	UNHRO		
	NDA		
REVIEWERS	Guidelines Taskforce		
	FRECU		
DOCUMENT REVISION RECORD			
NEXT REVISION DATE	DESCRIPTION	CHANGES	DATE
28.01.2021	<p>Review the document in relation to:</p> <p>The status of the pandemic</p> <p>Comments from the users</p> <p>Provisions of the updated National Guidelines</p> <p>Conformity with the international guidelines</p>		

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