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| Date |  | | | |
| Proposed study title |  | | | |
| Purpose of study | *What is the expected impact? (e.g. improving patient care, changing protocols, driving policy change). What role will the study play in that?* | | | |
| Research question | *Describe the main study question in 1 sentence* | | | |
| **Objectives** | *State the primary objective (as it would appear in a protocol), as well as secondary objectives if there are any* | | | |
| **Background/significance**  *1 paragraph* | *Outline “the problem” – why is the study question important?*  *Has anyone else tried to answer it? Summarise your literature review.* | | | |
| ***Study topic***  *Check all that apply* | Is the study part of an approved OCA topical research agenda?  No  Yes, namely:  If yes, please provide a link to, or submit research agenda with this concept paper | | | |
| AMR  Cholera  Covid-19  Ebola  Environmental Health  Emergency  HIV  Leishmaniasis  Malaria  Nutrition  Other disease outbreak  If Other or Other disease outbreak, please state: | Maternal & women's health  Measles  Meningitis  Mental health  Mortality  NTDs (excluding leishmaniasis)  Neonatal & child health  Non-communicable diseases  Other | | Upper/lower respiratory tract disease (excluding Covid-19)  Sexual violence  Surgery  Tuberculosis  Vaccination  VHF (excluding Ebola)  Violence  Water & Sanitation |
| **Methods - design**  *Check one study design* | Please consult the relevant study reporting guidelines\* listed at the end of this concept note. | | | |
| Observational study  Randomised trial  Systematic review  Case report  Diagnostic study  Brief explanation for chosen study design: | | Mixed methods study  Qualitative research  Quality improvement study  Prediction model  Other | |
| **Methods - setting** | **Study location/setting:** *describe where you propose doing the study.*  **Context (1 paragraph):** *outline benefits/risks of using proposed study sites.* | | | |
| **Methods – participants, procedures, analysis**  *For retrospective analyses of routine data, if this section is sufficiently complete, this concept note will serve as the study protocol.* | **Study participants**: *sampling strategy including where and how they will be found, over what time period, and inclusion/exclusion criteria; sample size (including sample size calculations if appropriate).*  **Data variables (quant):** *describe the main outcome and explanatory variables of interest*  **Data sources and collection**: *how you will obtain your data, from what sources, how confidentiality and quality will be assured, training and supervision of data collectors, translation and transcription issues, how data will be transferred and stored safely*  **Data analysis:**  *Description of the analysis approach, including theoretical basis for qualitative methods, software used, statistical tests that will be used in the analysis of quantitative data, additional data validation steps for qualitative studies, pre-identified limitations. (Note - if post-hoc analyses are conducted, they must be identified as such in study outputs)* | | | |
| **Resources/costs:** | *List resources needed e.g. statistician, input from other specialists, field time. Include cost estimate if known.* | | | |
| **Planned dates**  *List proposed* ***start/end date******[mm/yyyy]*** *of each stage and any time restrictions* | **Protocol development:**  **Ethics review:**  **Study preparation:**  **Data collection:**  **Data analysis:**  **Write up (report):**  **Write up (other study outputs):** | | | |
| **Ethics** | **Benefits:** *Likely benefits to participants, projects, community, national.*  **Risks:** *Potential harms to patients/community and risks to study completion.*  **Involvement of / collaboration with relevant local stakeholders: *please describe the role that they will play***  **Obtaining informed Consent**: *Describe how you plan to obtain consent.*  **Confidentiality and privacy:** *Describe how you plan to protect confidentiality*  **How will the study demonstrate respect for study participants:** *including how findings are shared with them*  **In-country permissions and regulatory review:**   1. Has a protocol been submitted to or approved by National/ Local Ethics Review Committee(s)?   No/Not yet  Yes   1. If not yet submitted, please indicate when and to which committee the protocol will be submitted: 2. If not planned to be submitted to local committees please note why not, and which alternative permissions have been obtained:   **Do you believe your study meets MSF ERB criteria for exemption from full review?:**   1. No. 2. Yes, because it is a retrospective review of routinely collected data. If so, it must meet all [5 criteria to qualify for exemption](https://fieldresearch.msf.org/handle/10144/618714) 3. Yes, because it is a survey that follows the MSF Intersectional Standardized Survey Protocol. If so, it must meet the [exemption criteria](https://scienceportal.msf.org/assets/6996) 4. Yes, for any other reason (please explain here)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| **Roles and responsibilities**  If responsibilities are split differently between the roles outlined below or held by other members of the research team, please describe clearly in the sections below. ReMIT responsibility must be held by an MSF staff member. | | | | |
| **Primary Investigator (PI)**  *Responsible for carrying out the study with support and consultation from research team. Will usually lead on all journal correspondence. TOR is* [*here*](https://msfintl.sharepoint.com/sites/OCA-dept-PHD/Shared%20Documents/Research%20%26%20Innovation/Operational%20Research%e2%80%8b%e2%80%8b/Research%20System%20Processes/Research%20Team%20ToR.pdf) | Name:  Email address: | | | |
| **Study Coordinator (SC)**  *Overall responsible for study, must be MSF HQ staff, usually topic specialist or epi advisor. Responsible for: ensuring HA and PI have fulfilled their roles; ensuring everyone named in this CP is clear about their involvement; updating ReMIT, translating findings into impact, appropriately disseminating materials (see later section). TOR is* [*here.*](https://msfintl.sharepoint.com/sites/OCA-dept-PHD/Shared%20Documents/Research%20%26%20Innovation/Operational%20Research%e2%80%8b%e2%80%8b/Research%20System%20Processes/Research%20Team%20ToR.pdf) | Name:  Email address:  Is the topic specialist / topic holder informed/involved? | | | |
| **MSF research team** | Name(s):  Email address(es):  Responsibilities: | | | |
| **Field involvement** | Are national/other field staff informed/included as co-investigators?  No  Yes  Will protocol development include field team input?  No  Yes  If no to either of above, please provide explanation:  Please describe any planned capacity building activities for national staff: | | | |
| **Health Advisor (HA)**  *Responsible for facilitating study operationally, ensuring desk/field have agreed to study and feeding back to PI/SC.* | Name of relevant HA(s):  Is/are the HA(s) supporting the study on behalf of the countries they manage?  No  Yes | | | |
| **External partners/MoH**  *Name, position, role of external collaborators.* | **International:**  **Local:** *e.g. Ministry of Health, NGO*  **Community**: *if relevant, describe consultation with a body representing the community.*  Are **resource agreements in place**, e.g. Open Access publication costs?  No  Yes, namely: | | | |
| **Competing interests** | *Declare any competing interests of the research team, or collaborators. Note if this work will contribute to an academic qualification for any of the research team.* | | | |
| **Data management and sharing**  *Contact details of those responsible for ensuring data are managed and shared in accordance with MSF’s Health Data Protection Policy and GDPR* | Name:  Email:  Data management plan: *describe how data will be managed and stored.*  Will data be shared with an external partner such as an academic institution?  No  Yes, namely:  *Complete the* [*OCA Data Sharing Agreement*](https://msfintl.sharepoint.com/:w:/s/Researchsystem/EUzjH4uorYtApQ2oduCHxO0BQXa7WT97eyajiqacMxr-1w?e=tnvzUh) *and submit for Medical Director signature.* | | | |
| **Opting out**  *All concept papers and/or (ERB approved) protocols are made available on ReMIT and the MSF Field Research website*. Questions about ReMIT? Email  *oca.research@london.msf.org* | This concept paper and/or accompanying protocol cannot be made available on:  ReMIT; because:  MSF Field research website; because: | | | |
| **Implementation/ impact and dissemination**  Responsibility of the Study Coordinator (unless otherwise noted in roles/responsibilities section) | | | | |
| **Implementation/impact** | *How will findings be implemented in MSF or externally?*  *Go back to the purpose statement – how will each expected impact be achieved?* | | | |
| **Dissemination**  *Note on journal publication - MSF has an Open Access (OA) journal publication policy. Fee reduction must be requested* ***at article submission.*** *See* [*guidance*](https://msfintl.sharepoint.com/:b:/r/sites/OCA-dept-PHD/Shared%20Documents/Research%20%26%20Innovation/Operational%20Research%E2%80%8B%E2%80%8B/Publication%20and%20Dissemination/Publication%20and%20data%20advice.pdf?csf=1&web=1&e=lCVTiD) *on publication.* | **Dissemination of findings:** *Describe how findings will be disseminated:* *including translation of research into booklets or other advocacy materials as appropriate.*  MSF – project, mission, headquarters:  Community:  In country partners (including MoH):  International dissemination (including WHO and other agencies, scientific publication):  **Budget: Has budget been allocated for dissemination, including potential scientific editing costs?**  **Agreements**  Authorship: *list possible authors (at least 1st and last):*  Has the dissemination plan got the support of the Health Advisor (HA)?  No  Yes  *Research outputs must be sent in parallel, before wider distribution, to the OCA Research Committee for quality review and to the HA, who will have 1 week to raise any context concerns with the Committee. Context concerns arising since Concept paper approval or quality of output likely the main reasons to postpone outputs.* | | | |

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| **\*Study Reporting Guidelines**  To assist authors in writing up their studies to meet scientific journal criteria | |
| Observational studies – [STROBE](http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0040296) ([& extensions](http://www.equator-network.org/?post_type=eq_guidelines&eq_guidelines_study_design=0&eq_guidelines_clinical_specialty=0&eq_guidelines_report_section=0&s=+STROBE+extension&btn_submit=Search+Reporting+Guidelines))  Randomised trials – [CONSORT](http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000251) ([& extensions](http://www.equator-network.org/reporting-guidelines/consort/))  Systematic reviews – [PRISMA](http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000097) ([& extensions](http://www.equator-network.org/reporting-guidelines/prisma/))  Case reports – [CARE](http://jmedicalcasereports.biomedcentral.com/articles/10.1186/1752-1947-7-223) | Qualitative research – [SRQR](http://journals.lww.com/academicmedicine/Fulltext/2014/09000/Standards_for_Reporting_Qualitative_Research___A.21.aspx) ([& extensions](http://intqhc.oxfordjournals.org/content/19/6/349.long))  Diagnostic studies – [STARD](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4623764/)  Quality improvement studies – [SQUIRE](http://qualitysafety.bmj.com/content/17/Suppl_1/i3.long)  Prediction model studies - [BMJ](http://www.bmj.com/content/350/bmj.g7594.long) |