



NATIONAL GUIDELINES FOR COMMUNITY ENGAGEMENT IN RESEARCH



FEBRUARY 2022

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Document Errors

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Preface

Globally, there is an increasing need for community engagement in research. Community engagement is an opportunity for communities to participate in the design and conduct of research. Such engagement enhances the relevance, ownership, and applicability of research findings. In community engagement, researchers use both formal and informal structures, like community advisory mechanisms and local administrative councils, to engage with civil, political, and social networks, as well as governmental agencies. The need for this process is highlighted in national and international guidelines on community engagement as a key requirement in all research processes. Although the importance of community engagement in research is acknowledged in the existing national guidelines for research involving humans as research participants, there was need to provide detailed guidance on how community engagement can be effectively undertaken. The need to provide a detailed guidance was partly informed by evidence from the situational analysis of existing community engagement approaches and practices in Uganda, and regulatory aspects for community engagement conducted in 2020, SCINE – U (CSA2018ERC-2318).

Building on the evidence from this situational analysis, a consultative process was initiated to draft these guidelines. This process consisted of task force meetings, drafting retreats and a national stakeholder consultative meeting and broad consultations. The stakeholders included: researchers from health, humanities and social sciences, agriculture, wildlife, veterinary, environment and forestry; research regulators, policy makers, representatives from communities, bioethicists, research ethics committee members, and members of community advisory boards.

The goal of these guidelines is to provide comprehensive guidance to stakeholders on how to ensure meaningful engagement of communities in research as a strategy for improving the responsiveness to community needs and accountability in research. These guidelines should be read and understood in the context of research and the national laws, policies and regulations that govern research.

Martin Patrick Ongol (PhD.)

OngoMartin

For: Executive Secretary, Uganda National Council for Science and Technology

Foreword

Generally, research is essential for human progress and the environment at large. In principle, if research is to be responsive to the needs and priorities of communities, then communities should be involved in the entire research process right from the identification of the research problem to the implementation of its findings. Community engagement is an important part of the research process, which involves working collaboratively with and through individuals and or groups of people linked by geographical location, special interests, similar situations or other identities, to address shared challenges. It helps in ensuring that research is conducted ethically, enhances the social value and improves ownership of the outcome of research.

The UNCST has developed these guidelines by virtue of its mandate of research oversight. The guidelines complement the existing national guidelines for research involving humans as research participants by providing additional guidance to researchers and other stakeholders on how to effectively engage communities in research. The Council believes that the guidelines will go a long way in improving the quality and relevance of research in Uganda.

Dr. Theresa Sengooba

Lawta

Chairperson, Uganda National Council for Science and Technology Board

Acronyms

CAB	Community Advisory Board
CAG	Community Advisory Group
СВО	Community Based Organization
CSO	Civil Society Organization
CV	Curriculum Vitae
DHO	District Health Officer
DHT	District Health Team
EDCTP	European and Developing Countries Clinical Trials Partnerships
GPP	Good Participatory Practice
IACUC	Institutional Animal Care and Use Committee
LC	Local Council
МОН	Ministry of Health
MRC	Medical Research Council
MUJHU	Makerere University Johns Hopkins University Research Collaboration
NGO	Non-Governmental Organization
PI	Principal Investigator
PWD	People With Disabilities
REC	Research Ethics Committee
SACCOs	Savings and Credit Cooperative Organizations
SCINE-U	Strengthening Community Structures in Clinical Research to Improve the Role of National Ethics Regulatory Bodies in Uganda
SOPs	Standard Operating Procedures
TASO	The AIDS Support Organization
UNAIDS	United Nations AIDS Program
UNCST	Uganda National Council for Science and Technology
UVRI	Uganda Virus Research Institute
VHT	Village Health Team

Preamble

Globally, respect for, and protection of communities in the process of research is an ethical obligation for researchers. In research processes, individual research participants, research communities, researchers, and other key stakeholders such as governmental agencies, non-governmental entities, civil society actors, Research Ethics Committees (RECs), Institutional Animal Care and Use Committees (IACUCs), sponsors and funders, regulatory authorities as well as social-cultural institutions and groups ought to, as they often do, play complementary roles. One of the strategies for achieving this complementarity is through community engagement. Community engagement is a process of working collaboratively with and through individuals and or groups of people linked by geographical location, special interest, similar situations or other identities, to address issues affecting their interests.

In the context of research, community engagement may involve a range of activities and interaction between researchers, members of the research community and other stakeholders that are affected by or can affect the success of the research. A community is defined as a group of people linked by either geographical location, identity e.g., disease, disability, ethnicity, religion, or any other identity which forms a basis for common interests. According to UNAIDS Good Participatory Practices (GPP) guidelines 2011, a community refers to "a group of people who have a common set of interests, share a common set of characteristics or live in a common area". GPP further indicates that "The term "community" is also used to refer to the public at large or physical location". Even though a community is defined by a common identity among its members, some religious, social and cultural norms may affect the effective representation of some groups within the community.

The goal of community engagement is to build transparent, meaningful, collaborative, and mutually beneficial relationships with interested or affected individuals, groups of individuals, or organizations, which shape research collectively. Additionally, community engagement ensures that research is responsive to the needs, priorities and expectations of the communities involved in research and or being researched on. It ensures the relevance of the proposed research to the affected community and its acceptance and ownership by the community; as well as building, strengthening, and sustaining trust between researchers and communities.

Researchers should make reasonable effort to involve community stakeholders at the earliest opportunity, preferably from the identification of the research problem and throughout research implementation to the post research period. Community engagement encompasses a broad range of activities, which include but not limited to: community consultation, mobilization, sensitization, education, capacity strengthening, community involvement, community participation, community

empowerment as well as monitoring and evaluation. Community engagement efforts should be structured, focused, and should follow consistent standards across research settings to ensure adherence to international and local ethical principles, and values. It is important to note that critical as it is to research, community engagement is an evolving practice in Uganda. Therefore, it is necessary to provide guidance to stakeholders in research on how to design, implement and evaluate community engagement activities.

Community engagement is an ongoing process right from inception of research to the dissemination of its findings and post research activities. Researchers should identify and consult community stakeholders early enough right from project conception and design in a transparent and participatory manner. Consultations should involve obtaining agreements from community gatekeepers such as local leaders or heads of organizations where research is to be conducted prior to seeking approvals from RECs or IACUCs and other relevant regulatory bodies. In addition, permissions from community stakeholders should not be taken as a substitute for the formal regulatory processes.

1.0 GENERAL PROVISIONS

1.1 Rationale for Community Engagement

Community engagement facilitates meaningful community involvement and participation in the research process. It helps researchers to reach communities better with acceptable and culturally relevant messages and research activities. This ensures that affected communities are supportive of the research being conducted, thus leading to community ownership of research, and increasing the likelihood of uptake of research results. Collaboration between communities and researchers should ensure that research is in line with the needs, priorities, and expectations of the community and that the community is left better-off or at least not worse-off than it was before the research was conducted.

1.2 Goal

The goal of these guidelines is to provide comprehensive guidance to stakeholders on how to ensure meaningful engagement of communities in research as a strategy for improving the responsiveness to community needs, the quality of research and accountability in research.

1.3 Scope of Application

These guidelines apply to all research which can potentially affect individuals, communities, and/or the environment as determined by the RECs/IACUCs. These include; research activities undertaken in health, agriculture and environmental sciences, physical and biological sciences, humanities and social sciences, industrial and engineering sciences, and information sciences. It also applies to all individuals carrying out research in Uganda, and to research and academic institutions, government ministries, departments and agencies, private companies/enterprises, nongovernmental and Intergovernmental organizations, international agencies, and community based organizations among others.

1.4 Principles of Community Engagement

According to UNAIDS Good Participatory Practices (GPP) guidelines 2011, community engagement should be guided by principles which include; mutual respect, mutual trust, mutual understanding, integrity, transparency, and accountability.

a. Mutual Respect

Stakeholders should always ensure mutual respect during community engagement. Respect is key to communicating effectively, fostering trust, and developing partnerships to achieve shared goals. This includes, among others, respect for community autonomy considering local values, cultures, and perspectives as well as the scientific processes. Respect is demonstrated when stakeholders communicate and act in ways that value and honor each other's perspectives and realities.

b. Mutual Trust

Community engagement should aim at building, strengthening, and sustaining trust between researchers and communities. An open, truthful, and active community engagement is critical for building and maintaining trust among stakeholders. The success of an individual research program as well as the sustainability of conducting research in communities depends on mutual trust between communities and researchers.

c. Mutual Understanding

A common understanding about the objectives of the proposed research and how to achieve them is essential to effective partnerships among stakeholders. This requires stakeholders to become aware of and appreciate the social-cultural dynamics of the concerned community and research processes. Through community engagement researchers make efforts to understand the norms, practices, and beliefs of relevant local communities, and local social stances, as well as diverse community stakeholder perspectives, priorities, and research needs. They also make reasonable effort to explain to the community the nature and goals of the research and the relevant information necessary for the community to appreciate the value and process of the planned and ongoing research.

d. Integrity

Community engagement should be guided by the virtues of honesty, openness, and highest scientific and ethical standards among stakeholders. This is vital for achieving the scientific goals of research and maximizing its benefit to the community and society. Researchers should, therefore, adhere to sound scientific processes and appropriately weigh and address ethical issues in their research.

e. Transparency

Community engagement demands openness and honesty about the goals and objectives of the research, research processes as well as the risks and benefits of the research to be carried out in, or about the community. Transparency requires timely and reliable access to information and clear decision making procedures and redress mechanisms. It ensures that feedback from a broad range of stakeholders is acknowledged and where applicable addressed. It also includes ensuring that stakeholders are clear on their respective roles and responsibilities and the extent to which their input may influence research-related decisions.

f. Accountability

Community engagement is one of the strategies for ensuring that stakeholders in research take responsibility for their decisions and actions (or inactions) in research. Accountability is fundamental in sustaining relationships built in trust and mutual respect. Research funders, sponsors, researchers, research regulators, research ethics committees, among others are accountable to the society at large for conducting scientifically valid and ethical research. They also ensure that funding is adequate to enable optimal engagement between research teams and other stakeholders. Researchers should put in place strategies for improving research participants' and communities' participation in the research process.

2.0 APPROACHES TO COMMUNITY ENGAGEMENT

There are several ways through which researchers can effectively engage communities in research. For the purpose of these guidelines, the various ways of engaging communities are referred to as 'approaches'. This section describes several community engagement approaches that can be used, including structures, and methods through which community engagement can be undertaken. It also highlights some of the activities that can be undertaken to achieve the goals of community engagement in research. It is important to note that the choice of the appropriate approach(es) may vary from one research to another. Researchers are encouraged to be critical and innovative in the application of these approaches, including the possibility of combining two or more approaches in a single research project to ensure better outcomes. Researchers are also free to be innovative including devising approaches and methods beyond those described in these guidelines, provided they do not contradict the essence of community engagement as described in these guidelines, or other relevant guidelines for research, including national laws and policies.

Community engagement approaches include, but are not limited to the following:

- a. Formative consultations
- b. Existing community structures and groups
- c. Community leaders
- d. Community events
- e. Mass media
- f. Community Advisory Boards (CABs)
- g. Other community advisory mechanisms

2.1 Formative Consultations

Formative consultations are a basis for developing effective community engagement strategies and plans. It helps researchers identify and understand the population characteristics, interests, priorities, behaviors and needs of target populations that influence their decision making and actions.

Formative consultation enables research teams to gain an informed understanding of local populations, socio-cultural norms and practices, local power dynamics, local perceptions, and local history of research. These usually constitute the initial

phase of stakeholder outreach and engagement. Some of the activities which can be conducted during formative consultations may include but not limited to the following:

- a. Research area and population mapping: It is advisable that researchers should make efforts to gain sufficient familiarity with the geographical and demographic characteristics, governance structures, etc. of the areas, and populations among whom they intend to conduct research. This helps to identify the key stakeholders within such communities and plan resources and appropriate activities that can be conducted in such areas and populations. Consultations and or dialogue with key individuals e.g., gatekeepers, influencers and other stakeholders helps to identify the most pressing needs of the community, get permission for entry into the community, advise on possible ways of engaging community members and identifying potential research participants.
- b. Social community mapping and in-depth interviews: It provides a construct of the local environment, physical boundaries, social and cultural histories, economic conditions, political leadership and demographic characteristics of the population. Social community mapping and in-depth interviews enable researchers to gain cultural competence by understanding the predominant attitudes, perceptions, and practices of the community. The local knowledge about the research location can facilitate planning for research, identify research sites and inform recruitment (and retention) strategies for community based studies. It is important to identify the objectives and the methods to undertake the mapping.

Note: Apart from the above suggestions on how to initiate contact and relationship with the target community, researchers are encouraged to identify other methods of gaining understanding of the dynamics of a given community.

2.2 Existing Community Structures and Groups/Community Stakeholders' Partnerships

Effective community engagement may require working through community structures and with stakeholders that have sufficient understanding of the target community depending on community engagement goals. The structures include, but are not limited to: local government technical departments such as; District Education Department, District Veterinary Department, Gender Culture and Community Development Department, District Agriculture Department, local administrative structures, District Health Teams (DHTs) and School Management Committees. Other stakeholders including: Village Health Teams (VHTs), Civil Society

Organizations (CSOs), Community Based Organizations (CBOs) such as farmers' groups/associations, business groups/associations, women groups/associations, Community Health Workers, health care providers, patient groups, project focal persons, peer-led groups, and Non-Governmental Organizations (NGOs). For effective community engagement researchers should identify the most appropriate existing community structure or stakeholder to facilitate community entry, consultation, and involvement.

2.2.1 District Health Teams

Regarding health-related studies, the Ministry of Health (MoH) and other key health providers are often important key community stakeholders to involve. The DHT is enlisted as one of the MoH governance and management structures. This structure was developed to facilitate the management and implementation of primary health care at district level. They coordinate health service delivery and can support the scale-up of proven health interventions. The DHTs can be engaged throughout the research process.

2.2.2 Village Health Teams/Community Health Extension Workers

Village Health Teams and or Community Health Extension Workers/Agricultural extension workers are lay persons selected by the village and trained to deliver, provide, or advise on basic or first aid emergency care, disease surveillance and other health related community initiatives. They mobilize communities for health programs and sensitize or educate on health and other social issues, and make community referrals to the nearest health facilities. They reach out to communities through counseling, home visits, and community dialogue sessions. They also help frontline health workers to address resistance from communities since they know the communities better than the health workers. Given their knowledge and familiarity with their communities, they can assist in some of the community engagement activities such as mobilization, identification of potential participants, participant recruitment and general information about the research.

2.2.3 Local Administrative Structures

In Uganda, each geographical community is governed by the jurisdiction of political structures or units called Local Councils (LCs), at different levels from LC1 to LC5. The LCs are in direct contact with the community members and hold regular meetings which provide a forum for the community to voice any complaints, appreciation, and any criticism of ongoing community projects. Leaders of these community structures/units can be consulted and involved during initiation of, and throughout the research process.

2.2.4 Special Groups

Some of the special groups that can be consulted and involved in the research process include but are not limited to; youth groups, patient groups, peer groups, gender-based groups, People With Disabilities (PWDs), among others. Such groups can be leveraged to mobilize peers, advise on participant recruitment and retention strategies where applicable.

2.3 Community Leaders

Many research communities have opinion leaders that can play a role in community engagement. These are individuals with considerable authority and influence on community opinion by virtue of their roles, status, knowledge, reputation, or other attributes. Dialogue with these leaders can establish endearing relationships built on trust, transparency, and commitment to community engagement activities. Such leaders include local leaders, opinion leaders, religious leaders, cultural leaders, traditional leaders among others. Some of these leaders exist under traditional decision–making structures. Researchers can engage such community leaders directly or through existing structures in form of consultation on the local, social, religious, cultural, economic, and power dynamics that may influence the relevance and success of a proposed research project.

2.4 Community Events

These are community based activities that can attract a large number of community members. Researchers may find it necessary to reach out to and sensitize different sections of the community and obtain feedback in real time. This can be done through holding events such as:

- a. Community meetings, workshops, seminars
- b. Edutainment and drama skits
- c. Sports events
- d. Community health outreach activities
- e. Public meetings

2.5 Mass Media

Mass media is a means of communicating to many people. Researchers may find it necessary to use mass media to engage their research communities. This approach may be preferable when reaching out to a broader community where your research is

not under one geographical area or to a particular group of individuals. It can also be used for education, sensitisation, communication and obtaining feedback as well as participant recruitment. Some of the mass media outlets include but are not limited to:

- a. Broadcast media like radio, television, films
- b. Digital media like internet and mobile telephones (phone text messages, calls)
- c. Print media e.g., newspapers, flyers, brochures, posters
- d. Internet media e.g., social media, emails, websites, Facebook, twitter, WhatsApp
- e. Community megaphones or loudspeakers
- f. Community public address system drives

All mass media recruitment and research information materials should be reviewed and approved by the REC or IACUCs, where necessary should be appropriately translated.

2.6 Community Advisory Boards (CABs)

A CAB also known as Community Advisory Group (CAG) is a group of individuals with diverse backgrounds, selected from the community to advise and facilitate dialogue between the community and the research team. CABs help researchers to understand the social and cultural dynamics of the research community as well as facilitate community understanding of the research. Further, CABs provide an infrastructure for community members to voice concerns and priorities that otherwise might not be included into the researchers' agenda and advise about suitable research processes that are respectful of, and acceptable to the community. It should be noted that CABs are just one alternative among many approaches to community engagement. However, given their functions and mode of operation, it is important to provide more details about their establishment, composition, functions among others, as highlighted below.

2.6.1 Establishment

The formation of a CAB shall be a responsibility of the research institution and or Principal Investigator (PI) or as may be guided by UNCST. This process includes soliciting and receiving recommendations of potential CAB members from organizations and structures broadly representing various sectors and stakeholders. CAB members should be identified from communities where research is to be undertaken. Representatives should be drawn from groups and organizations who can influence or are affected by the conduct and or outcome of the research.

Once a CAB is fully established, the PI in consultation with the CAB, may invite or co – opt individuals with competence in special areas and populations or ex–CAB members to provide assistance in CAB operations based on the needs of the research being conducted. Researchers should note that some members of certain groups may not freely express themselves while in broad based CABs. Therefore, the need for effective representation of the different social stratifications within research communities might require researchers to consider the possibility of forming CABs based on the subject/area of research or target population.

2.6.2 Composition

Each CAB shall be composed of at least five (5) members, with diverse background. Members of a CAB may include, but are not limited to the following:

- Individuals with understanding of local laws, cultural values and gender issues as well as social and economic dynamics which have potential for affecting the success of the proposed research;
- b. Peer leaders;
- c. Political leaders;
- d. Religious leaders;
- Representatives from local government technical departments, Public servants, NGOs, CSOs and CBOs;
- f. Representatives of the research population, individuals representing potential and or former research participants;
- g. The Media;
- h. Professionals who possess technical knowledge and understanding of the research being proposed.

2.6.3 Term for CAB Members

Membership in any CAB shall not exceed two (2) consecutive terms, each term being four (4) years. No individual shall serve as a CAB member of more than one institution concurrently.

2.6.4 Functions

The primary function of a CAB is to advise researchers on the ways to identify and incorporate community concerns into their research activities. CABs can contribute to the ethical and scientific quality, relevance, and acceptability of the proposed research in several ways, by advising the research team on:

Local, cultural community norms and values that may impact the proposed research.

- a. Appropriate community entry, recruitment, retention, and compensation to individuals for participating in research.
- b. Key issues such as potential risks and burdens for participants or host communities, and how these can be minimized as well as potential benefits and how these could be maximized.
- c. Key issues regarding safety, care and welfare of animals in research and environmental protection.
- d. The recruitment materials, informed consent process, informed consent documents, data collection tools among others.
- e. The development and implementation of information, education, and communication materials for the research.
- f. Effective methods for disseminating information about the research project and its outcomes.
- g. Submission of the progress report of the CAB activities based on their work plans for each research to the REC and UNCST through the PI at least once a year.

However, CABs should not directly get involved in recruitment and follow up of research participants. The CAB's role and expectations should be clearly stated in its charter.

Note: A CAB shall serve up to a maximum of three related research projects within the same institution.

2.6.5 Independence of the CAB

A CAB should function with independence and impartiality to adequately represent the community and work for the protection of research participants and their communities. Efforts should be made to ensure a cooperative dialogue between the research team and the CAB while maintaining the CAB's independent voice. The PI or the designee shall allow and facilitate some meetings that do not involve the research

team to give CAB members an opportunity to discuss freely matters that affect the research as one of the ways to enhance CAB independence.

2.6.6 Roles and Responsibilities of Research institutions and or Principal Investigators

Research Institutions and or PIs shall;

- a. Initiate the process of recruitment of CAB members.
- b. Coordinate CAB activities, including orientation, conference calls, forums, trainings, operational meetings, educational sessions, and briefings.
- c. Provide administrative support to the CAB (including but not limited to meeting operational costs such as logistics, space for the meetings, where necessary allow access to equipment to facilitate minute taking and access to communication means) that enables them to effectively undertake their core functions.
- d. Compensate CAB members for their time, effort and transport.
- e. Where applicable, update CAB on all relevant research plans, research projects that are being considered, status of ongoing research projects in the research institution, and research results.
- f. Facilitate exchange of information between community and the research team.
- g. Ensure that CAB members and research team possess requisite competencies to enable them to effectively perform their duties. To this effect, investigators shall identify and address training needs of the CAB and research team to help increase research understanding and scientific and research ethics literacy.
- h. Ensure transparency in the community engagement processes including making the protocol available to the CAB.
- i. Develop strategies for recruiting and retaining CAB members.
- j. Designate a research staff member who is responsible for working with the CAB.
- Submit the annual progress report of the CAB activities to the REC/IACUC and UNCST.
- Notify CAB members, REC/IACUC and UNCST in writing once a CAB has been dissolved.

2.6.7 Training and Capacity Strengthening

Pls and research institutions should be cognisant of the fact that members from communities appointed to the CAB are usually unfamiliar with research, its processes as well as ethical norms. Therefore, researchers and research institutions should make effort to provide basic and appropriate training to CAB members to enable them to perform their functions in a more effective way. These trainings may cover a range of topics including but not limited to:

- a. Protocol specific training
- b. Basic concepts in research
- c. Research ethics
- d. Regulatory systems and processes
- e. Roles and responsibilities of CAB members
- f. Communication skills
- g. Basic concepts in community engagement

Each CAB member shall undertake training before commencement of the CAB roles, and thereafter, should undergo refresher training at least once every two years.

2.6.8 Records

The CAB should have a mechanism for accurate record keeping and shall prepare and maintain adequate documentation of their activities including but not limited to: detailed written charter/by laws; work strategies/plans; profiles and training records of members and minutes of CAB meetings. All these records shall be accessible for inspection by the REC/IACUC, UNCST and other authorized bodies.

2.6.9 General Requirements

Each CAB shall:

- a. Be registered by UNCST including its membership and constituency represented by the members. Registration shall be updated every after four (4) years.
- b. Develop a charter/by laws or any other similar document which governs their operations. In particular, charters should address the following minimum requirements: mission, goals, objectives, membership, roles and responsibilities, CAB operations, capacity strengthening, decision making, conflict of interest, confidentiality, office bearers, CAB meetings, obligations and responsibilities of researchers and CAB members, and the terms of reference including clarification

that CAB membership is voluntary.

- c. Meet as often as possible but at least once every three (3) months.
- d. Have a clear and systematic mechanism for record keeping.

2.7 Other Community Advisory Mechanisms

For research that involves socially vulnerable, stigmatized, or marginalized populations and those involved in illegal activities, alternative community advisory mechanisms may be considered in addition to the CAB e.g., groups from the target populations who are knowledgeable about their activities and can represent their views. This is very important for such groups'/communities' privacy which would be compromised if the existing CAB were to be allowed to identify and work among them. Training and record keeping as applicable to the CAB would apply to these alternative advisory mechanisms as well.

2.8 General Considerations

These general considerations apply to all the approaches for community engagement as listed above. Researchers' choice of the approaches for community engagement should consider the fact that not every approach can be appropriate for every research. Hence, researchers should consider the following for whichever approach(es) they choose;

- a. Nature of the research, for example, if participation in the research may lead to stigma and discrimination, then it may not be appropriate to use mass media and any other approach that may compromise participants' privacy and confidentiality.
- b. The characteristics of the target community/population e.g., age, literacy levels, reading culture, gender, culture and religion.
- c. The goals of community engagement and the research project.
- d. The cost implications on both the researchers and the community, for example, using internet-mediated communication may impose costs on the community. Researchers need to consider the magnitude of the costs and how they will be covered.
- e. Potential conflicting beliefs, desires, and interests among groups.
- f. Privacy and confidentiality issues, including the venue and number of participants attending the meetings, and their frequency, cyber security among others.

- g. Local/community power dynamics which can potentially affect the success of the research and uptake of the results. Although a community is defined by a common identity among its members, researchers should take into account the religious, social and cultural norms that may silence the voices of some of the community members or groups.
- h. Potential politicization of the research.
- Potential misconceptions about the research that may be left unaddressed and or unresolved.
- j. Potential perceptions of sectarianism and other discriminatory tendencies. For example, use of social and cultural institutions that may be associated with groups of individuals.
- k. Need for social cultural sensitivitu.
- The language to be used should be appropriate to the target community.
- m. Accessibility and ability to effectively and sustainably use the selected community engagement approach.
- n. Timing of activities e.g., when targeting rural communities there is need to take into consideration the seasons and the times of the day.
- o. Appropriate feedback mechanisms. Where required these should be accessible, convenient, affordable, and secure.
- p. Potential for misuse of the medium of communication.
- q. Risks of infection during outbreaks of infectious diseases.
- r. Applicable national laws, regulations, and policies.

3.0 COMMUNITY ENGAGEMENT PLAN

Community engagement requires a clear and detailed plan that describes the goal and objectives to be achieved as well as the approaches and activities that will be employed to that effect.

3.1 Purpose of a Community Engagement Plan

A community engagement plan helps researchers design and implement engagement activities in a systematic manner as it provides a point of reference for those involved in this process. It also provides evidence and, or criteria against which to monitor, evaluate and improve the quality of community engagement efforts.

3.2 Minimum Elements of a Community Engagement Plan

The community engagement plan shall include among others:

- a. Goal and objectives to be achieved.
- b. The key community stakeholders to be involved.
- c. The research team responsible for managing community engagement activities.
- d. Approach(es), activities and mode of implementation as well as the justification for selecting the approach(es).
- e. Communication strategy for the engagement.
- f. An evaluation plan for the community engagement activities.
- g. Plan on mitigation, identification, documentation and addressing of risks, conflicts as well as grievances resulting from community engagement efforts.

3.3 General Requirements for Community Engagement

Researchers shall;

- a. Develop a community engagement plan in consultation with key community stakeholders who are conversant with the dynamics of the target community.
- b. Include their community engagement plans as part of the research protocol to be reviewed by the REC/IACUC, UNCST and any other relevant regulatory bodies.
- c. Identify and address training for key staff involved in community engagement activities concerning community dynamics, norms and values.

- d. Ensure documentation of community engagement activities.
- e. Report on the progress of community engagement activities as part of the annual progress report. The report may cover among others; the activities undertaken, objectives achieved, challenges encountered and steps taken to address them, lessons learned, recommendations and the next steps.
- f. Have sufficient resources for the proposed community engagement activities and a budget line that shall be reviewed by the REC/IACUC and UNCST.
- g. Be required to form a CAB for clinical trials and cohorts. For other studies, this requirement shall be left to the discretion of the researchers and the REC of record.
- h. Have an obligation of identifying, addressing and where necessary reporting non-compliance with these guidelines to the REC/ IACUC and UNCST.
- Have in place provisions for fair sharing of research benefits with the community, where applicable.

4.0 IMPLEMENTATION, MONITORING AND EVALUATION

Effective community engagement is an ongoing process right from the research conception to dissemination of research results to facilitate uptake of the research findings. Monitoring and evaluation of community engagement activities should cover the entire research process. Comprehensive monitoring and evaluation of community engagement includes documenting and analyzing how well the community engagement plan is being implemented. In addition, researchers should pay attention to whether and to what extent community engagement is achieving the intended goals including how the community members feel about the research project. Monitoring and evaluation should be conducted at all stages of community engagement based on the community engagement plan by the PI or their representative.

4.1 Stages of Community Engagement

a. Pre-research: Some of the activities that can be conducted during this stage include but are not limited to: community mapping, identifying and consulting with the relevant key stakeholders, meeting with local/community leaders, identifying the values and norms of the community, introduction of the research team to the community, mobilization of the target audience, community sensitization, and formative consultations where applicable.

- b. Research Implementation: During this stage, researchers can among others engage in continuous consultation with the relevant key stakeholders, mobilization, community sensitization and ongoing education/capacity strengthening, community involvement, community participation and community empowerment.
- c. Post-research: Activities that can be taken into account during the post research stage include but not limited to: feedback and dissemination of research findings, discussion of application of research results with host community and other relevant key stakeholders.

5.0 NON-COMPLIANCE

Non-compliance with these guidelines may be identified by the researchers, REC, IACUC, UNCST or any other stakeholder. Non-compliance shall be documented whenever it is identified and managed by the REC/IACUC or UNCST. The REC, IACUC or UNCST shall subsequently communicate non-compliance to the affected researcher's institution of affiliation and other relevant authorities as appropriate. The addressee shall be required to respond to this communication within a period not exceeding thirty (30) days after notification. The response shall specify any measures/steps taken to address each of the concerns raised and actions taken to avoid further non-compliance with these guidelines.

Once noncompliance with these guidelines has occurred, UNCST, REC or IACUC may schedule an audit to confirm the adequacy of corrective actions taken. Noncompliance with these guidelines may lead to:

- a. Revocation of research approval for a study found to be non-compliant;
- b. Withhold approval of new studies proposed to be conducted at the institution following failure of the institution to address such noncompliance:
- c. Any other action deemed necessary.

GLOSSARY

Clinical Trial: is a systematic research of medical, surgical, behavioral interventions in human research participants to discover or to verify the beneficial or adverse effects.

Community: is a group of people linked by either geographical location, identity e.g., disease, disability, ethnicity, religion, or any other identity which forms a basis for common interest.

Community Empowerment: is a process of assisting communities to gain control over the factors and decisions that shape their lives.

Community Engagement: is a process of working collaboratively with and through individuals and or groups of people linked by geographical location, special interest, similar situations or other identities, to address issues affecting their interests.

Community Involvement: means the practice or ability of communities to play an active part in decision making and activities that have potential to influence their wellbeing and or interests.

Meaningful Community Engagement: should be understood as that in which the views or perspectives of the target community and key stakeholders influence the design and conduct of research.

Monitoring and Evaluation: Monitoring is the systematic and continuous process of collecting, analyzing and using information to track the progress of activities and strategies/approaches toward reaching its objectives and to guide management decisions, while Evaluation is the systematic assessment of activities and strategies/approaches with the aim of determining their relevance, impact, effectiveness, efficiency, and sustainability in pursuit of goals and outcomes.

Research: means any type of systematic investigation, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Stakeholder: is an individual or an entity at the local, national, or international level who can affect or be affected by the research.

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