malaria consortium
disease control, better health

Malaria Consortium

Research and Evaluation Ethics Policy



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1 Purpose and context

Malaria Consortium conducts a range of research and evaluation activities to generate evidence for our programs, in partnership with various academic and research institutions. Often these activities meet criteria for human subject research and thus, according to international and national norms, require review by a recognised Research Ethics Committee (REC), sometimes known as an Ethics Review Committee (ERC) or Institutional Review Board (IRB). Review of protocols before the research starts helps to ensure the welfare and rights of participants are protected and harms are minimised. However, there are important ethical considerations to help protect research participants throughout the life course of a project. Furthermore, our research is typically conducted with vulnerable populations who may have limited access to health care, and as such, there are particular ethical concerns that must be considered.

Malaria Consortium endorses the World Medical Association Declaration of Helsinki (WMA, 2013) and the International Ethical Guidelines for Health-related Research Involving Humans prepared by the Council for International Organizations of Medical Sciences and the World Health Organization (CIOMS-WHO, 2016). These are internationally recognised guidelines for research ethics, which stipulate that all research involving human participants should be subject to independent ethics review, seek informed consent and ensure confidentiality, outline special procedures to protect vulnerable groups, especially children and be listed in a research register. These international ethical guidelines are based on three key principles of **respect for persons, beneficence** and **justice** (described in section 2).

The purpose of this policy document is to describe procedures and guidance for protecting the rights and welfare of people enrolled in research conducted by or under the direction of Malaria Consortium.

2 Ethical principles

Ethics refers to moral principles that govern behaviour or the conduct of an activity. In the context of research, ethical principles are broad statements to guide actions or policies. We encourage Malaria Consortium researchers to refer to key ethical principles when writing proposals for research and evaluation, to justify the methods and approaches used and to ensure ethical issues are considered. When conducting research or evaluation activities that involve data collection with human participants, Malaria Consortium will abide by the following three key ethical principles, and the applications that follow from each principle. Section 4 provides further information about how these principles are implemented in Malaria Consortium.

- **Respect for persons**: This principle concerns treating people with dignity, making sure they are fully informed and recognising their autonomy when deciding whether to participate in any research activity. The concerns and culture of communities should be acknowledged, and steps taken to ensure the meaningful engagement of

communities in the research. The important applications of this principle are: a) seeking voluntary, informed consent from individuals capable of considering the risks and benefits of participation and b) protecting the privacy and confidentiality of research participants, and c) respect for the culture and the community engaged in research.

- **Beneficence**: This refers to the obligation to maximise benefits and minimise harms in any research activity involving human participants**.** The risks to participants must be reasonable in light of the expected benefits, and appropriate steps taken to protect the wellbeing of research subjects. The main applications of this principle are: a) the steps taken to maximise benefit and minimise harm throughout the study, b) the competence of researchers to carry out the study.
- **Justice**: Research should be responsive to the health needs and priorities of the researched population, and research should leave low-resource countries or communities better off, or at least no worse off than before. There should also be equitable distribution of both the benefits and risks of participating in the study, and particular consideration of the rights and welfare of vulnerable groups. There is increasing recognition that some vulnerable groups, for example pregnant women and older children, should not be excluded from studies but given the opportunity to participate in research provided risks and benefits are fully explained. The main applications of this principle are: a) ensuring fair selection of research participants (including attention to inclusion and exclusion criteria), b) protection of vulnerable groups and c) access to successful interventions post-study.

In addition to the key principles, adequacy of resources, transparency and misconduct are important issues that can impact on the ethical conduct of research[1]. Adequacy of resources and transparency are addressed in this policy, and the procedure for dealing with research misconduct is outlined in detail in the Research Misconduct policy.

- **Adequacy of resources**: This refers to the level of resources allocated to the research and whether these are sufficient to carry out the study ethically. Inadequate logistical, human or financial resources could put participants at risk. Researchers should therefore describe and justify the resources in detail, including: a) the study sites and facilities and/or equipment available for the safe and appropriate conduct of the study, b) the research team and their qualifications and experience to justify adequate expertise, and c) the amount of funding available and a time plan for the research in order to demonstrate sufficient resourcing.
- **Transparency**: A number of items can be included in a protocol to ensure transparency in the research process. These include: a) a clear statement of

[1] Global Health Training Centre. Research Ethics Online Training: https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/

justification that highlights the significance of the research and its relevance to the country and population b) declaration of any conflicts of interest at all stages of the research cycle and c) a statement about making the research findings widely available and sharing negative results as appropriate.

Most of Malaria Consortium's research and evaluation is conducted in low- and middle-income countries, where resources are limited, infrastructure is weak and where populations have limited access to health care. In these circumstances it may be difficult to apply the key ethical principles outlined above, and local needs and cultural context are important in applying the principles. The Nuffield Council on Bioethics produced a framework[2] for health research in developing countries that emphasises four principles:

- to alleviate suffering,
- to show respect for persons,
- to be sensitive to cultural differences and
- to not exploit the vulnerable

Malaria Consortium encourages all staff involved in research and evaluation to take account of these principles when designing and implementing research.

3 Scope

This policy applies to all individuals in the organisation either involved in, responsible for, or providing oversight to research or evaluation activities that involve data collection with human participants. This includes employees (whether permanent, fixed term or temporary), volunteers and interns, consultants, partners and any other person or organisation involved in research or evaluation activities for Malaria Consortium whether paid or unpaid.

4 Implementation of ethical principles

Research should only be conducted by individuals with **qualifications relevant to the study**, who are **familiar with ethical considerations** applicable to the research, who **submit the necessary information to a REC** for review, and who **carry out the research in compliance with the requirements of the REC** that approves the study. The following checklists are designed to guide Malaria Consortium staff who are either involved in, responsible for, or provide oversight to research or evaluation activities that involve data collection with human participants. The checklists contain information about ethical considerations that must be addressed as well as the procedures to be followed before, during and after the research is conducted.

[2] Nuffield Council on Bioethics (2002). The ethics of research related to healthcare in developing countries: http://nuffieldbioethics.org/wp-content/uploads/2014/07/Ethics-of-research-related-to-healthcare-in-developing-countries-I.pdf

4.1. Qualifications and training

Research should only be conducted by individuals with qualifications relevant to the study, and who have completed the necessary training requirements. Please refer to the checklist in Annex 1.

4.2. Submission to a Research Ethics Committee

To ensure Malaria Consortium adheres to international standards on human subject research, all Malaria Consortium projects/programs that have research or evaluation activities involving data collection with human participants, whether by Malaria Consortium or a partner, will have the research or evaluation protocol reviewed by an external Research Ethics Committee (REC), and must receive either an exemption or approval from them before proceeding. The cost of ethics review will be incurred in the first instance by the project; when this is not possible use of core budget will be reviewed on a case by case basis. Please refer to the checklist in Annex 2.

4.3. Conducting the research

The ethical principles contained in this policy are universally applicable, although some adaptation may be needed to take account of cultural values and local context. The key international ethics guidelines may not always agree and as a researcher you will need to defend the decisions you make about the design and implementation of your study so that it meets the principles. The study should always be carried out in accordance with the conditions of the approving REC and ethical principles should be upheld throughout the research process (see Annex X) in order to protect the rights and welfare of research participants. The checklist in Annex 3 identifies the key principles and how to apply them when conducting your research.

4.3. Approval and Sponsorship

Malaria Consortium acts as Sponsor for all research and evaluation activities conducted by its staff. As Sponsor, Malaria Consortium is responsible for managing the funding, ongoing management including safety and data integrity of the research, and providing indemnity to participants and researchers where necessary. Project leads must be granted Sponsor approval before a study can commence. Once ethical approval is obtained from the recommended UK REC and the country in which the research is to be conducted, the Global Technical Director will issue a letter from Malaria Consortium as Sponsor, giving approval for the research to begin.

5 Training Requirements

Training Course Type	Training Course Specifics	Training Type	Staff Required to Complete
Research Ethics	This comprises **ALL** of the following Training and Resources in Research Ethics Evaluation (TRREE) courses: • **1. Introduction to Research Ethics (2h)** • **2.1 Research Ethics Evaluation (2h)** • **3.1 Informed Consent (2h)** • **Relevant national supplements where applicable.**	Online	Malaria Consortium staff who are involved in, responsible for, or provide oversight to research or evaluation activities that involve data collection on human subjects. Waivers will be given to staff who can demonstrate certificates from similar courses elsewhere, subject to approval from the Senior Research Adviser/Research Specialist.
Good Clinical Practice (GCP)	This comprises the following Training and Resources in Research Ethics Evaluation (TRREE) courses: • **3.2 Good Clinical Practice (GCP) (6h)**	Online	Malaria Consortium staff who are responsible for assessing proposals and providing the technical sign off for research proposals/evaluation plans or Malaria Consortium staff that are involved in research on human subjects. Waivers will be given to staff who can demonstrate certificates from similar courses elsewhere, subject to approval from the Senior Research Adviser.

6 Monitoring Mechanisms

What are you monitoring?	Data source	Action Owner	Escalation levels	Frequency
Compliance with the Research and Evaluation Ethics Policy	• New employees in the Technical Team will be trained on this policy as part of their technical induction and will be asked to sign that they have read, understood and agree to abide by its content	HR	Research Group Lead	As per HR induction schedule
	• Clinical trial was registered on ClincalTrials.gov PRS[3] • In-country ethics approval was obtained and is up to date • UK ethics approval was obtained for all research projects[4] • Research proposals/protocols and evaluation plans • Ensure REC progress reports are reviewed before submission	PIs	Research Group lead	As per schedule of the research project
Compliance with the Research and Evaluation Ethics Policy	• Use existing QA site visits to check research activities are being conducted ethically	CTCs	Research Group lead	As per routine site visit schedule
Compliance with training requirements set out in the Research and Evaluation Ethics Policy	• All Technical Staff members will complete research ethics and good clinical practice courses, as specified under section 4, as part of their induction to Malaria Consortium	HR	Research Group	As per HR induction schedule
Policy and procedures are reviewed and checked for compliance with international	• Review of international standards of research ethics	Senior Research Officer	Research Group lead	Every 2-3 years

[3] https://register.clinicaltrials.gov – Protocol Registration and Results System (PRS) provided by the US National Library of Medicine. The Senior Research Advisor is the Principal Account Administrator.
[4] All research projects involving humans and higher order animals (mammals and vertebrates).

standards of research ethics	• Feedback on policy from staff members			

7 References

- World Medical Association, Declaration of Helsinki: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
- Council for International Organizations of Medical Sciences (CIOMS) & World Health Organization (WHO). International Ethical Guidelines for Epidemiological Studies. CIOMS, Geneva; 2009. Available from: https://cioms.ch/wp-content/uploads/2017/01/International_Ethical_Guidelines_LR.pdf
- Council for International Organizations of Medical Sciences (CIOMS) & World Health Organization (WHO). *International ethical guidelines for biomedical research involving humans*. CIOMS, Geneva; 2016. Available from: https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/
- Nuffield Council on Bioethics. *The ethics of research related to healthcare in developing countries*. London, Nuffield Council on Bioethics; 2005. Available from: http://nuffieldbioethics.org/wp-content/uploads/2014/07/HRRDC_Follow-up_Discussion_Paper.pdf
- Boddy J, Neumann T, Jennings, Morrow V, Alderson P, Rees R, and Gibson W (2010). *The research ethics guidebook: a resource for social scientists.* Available from: http://www.ethicsguidebook.ac.uk
- Malaria Consortium's Child Safeguarding Policy
- Malaria Consortium's Code of Conduct
- Malaria Consortium's Research Misconduct Policy

Annex 1. Qualifications and training checklist

Appropriate qualifications		Tick
1.	All staff involved in research/evaluation should have completed an initial training on research ethics as listed under *Training requirements* in this policy.	
2.	All staff involved in research/evaluation should complete refresher training in research ethics every two years as listed under *Training requirements* in this policy.	
3.	Malaria Consortium staff who are responsible for assessing proposals and providing the technical sign off for research proposals/plans or Malaria Consortium staff that are involved in research with human participants must have completed a course in Good Clinical Practice (GCP) as listed under *Training requirements* in this policy, in addition to the human research ethics course listed above.	
4.	All individuals involved in research or evaluation activities that involve data collection on human subjects on behalf of Malaria Consortium must have a section on confidentiality and ethical research conduct incorporated into their induction or training.	

Annex 2. Submission to a Research Ethics Committee checklist

Ethics review process		Tick
1.	Malaria Consortium staff who are responsible for providing the technical sign off for research proposals/evaluation plans must ensure that the following ethical considerations are addressed in the protocol: ○ Eligibility or inclusion and exclusion criteria to ensure participants are fairly selected ○ Recruitment process (with attention to non-coercion) ○ Informed consent including when and how information will be provided to potential participants, so they can make an informed decision ○ Identify harms and how they will be minimised ○ Identify risks or discomfort to participants, researchers and public and how they will be minimised ○ Proposals that include clinical activities for which there may be safety concerns for participants (for example, invasive specimen sampling) must outline how these will be dealt with ○ Consequences for health services and how these will be addressed ○ Measures to protect confidentiality and privacy	

	○ Research uptake ○ End of study treatment and access to successful interventions post-study See Malaria Consortium's research protocol template. For other relevant research design tools and templates see Annex 4.	
2.	Malaria Consortium staff involved in research/evaluation will submit the protocol for review by the relevant Research Ethics Committee in each country in which the research/evaluation is to be conducted[5]. Requirements for submission will vary by committee, however an application will usually need to include the following documents: ○ Protocol that has addressed the ethical considerations above ○ Participant information sheet ○ Informed consent process and form (including assent where needed) ○ Draft data collection tools or topic guides	
5.	Ethical approval for the research/evaluation should also be sought from a Research Ethics Committee[6] in an OECD country such as the United Kingdom for all projects involving humans and higher order animals (mammals and vertebrates).	
6.	Respond to REC comments. Most REC's will provide detailed feedback on proposals submitted to them, and it is very common for REC's to stipulate things they want to be addressed before they give approval. ○ Make sure you understand what is being asked for. Usually they ask for clarifications, minor changes or substantial changes. ○ Be thorough in your response. Provide a detailed point by point response to the REC; if any points are not addressed sufficiently it is likely the application will be returned.	
7.	Once ethical approval is obtained from the recommended UK REC and the country in which the research is to be conducted, the Project Lead can request the Global Technical Director to issue a letter from Malaria Consortium as Sponsor, giving approval for the research to begin.	

Annex 3. Conducting the research checklist

Carrying out the research ethically	Tick

[5] To note that ethical approval for data analysis in a country outside of where the research is being conducted is not typically required, as long as there is approval from all the countries where the data is being collected and that the countries concerned have been made aware in the protocol that data will be transferred to another country for analysis. This is to ensure that any data-transfer and protection issues would have been considered and addressed during their ethical review and approval mechanisms.

[6] LSTM REC is the recommended committee in the UK. Contact the Research Group for details on submission.

1.	All staff involved in the research/evaluation study should adhere to the **conditions of ethics approval** as set out by the REC: o Conduct the research as per the protocol approved by the REC. o Only use documents approved by the REC (participant information sheet, informed consent, data collection tools) o Do not deviate from the approved protocol or make changes to the way the research is conducted without prior approval from the REC. o Inform the REC of any changes to the study site that may affect the conduct of the research, increase the risks or affect the welfare of participants o Report any serious adverse events or unanticipated problems related to the study promptly to the REC o Submit a written summary of the status of the research, usually annually, if requested by the REC o Submit a summary of the research to the REC when completed.	
2.	Provide information about the study and adopt appropriate **informed consent** and/or assent procedures: o Every participant should receive information necessary to give fully informed consent in a culturally appropriate way in her/his own language, including i) description of research, ii) any potential risks, iii) the potential benefits, iv) option to participate, not to participate or withdraw and receive the same care and medicines regardless, v) confidentiality of information s/he provides, vi) compensation or not for participation, vii) and contact information of researcher. Those obtaining consent should ask the prospective participant if s/he has any questions or concerns. o Written consent will be in the local language, at the appropriate reading level that has undergone translation and back-translation process, and been pilot-tested. Hard copy signed consent forms will be kept in a secure place at least to the end of the project. The participant should also keep one copy of the signed consent form. o In some cases, gaining written consent will be impractical, culturally inappropriate or the participant may be illiterate. In which case provide the study information verbally, in the most appropriate language using short simple words and language that is relevant and understandable to the participant group. Researchers will indicate on a document (kept by study staff) that attests witnessing that the participant provided oral consent. o For participants unable to give written informed consent, a literate witness must sign the consent form. If possible, this person should be selected by the participant, not be a relative and should have no connection to the research team. Finding such a person can	

	be challenging. They will usually need to receive an allowance or be reimbursed for any costs incurred but cannot be paid. ○ Community consent will be gained where appropriate for an intervention that affects the whole community, for example release of genetically modified mosquitoes. ○ When children are the study participants, consent must be obtained from an appropriate adult and assent obtained from the child. Exceptions can be made when parental involvement may not be in the best interest of the child, such as studies about sexual or illegal behaviour. Age of parental and participant consent is dependent on national laws. ○ Assent will be obtained from the child using an assent form (a simplified version of the informed consent form) that allows them to say yes or no to the research even if they don't understand everything about it. The age limits within which assent is needed varies by country. Assent will be obtained on the basis of various factors, such as age, level of maturity and nature of the study; it is usually considered inappropriate to obtain assent from very young children. See Malaria Consortium's Participant Information sheet and Consent form and Assent form templates. For other relevant research design tools and templates see Annex 4.	
3.	Adopt appropriate **confidentiality and privacy** procedures, sensitive to participant's needs: ○ Ensure that recruitment, consent and study activities with participants are conducted such that third parties do not know about the participant's involvement in research. ○ Ensure that all persons involved in the activity, including data gatherers, data input staff and translators have received training on the confidentiality procedures and signed an appropriate confidentiality agreement. ○ Note situations where confidentiality may need to be breached to provide immediate protection to a participant. Participants must be made aware of the confidentiality procedures before being asked to provide any information. Ensure that confidentiality procedures are consistent with local laws.	
4.	Adopt appropriate systems for **data management** to ensure confidentiality during data capture, analysis, transfer and storage: ○ As part of the informed consent process ensure you must explain to participants how their data will be stored, who will have access to their data and how long their data will be kept for as well as any planned use of the data in future ○ For all data formats (e.g. hard copies, computer files with anonymised data, computer files containing identifiable data, USB sticks), consider	

	how data will be stored, who will have access to the data and how they will be able to access it. ○ Ensure that the minimum amount of personally identifiable information is collected. ○ Ensure the protection and security of personally identifiable data. ○ Share data only for legitimate purposes via data user agreements. ○ Data is to be maintained in a secure environment and transmitted only through secure methods ○ Minimise the number of persons and entities granted access to identifiable data See Malaria Consortium's Data sharing and use agreement and Data protection practices presentation. For other relevant research design tools and templates see Annex 4. We encourage all Malaria Consortium staff who are involved in, responsible for, or provide oversight to research or evaluation activities to read and comply with the following Malaria Consortium policies: IT User Policy, the Data Protection Policy and the Telecommunications Policy. Collectively these policies set out principles for appropriate use of computing infrastructure, documents, files and data as well as procedures for data security and handling personal data to ensure compliance with the General Data Protection Regulation (GDPR).	
5.	Ensure **participant safety and welfare** at all times: ○ Adhere to Malaria Consortium's Child Safeguarding Policy. ○ Ensure that participation is in the person's best interests and does them no harm. ○ Ensure that information gathering with children is appropriate to their age and stage of development. ○ Anticipate serious adverse events or unanticipated problems related to the study and proactively develop appropriate responses and a procedure with names person(s) for managing these. ○ Be cautious and protective and undertake ethical checks as you proceed with any activity. ○ Be sensitive and flexible; if situations change you must be prepared to stop or change an activity if ethical issues cannot be resolved as guided by the ethics review board in country. ○ Reimbursement of participant costs should consider and be proportionate to the "burden" imposed by the research. Such burdens may often be significant without involving excessive risk e.g. number of hospital visits.	
6.	**Respect for culture and community** of research participants: ○ It is important to have one or more community representatives participate in the research process in order to i) build a bridge between	

	the community, the research, and the researchers, ii) allow them to voice questions and concerns, and iii) represent the best interests of the participants. ○ Determine whether local permission from community stakeholders or authorities is needed to proceed and adhere to any locally established institutional policies or guidelines for conducting research. ○ Information about the activity must be provided to all stakeholders, and updates communicated as required. ○ Prepare local communities and explain the purpose and aims of the research activity. ○ Researchers have a responsibility to be mindful of cultural, religious, gender, and other significant differences within the research population in the planning, conduct, and reporting of the study findings. ○ Ensure that those gathering information from children and/or vulnerable communities are adequately trained and ready to follow up or refer children who might need special attention as a result of research/investigation in sensitive themes. ○ Ensure children and/or vulnerable communities are not exploited to achieve research objectives, particularly in regard to the level of risk and what benefits individuals or communities are likely to receive. ○ Recognise and communicate to study participants that they have the right to remain anonymous.	
7.	**Transparency** and **accountability** ○ Make sure that a complaints and feedback mechanism is in place for children and adults participating in the activity. ○ Ensure accuracy of information during analysis, interpretation and reporting. Remain open to the findings of any study and do not allow vested interests to interfere. ○ When publishing results, proper acknowledgement must be given about the contribution of stakeholders, participants and communities in the success of the research as appropriate. ○ Anyone that suspects or is concerned about possible research misconduct involving activities that Malaria Consortium is involved in should consult Malaria Consortium's Research Misconduct policy and report it as per the policy.	

Annex 4. Malaria Consortium research design tools and templates

The Malaria Consortium Research Cycle infographic contains links to all research-related resources produced by Malaria Consortium.

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Malaria Consortium
The Green House, 244-254 Cambridge Heath Road,
London, E2 9DA, United Kingdom

www.malariaconsortium.org
info@malariaconsortium.org

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US EIN: 98-0627052

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