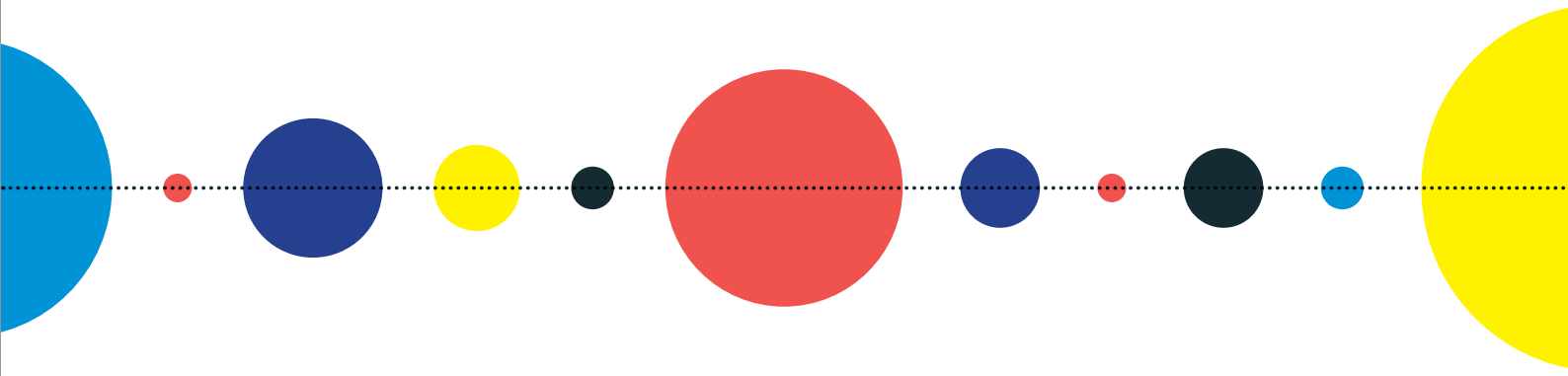
Quality Assurance Plan for Research



The World Health Organization Centre
for Health Development (WHO Kobe Centre)

World Health Organization
Centre for Health Development

Quality Assurance Plan for Research

The World Health Organization Centre
for Health Development (WHO Kobe Centre)

WHO/WKC/2019.2
© World Health Organization 2019

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo).
Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. The World Health Organization Centre for Health Development (WHO Kobe Centre), Quality Assurance Plan for Research (2018 – 2026). Kobe: World Health Organization; 2019 (WHO/WKC/2019.2). Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Table of Contents

Acknowledgments

The World Health Organization Centre for Health Development, WHO Kobe Centre (WKC) prepared this document following recommendations from its Advisory Committee in November 2017. The WKC sincerely thanks the constructive comments and suggestions received from members of the Advisory Committee and WKC Scientific Advisory Working Group, including Professor Irene Agyepong, Dame Sally Davies, Dr Hiroyoshi Endo, Professor Hideki Hashimoto, Professor Ichiro Kawachi, Professor Norah Keating, Professor Florencia Luna, Professor Lenore Manderson, Professor K. Srinath Reddy, and Dr Viroj Tangcharoensathien. We also thank WHO experts for their comments, including Dr Nima Asgari-Jirhandeh, Dr James Fitzgerald, Dr Laragh Gollogly, Dr Metin Gulmezoglu and Dr Vivian Lin. The contributions of the WKC staff to drafting and reviewing this document are also acknowledged. All errors and omissions are the responsibility of the WKC.

Quality Assurance Plan for Research

1.0 Background

1.1. WHO's General Programme of Work

Research forms an important part of the WHO core functions articulated in the 12th General Program of Work. These include WHO's functions in *shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge; articulating ethical and evidence-based policy options; and monitoring health situations and assessing health trends.*[1] The 13th General Program of Work highlights research and innovation as a vital part of WHO's work through advocacy for evidence based policies, normative guidelines, and shaping and scaling up innovations. It is widely recognized that research is critical to WHO's constitutional mandate to support the attainment of the highest possible level of health for all.

1.2. The WHO Kobe Centre

The objective of the WHO Kobe Centre (WKC) is to carry out quality research in a systematic way with the aim of identifying new facts and innovations that promote Universal Health Coverage (UHC) in light of population ageing. The endpoint of such research is to support national health systems towards UHC for the promotion of long and healthy lives and prevention of health-related financial hardship across populations. As such, the WKC seeks to create and disseminate research in cooperation with partners to accelerate UHC in line with its strategic objective.

1.3. Guiding documents

As a department of the WHO headquarters, the work of the WKC complies with the WHO General Programs of Work[1,2] and complements the normative work being carried out by the technical departments. The research thus aims to builds on the 2013 World Health Report on *Research for UHC*.[3]

Research conducted by the WKC complies with the guidelines set forth for the Secretariat as a whole, including the *WHO Strategy on Research for Health*[4] and World Health Assembly (WHA) Resolution A63/22 2010 on WHO's roles and responsibilities in health research. It also complies with ethics standards set forth by the Secretariat including WHO's *Standards and operational guidance for ethics review of health-related research with human participants,*[5] *Code of Conduct for Responsible Research,*[6] *WHO Policy on Misconduct in Research,*[7] the *Code of Ethics and Professional*

1 Twelfth General Program of Work, 2014-2019. Not merely the absence of disease. (2014) Geneva: The World Health Organization.
2 Thirteenth General Program of Work, 2019-2023. WHA71/2018. Geneva: The World Health Organization.
3 The World Health Report 2013: Research for Universal Health Coverage. (2013) Geneva: The World Health Organization.
4 The World Health Organization Strategy on Research for Health. (2012) Geneva: The World Health Organization.
5 Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. (2011) Geneva: The World Health Organization.
6 Code of Conduct for Responsible Research. (2017) Geneva: The World Health Organization.

Conduct,[8] as well as WHO's Framework for Engagement of Non-State Actors (FENSA).[9] FENSA is a process for identifying the risks and benefits of engagement with non-state actors, with the goal to protect and preserve WHO's integrity, reputation and health mandate. FENSA applies to all of WHO's engagement with non-state actors, including nongovernmental organizations, private sector entities, philanthropic foundations, and academic institutions.

1.4. Definition of research

The WHO Research Strategy and WHA Resolution A63/22 define research as the *development of knowledge with the aim of understanding health challenges and mounting an improved response to them. This definition covers the full spectrum of research, which spans five generic areas of activity: measuring the problem; understanding its cause(s); elaborating solutions; translating the solutions or evidence into policy, practice and products; and evaluating the effectiveness of the solutions.*[10]

The WKC's research to advance UHC implies a focus on measuring the problems of access, coverage and financial protection and understanding the causes and barriers to overcoming these problems from a health systems perspective. This recognizes the components of human resources, medical products, infrastructure, service delivery, financing, governance, and information systems, along with the communities, organizations, processes, and values that make up a health system.[11] Research for solutions involves investigating policy, systems and technological innovations to address health systems constraints, and ensuring that evidence about such solutions is incorporated into policy and practice. Implementation research is an important tool to test how well an innovation worked in real world settings. Evaluation of the impact is critical, and evaluations should be designed prospectively to enable assessment of the impact in a rigorous way. The research carried out by the WKC is non-clinical and aims to adhere to the standards and principles for good research practice. The WKC's research is methodology neutral. Depending on the questions being asked, quantitative and qualitative studies as well as mixed methods can be used. There are some important differences in quality assurance criteria depending on design, and these differences are taken into consideration when they are applied to specific research proposals (see **Annexes 1 and 2**).

1.5. Quality assurance systems

The purpose of this Quality Assurance Plan for Research is to set forth the principles for good research practices, which will in turn be used to institutionalize quality assurance processes through the routine management of research products. The institutionalization of quality assurance can be done through each step in the managing and carrying out of the research including design of the research plan, procurement procedures and competitive bidding, screening research applications, external review of technical merit, ethics review process, contracting research products, and monitoring and evaluating implementation.

7 WHO Policy on Misconduct in Research: Policy and Procedures. Office of Compliance, Risk Management, and Ethics. (2017) Geneva: The World Health Organization.
8 Code of Ethics and Professional Conduct. (2017) Geneva: The World Health Organization.
9 Framework of Engagement with non-State Actors. WHA 69.10, (28 May 2016) Geneva: The World Health Organization.
10 The World Health Organization Strategy on Research for Health. (2012) Geneva: The World Health Organization.
11 Sheikh K et al. (2011) Building the Field of Health Policy and Systems Research: Framing the Questions. PLoS Med 8(8): e1001073.

As such, this Quality Assurance Plan for Research applies to all staff of the WKC, including technical, administrative and managerial staff, interns, volunteers, secondments, and visiting researchers. It also applies to all collaborators and contractors who participate in research activities in cooperation with staff of the WKC.[12] Furthermore, it is applicable to all research activities, including the funding, sponsoring, endorsing, or coordinating of research; providing technical advice either directly or through advisory groups; and directly conducting the research. Through its code of conduct, the WKC must ensure that contracting institutions uphold principles in line with the WHO Code such that any infringements may cause the WKC to terminate its collaboration arrangement following consultation with the legal bureau.

1.6. Quality assurance culture

Quality assurance will be cultivated among staff and researchers. Creating such a culture involves encouraging creative and critical thinking and constructive technical criticism among staff and researchers as a means to improve research quality. Such comments should not be confused with personal criticism. The objective is to promote cooperation, intellectual curiosity, and excellence rather than solely promoting compliance with rules and procedures. Such an environment facilitates compliance with high scientific and ethics standards, as well as professionalism and an open exchange of ideas.

Meeting this objective can be done, for example, through regular in-house technical presentations and forums, with the presence of the Principle Investigator (PI) of the research if appropriate, to invite critiques from colleagues on research ideas, plans, progress and products. At the same time, staff capacity and competency to oversee and implement quality assurance in the research activities of the WKC should be ensured through the appropriate assignment of roles and responsibilities, performance management, and staff development and training.

12 Individuals who work for WHO as non-staff members (including consultants, holders of Agreements for Performance of Work (APW), Technical Services Agreement (TSA) holders, Special Service Agreements (SSA) or letters of agreement, Temporary Advisers), and third party vendors, contractors or technical partners who have a contractual relationship with WHO.

2.0 Guiding principles

2.1. Relevance and impact

The research carried out by WKC staff and contracted researchers should clearly address policy relevant issues with the greatest public health impact and potential to improve global health goals. Activities should fall under the priorities set forth within the documents guiding WKC work (paragraph 1.3). Impact is one of the guiding principles for the WHO Secretariat as a whole in prioritizing research and innovation, and to ensure the greatest value for research spending. To achieve impact, the WKC also emphasizes dissemination and communication activities as part of each research program.

2.2. Excellence

Excellence is another guiding principle for the WHO Secretariat in carrying out high quality and peer reviewed research that is monitored and evaluated. Researchers and staff should strive to conduct research that is excellent in technical quality, and maximizes impact and generalizability both within and external to the study setting. Checklists that are appropriate to the research design will be used to increase technical quality and ensure consistently high quality (see **Annexes 1 and 2**).

2.3. Integrity

Research supported by the WKC should comply with high standards of integrity and honesty in all steps of the research process, including proposal submission, data analysis and reporting. In addition, the research should include appropriate acknowledgment of one's contribution and the contribution of others, and refraining from using the work of others without permission or acknowledgement and other infringement of intellectual property. All research products must be made available for monitoring and verification.

2.4. Freedom from conflict of interest

WKC staff – similar to all WHO staff —are expected to comport themselves with independence and act solely within the interests of WHO and without influence from external parties. As outlined in the *Code of Conduct for Responsible Research*:

WHO staff members are expected to conduct themselves with the interests of WHO only in view and under the sole authority of the Director-General. Professional and ethical conduct requires that the international character of WHO is respected and that staff maintain their independence and not seek or receive instructions from any Government, external entity, or person external to WHO.

WHO staff members must ensure that personal views, convictions, previous experiences or future ambitions do not compromise the objective scientific process, the performance of their official duties or the interests of WHO. Bias, prejudice, conflict of interest or undue influence must not be permitted to supersede the professionalism of their conduct. Staff members must exercise the utmost discretion in their actions, refrain from participating in any activity that is in conflict with the interests of WHO or might damage WHO's reputation, and respect and safeguard the confidentiality of information, which is available or known to them because of their official functions[13]

Those involved in carrying out and reviewing research should declare any conflict of interests, to identify any interest or circumstance that may conflict with their work at WHO, and take actions to resolve any potential conflicts of interest or recuse oneself. WKC staff are obligated to monitor and report any cases of misconduct that takes place during research implementation, including conflicts of interest that arise, misrepresentation, failure to follow ethics procedures or other wrongdoing. Wrongdoing is defined as "*intentional, knowing or reckless fraudulent behavior such as fabrication, falsification, plagiarism, misrepresentation or other practices that deviate from the principles of the Code of Conduct for responsible Research.*"[14]

2.5. Adherence to ethics guidelines and other legal agreements

Researchers and staff must adhere to ethics guidelines, including obtaining ethics approval from the WHO Research Ethics Review Committee as well as from any local Institutional Review Board where the research will be carried out. Appropriate handling of data and considerations of confidentiality must be incorporated into the research plan. Dignity and well-being of human subjects must be considered in all research plans. Similarly, actions that avoid unreasonable risk or harm to human subjects are to be enforced.

WKC staff are responsible for ensuring that the allocation of funding complies with the donor agreements and other legally binding guidelines. They must also ensure that any research investments made by the WKC achieve value for money, in that the financial investments are commensurate with the potential public health impact in improving global health and reducing health inequalities.

13 Code of Conduct for Responsible Research. (2017) Geneva: The World Health Organization.
14 WHO Policy on Misconduct in Research (2017); see pp 6-7.

2.6. Intellectual property

All contracts or agreements will include provisions related to intellectual property, including ownership of data, and other research findings and scientific publications. Disclosure of research findings should comply with the agreements for the management of intellectual property. Research products funded through the WKC should be open to public access and disseminated on the website or other forum in line with the public health mandate of WHO. In particular, data funded by the WKC should be made publicly available where possible for secondary analysis.

2.7. Research capacity development

The WKC is committed to support research capacity development among staff and researchers to the greatest extent possible. It will work to ensure that the necessary resources and support are available to carry out research to the highest possible standard. This effort will be done through collaboration with academic institutions, the WKC Scientific Working Group (SWG), Advisory Committee for the WKC (ACWKC), and experts in relevant methods and subject areas; training and mentoring in high quality research and research ethics; and finally the institutionalization of quality assurance processes.

Special consideration will be given to developing research capacity in low- and middle-income countries (LMICs). Decisions to pursue such opportunities will be made by the WKC in the early phase of developing a research program, taking into consideration various factors including the state of current knowledge and capacity in the country of interest, the rationale and objectives for the research, stakeholder interests, resource availability, and the expected timeline for the research.

Such research capacity building may often involve a partnership between researchers and institutions in high-income countries with those in LMICs. In such circumstances, special attention will be paid to ensure the ethical conduct of research and the fair and appropriate distribution of resources, decision-making power and benefits to the research partners given the inherent disadvantage of researchers and vulnerability of populations in LMICs. This attention includes requiring that the research proposal identifies a PI (or co-PI) based in the LMIC in which the study will be conducted. The WKC will also ensure that the proposal articulates the expected benefits to the communities in the LMIC, roles and responsibilities of the research partners, shared ownership of research data and outputs (ideally placed in the public domain after completion of the study), and a dissemination plan which includes feedback to the research participants and communities in the LMIC.

3.0 Developing the research program

3.1. Identifying research themes

In order to ensure relevance and promote a coherent body of research carried out by WKC, the research plan moving forward for 2018-2026 will slowly converge towards a series of prioritized themes in order to produce, by 2026, a comprehensive body of evidence that addresses important gaps in knowledge or presents models and practical policy options that supports health policy and systems development for achieving sustainable UHC in light of demographic change. New research, meetings, and fora will be in line with the established research themes to ensure relevance and coherence of WKC activities. To identify themes, the WKC will consult internally within WHO to ensure alignment with WHO General Programme of Work and other internal strategies and priorities.

3.2. Matching themes to research methods and products

The WKC will determine the optimal research method (both quantitative and qualitative) and products for a given research theme or research question by taking into consideration various factors, including the state of current knowledge on the topic in certain countries, the expected target audience or end-users of the research findings, the technical expertise and capacity of the (potential or identified) researchers, and resource availability. This judgment may be made before issuing a call for proposals or determined in discussion with researchers. For example, the WKC will set forth in advance whether the research theme or question requires identifying evidence regarding a specific strategy, in which case an appropriate research product may be a global systematic review. Another example could be identifying gaps in existing research or collating research to inform policy makers, which may require a rapid review or focus group discussions. UHC country level implementation research, on the other hand, may require primary data collection to respond to the research question.

The exact nature of the research has implications for the implementation of the quality assurance process. For each case, the WKC determines the implementation requirements, i.e., an expression of interest for the research, the scope of the call for proposals, and the processes for internal screening, external technical review and ethics approval. Regarding ethics approval, a systematic review does not involve human research subjects and thus would not require approval from institutional review boards. Quality assurance criteria that are appropriate to the nature of the research question and research design will also need to be applied (see **Annex 2**). As such, the process would be tailored to each individual research study, and where appropriate, the quality assurance process would be expedited without compromising research quality.

3.3. Calls for proposals

The WKC requires competitive bidding, where expressions of interest or calls for proposals are listed on the WKC website and widely disseminated to interested bidders. Such calls should be tailored to the specific nature of the work, type of contract, and number of proposals to be funded. While the specifications will vary, in general, several steps can be taken to ensure that the WKC receives quality research proposals from the appropriate groups of researchers. These steps include targeted communication and dissemination, clearly defining the scope of the call, facilitating competitive bidding, developing templates for screening, and using checklists for the proposal review and application requirements (see **Annex 3**).

4.0 Internal Screening

Before carrying out external evaluations of technical merit and quality, the WKC screens expressions of interest and proposals to ensure relevance and completeness (see **Annex 3**).

4.1. Expressions of Interest

In some cases, the WKC initially requests a submission of Expressions of Interest (EoI), which gives a brief overview of the proposed research. While the process may vary, rapid technical and administrative screening can be facilitated through standardized templates to incorporate key elements and criteria to determine eligibility for further consideration.

4.2. Proposals

Full proposals will undergo internal screening guided by specific technical guidelines and available checklists appropriate to the study design (see **Annex 2**). Such screening will include an assessment of the completed fields in the application, value for money, budget justification, and capacity building requirements

5.0 External Evaluation

The external peer review process is essential to research quality assurance. It is also integral to the WHO research ethics review process. The WHO Research Ethics Review Committee requires the independent review of a research proposal, including the study protocol, budget, study materials, and other required documents and a satisfactory response from the PI to the reviewers' comments (see **Annex 4**).

5.1. External experts for technical review

The members of both the ACWKC and the SWG provide of external reviews for WKC research initiatives.

The SWG is comprised of between 8-20 senior academics who are appointed by the WKC on a two-year rotational basis. The group gives periodic evaluation of proposals submitted, makes recommendations to translate research into policy options, carries out reviews of the evaluation of results for individual projects, and recommends potential funding sources for additional work. Generally, one to two members of the SWG should review large-scale proposals for scientific merit, where their expertise is aligned with the proposal objectives.

The ACWKC was established by the WHO Director-General in 1996 to serve as an Advisory Group of Experts to advise the Director-General and the WKC Director on technical and programmatic issues. The ACWKC provides high-level strategic recommendations to the WKC. Its nine members represent each of the six WHO regions, the host country (Japan), the local area (Kobe) and the donor (the Kobe Group). Members can serve as external reviewers where there is a strong proposal and their expertise is aligned with the proposal objectives.

In addition, ad-hoc reviewers will be identified from the global academic community in cases where specific expertise is required or members of the SWG and ACWKC are unavailable.

5.2. Process of external review

This external review process should generally be carried out for all types of research regardless of their method or expected products. The process of external review is coordinated by the WKC, who will communicate with the external reviewers and inform the research team about the review comments. Generally, the WKC will design an instrument for external review to evaluate technical merit, identify the appropriate external reviewers, ensure responsiveness to reviewer comments and completeness, and provide technical support where required.

6.0 Ethics Review Committee submission[15]

All research protocols must be cleared by the WHO Research Ethics Review Committee (ERC) prior to entering any contractual agreements to implement the research (see **Annex 5**). The ERC is a 27-member committee established and appointed by the WHO Director-General. Its mandate is to ensure that WHO supports research of the highest ethical standards. The ERC reviews all research projects supported financially or technically by WHO involving human participants.

6.1. Definition of research involving human participants

The WHO ERC defines "research involving human participants" as any social science, biomedical, behavioral, or epidemiological activity that entails a systematic collection or analysis of data with the intent to generate new knowledge, in which human beings (i) are exposed to manipulation, intervention, observation, or other interactions with investigators either directly or through alterations of their environment, or (ii) become individually identifiable through investigators' collection, preparation, or use of biological material or medical or other records.

6.2. Submission process

All research proposals involving human participants need to be submitted to the ERC Secretariat using an online submission portal, ProEthos. Documents to be submitted include:

- Research protocol
- Informed consent forms
- Associated study instruments, such as interview guides, questionnaires, etc.
- Data collection forms, case report forms, etc.
- Patient recruitment materials
- Final approval by the scientific/technical review committee or peer reviewers
- Comments made by the scientific peer review group
- PI's point-by-point response to the peer review
- A letter from the local/national ethics committee acknowledging receipt of submission for review or an approval from them.

6.3. Types of review

The ERC will determine the appropriate type of review. Most protocols considered by the WKC will fall into one of the following types of review:

- Full committee review of proposals for research that presents more than minimal harm to human subjects.
- Expedited review of proposals for research that presents no more than minimal harm to research participants.
- Exemption from ERC review for research that presents no possibility of harm or when the information being collected is available from the public domain.

The ERC determines whether the proposal requires expedited review (for exemptions) or full review. The length of time for approval for both expedited and regular reviews depends on the promptness of the responses from the PI to ERC queries.

15 This section summarizes the review process described in detail on the WHO website (http://www.who.int/ethics/review-committee/review_process/en/, Accessed 2 March, 2018).

7.0 Monitoring and Evaluating Research Products

7.1. Incorporating quality into the contractual mechanisms

The WKC seeks to be an evidence based research centre that upholds and champions strong research. Where the WKC is a funder of research through a Technical Service Agreement (TSA) or other mechanisms, the WKC and the contracting institution should comply with the terms of the contract, including good research practices and adherences to ethics guidelines as outlined in the WHO *Code of Conduct for Responsible Research*.[16] The completion of appropriate checklists (see **Annexes 1 and 2**) and ERC project reporting forms will be incorporated into the deliverable requirements outlined in the contractual agreements. The WKC is responsible for monitoring progress, maintaining regular communications with the PI, evaluating the mid-term and final reports, and monitoring compliance with the WHO ethics guidelines (see **Annex 6**).

7.2. Monitoring progress

Regular communication with the PI is essential to ensure the quality of implementation. The optimal frequency of communication will vary depending on the study or the phase of the study, but at minimum a monthly check-in is required throughout the project period.

A mid-term progress report will be required and scheduled according to the total duration of the project. The progress report will be evaluated with a focus on whether the research is progressing according to plan, noting any actual or anticipated changes to the plan, and whether there have been any new developments in the field that impacts the research design or relevance.

7.3. Evaluating the final research products

A template will be developed and used for the preparation of a final project report. Additional research outputs, such as manuscripts for journals, statistical analysis results, etc., could also be submitted and reviewed. The final evaluation will be based on the implementation of the research, achievement of objectives, and quality of the completed research.

7.4. Dissemination

Dissemination of the research is also a mechanism for quality assurance, as it increases transparency and accountability, and creates the opportunity for public review and critique. The WKC will therefore work closely with the research team to develop an appropriate communication and dissemination plan, from the launch of the project to the dissemination of its final products. Possible vehicles for dissemination include theme-based symposia, press releases to the mass media, social media, the WKC website and WKC knowledge hubs. As such, a specific communication plan will be designed for each product based on the target audience.

16 World Health Organization (2017) Code of Conduct for Responsible Research.

8.0 Measuring success

The research quality assurance plan will be linked to the research plan in order to evaluate implementation. Both plans will be evaluated in terms of research products, translation of research evidence to practice, and capacity building.

8.1. Research products

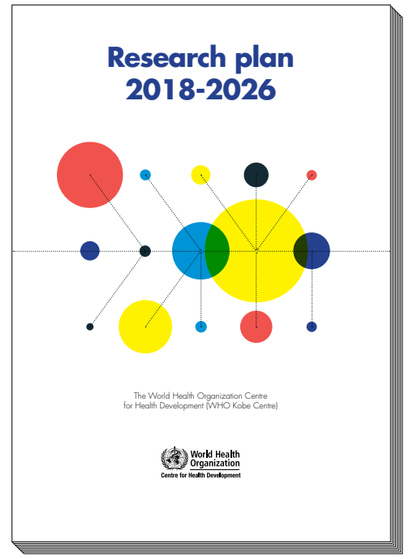
Research products will be an important measure of success. Research products can include peer reviewed journal articles and book chapters, WKC policy briefs, and other published materials. They may also include study protocols or survey instruments that are developed as a direct result of the research.

8.2. Evidence to practice

The WKC has as part of its mandate the translation of evidence to policy and practice. This translation can be done through the publication of focused research products, such as systematic reviews. Assessments can be made to evaluate whether the research has contributed to the development of WHO normative guidelines, regional frameworks or national policies. In addition, the website and communications function of the WKC can support the dissemination of evidence to local, regional and national governments and to the global community. Communication products could include press releases, poster displays, brochures, and website development and numbers of people accessing the web materials.

8.3. Capacity building

The WKC has a responsibility to strengthen research capacity in line with WHO's organizational mandate. As a measure of fulfilling this responsibility, WKC will assess the number of research projects and products that successfully pass technical peer-review, gain ERC approval, and are completed, along with the number of participating LMICs. The WKC can also assess whether researchers were able to leverage additional research support (funding) or influence national policy using the results of the research.



Annexes with Operational Details

Table of Contents

Annex 1

General checklist for research quality[1]

Relevance and objectivity

1. The need for carrying out the study has been established.
2. The study addresses a significant public health issue and will inform public health policy and practice.
3. The relevance of the research to Universal Health Coverage (UHC) has been established.
4. There is a clear statement of objectives, research questions, and a hypothesis or theoretical/conceptual framework to guide the enquiry
5. There is a clear description of the main outcomes to be measured (where applicable).
6. There is a clear description of the beneficiary population.
7. There is a clear description of key variables and how they may allow for adjustment of confounding (where applicable).
8. There is a clear description of the intervention if applicable and evidence of impact in prior studies.
9. For intervention studies, sufficient time is given for compliance to accurately measure impact.

Validity and reliability

1. Statistical procedures and data analysis methods are described and appropriate for the research question.
2. The assumptions and limitations are identified and ways to manage them are addressed.
3. The study will provide answers to the research questions or hypothesis.
4. The questions are appropriate for the target population.
5. The process for developing the instrument/questionnaire is appropriate (i.e., technical review, field-tests).
6. If instruments have been developed, they are attached, and prior validation or pretesting has been demonstrated.
7. A conceptual framework was set forth to measure or study concepts in the most accurate way possible.
8. The study has sufficient power, and the sample size is sufficient to measure change (where applicable).

1 Adapted from Downs and Black. (1988) The feasibility of creating a checklist for the assessment of the methodological quality both of randomized and non-randomized studies of health care interventions, J of Epi Comm Health; 52:377-384

Sound data management and integrity

1. The data needed to answer the research questions have been identified.
2. The data available can answer the research questions, and the limitations have been identified.
3. The data collection plan and procedures along with the timeline are clarified.
4. The procedures are in place to allow for analysis of the characteristics of non-responders and the potential bias to the findings.
5. Procedures to handle missing data are in place.
6. Challenges and limitations in data collection and analysis are anticipated and addressed.
7. Confidentiality measures are assured for participants, and ethical issues are identified and planned for.
8. Systems are in place to report adverse events that may arise as a consequence of the intervention.

Generalizability

1. Sampling methods are applied to maximize generalizability to the target population (where applicable).
2. The selected staff, patients and facilities are representative of the location where the majority of patients receive care, if applicable.
3. The sample is representative of the target population.
4. The study addresses errors that limit generalizability (e.g. removal of possible sources of bias).

Dissemination

1. The study findings contribute to the body of literature and can be published.
2. The study findings can be used for further research, policy, education or program improvement.
3. Plans for publication and dissemination plans to key stakeholders and academia are in place.

Annex 2

Publication checklists by study type

Using publication checklists help researchers think through the essential elements of their study, facilitate complete and transparent reporting, and ensure quality for peer review and dissemination. Some examples of checklists are given in this annex.

Meta-Analysis. A quantitative study that combines data from many research studies and uses a statistical process to derive conclusions and obtain a precise estimate of the effect or risk factor for disease. • **PRISMA checklist** http://www.prisma-statement.org/	**Systematic Review**. A systematic review is a critical assessment and evaluation of all research studies that address a particular research question and include a description of the findings of the collection of the research studies. It may also include a meta-analysis. • **PRISMA checklist** http://prisma-statement.org/PRISMAStatement/Checklist.aspx
Rapid Review. A more focused systematic review that is carried out in cases where there is a need to synthesize knowledge within a relatively short time period (<12 months). • **AMSTAR checklist** https://amstar.ca/Amstar_Checklist.php	**Randomized Controlled Trial**. A controlled experiment that randomly assigns participants to two or more groups. • **CONSORT statement, checklist, flow diagram for reporting RCTs** http://www.consort-statement.org/

Nonrandomized Controlled Trial. An experiment or evaluation with non-randomized intervention and comparison condition(s). • **The TREND statement** complements the widely adopted CONsolidated Standards Of Reporting Trials (CONSORT) statement developed for randomized controlled trials https://www.cdc.gov/trendstatement/pdf/trendstatement_TREND_Checklist.pdf	**Cohort Study**. Can be a prospective or retrospective observational study in which people who have a certain condition or receive an intervention are followed over time and compared with another group of people who do not have the condition or receive the intervention. • **STROBE checklist** https://www.strobe-statement.org/fileadmin/Strobe/uploads/checklists/STROBE_checklist_v4_cohort.pdf
Case-control Study. A study that selects cases with outcomes of interest for interview and identifies exposures to compare the odds of having an exposure with and without the outcome. • **STROBE checklist** https://www.strobe-statement.org/fileadmin/Strobe/uploads/checklists/STROBE_checklist_v4_case-control.pdf	**Cross-sectional Study**. The observation of a defined population at a single point in time or time interval. Exposure and outcome are determined simultaneously. • **STROBE checklist** https://www.strobe-statement.org/fileadmin/Strobe/uploads/checklists/STROBE_checklist_v4_cross-sectional.pdf
Case Reports. A report on a set of subjects with an outcome of interest or exposure, but no control group. • **CARE checklist** http://www.care-statement.org/resources/checklist	**Economic evaluation** • **CHEERs checklist** http://www.equator-network.org/wp-content/uploads/2013/04/Revised-CHEERS-Checklist-Oct13.pdf
Qualitative research. This can include qualitative evidence synthesis as well as in-depth studies to understand complex social phenomena such as systems, processes, and human and organizational behavior. • **Standards for reporting qualitative research (SRQR) checklist** https://www.elsevier.com/__data/promis_misc/04262_SRQR_Checklist.docx • **COREQ consolidated criteria for reporting focus group and interviews** http://cdn.elsevier.com/promis_misc/ISSM_COREQ_Checklist.pdf • **Blaxter M. Criteria for the evaluation of qualitative research papers. *Medical Sociology News* 1996;22:68–71**. http://www.medicalsociologyonline.org/resources/Vol7Iss1/7.1-Criteria-for-evaluating_Blaxter.pdf	

Annex 3

Internal screening of research products

This annex sets forth several implementation principles related to the WKC internal screening of research products. The first category is **calls for proposals**. It is recognized that any calls for proposals should be tailored to the specific nature of the work, type of contract (e.g., Agreement for Performance of Work (APW), Technical Service Agreement (TSA)), and number of proposals to be funded. While the specifications will vary, in general, the following steps should be taken to ensure that the WKC receives quality research proposals from the appropriate groups of researchers. These steps include:

- Clearly defining the scope of the call to ensure that sufficient quality submissions are received from the targeted groups of researchers. This clarification will allow for a sufficiently competitive process. Responsible Officers will incorporate the following components to ensure quality:
  - Identify research gaps through a literature review.
  - Articulate a clear research hypothesis that is measurable.
  - Articulate the assumptions underlying the hypothesis and the causal chain to the desired outcome.
- Facilitating competitive bidding by researching the targeted groups of researchers to identify an effective dissemination strategy for the call (i.e., location and how can the researchers best be reached). A list of the targeted groups of researchers can be generated in order to disseminate the call through different channels.
- Developing and continuously refining templates for applicants to use when preparing Expressions of Interests (EoI) and full proposals, including the appropriate checklists from Annexes 1 and 2.
- Using checklists for the proposal review and as tools for the principle investigators (PIs). The PIs will be required to complete quality checklists relevant to the study design in response to the call and ensure that the study is designed in such a manner that complies with the checklist requirements (for example, Annex 2).

In some cases, the WKC will initially request a submission of EoI, which gives a brief overview of the proposed research within a limited number of pages. EoIs will be subjected to a screening process that is internal to the WKC prior to submission of the full proposal. Generally, a few principles can be applied in the preparation and screening for EOIs. These include:

- Standardized templates. The EoI will be prepared by applicants using the template provided by the WKC that incorporates key elements for the screening.
- Screening process. The Responsible Officer and at least one other Technical Officer will identify screening criteria (inclusion/exclusion) to determine eligibility for further consideration. Such criteria will be tailored to the specifications of the particular call for proposals, but should generally focus on the responsiveness and relevance to the call and also the qualifications of the research team members. A short list of applicants will be created based on the screening of the EoIs. This list will be presented to the Director as a recommendation of those who should be invited to submit full proposals.
- Capacity building. If the nature of the Call for Proposals includes the aim to build research capacity, the EoI will be the first possible trigger or indication of need for research capacity building. Researchers who submit EOIs considered to be promising but in need of substantial improvement will be offered technical assistance throughout the subsequent steps of the research proposal development process to enhance the quality of their proposed research.

Full Proposals will undergo internal screening guided by specific technical guidelines and available checklists relevant to the study design (Annex 2). Screening should involve Technical Officers who could be assigned responsibility to oversee the research. Other WHO colleagues may be consulted at this stage to inform the short-listing, if deemed necessary and appropriate (e.g. Regional and Country Offices for country-specific studies). Based on the internal screening results, the Responsible Officer will prepare recommendations to the Director on which proposals should be accepted for external review, rejected, or invited to revise and resubmit. Components of the internal screening should include an assessment of the following factors:

- Completeness. Full proposals will be screened for completeness in terms of compliance with the information in the protocol guidelines.
- Value for money. The technical staff should assess whether the total budget and breakdown by category is justified in relation to the importance of the research question and implications for UHC.
- Budget review. The administrative team will review the proposed budget to determine compliance with budget guidelines. (This step focuses solely on budget procedures and should not be confused with "value for money," which involves assessment of technical value or merit.)
- Capacity building. If the nature of the Call for Proposals includes the aim to build research capacity, the full proposal is the second possible trigger for research capacity building. Proposals that are promising but not yet considered sufficient quality may be supported by WKC Technical Officers and external experts to further develop and strengthen the proposal, if deemed appropriate.

Where possible, the Responsible Officers will present fully developed proposals to other Technical Officers for their review and comments before the proposals are circulated for external review. Only when proposals are considered complete in compliance with budget rules and technically sound can they be accepted and advanced to the external evaluation.

Annex 4

External evaluation of research products

The external peer review process is essential to research quality assurance. It is also integral to the WHO research ethics review process. The WHO Research Ethics Review Committee requires the independent review of a research proposal, including the study protocol, budget, study materials, and other required documents, by at least two external experts, and a satisfactory response from the PI to the reviewers' comments. A minimum of two external experts will be identified for each proposal. Ideally, one should be an expert on the substantive topic and another should be an expert on the proposed study design/method. Each external reviewer will have completed a Declaration of Conflict of Interest prior to reviewing the proposals.

The process of external review is coordinated by the responsible Technical Officer, who will provide the link among the research team and the WKC, and communicate with the external reviewers. Generally the Responsible Officer will be required to:

- Develop an instrument for external review to evaluate technical merit. This instrument will incorporate the appropriate checklist from Annex 1 or 2 based on the study design, and it will also enable detailed written comments from the external reviewers.
- Identify the appropriate external reviewers. The terms of reference for both the WKC Advisory Group and the WKC Scientific Advisory Group are to support the technical quality of the WKC research. At least two external reviews with written comments for improvement should be requested. Once the comments are received, the Responsible Officer should collate all reviewers' comments, identify the key recommendations, communicate with the PI in terms of the key recommended modifications, and develop response guidelines and a timeline.
- Ensure responsiveness to reviewer comments and completeness. Once the responses are received from the PI, the Responsible Officer should check to ensure completeness in terms of the PI adequately responding to the reviewers' comments and revising their proposal accordingly. Should the PI fail to fully respond, the Technical Officer should work with the PI on identifying the gaps and develop a new timeline for fully responding to the comments.
- Capacity building. Technical assistance may be required at this stage to support the PI in revising their proposal in accordance with the reviewers' comments. Based on the outcomes of the external peer review process and whether the PI sufficiently revises their proposal in accordance with the reviewers' comments, the WKC will determine whether the proposal can advance to the WHO Research Ethics Committee (ERC) clearance process.

Annex 5

Summary of the Ethics Review Committee submission[2]

Research protocols should be cleared in most cases by the WHO ERC prior to entering any contractual agreements to implement the research. The ERC is a 27-member committee established and appointed by the WHO Director-General. Its mandate is to ensure that WHO supports research of the highest ethical standards. The ERC reviews all research projects that are supported financially or technically by WHO and involve human participants.

The WHO ERC defines "research involving human participants" as any social science, biomedical, behavioral, or epidemiological activity that entails the systematic collection or analysis of data with the intent to generate new knowledge in which human beings (i) are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment, or (ii) become individually identifiable through investigators' collection, preparation, or use of biological material or medical or other records.

All research proposals involving human participants need to be submitted to the ERC Secretariat using an online submission portal, ProEthos. The Responsible Officer works closely with the PI in order to facilitate the ethics review and oversee the WHO ERC clearance process. The documents to be submitted for ERC review include:

- Research protocol, formatted according to ERC guidelines: This must be the version approved by the peer review group and include the changes recommended by the external reviewers either in track change or in highlighted mode.
- Informed consent forms
- Associated study instruments, such as interview guides, questionnaires, etc.
- Data collection forms, case report forms, etc.
- Patient recruitment materials
- Final approval by the scientific/technical review committee or peer reviewers
- Comments made by the scientific peer review group
- PI's point-by-point response to the peer review
- A letter from the local/ national ethics committee either acknowledging receipt of submission for review or indicating a final decision of approval.

2 The review process is described in detail on the WHO website (http://www.who.int/ethics/review-committee/review_process/en/, Accessed 2 March, 2018).

Within the WKC, where feasible, the final proposal should be presented in person (oral presentation) by the Responsible Officer (and/or the PI) to all Technical Officers before submission to the WHO ERC in order to establish common understanding of the final approved protocol that is to receive technical and/or financial support from the WKC.

Based on a certain set of criteria, the ERC will determine the appropriate type of review. Most protocols considered by the WKC will fall into one of the following types of review:

- Full committee review of proposals. All research proposals that present more than minimal risk to human subjects are reviewed by two ERC members who present the proposal to the ERC committee, followed by a decision.
- Expedited review of proposals. A proposal is circulated for expedited review when the research procedures present no more than minimal harm to the research participants or communities. In this case, the proposal is sent to two ERC members who are required to provide their feedback to the secretariat within 10 working days. As appropriate, the proposal is then either approved or returned for further action.
- Exemption from ERC review. Proposals are exempt from ERC review when there is no possibility of harm arising as a result of the conduct of the research project or when the information being collected is available from the public domain.

The initial screening is done on the first day of receipt of the proposal to ensure that all the documentation has been submitted. A more detailed technical screening at the Secretariat level is then carried out within 5 working days.

- Expedited review. Once submitted for expedited review, the proposal is reviewed within 10 days. Consequently, a Responsible Officer can expect a response from the Secretariat within 2-3 weeks of the initial submission.
- Full Committee review. If a proposal is sent for regular review, it will be discussed at the next meeting to the date of receipt of a satisfactory submission. As a general rule, ERC meetings take place on a monthly basis. The cut-off date for receiving a proposal for discussion at a particular meeting is listed on the ERC meeting dates and deadlines for submission of protocols.

The length of time for approval for both expedited and regular reviews depends on the promptness of the response from the Responsible Officers and the PIs to ERC concerns. A study will only receive final approval from the ERC when all core documentation has been satisfactorily submitted, including local ethics approval.

Annex 6

Monitoring research products

The WKC is responsible for monitoring progress, maintaining regular communications with the PI, evaluating the mid-term and final reports, and monitoring compliance with the WHO ethics guidelines.

Where the WKC is a funder of research, through a TSA or other mechanisms, the WKC and the contracting institution should comply with the terms of the contract, including good research practices and adherences to ethics guidelines as outlined in the WHO Code of *Conduct for Responsible Research*.[3] The completion of appropriate reporting forms will be incorporated into the deliverable requirements outlined in the contractual agreements.

The Responsible Officer should maintain regular communication with the PI to ensure the quality of implementation. The optimal frequency of communication will vary depending on the study or the phase of the study, but at minimum a monthly check-in is required throughout the project period.

A mid-term progress report will be required and scheduled according to the total duration of the project. A general template will be developed and used for the preparation of this progress report. The progress report will be evaluated with a focus on (a) whether the research is progressing according to plan, noting any actual or anticipated changes to the plan, and (b) whether there have been any new developments (e.g. new publications by other researchers) in the relevant research field that impacts the relevance or implications of the present research. The progress report will be primarily evaluated by the Responsible Officer, but with other Technical Officers, WHO colleagues, or external experts as necessary and appropriate. Where feasible, the Responsible Officer and/or PI will present the progress report in person (oral presentation) to all other Technical Officers. Necessary corrective actions will be communicated to the PI by the Responsible Officer.

3 World Health Organization (2017) Code of Conduct for Responsible Research.

A template will be developed and used for the preparation of a final project report. Additional research outputs, such as manuscripts for journals, statistical analysis results, etc., could also be submitted and reviewed. The final evaluation will be based on (a) the implementation of the research according to the plan, (b) the achievement of the objectives, (c) the quality of the completed research using the checklists in Annexes 1 and 2, and (d) whether the research outcomes are publishable.

The final evaluation will be primarily carried out by the Responsible Officer, but with other Technical Officers, WHO colleagues, or external experts, as necessary and appropriate. The PI will be invited to the WKC to give a final presentation of his/her research in person, either for an internal presentation or as part of a public symposium or forum organized by the WKC. In some cases, particularly for multi-year research or research that has differed significantly from the original research plan, the final report should be sent to external reviewers for recommendations.

Dissemination of research is also a mechanism for quality assurance, as it increases transparency and accountability, and creates the opportunity for public review and critique. The Responsible Officer will work closely with the Communication Officer and other staff to develop an appropriate communication and dissemination plan for the research, from the launch of the project to the dissemination of the final products. Possible vehicles for dissemination include theme-based symposia, press releases to the mass media, social media, the WKC website and WKC knowledge hubs.


World Health
Organization
Centre for Health Development