Quality Assurance Plan for Research

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

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Annexes with Operational Details (attached as separate document)

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] A draft of 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.[2] 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 Center

The objective of the WHO Kobe Center (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 demographic changes. 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 research 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 WHO cluster for UHC and Health Systems. 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*

[1] World Health Organization, Twelfth General Program of Work: Not merely the absence of disease, 2014 (http://www.who.int/about/resources_planning/twelfth-gpw/en/)
[2] World Health Organization, draft of Thirteenth General Program of Work 2019-2023, EB142/3, 5 January 2018 (http://apps.who.int/gb/ebwha/pdf_files/EB142/B142_3-en.pdf?ua=1)
[3] World Health Organization, Research for Universal Health Coverage: World Health Report 2013 (http://www.who.int/whr/2013/report/en/)
[4] World Health Organization Strategy on Research for Health 2012 (http://apps.who.int/iris/bitstream/10665/77935/1/9789241503259_eng.pdf?ua=1)
[5] World Health Organization Standards and Operational Guidance for Ethics Review of Health-Related Research

Research,[7] *the Code of Ethics and Professional 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 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 effort recognizes the hardware or building blocks of human resources, which includes medical product access, infrastructure and service delivery, financing and governance, and information systems, along with the software or mortar of people, which includes 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 the 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**).

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with Human Participants 2011 (http://apps.who.int/iris/bitstream/10665/44783/1/9789241502948_eng.pdf?ua=1&ua=1)

[6] World Health Organization 2017 Code of Conduct for Responsible Research (http://www.who.int/about/ethics/code-of-conduct-responsible-research.pdf?ua=1)

[7] World Health Organization 2017, WHO Policy on Misconduct in Research (http://intranet.who.int/public-drives/PubDept/DGO-CRE%20-%20Compliance%2C%20Risk%20Management%20and%20Ethics%20Office/ResponsibleResearch/pmr.pdf)

[8] World Health Organization, 2017, Code of Ethics and Professional Conduct (http://www.who.int/about/ethics/code_of_ethics_full_version.pdf?ua=1)

[9] World Health Organization WHA 69.10, 28 May 2016. Framework of Engagement with Non State Actors (http://www.who.int/about/collaborations/non-state-actors/A69_R10-FENSA-en.pdf?ua=1)

[10] World Health Organization Strategy on research for health 2012.

[11] Sheikh K., Gilson L., Agyepong I.A., Hanson K., Ssengooba F., Bennett S. (2011) Building the Field of Health Policy and Systems Research: Framing the Questions. PLoS Med 8(8): e1001073. Doi:10,1371/journal.pmed.1001073

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.

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 criticism 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]

[13] World Health Organization 2017 Code of Conduct for Responsible Research

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.

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 forums 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.

[14] WHO Policy on Misconduct in Research 2017; see pp 6-7.

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 a priori to issuing a call for proposals or be determined in discussion with researchers who submit proposals. 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, generally requires 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 method/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

In most cases, 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 (APW, TSA), and number of proposals to be potentially 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 WKC SWG provide support in terms 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]

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

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.

7.0. Monitoring and Evaluating Research Products

7.1. Incorporating quality into the contractual mechanisms

The WKC seeks to be an evidence based research center 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

[16] World Health Organization 2017 Code of Conduct for Responsible Research

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.

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.