MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

AVAREF
African Vaccine Regulatory Forum

# Research Ethics Review: Guidance for Clinical Trials

## Introduction and Use

This guidance document is intended to be used as a tool to supplement the review, discussion, and deliberation of Research Ethics Committees reviewing clinical trial protocols. The document is divided into sections, roughly paralleling the way that protocols are typically written and reviewed. The sections are:



Not every question is relevant to each clinical trial protocol; trials differ in innumerable ways. Both the relevance and the importance of these considerations will, therefore, change from protocol to protocol. The questions and considerations below are meant to stimulate thinking as the reviewer is considering the protocol; not every question will be answered—or even mentioned—within the written protocol. If the reviewer has a concern, however, it is generally better to ask the investigator for an explanation rather than assume that one exists.

As with all guidance documents, this is a living document. We welcome user feedback, questions, or suggestions. Please email us at mrct@bwh.harvard.edu.


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*Please note that all research studies involving human participants must be conducted in accordance with all relevant regional, national, and local laws, regulations, guidelines, and requirements. The suggestions below, framed for the reviewer, do not include questions about laws, regulations, and other requirements.*

## 1. Study Team

*This section refers to the review of the study team. Kindly read through the questions and summarize your comments and/or concerns in the section below.*

1. Has the local lead investigator been identified, and what is their role? Have the qualifications of the local investigator been verified, i.e., is there sufficient documentation to ascertain their qualifications? Does the local lead investigator have the time and support to have responsibility for the trial (e.g., how many and how complex are the other trials they are leading, and what is their clinical load?).

   *Note:* The local lead investigator should be sufficiently qualified and competent to carry out the study, and where necessary, have the appropriate professional license to practice as per applicable national laws and regulations. Clinical trials ought to be supervised by a competent and appropriately qualified physician or other health care professional.

2. Have the other members of the study team been identified and what are their roles? Have the qualifications of the study team been verified, i.e., is there sufficient documentation to ascertain their qualifications? Where necessary, do the study team members have the appropriate professional licenses to practice as per applicable national laws and regulations?

3. Are there any arrangements/documentation for the study team to undertake required training/re-training, prior to the commencement of (and, if needed, during the period of) the trial? (e.g., GCP, protocol training, research methods, RCR, etc.)

4. Are there documentation/mechanisms that the lead local investigator has put in place/intends to put in place to ensure that the study team has acquired the necessary expertise and skills to carry out their respective tasks in the research study?

5. Have any potential conflicts of interest been disclosed by the study team, and if so, how have they been managed?

## 2. Scientific Question/Justification

*This section refers to the scientific question/justification of the study. Kindly read through the questions and summarize your comments, questions, and concerns in the section below.*

1. Has the study protocol been reviewed by an independent scientific committee?
    a. If yes, have the comments of the scientific committee been adequately addressed?
    b. If no, do you/the Committee have sufficient scientific expertise to conduct the review? (If no, consider designating an ad hoc reviewer(s) or outsourcing the protocol review.)
2. Have the researchers provided a plain language summary suitable for a lay audience? Is the summary free of technical language and written so a grade-school student could read it?
    a. Is the summary translated to the preferred language(s) of the participants?
    b. Has the summary been reviewed by non-scientists or community members?
3. Has the researcher articulated and linked the background, rationale, hypothesis, and research question?
4. Has the researcher shown that the literature review supports the research question? Are there any published or unpublished studies that have attempted to answer the research question? If yes, do the studies support the methods being used?
5. Has the researcher described the potential societal benefits of the study clearly? In your view is the study reasonably likely to produce societal benefits? Is the study appropriate for the local community? Have community views been solicited and considered?
6. In your opinion, will the study be informative? Will the study add new knowledge to already existing scientific knowledge? If not, is replication of previous research necessary and justified? Alternatively, has the research question already been adequately answered?

## 3. Scientific Design & Methods

*This section refers to the scientific design and methods of the study. . Kindly read through the questions and summarize your comments, questions, and concerns in the section below.*

1. Have the researchers described the selection of the research population? Is it appropriate for the research question? Does it reflect the incidence and prevalence of the disease or condition being studied? If not, why not?
    a. Are the inclusion criteria rationally defined and representative?
    b. Are the exclusion criteria justified by ethical and/or scientific rationale? Are the exclusion criteria consistent with the safety profile of the intervention?
2. Has the sampling strategy been described? Is it appropriate to the study design and intended population?
3. Will the power calculations and sample size estimates answer the research question?
4. Have the researchers considered missing data, withdrawals, and loss to follow up in the data analysis and statistical analysis?
5. Have the researchers described the intervention?
    a. Does the description, risks, and safety profile reflect the information in the investigator's brochure if available?
6. Have the researchers described the comparator, i.e., active control, standard of care or placebo? Is the chosen control group appropriate to the local community, national standards, or international standards of care? Is the choice of comparator justified?
7. Will any auxiliary medical products be used in the trial? Are these medical products necessary and well-described? Are any devices used in the trial? Are any of these devices investigational?
8. Is the study blinded (e.g., masked)? If yes, have emergency provisions for unblinding been described in the event of an actionable laboratory or imaging result or adverse reaction? Have procedures been described to retain blinding of the rest of the trial?
9. Is there a risk of the study intervention or comparator to an embryo or fetus? If so, have appropriate contraception methods been described?

10. Have the study procedures been adequately described? Is the frequency of study visits and monitoring justified?
11. Have the study limitations been described adequately?
12. Have the outcome measures been adequately described? Have the data collection tools and instruments been validated in the language in which they will be used?
13. Have the researchers justified the use of the selected data collection tools and instruments?
14. For new drugs and vaccines, are there any inconsistencies between the Investigators Brochure, the national drug regulatory authority review, and the study protocol and documents?

## 4. Ethical Considerations

Please note that the ethical considerations outlined in this section should be read together with the Consent Considerations noted below.

*This section refers to the ethical considerations related to the study. Kindly read through the questions and summarize your comments, questions, and concerns in the section below.*

1. Has this study been reviewed by other research ethics committees or in other locations? Do you have access to those reviews, and have comments been adequately addressed?
2. Has this study been rejected by other research ethics committees or in other locations, and if so, on what grounds? How does the study or proposed target population differ from the previously reviewed study?
3. If the study includes assignment to different intervention arms, what are the potential benefits and risks to participants and/or groups in each intervention arm? Is there genuine uncertainty in the clinical community (i.e., clinical equipoise) as to whether any arm is safer, preferable, or better than another? How has the research team demonstrated this?
4. How does the local standard of care or standard of practice compare with the intervention and/or the comparator arm? If the local standard of care is inferior to the standard of care in other regions, is its use as a comparator justified? In what ways might the intervention pose greater risks or benefits to participants?
5. How might the interventions and procedures, if proven to be successful, change the local standard of care? Would such a change be implementable and sustainable where the trial is taking place?
    a. If not, what would be needed to ensure that such changes might be implemented and sustained?
    b. If not, is it appropriate to site the trial at this site or location?
6. What are the potential risks associated with the study and what are the potential benefits? What are the ways in which risks are minimized, and could more be done to minimize the risks or increase the potential benefits? In what ways do the potential benefits outweigh the potential risks?
7. Has the study team outlined stopping rules, discontinuation criteria, dose adjustment/ interruption criteria? Do these promote participant safety and withstand scientific scrutiny? Does the protocol describe collection of data from those who withdraw?

8. Does the study seek to recruit individuals or groups who have a diminished ability to safeguard their own interests in the context of research due to limited capacity or limited access to social goods, rights, opportunities, etc?

    If yes:

    a. What is the justification for including these populations?

    b. What are the potential harms to these individuals or groups?

    c. In what ways might these individuals and groups be unable to safeguard their interests, and what measures have been taken to protect and respect them?

    d. For each area of concern, have additional safeguards been described in the study protocol?

    e. How might study findings produce inequities or stigmatize particular individuals or groups and what steps have been taken to minimize such inequities and stigma?

    f. If minor children or people with impaired decision-making ability are included, does the research offer some direct benefit to them or the potential to yield important knowledge about their disorder or condition to the population that they represent?

9. If certain populations are excluded from research, what is the scientific and/or ethical justification for the exclusion? Is the justification included in the protocol?

10. Are participant-facing materials translated into the languages most often spoken by the intended population? Are there interpretation services available? What other provisions have been included to render materials accessible to the participants?

11. How is the recruitment process described, and is the process likely to be fair, reasonable, and equitable?

    a. Have adequate outreach activities been described?

    b. Have compensation or arrangements for costs, travel, transportation, lodging, and meals been considered?

    c. Has translation of participant-facing documents been provided, and if not, are there provisions for the inclusion of people whose preferred language differs?

    d. Have accommodations for accessibility been provided for those who need them?

12. What are the costs to participants to partake in the study? Will costs undermine the ability of some members of the intended participant population to participate? Can the study sponsor or study team absorb these costs (e.g., additional transportation costs, laboratory tests, supplies, cost of the study drug/intervention if it becomes commercially available, etc.)?

13. What is the nature, form, and extent of compensation for study participation (e.g., reimbursement for transport, time, effort, inconvenience, etc.) If research participants are to receive any incentives (monetary or other), what is the amount/value and is this amount/value justified and reasonable? When do participants receive the incentive?

14. In case the research study involves children who may need to be accompanied by a parent or guardian to partake in the study, are the proposed amounts for transportation and other expenses sufficient to cover the cost for both child and guardian?

15. In what ways do potential participants have meaningful opportunities to refuse to participate in the study, and how might individuals feel pressure (e.g., through access to care, lack of independent decision-making ability) to partake in the study? Might the lack of meaningful opportunities to refuse participation or pressure from external sources prevent individuals from voluntarily participating in the study? How is voluntariness demonstrated?

16. Are potential participants likely to be unduly influenced to participate in the study? Are there safeguards to protect against undue influence? What are these safeguards?

17. Under what circumstances, if any, will post-trial access to the interventional product be offered at the end of the trial? What provisions are made for referring the participant to a local healthcare provider at the end of the trial?

18. What is the plan for disclosing incidental findings to participants and/or third parties, and does the plan minimize harm and risks to participants and third parties to whom incidental findings are disclosed?

19. What is the plan for community engagement? What approaches/strategies and activities are planned to ensure continuous and effective community engagement? Note: community engagement ought to be an ongoing process right from the inception of research to the dissemination of its findings and post-research activities. It is a process of working collaboratively with and through individuals and/or groups of people linked by geographical location, special interest, similar situations or identities, or other commonalities to address issues affecting their interests.

20. Have participant privacy and confidentiality been protected?
    a. Have the data collected been minimized to those needed for the outcome measures of the trial?
    b. Are there organizational and technical arrangements to avoid unauthorized access, disclosure, dissemination, alteration, or loss of information and processed personal data been described?
    c. Have measures been described that will be implemented in the case of a data security breach?
    d. Will the data be deidentified or anonymized prior to disclosure or sharing?
21. Will biospecimens be collected?
    a. Is the future use of these biospecimens adequately described?
    b. Are procedures in place to protect the identity of the participant?
22. How have the researchers justified the intervention in their protocol? How have they evaluated and described the clinical equipoise among the proposed interventions? What are the standard-of-care (SOC) options available to the participants within the clinical trial, and are they equivalent to those in the participants' community? Will the SOCs be provided free of charge during the clinical trial, and what happens if the participant withdraws from the trial? Under what conditions will the experimental intervention be available to the participant at the end of their participation in the clinical trial, or after the clinical trial in its entirety has concluded?
23. Does the researcher/study protocol provide a clear description of the methods that will be used to collect data, including participant recruitment, timeframe, and consent? How has the researcher described how the methods were determined, what alternatives were considered, and how the intervention procedures will be monitored and documented?
24. If the study involves a placebo group, how has the researcher/study protocol justified the use of a placebo scientifically, medically, and ethically? Are there standard-of-care options available to participants in this study or anywhere outside the study, and will the prospective participants be informed of the availability of alternatives?
25. If blinding is required, has the researcher/study protocol described how blinding will be accomplished and whether the blinding method is adequate? Are there strategies that will be employed to minimize the risk of unblinding?

26. How has the researcher/study protocol described the procedures for the monitoring and reporting of adverse events or effects? Is there a responsible person or entity identified and accountable for the monitoring and reporting?

27. How has the researcher/study protocol described the processes for monitoring data to ensure the safety of participants and the integrity of the data? For example, how often will the data be monitored and reported? Will the interim analysis be blinded? How will potential safety events be identified and managed?

28. Has a data monitoring committee (DMC) been described and constituted? The DMC is a group of clinicians and biostatisticians appointed by study sponsors who provide an independent assessment of the safety, scientific validity, and integrity of clinical trials. The DMC provides relevant information, e.g., whether stopping rules have been met, futility has been shown, safety concerns that may have arisen, over the course of the trial, so that the research ethics committee can determine the continued acceptability of the study.

29. Is there a Study Steering Committee (SSC)? An SSC is the executive committee that oversees the trial and considers the recommendations from the Data Monitoring Committee. If yes, who are they, and how have they been identified? Is there adequate membership diversity, and are there representatives of the anticipated study populations? How have these representatives been empowered to represent the study population? Does the study protocol provide the roles and responsibilities of the committee, and whether the members have reviewed and accepted their responsibilities?

30. Are there reproductive risks of participation for males and females and, if so, have they been adequately described within the protocol and informed consent documents? Are there potential risks to an embryo or fetus, and if so, does the protocol describe them and the options should the participant or the participant's partner become pregnant?

## 5. Consent

*This section refers to informed, ongoing, and voluntary consent. Kindly read through the questions and summarize your comments, questions, and concerns in the section below.*

1. Does the informed consent form contain all important information related to the study to enable research participants to provide informed consent? (e.g., sponsor information/contacts, investigator information/contacts research institutions, title of the study, purpose of the study, study interventions, target population, local and total number of participants, study procedures, duration of the study, time commitments, timing of the procedures, mandatory vs optional components of participation, statement that participation is voluntary, potential/foreseeable risks/discomforts and how they will be mitigated and or managed, study benefits, costs/study, participant payments (e.g., reimbursement, compensation), alternatives to participation, potential consequences of early withdrawal from the study, participants rights, who to contact, name and contacts of individuals(s) to contact at any time in case of questions about the research study, research participant' rights and welfare (i.e., research team, national regulatory bodies, and/or REC), circumstances under which participation may cease, disposition of data and biological samples, assurance of confidentiality, access and purpose of access to data, data protection, conflict of interest disclosure, and others.)
2. How does the consent form denote that the study is a research study rather than the provision of clinical care?
3. Is it clear in the consent form what aspects of the study are not part of usual practice or care? If yes, how are the alternatives to participation described? And will the prospective participant have access to the usual or standard practice or care?
4. How is the likelihood of being assigned to each intervention group or arm described within the consent form (i.e., is the process described in lay terms?). How has randomization been described? For example, does the participant know that they have no choice whatsoever about which arm they end up in? How will participant understanding be assessed? Has the written language been reviewed by community members to optimize understanding? Has the consent form been translated into the preferred language of the participant?
5. How much time are participants given to provide informed consent? Is the time allotted sufficient to make an informed decision?

6. After the informed consent discussion, how will the participant's comprehension of the content be determined?

7. What are the procedures and limitations for withdrawing consent? Are they clearly laid out in the consent form? (e.g., what happens to the data collected up to the time of withdrawal?)

8. How does the language used in the consent form avoid therapeutic misconception (the mistaken impression held by participants in research that the research is designed to be beneficial to them personally)? Has the researcher/study protocol described how the participant's understanding of the research is assessed, evaluated, and documented?

9. If the study involves secondary use of data or samples, is the participant able to opt out of secondary use of the data or samples or is secondary use a requirement of participation? Is the process for opting out of the secondary use described in the consent documents, and is the process for subsequent withdrawal of consent clear? Does the process respect the autonomy of participants?

10. Are the data management details– e.g., data storage/retention, data security, data access, record keeping, etc.–clearly laid out in the consent form?

11. How does the consent form describe the way participants (and healthcare providers) learn study findings, study progress, and clinically relevant findings related to the participant's safety and well-being?

12. How does the consent form describe the compensation and medical treatment that will be available if injury occurs, and where participants should go for further information?

13. Are there any instances of exculpatory language in the consent form through which the research participant or representative/guardian/parent/ is (i) made to waive or appear to waive any of the research participant's rights, or (ii) appears to release the researcher, sponsor, organization, or its agents from liability? If so, this should be removed.

14. What is the process for obtaining voluntary, informed, and ongoing consent, and how does the process respect the right of participants should they change their mind and no longer wish to be part of the study?

15. If participants are unable to consent for themselves to partake in the study–for example, due to cognitive capacity – what is the rationale for the inclusion of these participants, and is the rationale justifiable and fair? In such cases, assent should be obtained from participants (where possible) and research teams should outline how assent will be ascertained.

16. In the case of a research study involving participants who are unable to consent for themselves, is the proposed process for (1) identifying their representative/next of kin/guardian/relative/legally authorized decision makers and (2) obtaining surrogate consent adequately described? How will competency be determined?
17. For research participants who are not capable of providing informed consent, what mechanisms are in place for obtaining assent from participants? In the case of younger participants, how is the ability/capacity to provide consent or assent evaluated? (e.g., age, comprehension level, etc.)
18. Where necessary, how will provision for a witness at appropriate specific stages of the informed consent process take place? For example, in the case of individuals with limited cognitive capacities, will a witness attest to consent/assent taking place?
19. What are the languages spoken by the study population, and are the consent documents properly translated into these languages?
20. Is the research team proposing to use an alternative(s) to written consent? What is the justification for the alternative(s)? Are the justification/alternative consent method(s) reasonable? If electronic consent is used, how will the participant's identity be verified? Will the process be witnessed? How will the understanding of consent be determined?
21. How is consent documented, where are the records stored, for how long, and how can consent be verified later?

*Note:* The information that is given to the research participant or the representative/guardian/parent should be in a language and form understandable to the participant and/or the representative/guardian/parent.

*Note:* Where written consent is required, a copy of the form should be given to the research participants, if they wish to have one.

## 6. Data Management

*This section refers to data management. Kindly read through the questions and summarize your comments, questions, and concerns in the section below.*

1. What type of data will be collected in the research study? Is it qualitative or quantitative data or both? What are the associated risks of such data collection?
2. What are the proposed research methods to be used for collecting data?
   Are they appropriate for the type of data to be collected?
   Are they respectful of cultural/social norms?
3. How will the data be analysed? Is the data analysis plan likely to produce any related harms, such as stigmatizing certain groups/populations? (N.B. the proposed data analysis plan should be suitable/applicable with the type of data to be collected.)
4. What measures have been put in place by the researchers to control for confounders in their data analysis?
5. What provisions/safeguards have been put in place in the protocol to protect the privacy and confidentiality of participants' data? (e.g., de-identifying data, anonymizing data, and other safeguards in place to protect personal information, personal health information, and research data)e
6. What is the plan for data retention and destruction, and how is this plan respectful of local cultural norms?
7. What steps are in place to ensure that data will be safely retained?
8. What measures are described in the event of a data breach or unapproved release of data? What are the potential risks to the participant of a data breach or release of data?
9. How long will research data be stored? Where will the data be stored?
   Who will have access to the data?
10. What plans do the research team have regarding data sharing with other investigators/third parties? Are these plans respectful of participants, local cultures, and salient data-sharing norms?
11. Can the participant choose not to share data or withdraw their consent to share data?

## 7. Genetic Considerations (if study involves genetic component)

*This section refers to research involving genetics. Kindly read through the questions and summarize your comments, questions, and concerns in the section below.*

1. How have the anticipated uses of genetic material been outlined and described? Are future uses envisioned? If so, future use (and any restrictions) should be provided.
2. How have the privacy and confidentiality risks associated with genetic research been described? Take into consideration both the risks to self and family members, including risks related to employment, insurance eligibility, and healthcare access.
3. How has the researcher/study team described the plan for managing information that may be revealed through the genetic research? Does the plan include who will have access to the information, i.e., does any person other than the participant have access to the genetic results? Will the information be communicated to the participant and/or others? Will there be any future use of the genetic material?
4. Does the researcher/study team intend to share the genetic sequence? If yes, how will new information be transferred, stored, and communicated?
5. How will the researchers explain clinically significant genetic findings? Are there resources provided to enable participants and themselves to understand the findings?
6. How does the plan for managing information that may be revealed through the genetic research consider the clinical relevance of the information that may be revealed from the study? Does the plan include future learning about the clinical relevance of the information? Have the risks and potential benefits for the participant, as well as for family members who may be affected by the information, been described?
7. How has the researcher described the plan to return results revealed through the genetic research? Is the plan clearly described in plain language in the informed consent document? Does it give participants the option to decline to receive the information (or change their minds)? And if so, how? Will genetic counselling or other supports be available for the participants as part of the plan to return the information?
8. Does the researchers' plan to share genetic findings explain to the participant that others are entitled to receive the information, whether the participant agrees or not? (e.g., government and authorities' right to access that information.
9. Have the researchers confirmed that, and detailed when, genetic counselling will be made available to participants and/or impacted or affected individuals? Are there any limitations and costs to the provision of genetic counselling?

## 8. Continuous and Ongoing Review of Clinical Trials

*This section highlights those considerations related to the ongoing and continuous ethics review of clinical trials (Note: Research ethics review and oversight do not just take place before the study begins but are continuous throughout the conduct and close-out of the trial.) Kindly read through the questions and summarize your comments, questions, and concerns in the section below.*

1. Has the researcher identified and described all suspected and unexpected serious adverse events and unanticipated problems that have occurred, and were they reported in a timely and appropriate manner to all appropriate bodies/individuals? Were steps taken to minimize risks to participants and prevent future serious adverse events, and were individuals compensated accordingly?
2. Is the study team on track with their recruitment/enrolment targets, and have they made adequate progress in conducting the clinical trial? If not, have they explained/justified why and proposed strategies to better recruit participants?
3. Has the study team submitted any changes/amendments to their initial submission, and have these changes been reviewed based on this document (i.e., Research Ethics review: Guidance for Clinical Trials)?
4. Did any protocol deviations, violations, or audit findings take place, and if so, were these reported to the research ethics committee in a timely manner? Were safeguards implemented to help ensure that such deviations do not take place in the future?
5. Have any new conflicts of interest arisen since the initial approval of this study? If so, have they been disclosed and properly managed?
6. Have there been any new scientific findings related to the study that affect the benefit-risk ratio to participants or the social or scientific value of the clinical trial? Does the study still have a positive benefit-risk ratio?
7. Have there been any complaints or serious feedback from participants or members of the local community where the trial is taking place, and if so, what were these complaints/feedback? Have the complaints/feedback been reviewed, and have measures been implemented to improve the conduct of the clinical trial?
8. Have all participants been reimbursed, compensated, and paid as laid out in the study protocol?
9. Has the study been conducted and completed as laid out in the study protocol? (e.g., have post-trial obligations to participants and communities been offered/implemented? Have study findings been shared?

## 9. Close-out of Clinical Trials

*Clinical study close-out occurs once participants are no longer receiving any research-related interventions or engaged in research procedures, all the data have been collected, all outstanding queries and data clarifications have been resolved appropriately, the database is locked and ready for statistical analysis, and the study conduct has ended. Kindly read through the questions and provide a summary of your comments in the box below.*

1. Are all research interventions and procedures completed, data collected, queries resolved, and the database locked?
    a. Have all adverse events, unanticipated problems, and serious adverse events been captured, followed, and resolved per protocol, and reported to the appropriate parties (sponsor, ethics committee, and regulatory authorities, if applicable), as detailed in the protocol reporting requirements?
    b. Have all protocol deviations been noted in source documentation and reported to the ethics committee as appropriate?
2. Has appropriate follow-up been provided and documented for any participant experiencing an ongoing unanticipated problem (e.g., serious adverse event) at study end? How will the participant(s) be contacted for further information after the study is closed?
3. Do all participants have:
    a. A decision as to whether continued access to the study product will be provided, if appropriate, and a means to receive it?
    b. A referral or plan for further treatment and care, if needed?
    c. A means to contact the investigator if late adverse events occur or questions arise?
    d. Access to the results of the study when available?
    e. Access to their individual results, if appropriate?
4. In the event that a study is closing early, has an adequate explanation been provided?
    a. Have participants been notified and given an explanation?
    b. In this instance, it is particularly important to ensure that provisions for follow-up for potential adverse events, consideration of continued access to medication or treatment, and referral to ongoing follow-up care have been considered.

5. Have all study documents and specimens bearing participant identification information been stored securely, deidentified with the code to identification, if one exists, secure, or destroyed, per study protocol?
6. Are all specimens collected for future use appropriately consented? Is their location recorded and appropriately secure?
7. Did the study achieve its goals of enrolment and retention of the intended representation of the study population? If not, why not?
8. Will the communities involved in the study be provided with a plain-language summary of the results? Is the process well-defined?
9. Has the sponsor conducted a close-out visit, and if so, what were the findings?
10. Have research results from the research been published, submitted for publication, or presented?
11. Have the study methods and findings been accurately and promptly verified and reported, and will they be shared/disseminated in a way that maximizes social and scientific value?
12. How are the study findings expected to impact the standard of care?
13. Do the study findings pose any risks to participants, groups, or communities (e.g., aggravate health inequities, stigmatize individuals, etc.) and have these risks been adequately addressed?

*Note:* During public health emergencies, the above ethics tool should still be used when reviewing research involving human participants. The turnaround time of the review, however, may need to be expedited based on the importance of the study and the nature of the public health emergency. Research conducted during public health emergencies needs to adhere to the highest scientific and ethical standards.

## Related Resources

ICH E6(R3) Guideline On Good Clinical Practice (GCP)

CIOMS International Ethical Guidelines For Health-Related Research Involving Humans

WMA Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects

AVAREF Assessment Templates