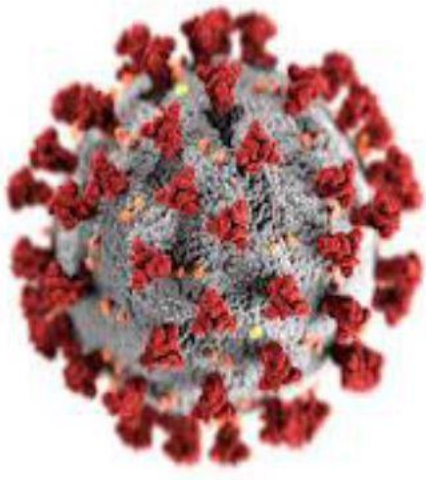
MALAWI GOVERNMENT

MINISTRY OF HEALTH

MALAWI COVID-19 GUIDELINES ON CONDUCTING HEALTH RESEARCH



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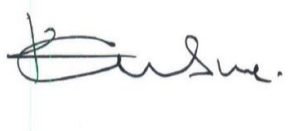
Foreword

The World Health Organization (WHO) declared Corona Virus Disease 2019 (COVID-19) a pandemic on 11th March 2020. On 20th March 2020, COVID-19 was declared a national disaster in Malawi and registered its first cases of COVID-19 on 2nd April 2020[1]. The highly infectious novel virus transmitted mainly by respiratory droplets remain a public health threat globally and locally. There are several on-going research and developments to curb the disease as such local support to research activities amidst the pandemic is paramount.

These Guidelines have been prepared by the National Health Sciences and Research Committee (NHSRC) Secretariat to streamline the conduct of research during the COVID-19 pandemic. These will be implemented in harmony with COVID-19 Guidelines approved by the Government of Malawi. The guidelines 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 document has been developed in the most participatory process. The guidelines have been reviewed by researchers, NHSRC members and Community representatives. This is a dynamic document and more updates will be made as more information, evidence and data becomes available.

The Ministry of Health wishes to assure Malawians that it prioritizes research and development to ensure evidence informed policy making. It is our hope that these guidelines will ensure prevention of spread of COVID -19 when conducting health research.



Hon Khumbize Kandodo Chiponda, MP

Minister of Health

Preface

The Ministry of Health (MoH) developed this set of guidelines which shall serve the purpose of accelerating the attainment of research of the highest quality, a precursor for improved health service delivery in Malawi.

The guidelines will not only ensure human subjects protection but will also ensure standardized protocol review, promote co-ordination of activities of the National Health Sciences Research Committee (NHSRC) and provide information regarding recommended steps for conducting health research in Malawi.

I would like to thank a drafting team for working tirelessly to finalize the guidelines. In this regard, let me thank the Drafting Team Chairperson, Dr Collins Mitambo for spear-heading this process. I would also like to thank the drafting team members namely Faith Kanjira, Dr Stellah-Ashley Lungu, Dr Clara Sambani, Watipaso Kasambara and Yalenga Vinkhumbo.

In addition, I would like to acknowledge MoH-Research Department Staff namely Dr Dzinkambani Kambalame, Ziliro Jere, Douglas Mhone and Billy Nyambalo for their support. I also thank Dr Martias Joshua and all NHSRC members for reviewing the document. Lastly I would like to thank the National Commission for Science and Technology for their financial support.

I sincerely hope that all stakeholders will adhere to these guidelines when conducting health research in Malawi.

Dr Charles Mwansambo

Secretary for Health

ABBREVIATIONS AND ACRONYMS

ARDS	Acute Respiratory Distress Syndromes
CDC	Centers for Disease Control and Prevention
CIOMS	Council for International Organizations of Medical Sciences
COVID-19	Coronavirus Disease 2019
CTA	Clinical Trials Applications
IDMC	Independent Data Monitoring Committee
MOH	Ministry of Health
NHSRC	National Health Sciences Research Committee
PHEIC	Public Health Emergency of International Concern
PMRA	Pharmacy Medicines Regulatory Authority
PPE	Personal Protective Equipment
PI	Principal Investigator
PHIM	Public Health Institute of Malawi
RMPS	Risk Management Plans
REC	Research Ethics Committee
SARS-COV2	Severe acute respiratory syndrome coronavirus 2
WHO	World Health Organization

INTRODUCTION

Background

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 the senses of smell and taste. According to the World Health Organization, the majority of cases result in mild symptoms whereas 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 days but may range from two to fourteen days. The virus is primarily spread between people in close contact, more often via small droplets produced by coughing, sneezing, singing and talking.

The WHO declared the COVID-19 outbreak a public health emergency of international concern (PHEIC) on 30 January 2020 and a pandemic on 11 March 2020. Globally, as of, 8 January 2021, there have been 86,436,449 confirmed cases of COVID-19, including 1,884,341 deaths..(*WHO Coronavirus Disease (COVID-19) Dashboard*, n.d.).

The recommended measures to prevent infection include frequent hand washing and sanitizing, maintaining physical distances from others (particularly 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 minimize the risk of transmissions, with some authorities requiring their use. Medical grade facemasks such as N95 masks are encouraged to be used by healthcare workers, first responders and those who care for infected individuals.

According to the World Health Organization (WHO), there are several ongoing developments and trials for effective vaccines. Management of virus, involves the treatment of symptoms, supportive care, isolation and experimental measures.

The WHO recommends 1 meter (3 ft) of social distance; the U.S. Centres for Disease Control and Prevention (CDC) recommends 2 metres (6 ft). People may transmit the virus without showing symptoms, but it is uncertain how often this occurs. People are most infectious when they show symptoms (mild or non-specific symptoms), these are infectious for up to two days before symptoms appear (pre-symptomatic transmission). They remain infectious to an estimated seven to twelve 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. The amount of active virus decreases over time on surfaces until it can no longer cause infection. Therefore, 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.

COVID-19 has resulted 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 endeavors were seriously impacted leading to severe loss of income, productivity and self sustainable at household levels.

MALAWI'S SITUATION

Malawi registered its first cases of COVID-19 on 2nd April 2020. According to Public Health Institute of Malawi (PHIM) October 2020 report, the average age of the cases was 36.7 years, the youngest case was aged 1 month, the oldest was 98 years and 68.4% were males. (*Public Health Institute of Malawi - October 2020*, n.d.).

Since early-August, there was a downward trend in the number of new COVID-19 cases and deaths in the country, which led to the gradual easing of public health safety measures that were being implemented in response to the pandemic.

Since Mid-December, there has been an upward trend in the number of new cases and deaths in the country. The Ministry of Health and its stakeholders are closely monitoring the easing of the public health safety measures to ensure that Malawians are protected from the COVID-19 pandemic and that the country can detect and respond to any cases that may arise. Active tracing and monitoring of contacts of confirmed COVID-19 are ongoing.

CHAPTER 1

PURPOSE OF THE GUIDELINES

PURPOSE OF THE GUIDELINES

Committed to the fundamental ethical recognition that human subjects are partners and participants in health research and recognizing that human subject research is a privilege not a right, this set of guidelines shall serve the purpose of accelerating the attainment of research of the highest quality, a precursor for improved health service delivery in Malawi, through ensuring the protection of human subjects.

The guidelines will not only ensure that review of proposals is standardized, but will also promote the co-ordination of activities of the NHSRC. Furthermore, the guidelines provide researchers with information regarding recommended steps for conducting health research in Malawi including submission of research proposals, data collection and analysis, monitoring and evaluation of research studies approved by NHSRC and dissemination of research findings.

As the situation with COVID-19 continues to evolve, having information and facts about COVID-19 will help diminish fears and anxieties that arise due to lack of knowledge of 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.

The guidelines will help Research teams / Principal Investigators to develop and adhere to Standard Operating Procedures for emerging infections. These guidelines will also support in developing Risk Management Plans (RMPs) for addressing the requirements of conducting research amidst COVID-19. 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 Pharmacy Medicines Regulatory Authority (PMRA) where applicable for technical clearance and final approval.

Who should Use the guidelines?

- These guidelines should be used by institutions, Individuals and Students conducting research in Malawi.

How to use the guidelines?

- These guidelines will act as a reference to guide researchers on implementation of research during COVID-19 pandemic. The guidelines contain guidance on how to handle study participants and preventive measures for researchers. The guidelines will complement the already existing National Health Sciences Research Committee Guidelines on Health Research in Malawi.

CHAPTER 2

NATIONAL GUIDELINES FOR RESEARCH INVOLVING HUMANS AS RESEARCH PARTICIPANTS

NATIONAL GUIDELINES FOR RESEARCH INVOLVING HUMANS AS RESEARCH PARTICIPANTS

Research is a key aspect of response to public health emergencies, yet it should never impede response efforts. This means that research should not be conducted if it can be expected to take away personnel, equipment, facilities and other resources from those required for outbreak response. In addition, resources allocated to research must not take away from routine health care and public health services(WHO, 2020).

These guidelines have been developed basing on a number of resource materials including the Republic of Malawi Constitution; National Health Research Policy; National Science and Technology Policy; National Procedures and Guidelines for the conduct of Research in Malawi; Policy Measures for the improvement of Health Research Co-ordination in Malawi; Council for International Organizations of Medical Sciences (CIOMS); WHO Operational Guidelines for Ethics Committee that Review Biomedical Research; UNESCO Declaration on Bioethics and Human Rights and other many relevant international ethical guidelines and regulations.(*The National Health Research Committee General Guidelines On Health Research*, 2007)

Thus, the procedures for safety to minimize risk from COVID-19 must be based on the National Health Research Committee General Guidelines on Health Research.

SCOPE

These guidelines apply to all research involving humans as research participants in Malawi, 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 Malawi.

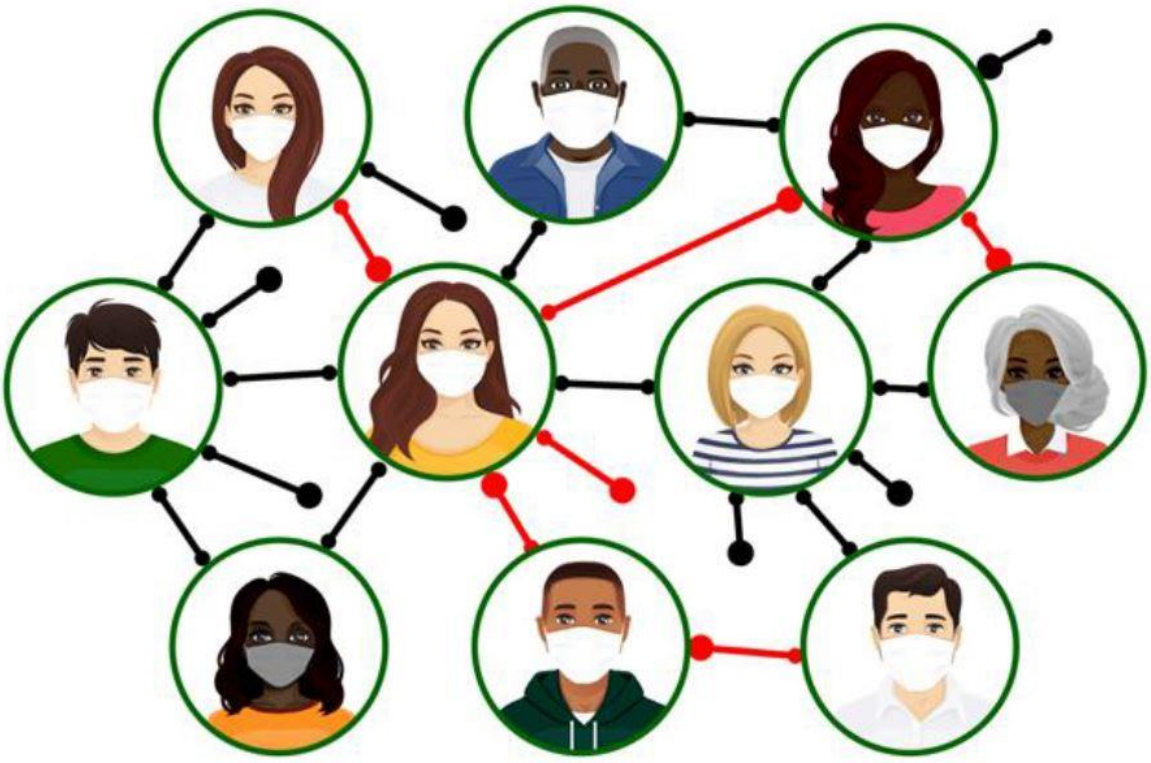
OBJECTIVES OF COVID-19 RESEARCH

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 Malawi. In particular, researchers shall promote the following:

i. Conduct research that is community responsive and aligned to national priorities
ii. 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.
iii. Share information about research findings and reviews of existing knowledge
iv. Develop a Cure and a vaccine through the conduct of clinical studies on care and management, prevention, and control of the pandemic
v. Undertake clinical trials on traditional and complementary medicine pertaining to COVID -19 pandemic
vi. Evaluate laboratory tools to improve quality assurance and simplify easy use
vii. Undertake operational and implementation research to determine the best practices and strategies for containment.

CHAPTER 3

INFECTION CONTROL MEASURES TO MINIMIZE RISK OF COVID-19



INFECTION CONTROL MEASURES TO MINIMIZE RISK OF COVID-19

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

i. 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. Participants should also be provided with appropriate facemasks if they do not have. Study team should also provide clear instructions on proper use of the face masks at the study clinic and in the community.

ii. There shall be proper 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 to immediately refer them for further assessment at designated centers. The process includes immediate isolation and referral of suspected cases with Corona Virus infection to prevent further transmission and optimize case management.

Note: Be aware that suspected and confirmed cases, and any visitors accompanying them, may be stressed or afraid and must be handled with care. The study team should provide the necessary psychological support to them.(The COVID-19 Risk Communication Package for Healthcare Facilities, 2020)

iii. 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.

- For those participants that have been identified at a Triage area 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), they will need to be isolated and evacuated further in the private room immediately.

- Clinical study personnel will be contacted and recommendations from Infection Prevention regarding referral for testing should be followed. The participants should not be responsible for cost of testing and treatment of COVID-19. If positive, participants will be referred to MOH designated center's or District COVID-19 Taskforce teams for further management.

B. 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:

i. Temperature screening for fever (Temperature≥37.5 Celsius).
ii. Additional findings of respiratory symptoms including a dry cough, sore throat, as well as general body symptoms of malaise.
iii. Any history of recent travel or contact with a person diagnosed with COVID infection or a person who has recent international travel.
iv. Any history of exposure to a patient with fever, of 37.5 degrees Celsius and above during the time of the COVID -19 outbreak.
v. If participant is suspected and has the COVID-19 symptoms, national guidelines on COVID -19 Management should be followed.

C. Physical Distancing

i. 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. The sitting area for participants should be marked 1.0-1.5 meters apart to maintain distance while waiting to be attended.

ii. No more than 10 people should converge in one place to undertake research procedures. It is recommended that research teams ensure at least 2 square meters for each person. Research teams should avoid handshakes and hugging at all times.

iii. Research that involves participants of 10 or fewer individuals in a group, such as a focus group, is allowed. Seating should be arranged to allow 1.0-1.5 meters between group members, and all focus group participants must wear masks.

D. 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.

E. 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.

F. Participant Visits

While most researchers use face to face visits in recruiting and following up study participants, however, some visits can be conducted as routine phone interviews, and even for those with smart phones, “WhatsApp” video chat and virtual video conferencing should be promoted.

Visits conducted in person must follow all preventative measures as stipulated in the Malawi national guidelines for COVID-19 to ensure that both participants and researchers are safe.

Phone Visits

Visits conducted with Phone interviews must use proper identification information that the participant provided to the research team to ensure information is given to the correct person. This may include but not limited to; the participant locator form that has participant information provided.

The researcher must confirm the following minimum requirements when conducting phone visits.

I. If the person speaking is the owner of the phone
II. Confirm if he/she is a study participant
III. Comfortability to speak on the phone
IV. If information can be shared with family members.

G. Informed Consent

Although COVID-19 research is taking place as part of a public health emergency, this 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. Therefore, proper consenting procedures need to be followed.

The consenting of research participants during the COVID-19 pandemic must follow principals set out in the National Guidelines for Research Involving Human participants (2007). 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.

In consideration of a gap in knowledge on COVID 19, some research activities will be carried out among COVID-19 confirmed cases, suspected cases and other members of the community. 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. The researcher should indicate how he/she plans to interact with any of the three groups in the Risk Management Plan (RMP) approved by the Research Ethics Committee.

The requirements for providing information and seeking consent will be consistent with the current provisions in the National Guidelines for Research involving Human Participants (2007).

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 NHSRC and any approved Research Ethics Committee and where applicable the PMRA.

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. 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.

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.

CHAPTER 4

ADMINISTRATIVE MEASURES TO MINIMIZE RISK OF CORONA VIRUS DISEASE INFECTION

ADMINISTRATIVE MEASURES TO MINIMIZE RISK OF CORONA VIRUS DISEASE INFECTION

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

A. Surface Disinfection

Surface disinfection at least three times a day or as frequently as the situation warrants, with sodium hypochlorite (bleach) at 0.1% (equivalent to 1000 parts per million, or ppm) for disinfection of surfaces, 70% 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.(*Environmental Cleaning and Disinfection in Non-Health-Care Settinfgs in the Context of COVID-19*, 2020).

B. Disinfection after Contact with 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% 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.

C. 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. These should be guided by Ministry of Health Guidelines and Protocols. Research Institutions should ensure that patients are not taken off care and treatment protocols.

D. Contingency Planning

Contingency planning for research teams will be in line with the Malawi 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.

E. Dissemination

Researchers should continue disseminating research findings. Research Institutions are encouraged to prefer the use of virtual meetings and conferencing to reduce the rate of COVID -19 transmission. Researchers should also utilize print, electronic and social media for disseminating research findings. Researchers should also publish research findings in peer review journals Participants, researchers, policymakers and community members should maximize these opportunities to its full capacity as a preventative measure. When research dissemination is done physically, organizers should adhere to Ministry of Health COVID-19 protocols or guidelines to avoid further transmission of the virus.

F. 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.

Participants should also be provided information that should be read as an addition to the original Consent process so as to give a clear understanding to those who have no information.

CHAPTER 5

CONDUCT OF CLINICAL TRIALS DURING COVID-19

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 and treatment disruptions; and 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 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:

i. 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.
ii. 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.

iii. Following the risk assessment, the Sponsor should consider establishing an Independent Data Monitoring Committee (IDMC) 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 missing data, additional measures on how to complete the trial and how to pause or stop the trial.

iv. Any resulting substantial changes to the design and conduct of the trial should receive prior review and approval by the National Health Sciences Research Committee unless these changes are considered urgent safety measures to ensure safety of the participants.

v. 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.

vi. Sponsors working together with Investigators are required to submit the Risk Management Plans (RMP) 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.

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