Transparent, Reproducible, and Ethical Evidence (TREE) Review Framework Questionnaire

Instructions

The objectives of the Transparent, Reproducible, and Ethical Evidence (TREE) Review Framework are to: (i) establish ethical standards for evaluations, (ii) better integrate best practices for transparency, reproducibility, and ethics into evaluation workflow; and (iii) establish timely, independent review of risks facing the evaluation team to produce credible, meaningful, ethical evidence and the efforts to mitigate such risks (See ***Appendix 1*** for examples).

The TREE Review Framework is based on 10 standard ethical standards for evaluations:

1. Use transparency as a tool
2. Maximize social value and meaningful use
3. Balance power and align incentives
4. Preserve standard of care
5. Value and prioritize community engagement
6. Use fair methods
7. Ensure fair treatment of participants
8. Ensure appropriate informed consent and protection of confidentiality
9. Ensure favorable risk-benefit ratio
10. Ensure favorable cost-benefit ratio

The TREE Review Framework Questionnaire is designed to pose specific questions regarding evaluation teams' actions and decisions related to achieving the 10 ethical standards. Teams may use the TREE Review Framework Questionnaire for two purposes:

1. Documentation only: Team members may use this Questionnaire as a guide for actions and decisions at the funding, design, data collection, and dissemination stages of the evaluation life cycle.
2. Documentation and submission for independent assessment and feedback: Team members may use this Questionnaire to document their actions and decisions at the funding, design, data collection, and dissemination stages of the evaluation life cycle and submit to the TREE Review Committee for assessment and feedback.

To fill in the Questionnaire, evaluation team members are asked to provide responses through two mechanisms:

1. Specific questions: For specific questions, the team members are asked to provide the response based on the drop-down options provided. If Not Applicable, the team members should select the Unknown or Not Applicable options. If the team's response is not available in the drop-down menu, the team can provide Notes in the Evaluation Team's Notes section.
    a. Certain answers to specific questions trigger a request for the team members to provide more detail, a justification, and/or a risk mitigation strategy. These questions have specific instructions in RED FONT.
2. Probing/open ended questions: The evaluation team members can provide more detail in the Evaluation Team's Notes section.

If specific questions or sections are not relevant given the stage of the evaluation life cycle, the evaluation team members can note Not Applicable or Too Early. Evaluation teams should anticipate submitting supporting documentation: Informed Consent/Assent(s), Questionnaire(s), Protocol(s), Data Management Plan(s).

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Evaluation Details

1. **Evaluation Title**
2. **Evaluation Type**
3. **Role of Evaluation Team**[1]
4. **Country or Countries**
5. **Intervention Description (Brief)**
6. **Intervention Materials**[2] **(Link)**
7. **Intervention Total Cost**
8. **Intervention Funding Source(s)**
9. **Total Beneficiaries**
10. **Average cost per beneficiary**

11. **Primary Evaluation Method**
12. **Evaluation Total Cost**
13. **Evaluation Funding Source(s)**
14. **% evaluation to intervention costs (Current)**
15. **% evaluation to intervention costs (Future)**
16. **Evaluation Status**

17. **Engagement with human subjects**[3]
18. **Personally Identifiable Information (PII)**[4]
19. **Description of PII**
20. **Location Data**[5]
21. **Description of location data**

[1] From Barnett and Eager (2021). 'External evaluator' role refers to evaluation guided by a high degree of independence, drawing extensively on the principles of research ethics underpinned by "do no harm" (e.g., protecting respondents through consent and anonymity, ethical review boards and ethical protocols). "Learning partner" role refers to delivering a combined outcome and process evaluation designed to feed into program learning and course correction. "Embedded evaluator' role refers to when the evaluator is embedded as core member of the program team, responsible for the development and adaptation of interventions to achieve impact. In contrast to the first case, the latter two require the evaluator to perform a proactive role: helping to improve the program on an ongoing basis, as it better understands its contribution to effects within a changing context.

[2] Consider how a decision-maker will use the results of the study. If the program is successful, how will decision-makers replicate or scale-up the intervention? If the program is not successful, how will decision-makers course correct or redesign or ensure they do not replicate the intervention? Consider the intervention materials to do this – operational manual, contracts, terms of reference, etc.

[3] *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens (direct engagement); or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (indirect engagement).

[4] *PII* refers to direct identifiers (name, address, phone number, GPS coordinates), as well as indirect identifiers (combinations of observable or known characteristics that can be used to re-identify an individual or other unit of observation where confidentiality was promised).

[5] Location data can include gps coordinates or other locality identifiers (census block, village, district, province, etc.)

22. **Private, Sensitive Data**[6]
23. **Description of private, sensitive data**

24. **Will identifiable data be stored/shared by the evaluation team across international borders?**
25. **Description of identifiable data flow across borders**

26. **Will the evaluation team share identifiable data with other stakeholders (outside the evaluation team)?**
27. **Description of identifiable data sharing**

[6] *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). *Sensitive data* refers to data that is often private. Informed consent typically promises confidentiality to research participants. If there is unauthorized disclosure of sensitive data, the research team is at risk of breaching this promise of confidentiality and research participants may be at risk of harm. While sensitive data is context specific, examples include income, assets, savings, bank account information, personal health information such as HIV status, racial or ethnic origin, political opinions, religious beliefs, sexual orientation, other classified information.

TREE Review Details

1. Roles & responsibilities

Roles and Responsibilities in Project	
Role	Name, Organization
Intervention funder(s)	
Intervention implementation partner(s)	
Evaluation funder(s)	
Evaluation and intervention coordination	
Evaluation quality oversight (If applicable)	
Principal Investigator (PI)	
Other Evaluators	
Project Manager	
Data Manager	
Field Coordinator	

2. Supporting documentation submitted with TREE Review Questionnaire:

Documents	Submitted for review
Protocol(s) and IRB documentation	
Informed consent/assent statement(s)	
Questionnaire(s)	
Data Management Plan(s)	
Other (Describe)	

3. TREE Review Committee

Role	Name, Organization	TREE Review Participation (Provide 1 response)
TREE peer		Led assessment and responses, Reviewed assessment and responses, No role
Sector peer		Led assessment and responses, Reviewed assessment and responses, No role
Context/regional peer		Led assessment and responses, Reviewed assessment and responses, No role

Section 1: Use transparency as a tool

1. Policy Requirements and Conflicts of Interest

1. Review institution policy and confirm agreement with policy requirements[7].

INSTRUCTIONS: If cannot answer 'Confirm' provide justification in Notes.

Evaluation Team Notes

2. Conflict(s) of interest

INSTRUCTIONS: If answer there is a COI or 'Incomplete' provide justification in Notes.

Evaluation Team Notes

2. Training in Protection of Human Subjects

1. What is the status of the evaluation team's (PI, CO-PI, project manager, assistants, etc.) training in protection of human subjects?

INSTRUCTIONS: If cannot answer 'Complete within last 3 years-All Staff' provide justification in Notes.

Evaluation Team Notes

2. What is the status of the field team's (field supervisors, interviewers, data entry personnel, etc.) training in protection of human subjects?

INSTRUCTIONS: If cannot answer 'Complete-All field staff' provide justification in Notes.

Evaluation Team Notes

3. IRB and other Review Requirements

1. What are the local IRB/ethics/other review requirements[8]?
2. What are the academic IRB review requirements (Describe evaluation staff)?
3. Please provide name, contact information, link to IRB(s) qualifications:
4. What is the status of the first[9] IRB Review (if multiple provide highest level)?
5. What is the status of the most recent[10] IRB Review (if multiple provide highest level)?

INSTRUCTIONS: If answer 'Complete – Exempt' or 'Incomplete' regarding IRB reviews provide justification in Notes.

6. What key issues did the IRB(s) raise? Provide link or attachment if available.

7. Insert link to IRB materials (internal and/or external)

Evaluation Team Notes

4. Pre-specification and Reporting

1. What is the status of the study registration?

INSTRUCTIONS: If answer 'Will not register study' provide justification in Notes.

2. Will the registration be updated (as necessary)

[7] For 3ie evaluation teams, please see policies here - Institutional policies and reports | 3ie (3ieimpact.org)

[8] Review resources with the US Health and Human Services International Compilation of Human Research Standards and Harvard School of Public Health

[9] Please refer to the first submission to the IRB. Was the first submission a Full, Expedited, or Exempt review?

[10] Please refer to the most recent submission to the IRB. Was the last submission a Full, Expedited, or Exempt review?

3. Who leads study registration?
4. Insert the registration(s) link

Evaluation Team Notes

5. What is the status of pre-specification with a PAP or protocol?

INSTRUCTIONS: If answer 'No pre-specification' provide justification in Notes.

6. Who leads pre-specification?
7. How are changes documented?
8. How are intervention/policy stakeholders involved in PAP process?
9. Has the evaluation team documented forecasted results[11]?
10. Insert link to the PAP (internal and/or external)

Evaluation Team Notes Click or tap here to enter text.

11. Will the evaluation team report analysis using standardized reporting templates[12]?
12. Does the final report/article align with (last defined) pre-specification?
13. Are pre-specified analysis and exploratory analysis clearly distinguished in report/article?

INSTRUCTIONS: If answer 'No' to any question provide justification in Notes.

Evaluation Team Notes

14. Does the report/article provide citation requirements?
15. Does the publication provide data citation requirements?
16. Who on the evaluation team is listed as an author?
17. Who on the evaluation team is not listed as an author?

Evaluation Team Notes Click or tap here to enter text.

5. Responsible Data Management

1. Describe general data management process.
2. What is the status of the Data Management Plan[13]?

INSTRUCTIONS: If answer 'Incomplete' provide justification in Notes.

3. What is the status of any Data Sharing Agreement(s) (DSAs)
4. What is the evaluation team's role in any DSA?
5. What is the status of any non-disclosure agreement(s) (NDAs)?
6. Insert link to DMP, DSA, NDA materials (internal and/or external)

Evaluation Team Notes

7. Describe secure data storage and transfer protocols. Provide DMP if available there. **Click or tap here to enter text.**
8. What is the status of secure data storage and transfer protocols?

INSTRUCTIONS: If cannot answer 'All data handlers use secure file storage and/or transfer' provide justification in Notes.

Evaluation Team Notes

[11] Research teams may use tools such as the Social Science Predication Platform - https://socialscienceprediction.org/
[12] Recommend referencing Equator Network reporting templates - https://www.equator-network.org/
[13] If organization does not have a standard DMP template, may reference DMP Tool - https://dmptool.org/

9. What is the data de-identification and sharing plan? Provide DMP if available there. **Choose an item.**

INSTRUCTIONS: If cannot answer 'Public-use de-identified data' provide justification in Notes.

10. Insert Link (internal and/or external)

Evaluation Team Notes

11. Will data providers be notified if there is an unauthorized disclosure of their private, sensitive data?

INSTRUCTIONS: Describe notification process or justification for no notification in Notes.

Evaluation Team Notes

6. Reproducibility

1. What is the status of the push-button replication?

INSTRUCTIONS: If cannot answer 'Yes' provide justification in Notes.

2. Insert link to reproducible data package (internal and/or external)

Evaluation Team Notes

7. Final Transparency Checklist

This checklist should be completed at closeout. There may be many reasons why some materials are published and some are not when balancing transparency and ethics. Please provide brief explanation for why materials are not published (if relevant) and how the explanation is communicated to new users/readers.

1. Published registration
2. Published PAP
3. Published Design Report
4. Published Baseline Report
5. Published Analysis Report(s)
6. Published Questionnaire(s)
7. Published IRB materials
8. Published data and code
9. (If using machine learning) Published explanation of models
10. Published Ethics Appendix

Evaluation Team Notes

Section 2: Maximize social value and meaningful use

1. Problem diagnostic, theory of change, forecasting

Specific question(s):

a. Has the intervention team defined the problem the intervention will address?

INSTRUCTIONS: If answer 'No' provide risk mitigation in Notes.

b. Has the evaluation team defined the problem the intervention will address?

INSTRUCTIONS: If answer 'No' provide risk mitigation in Notes.

c. What are the key outputs and outcomes along the intervention's theory of change?

If available in other format, feel free to link or attach document.

Outputs	Short-term Outcomes	Long-term Outcomes

d. Will the evaluation examine all elements of the theory of change or only some components?

e. Is there agreement with various stakeholders that the forecasted[14] results or minimal detectable effect (MDE) sizes for targeted outcomes are feasible?
   a. Evaluation team
   b. Implementing partners
   c. Policymakers
   d. Others

f. Have results been presented in the context of/compared to forecasted results?

g. Were forecasted results accurate?

Additional probing question(s): Is there a strong understanding of the problem this intervention will address? What data on the context/problem is available? Is it clear how the intervention will address this problem(s) or effect(s)? At design stage, describe or refer to any forecasted results and how these are linked/not linked to study design (such as power calculations). Are forecasted results realistic or is the MDE driven by budget/sample size restrictions? When forecasted results were inaccurate, are the findings useful for updating priors/reducing bias?

Evaluation Team Notes:

2. Motivation and evidence consumers

Specific question(s)

a. What is the primary motivation for this evaluation?

b. Who initiated the demand/interest for the evaluation?

c. Has demand/interest for the evaluation changed over time?

INSTRUCTIONS: If answer 'Less demand/interest' provide risk mitigation in Notes.

d. Is there a stakeholder engagement and evidence uptake plan?

[14] Evaluation teams may use tools such as the Social Science Predication Platform - https://socialscienceprediction.org/

Additional probing question(s): What is motivating the evaluation – is this a learning opportunity (to address a known evidence gap), is this an opportunity to replicate and/or scale-up interventions with limited evidence to inform better understanding of impacts across contexts and time? Is this strongly informed by questions of accountability? Is there a clear demand for the results of the evaluation for its primary evaluation question(s)? Is demand for the findings driven by the evaluation team, by the intervention team, by funders, or by policymakers? Some combination of these?

Evaluation Team Notes:

3. Incentives for use

Specific question(s)

a. What is the risk that decisionmakers do not use evaluation findings?
b. What is the risk that decisionmakers deliberately misuse evaluation findings?

INSTRUCTIONS: If answer 'High' for either question provide risk mitigation in Notes.

Additional probing question(s): What mitigation measures can be/have been introduced by the study team? How will the study team use transparency as a tool as risk mitigation – i.e. publish pre-specified analysis plans, align reporting with pre-specified analysis plans to limit selective reporting.

Evaluation Team Notes:

Section 3: Balance power and align incentives

1. Power dynamics and relationships

Specific question(s):

a. What is the relationship between the funder of the intervention and funder of evaluation? **Choose an item.**

INSTRUCTIONS: If answer 'Same funder' provide risk mitigation in Notes.

b. Is this information documented in Conflict-of-Interest assessment? **Choose an item.**

c. Is this information shared in the informed consent? **Choose an item.**

Additional probing question(s): Are there shared interests or competing interests for the evaluation to produce a rigorous, credible, unbiased analysis? If the same funder for the intervention and the evaluation, how has the team leveraged pre-specification and other transparency tools to mitigate incentives in place to minimize or downplay null or negative results? Are there any other relationships between the evaluation team and other stakeholders that may create a conflict of interest?

Evaluation Team Notes: Click or tap here to enter text.

2. Vulnerabilities

Specific question(s): *See Appendix 2 for definitions.*

a. What potential vulnerabilities are present between evaluation staff and field/data collection staff?

- **a.** Cognitive? **Choose an item.**
- **b.** Juridic? **Choose an item.**
- **c.** Deferential? **Choose an item.**
- **d.** Allocational? **Choose an item.**
- **e.** Other? **Choose an item.**

b. What potential vulnerabilities are present between study participants and field/data collection staff?

- **a.** Cognitive? **Choose an item.**
- **b.** Juridic? **Choose an item.**
- **c.** Deferential? **Choose an item.**
- **d.** Allocational? **Choose an item.**
- **e.** Other? **Choose an item.**

INSTRUCTIONS: If answer 'Yes' provide risk mitigation in Notes.

Additional probing question(s): How did the study team identify and manage vulnerabilities? Based on vulnerabilities, how will the study team manage vulnerabilities/mitigate power dynamics with field staff composition? Are additional field staff required to remain sensitive to vulnerabilities (such as ensuring women interview women)? Is there an additional cost for this team composition?

Evaluation Team Notes: Click or tap here to enter text.

3. Evaluation team's role in intervention

Specific question(s):

a. Is the evaluation team independent from or active in intervention design and implementation? **Choose an item.**
b. Is this information documented in Conflict-of-Interest assessment? **Choose an item.**
c. Is this information shared in the informed consent? **Choose an item.**

Additional probing question(s): What is the motivation for the evaluation team's independence from or active participation in intervention design and implementation? Does the evaluation team benefit from demonstrating 'positive' results of the intervention or minimizing null/negative findings? Have any evaluation team members published on this topic previously? Would their reputation in this area be affected by the results of this study (i.e., if the study has positive, negative, or null findings)?

Evaluation Team Notes: Click or tap here to enter text.

4. Restrictions on reporting

Specific question(s):

a. Are there known limitations on the ability of the evaluation team to report full analytical results of the evaluation, regardless of if the analysis findings are positive, negative, and/or null? **Choose an item.**

INSTRUCTIONS: If answer 'Yes' provide risk mitigation and/or justification in Notes.

Additional probing question(s): What are the contractual, institutional, political limitations placed on the evaluation team to report full results of the evaluation, regardless of if the results are positive, negative, and/or null? Is there incentive to highlight positive and downplay null or negative results for future funding? What are those restrictions and/or incentive and who drives them? What mitigation measures can be/have been established? What risks are accepted?

Evaluation Team Notes: Click or tap here to enter text.

Section 4: Preserve standard of care

1. Standard of care

Specific question(s):

a. Is it reasonable to believe the intervention will preserve or improve the standard of care (i.e. not result in inferior outcomes)? **Choose an item.**

INSTRUCTIONS: If answer 'No' provide description, justification, and risk mitigation in Notes.

b. Does the intervention or policy pose any risk of reduction or removal of participant and/or bystander access to:
    a. Housing **Choose an item.**
    b. Water and/or sanitation **Choose an item.**
    c. Health care **Choose an item.**
    d. Food security **Choose an item.**
    e. Education **Choose an item.**

INSTRUCTIONS: If answer 'Yes' provide description, justification, and risk mitigation in Notes.

c. Is there risk of harm to individuals (participants, bystanders, staff) from this intervention that are beyond "normal"[15]?
    a. Physical harm (injury, illness, death) **Choose an item.**
    b. Economic harm (loss of income, theft) **Choose an item.**
    c. Emotional harm (distress, depression) **Choose an item.**
    d. Social harm (reputational damage, exclusion) **Choose an item.**
    e. Legal harm (profiling, persecution) **Choose an item.**
    f. Other (Describe) **Choose an item.**

INSTRUCTIONS: If answer 'Yes' provide description, justification, risk mitigation in Notes.

d. Have any risks of harm to individuals (participants, bystanders, staff) from this intervention materialized?
    a. Physical harm (injury, illness, death) **Choose an item.**
    b. Economic harm (loss of income, theft) **Choose an item.**
    c. Emotional harm (distress, depression) **Choose an item.**
    d. Social harm (reputational damage, exclusion) **Choose an item.**
    e. Legal harm (profiling, persecution) **Choose an item.**
    f. Other (Describe) **Choose an item.**

INSTRUCTIONS: If answer 'Yes' fill in information requested in Appendix 3: Adverse Events.

Evaluation Team Notes: Click or tap here to enter text.

2. Awareness of participation

Specific question(s):

a. Are participants aware of participation in the intervention? **Choose an item.**

b. Are participants aware of participation in the evaluation? **Choose an item.**

INSTRUCTIONS: If participants not fully aware of participation in intervention and/or study, provide description, justification, and risk mitigation in Notes.

[15] For bystanders, examples of risks of harm include political threats/targeting, unwarranted arrest or targeting by law enforcement, targeted for violence or theft, or exposure to infectious disease/illness.

Additional probing question(s): What is the justification for any lack of awareness (consent)? Does the intervention and/or evaluation team intend to inform the participants of this after the intervention/study is complete?

Evaluation Team Notes: Click or tap here to enter text.

3. Legality

Specific question(s):

a. Is the intervention in alignment with relevant laws, regulations, other relevant processes? **Choose an item.**

b. Is the study in alignment with relevant laws, regulations, other relevant processes? **Choose an item.**

INSTRUCTIONS: If answer 'No' provide description, justification, and risk mitigation in Notes.

Additional probing question(s): Please explain and justify any interaction with or implementation of activities that may be considered illegal or questionable legality. Relevant laws include the laws within the country the study is conducted, as well as laws that govern the use of the funds (for example, United States Government (USG) funding requires attention to USG laws for federal funding).

Evaluation Team Notes: Click or tap here to enter text.

Section 5: Value and prioritize community engagement

1. Study participant representation

Specific question(s):

a. How does the evaluation team composition ensure an understanding of the study context and participant vulnerabilities? **Click or tap here to enter text.**

b. Did the evaluation team engage with various stakeholders in the community on study design (sampling, evaluation questions, questionnaire design)?
   a. Study participants **Choose an item.**
   b. Study participant communities **Choose an item.**
   c. Implementation partners **Choose an item.**
   d. Policymakers/funders/decision-makers **Choose an item.**

Additional probing question(s): How will the evaluation team empower and represent the needs of the study population in study design, implementation, and dissemination?

Evaluation Team Notes: Click or tap here to enter text.

2. Study participant feedback loop

Specific question(s):

a. Is community engagement/a feedback loop expected on any specific data results (such as water quality testing, anemia/biomarker tests)?
   a. Study participants **Choose an item.**
   b. Study participant communities **Choose an item.**
   c. Implementation partners **Choose an item.**
   d. Policymakers/funders/decision-makers **Choose an item.**

b. Is community engagement/a feedback loop expected for sharing final evaluation findings?
   a. Study participants **Choose an item.**
   b. Study participant communities **Choose an item.**
   c. Implementation partners **Choose an item.**
   d. Policymakers/funders/decision-makers **Choose an item.**

c. Did participant feedback validate the evaluation findings? **Choose an item.**

d. Does the final report or other documentation explain how participant feedback was used by the evaluation team? **Choose an item.**

Additional probing question(s): Is data collected that requires notification to the communities and/or individual participants (such as water quality testing, biomarker testing)? Are costs for this feedback loop built into the evaluation budget? If yes, what is the plan? If not, why not? Does the evaluation team plan to convey the findings of the evaluation more generally to the community? Are costs for this feedback loop built into the budget? If yes, what is the plan? If not, why not?

Evaluation Team Notes: Click or tap here to enter text.

Section 6: Use fair methods

1. Alignment of methods with state of project – efficacy vs. effectiveness

Specific question(s):

a. What best describes the state of the intervention in terms of design and implementation? **Choose an item.**
b. Is this study considered an efficacy study or effectiveness study? **Choose an item.**

Additional probing question(s): How has the evaluation team aligned evaluation questions and methodology with the state of the intervention? Is the evaluation considered more formative and iterative to inform real-time intervention design and implementation decisions or is the evaluation focused on more summative questions regarding intervention effectiveness?

Evaluation Team Notes: Click or tap here to enter text.

2. State of equipoise

Specific question(s):

a. Is there genuine uncertainty regarding the efficacy of the proposed intervention compared to other interventions/policies? **Choose an item.**
b. Is there genuine uncertainty regarding the effectiveness of the proposed intervention compared to other interventions/policies? **Choose an item.**

Evaluation Team Notes: Click or tap here to enter text.

3. State of scarcity

Specific question(s):

a. Do any specific characteristics – gender, income status, employment status – increase claim to and eligibility for the intervention? **Choose an item.**

INSTRUCTIONS: If answer 'Yes' provide description in Notes.

b. Does demand and/or need for the intervention by the eligible participant population exceed available resources?
    a. Financial **Choose an item.**
    b. Administrative **Choose an item.**
c. Could the results of the evaluation resolve scarcity of resources? **Choose an item.**

INSTRUCTIONS: If answer 'No' provide justification for burden placed on study participants in Notes.

Additional probing question(s): What specific characteristics – gender, ethnicity, income status, employment status, etc. – increase potential beneficiary need and prioritization? Is there a scarcity of resources to reach all potential beneficiaries based on problem definition and target population? If results of the evaluation cannot affect scarcity of resources (i.e., there is no intention of directing more resources to this intervention) what is the purpose of the evaluation?

Evaluation Team Notes: Click or tap here to enter text.

4. Alignment of methods with intervention details

Specific question(s):

a. Does evaluation design require withholding the intervention from a control group? **Choose an item.**

b. If YES, does the method rely on policy equipoise, scarcity, or both to justify? **Choose an item.**

INSTRUCTIONS: If answer 'Neither' provide description, justification, and risk mitigation in Notes.

c. How are program implementers involved in the method(s) decisions? **Choose an item.**

d. Is there a high, medium, or low risk to maintaining internal validity? **Choose an item.**

INSTRUCTIONS: If answer 'High' provide description, justification, and risk mitigation in Notes.

e. What are the sample size(s) and is the study appropriately powered to answer the evaluation question(s) based on agreed forecasted results/Minimum Detectable Effects? **Click or tap here to enter text.**

f. What is the exposure period (to treatment) and is this duration considered appropriate answer the evaluation question(s)? **Click or tap here to enter text.**

Additional probing question(s): Who will lead the assignment of treatment and control? How will the study team and/or implementation partner monitor assignment adherence? How will the study team establish and maintain commitment to this assignment across stakeholders for the necessary time?

Evaluation Team Notes: Click or tap here to enter text.

5. Data needs and quality

Specific question(s):

a. What protocols has the study team established to assess data quality (integrity) of secondary data used for analysis (such as administrative data or other existing data shared with evaluation team for analysis)? **Click or tap here to enter text.**

b. What protocols has the study team established to oversee and manage data quality for primary data collection? **Click or tap here to enter text.**

c. Will the study collect data that is outside defined data needs? **Choose an item.**

INSTRUCTIONS: If answer 'Yes' or 'Other' provide description, justification, and risk mitigation in Notes.

a. Does the study use machine learning methods? **Choose an item.**

INSTRUCTIONS: If 'Yes' provide description and risk mitigation (for potential bias) in Notes.

Additional probing question(s): How is the evaluation team managing, monitoring, addressing any risks facing the quality of data used for analysis? If the evaluation depends on secondary, administrative data from other sources, how has the evaluation team assessed quality and potential bias?

Evaluation Team Notes: Click or tap here to enter text.

Section 7: Ensure fair treatment of participants

1. Alignment of study participant selection with intervention selection

Specific question(s):

a. Define the intervention participant population. **Click or tap here to enter text.**
b. Define the intervention beneficiary[16] population. **Click or tap here to enter text.**
c. Define the study sample population. **Click or tap here to enter text.**
d. Does the study sample selection follow the intervention eligibility/selection criteria, or does it introduce new rules for intervention eligibility/selection criteria? **Choose an item.**

INSTRUCTIONS: If answer 'Creates new rules' provide description, justification, and risk mitigation in Notes.

e. Is the study expected to produce generalizable results?
   a. For other similar populations (defined by eligibility criteria)? **Choose an item.**
   b. For other populations (outside the eligibility criteria)? **Choose an item.**

Additional probing question(s): How does the study sample selection align with existing or new intervention selection criteria? How might the sample inclusion/exclusion criteria affect the external validity of results? How might the sample criteria affect bias in the results? How does the study sample facilitate assessment of any bias introduced?

Evaluation Team Notes: Click or tap here to enter text.

2. Fairness to control group

Specific question(s):

a. Will control group participants receive the intervention if found to be successful and scarcity is resolved? **Choose an item.**

Evaluation Team Notes: Click or tap here to enter text.

3. Participant payments and care

Specific question(s):

a. What is the interview duration per individual? **Click or tap here to enter text.**
b. How many individuals are interviewed? **Click or tap here to enter text.**
c. Are study participants compensated for time and risks? **Choose an item.**
d. How are study participants compensated for time and risks? **Choose an item.**
e. Is the study team responsible for any ancillary care[17] to study participants? **Choose an item.**

INSTRUCTIONS: If answer 'Yes' provide description, justification, and risk mitigation in Notes.

[16] For some interventions, the beneficiary population may be additional to or different from the participant population. For example, a teacher training program may include teachers as the participants, but the beneficiaries are teachers (knowledge improvements) and students (learning outcomes).

[17] For example, if the survey requires collection of biomarkers (body mass index, malaria, anemia, etc.) will the survey team provide ancillary care (referral to medical provider for treatment, provision of treatment)? If the study requires questions regarding traumatic events or identification of violence or abuse, will the study team provide ancillary care (referral to counseling, referral to support services)?

Additional probing question(s): How has the evaluation team considered the issue of payments to respondents to participate in the study – is it viewed as compensation or incentive to participate? How has this value been set? What if this data is used for purposes beyond the original study - would additional compensation be available? If participant payment is provided, how will the study team securely transfer it to participants? If participant payment is not provided, what is the justification?

Evaluation Team Notes: Click or tap here to enter text.

Section 8: Ensure informed consent and protection of confidentiality

If details from probing questions are available in the Data Management Plan (DMP), provide link, copy and paste, or indicate section of DMP and attach for reference.

1. Use of secondary data

Specific question(s):

a. Does the study leverage existing, administrative data? **Choose an item.**
b. Does the use of this secondary data align with its original purpose/informed consent? **Choose an item.**

INSTRUCTIONS: If answer 'No' provide description, justification, and risk mitigation in Notes.

c. Is additional informed consent and/or data sharing agreement required for secondary data use? **Choose an item.**
d. Are there any data privacy/protection laws that govern how the secondary data was collected that need to be considered? **Choose an item.**
e. Is this data linked/linkable to any primary data collected? **Choose an item.**

INSTRUCTIONS: If answer 'Yes' provide description, justification, and risk mitigation for re-identification risk in Notes.

f. Is management of the secondary data included in the IRB review/protocol? **Choose an item.**

INSTRUCTIONS: If answer 'No' provide description, justification in Notes.

Additional probing question(s): Where is this data stored and who else has access to it? For existing data with PII/sensitive data on human subjects, how will privacy, confidentiality, risk management and informed consent protocols for original human subjects be considered? Has a Data Sharing Agreement been established? Would inappropriate disclosure of this data pose any harm to the data respondent and/or original data owner? Discuss if this existing data serves as a linkage/re-identification risk for the study sample for future data sharing.

Evaluation Team Notes: Click or tap here to enter text.

2. Consent and assent requirements and comprehension

Specific question(s):

a. How will the study approach consent/assent? **Choose an item.**

INSTRUCTIONS: If study will waive consent, provide description, justification, and risk mitigation to individual respondent autonomy in Notes.

b. Does the study seek community consent? **Choose an item.**

INSTRUCTIONS: Provide description, justification, and risk mitigation to either (i) community rejection of interview staff and/or (ii) individual respondent autonomy in Notes.

c. Does the study require parental assent for child participation in study? **Choose an item.**
d. Does the informed consent/assent follow HHS regulations or different regulations[18]? **Choose an item.**
e. Was the informed consent/assent pre-tested with the questionnaire? **Choose an item.**
f. How is participant comprehension of informed consent assessed/measured? **Click or tap here to enter text.**

[18] See HHS regulations requirements for informed consent - https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116

g. Will the study re-consent[19] after the interview is complete? **Choose an item.**
h. Is de-identified data expected to be shared beyond the purpose of the original study (global public good)? **Choose an item.**
    a. Is this information shared in the informed consent? **Choose an item.**
i. What is the response rate? **Click or tap here to enter text.**
j. If the response rate is above 85[20]%, are there concerns that the participant population does not feel comfortable refusing to participate even if the informed consent describes the voluntary nature of the data collection? Click or tap here to enter text.

Additional probing question(s): How will the informed consent process be conducted and documented to respect cultural norms? How is it conducted with respect to specific vulnerable populations (such as children)? How will parental assent be attained if required? Are there concerns regarding comprehension of the informed consent/assent statement content? Has the budget fully accounted for informed consent/assent pilot testing and adaptation? What response rate is considered 'too high' a response rate? Are there concerns that a high response rate signals an unwillingness to refuse to participate even if the informed consent describes the voluntary nature of their participation?

Evaluation Team Notes: Click or tap here to enter text.

3. Promises of confidentiality

Specific question(s):

a. Is confidentiality promised? **Choose an item.**
b. According to the informed consent, which data handlers will have access to identifiable vs. de-identified vs. no access to data?
    a. Data collection team (interviewers, data entry) **Choose an item.**
    b. Evaluation team (PIs, Co-PIs, RAs, etc) **Choose an item.**
    c. Implementation partners **Choose an item.**
    d. Policymakers **Choose an item.**
    e. Other **Choose an item.**

INSTRUCTIONS: If answer 'Yes' provide description, justification, and risk mitigation in Notes.

Additional probing question(s): What promises of confidentiality will the study team make to participants? Do these promises define who needs access to identifiable data and whether de-identified data will be shared (for public use)? How has the team assessed respondent comprehension of these promises?

Evaluation Team Notes: Click or tap here to enter text.

[19] For some studies, it may be difficult for participants to understand the risks of their participation until they understand what information is gathered during the interview. The study team should assess if re-consent is required or how the study team will manage requests from participants for re-consent or ex-post consent.
[20] May vary depending on study type, risk, context. Study team may assess ex-ante with IRB what may be a threshold.

4. Disclosure risk and mitigation during data collection

Specific question(s):

a. What is the protocol the field team will follow to maintain confidentiality during data collection? **Click or tap here to enter text.**

b. What is the protocol the field team will follow if there is unauthorized disclosure of the PII and sensitive data collected in an interview (eavesdropping by neighbors, loss of computer, loss of USB, etc.)
   a. Reporting to evaluation team organization/management **Click or tap here to enter text.**
   b. Reporting to Institutional Review Board(s) **Click or tap here to enter text.**
   c. Reporting to participants **Click or tap here to enter text.**
   d. Reporting to participant communities **Click or tap here to enter text.**
   e. Reporting to other stakeholders (Describe) **Click or tap here to enter text.**

c. Have any unauthorized disclosures occurred during data collection (theft of laptop, neighbor eavesdropping)? **Choose an item.**

INSTRUCTIONS: If answer 'Yes' fill in information requested in Appendix 3: Adverse Events.

Evaluation Team Notes: Click or tap here to enter text.

5. Disclosure risk and mitigation for data storage, transfer, and sharing

Specific question(s):

a. Does the Data Management Plan define who will have access to what data when and how that data will be stored, transferred, shared, and destroyed? **Choose an item.**

b. How is data transferred to the evaluation team's system? **Choose an item.**

c. How is data stored in the evaluation team's system? **Choose an item.**

d. Are there any data privacy/protection laws that govern how PII data is stored/transferred that need to be considered? **Choose an item.**

e. Are there any data privacy/protection laws that govern how PII data is shared that need to be considered? **Choose an item.**

f. Is there specific linkage documentation (program beneficiary lists) that increases the potential for re-identification risk? **Choose an item.**

g. Does knowledge of treatment assignment increase potential for re-identification risk? **Choose an item.**

h. Will data de-identification and sharing procedures be reviewed before data sharing? **Choose an item.**

i. What is the protocol the evaluation team will follow if there is unauthorized disclosure of the PII and sensitive data collected in an interview (hackers, computer or USB loss, etc.)
   a. Reporting to evaluation team organization/management **Click or tap here to enter text.**
   b. Reporting to Institutional Review Board(s) **Click or tap here to enter text.**
   c. Reporting to participants **Click or tap here to enter text.**
   d. Reporting to participant communities **Click or tap here to enter text.**
   e. Reporting to other stakeholders (Describe) **Click or tap here to enter text.**

j. Have any unauthorized disclosures occurred during data storage or transfer (theft of laptop, hacking, etc.)? **Choose an item.**

INSTRUCTIONS: If answer 'Yes' fill in information requested in Appendix 3: Adverse Events.

Additional probing question(s): How will data storage and transfer procedures adhere to privacy, confidentiality, risk management, and informed consent protocols for human subjects? How will data sharing procedures adhere to privacy, confidentiality, risk management, and informed consent protocols for human subjects??

Evaluation Team Notes: Click or tap here to enter text.

Section 9: Ensure favorable risk-benefit ratio and accountability

1. Evaluation staff risk-benefit ratio and accountability

Specific question(s):

a. Is there risk of harm to evaluation staff for participating in this study that are beyond "normal" risks[21]?

- **a.** Physical harm (injury, illness, death) **Choose an item.**
- **b.** Economic harm (loss of income, theft) **Choose an item.**
- **c.** Emotional harm (distress, depression) **Choose an item.**
- **d.** Social harm (reputational damage, exclusion) **Choose an item.**
- **e.** Legal harm (profiling, persecution) **Choose an item.**
- **f.** Other (Describe) **Choose an item.**

INSTRUCTIONS: If answer 'Yes' provide description, justification, risk mitigation in Notes.

b. Have any risks of harm to evaluation staff materialized?

- **a.** Physical harm (injury, illness, death) **Choose an item.**
- **b.** Economic harm (loss of income, theft) **Choose an item.**
- **c.** Emotional harm (distress, depression) **Choose an item.**
- **d.** Social harm (reputational damage, exclusion) **Choose an item.**
- **e.** Legal harm (profiling, persecution) **Choose an item.**
- **f.** Other (Describe) **Choose an item.**

INSTRUCTIONS: If answer 'Yes' fill in information requested in Appendix 3: Adverse Events.

c. What is the mechanism for evaluation staff to report harms? **Click or tap here to enter text.**

d. Who is responsible for managing and addressing any materialized harms? **Click or tap here to enter text.**

e. Given current assessment, do benefits of conducting the study outweigh risks of harm? **Choose an item.**

INSTRUCTIONS: If answer 'No' document procedure to end study in Notes.

Additional probing question(s): What potential risks of harm face evaluation staff for participating in this study that are beyond "normal"? Consider COVID and face-to-face interview risks as relevant. Consider political and security environments – are evaluation staff at risk of targeting by local law enforcement and jail, targeting by local gang or other terrorist groups. Could the evaluation staff become targeted by opponents or competitors of the other stakeholders – implementing partners, policymakers. Consider road safety – what are safety conditions during day? During night? Consider secure food and lodging services – are these planned and available in all field locations?

Evaluation Team Notes: Click or tap here to enter text.

2. Field staff risk-benefit ratio and accountability

Specific question(s):

a. Is there risk of harm to field staff for participating in this study that are beyond "normal" risks[22]?

[21] For evaluation staff, examples of risks of harm include political threats/targeting, unwarranted arrest or targeting by law enforcement, targeted for violence or theft, exposure to infectious disease/illness, unsafe road conditions or transportation, inadequate access to food and secure lodging.

[22] For field staff, examples of risks of harm include political threats/targeting, unwarranted arrest or targeting by law enforcement, targeted for violence or theft, exposure to infectious disease/illness, unsafe road conditions or transportation, inadequate access to food and secure lodging.

a. Physical harm (injury, illness, death) **Choose an item.**
b. Economic harm (loss of income, theft) **Choose an item.**
c. Emotional harm (distress, depression) **Choose an item.**
d. Social harm (reputational damage, exclusion) **Choose an item.**
e. Legal harm (profiling, persecution) **Choose an item.**
f. Other (Describe) **Choose an item.**

INSTRUCTIONS: If answer 'Yes' provide description, justification, risk mitigation in Notes.

b. Have any risks of harm to field staff materialized?

a. Physical harm (injury, illness, death) **Choose an item.**
b. Economic harm (loss of income, theft) **Choose an item.**
c. Emotional harm (distress, depression) **Choose an item.**
d. Social harm (reputational damage, exclusion) **Choose an item.**
e. Legal harm (profiling, persecution) **Choose an item.**
f. Other (Describe) **Choose an item.**

INSTRUCTIONS: If answer 'Yes' fill in information requested in Appendix 3: Adverse Events.

c. What is the mechanism for field staff to report harms? **Click or tap here to enter text.**
d. Who is responsible for managing and addressing any materialized harms? **Click or tap here to enter text.**
e. Given current assessment, do benefits of conducting the study outweigh risks of harm? **Choose an item.**

INSTRUCTIONS: If answer 'No' document procedure to end study in Notes.

Additional probing question(s): What potential risks of harm face field staff for participating in this study that are beyond "normal"? Consider COVID and face-to-face interview risks as relevant. Consider political and security environments – are field staff at risk of targeting by local law enforcement and jail, targeting by local gang or other terrorist groups. Consider road safety – what are safety conditions during day? During night? Consider secure food and lodging services – are these planned and available in all field locations? How was compensation adequacy assessed and set? How will the evaluation team deliver compensation securely in a way that minimizes potential harm to field staff?

Evaluation Team Notes: Click or tap here to enter text.

3. Participant risk-benefit ratio and accountability

Specific question(s):

a. Is there risk of harm to participants for participating in this study that are beyond "normal" risks[23]?

a. Physical harm (injury, illness, death) **Choose an item.**
b. Economic harm (loss of income, theft) **Choose an item.**
c. Emotional harm (distress, depression) **Choose an item.**
d. Social harm (reputational damage, exclusion) **Choose an item.**
e. Legal harm (profiling, persecution) **Choose an item.**
f. Other (Describe) **Choose an item.**

INSTRUCTIONS: If answer 'Yes' provide description, justification, risk mitigation in Notes.

b. Have any risks of harm to participants materialized?

[23] For participants, examples of risks of harm include political threats/targeting, unwarranted arrest or targeting by law enforcement, targeted for violence or theft, or exposure to infectious disease/illness.

a. Physical harm (injury, illness, death) **Choose an item.**
b. Economic harm (loss of income, theft) **Choose an item.**
c. Emotional harm (distress, depression) **Choose an item.**
d. Social harm (reputational damage, exclusion) **Choose an item.**
e. Legal harm (profiling, persecution) **Choose an item.**
f. Other (Describe) **Choose an item.**

INSTRUCTIONS: If answer 'Yes' fill in information requested in Appendix 3: Adverse Events.

c. What is the mechanism for participants to report harms? **Click or tap here to enter text.**
d. Who is responsible for managing and addressing any materialized harms? **Click or tap here to enter text.**
e. Given current assessment, do benefits of conducting the study outweigh risks of harm? **Choose an item.**

INSTRUCTIONS: If answer 'No' document procedure to end study in Notes.

Additional probing question(s): What potential risks of harm face participants for participating in this study that are beyond "normal"? Consider COVID and face-to-face interview risks as relevant. Distinguish between TREATMENT and CONTROL participants. Are participants' access to future services or policies changed because of participation in the study? How are benefits and risks distributed across participants and potential future beneficiaries? Is one group bearing additional risk with less potential for benefit? If the evaluation identifies risks of harm to the participant – such as health biometrics, violence and abuse – how will the evaluation/field staff team respond? Is ancillary care – referral to health center, provision of treatment – provided? Why or why not?

Evaluation Team Notes: Click or tap here to enter text.

4. Bystander risk-benefit ratio and accountability

Specific question(s):

a. Is there risk of harm to bystanders from this study that are beyond "normal"[24]?

a. Physical harm (injury, illness, death) **Choose an item.**
b. Economic harm (loss of income, theft) **Choose an item.**
c. Emotional harm (distress, depression) **Choose an item.**
d. Social harm (reputational damage, exclusion) **Choose an item.**
e. Legal harm (profiling, persecution) **Choose an item.**
f. Other (Describe) **Choose an item.**

INSTRUCTIONS: If answer 'Yes' provide description, justification, risk mitigation in Notes.

b. Have any risks of harm to bystanders materialized?

a. Physical harm (injury, illness, death) **Choose an item.**
b. Economic harm (loss of income, theft) **Choose an item.**
c. Emotional harm (distress, depression) **Choose an item.**
d. Social harm (reputational damage, exclusion) **Choose an item.**
e. Legal harm (profiling, persecution) **Choose an item.**
f. Other (Describe) **Choose an item.**

INSTRUCTIONS: If answer 'Yes' fill in information requested in Appendix 3: Adverse Events.

c. What is the mechanism for bystanders to report harms? **Click or tap here to enter text.**

[24] For bystanders, examples of risks of harm include political threats/targeting, unwarranted arrest or targeting by law enforcement, targeted for violence or theft, or exposure to infectious disease/illness.

d. Who is responsible for managing and addressing any materialized harms? **Click or tap here to enter text.**
e. Given current assessment, do benefits of conducting the study outweigh risks of harm? **Choose an item.**
INSTRUCTIONS: If answer 'No' document procedure to end study in Notes.

Additional probing question(s): What potential risks of harm face non-participants? Does the implementation of the study introduce new risks to non-participants that would not exist in the absence of the study? How will non-participants be compensated for any risks that materialize due to this study?

Evaluation Team Notes: Click or tap here to enter text.

Section 10: Ensure favorable cost-benefit ratio and accountability

1. Costs compared to other methods

Specific question(s):

a. Given current assessment, do benefits of selected methods for this study outweigh any additional costs? **Choose an item.**

INSTRUCTIONS: If answer 'No' document procedure to end study in Notes.

Additional probing question(s): Were other methods considered? Is the proposed method higher or lower cost than other methods considered? How were costs assessed for balance with expected benefits? How did the evaluation team minimize costs?

Evaluation Team Notes: Click or tap here to enter text.

2. Costs compared to intervention investment(s)

a. Given current assessment, do benefits of conducting this study outweigh costs? **Choose an item.**

INSTRUCTIONS: If answer 'No' document procedure to end study in Notes.

Additional probing question(s): How much is the total intervention cost? Currently vs. potential future investments? What is the cost of the evaluation relative to the total current and potential costs of the policy/intervention?

Evaluation Team Notes: Click or tap here to enter text.

Appendix 1 Potential Risks, Harms, and Risk Mitigation Efforts[25]

Risk	Example(s) of Harm/Adverse events	Risk Mitigation Efforts
1. Intervention design and/or implementation violates ethical principles (beneficence, respect for persons and/or justice) NOTE: The risk can extend to PERCEPTION. When others PERCEIVE a violation of ethical principles, there remains a high risk to researchers, evaluators, and others for harms described.	• Unethical Intervention design and implementation can lead to physical, economic, emotional, social, or legal harm(s) for intervention participants, research participants, bystanders • Studying unethical interventions can pose reputational harm to researchers • Studying unethical interventions can lead to reduced funding for evaluation • Researchers become too risk averse to study controversial interventions and these interventions are allowed to continue without evidence to inform course corrections which result in harmful policies that affect the physical, economic, emotional, social, or legal status of populations of interest Example: A study in Nairobi examining effects of various mechanisms to increase payments for water supply, including cutting off water access, resulted in various discussions around the ethics of the study (see discussion on ethical considerations here).	• Carefully examine the standard of care and how the intervention(s) studied may affect the standard of care in the 'preserve standard of care' section • Carefully examine the social value of the study and whether there is a favorable risk-benefit ratio • Ensure all key research team members are trained in foundational principles of protection of human subjects • Ensure review of research protocol and informed consent by appropriate Institutional Review Board(s) • Complete timely and continuous ethical review using resources like TREE Review questionnaire • Establish mechanisms for participants, bystanders, staff to report harms/adverse events • Be accepting of risk – some interventions may be unethical, and how interventions are improved or removed may be research demonstrating the adverse effects. However, this requires additional emphasis on the need to use transparency as a tool for how the researcher navigates ethical concerns and abides by research ethical principles.
2. Research design and/or implementation violates ethical principles (beneficence, respect for persons and/or justice) NOTE: The risk can extend to PERCEPTION. When others PERCEIVE a violation of ethical principles, there remains a high risk to researchers and others for harms described.	• Unethical research design and implementation (failure to provide sufficient information for informed consent, poorly designed or executed data collection) can lead to physical, economic, emotional, social, or legal harm(s) for research participants as result of study itself • Findings from poor quality or biased research design can inform programs/policies that affect the physical, economic, emotional, social, or legal aspect of population of interest • Poor quality or biased research design and implementation can pose reputational harm to researchers • Unethical research practices can lead to reduced funding for research	• Ensure all key research team members are trained in foundational principles of protection of human subjects • Ensure review of research protocol and informed consent by appropriate Institutional Review Board(s) • Complete timely and continuous ethical review using resources like TREE Review questionnaire • Establish mechanisms for participants, bystanders, staff to report harms/adverse events • Be prepared to end a study if it is determined the study cannot be conducted in a way that aligns with ethical principles

[25] This is adapted from a resource from Amos Doornbos (www.thisisamos.com) – Available at this link - Identifying Potential Data Risks and Harms - This Is Amos

Risk	Example(s) of Harm/Adverse events	Risk Mitigation Efforts
	Example: A study in Montana on the effect of different communications flyers to increase voter turnout was likely illegal and failed to consider ethics of impacts on community.	
3. Research studies a solution that does not align with the context/problem	• Studying interventions that don't align with problems can bias the interpretation of results of the study. For example, the study can determine the intervention 'didn't work' when it was not aligned with context/original problems. This can affect future programming of policies or interventions that affect the economic and social status of research participant and bystander populations • The potential risks and actual costs of the research may outweigh the benefits, violating 'beneficence' principle • Research waste results in less funding for research	• Ensure there is a strong, data-driven understanding of problem the intervention will address in the 'maximize social value' assessment
4. Results of study are not useful or used by decision-makers	• The potential risks and actual costs of the research outweigh the benefits, violating 'beneficence' principle • Research waste results in less funding for research	• Ensure motivation of study and evidence consumers are identified early and engaged throughout research life cycle through 'maximize social value' assessment • Ensure quality of research through ensuring fair methods and fair treatment of participants
5. Research team and/or research funders have incentives to prioritize positive results, downplay null or negative results	• Selective reporting and/or specification searching can result in biased findings and biased evidence base • Bias can affect future programming of policies or interventions that affect the economic and social status of data provider populations • Selective reporting and/or specification searching can pose reputational harm to researchers • Research waste results in less funding for research	• Define research questions and outcomes through pre-specification in registration and pre-analysis plans • Assess power dynamics and incentives across stakeholders • Use transparency as a tool to mitigate misaligned incentives and allow for assessment of credibility of findings
6. Research participants experience specific vulnerabilities and/or power dynamics that affect their sense of autonomy to participate or refuse to participate in the research	• Research participants feel unable to be truthful during data collection, leading to bias in data • Research participants feel coerced or unduly influenced to provide private, sensitive data • Provision of private, sensitive data can lead to physical, economic, emotional, social, or legal harm(s) for research participants Example: UNHCR shared detailed database of the Rohingya refugee population with Myanmar's government.	• Assess and acknowledge vulnerabilities and power dynamics in 'balance power and align incentives' assessment • Limit collection of study data with any other purpose (such as intervention eligibility) • Define data purpose and use in informed consent • De-identify data before sharing if defined and allowed through informed consent process

Risk	Example(s) of Harm/Adverse events	Risk Mitigation Efforts
7. Data collected but not used or needed	• Unnecessary identifiable information collected and stored that is linked to private, sensitive data can be breached or have other unauthorized disclosure that leads to physical, economic, emotional, social, or legal harm(s) • Research waste results in less funding for research	• Define data needs with the pre-analysis plan or other pre-specification tool to clearly map data needs to research questions and analysis models • Clearly define data that is collected for 'unknown' purposes and assess risk and need • Support these efforts with a data inventory (example - Data Inventory Map - Fillable Template - This Is Amos)
8. Data scope creep and/or misuse that results in data used for something other than purpose for which it was collected	• Data that is used for purposes outside the original purpose can lead to physical, economic, emotional, social, or legal harm(s) • Under certain regulations, this data misuse can be illegal or result in legal repercussions for the research team • Misuse of data can cause reputational harm to researchers *Example: On April 20, 2010, Arizona State University (ASU) agreed to pay $700,000 to 41 members of the Havasupai Indian tribe to settle legal claims that university researchers improperly used tribe members' blood samples in genetic research.*	• Define data needs with the pre-analysis plan or other pre-specification tool to clearly map data needs to research questions and analysis models (same as above) • Define who has access to what data, when, and for what purpose in the Data Management Plan • Ensure alignment between Data Management Plan and information provided to the data provider in the Informed Consent and/or Data Sharing Plan • Under US HHS regulations, carefully consider use of 'broad consent' during informed consent
9. Incomplete data resulting from the study team not considering all data needs required to fulfill research objectives	• Incomplete data can bias the results of the study leading to false positive or negative findings that affect future programming of policies or interventions that affect the economic and social status of data provider populations • Inability to fulfill research objectives can pose reputational harm to researchers • Research waste results in less funding for research	• Define data needs with the pre-analysis plan or other pre-specification tool to clearly map data needs to research questions and analysis models (same as above) • Ensure alignment with research sample and intervention sample through fair subject selection assessment
10. Poor Quality Data (primary and/or secondary data sources)	• Poor quality data can bias the results of the study leading to false positive or negative findings that affect future programming of policies or interventions that affect the economic and social status of data provider populations and can pose reputational harm to researchers	• Ensure data quality management and assessment practices are established for primary and secondary data collection and detailed under fair methods assessment

Risk	Example(s) of Harm/Adverse events	Risk Mitigation Efforts
	● Research waste results in less funding for research Example: Data obtained from an implementing partner used to inform influential study later identified as fraudulent data.	
11. Loss of confidentiality – *with or without additional linkage to private, sensitive data* – is a risk driven by several potential actions, including: ● Intruders breaching systems and accessing raw data ● Unintentional leakage or unintentional disclosure of either the raw data or of the information/ knowledge resulting from analysis of the data can occur by (a) of a member of the project team; (b) of known third parties (e.g., government, research partners); who have requested or may have access, or who may be motivated to get access in order to misuse the data and information; or (c) by unknown third parties (e.g. due to hackers or other bad actors ● Anonymized or de-identified datasets combined with other datasets to re-identify participants	● Confidential data obtained by nefarious actors can result in physical, economic, emotional, social, or legal harm(s) to research participants ● Under certain regulations, loss of confidential data may be illegal or result in legal repercussions for the research team ● Irresponsible data management can cause reputational harm to researchers Example: UNHCR shared detailed database of the Rohingya refugee population with Myanmar's government; Biometric data on Afghan security forces potentially available to the Taliban.	● Align data collected with data needs – if do not need to collect direct identifiers, do not (see above) ● Ensure staff members have completed the information security awareness and data protection training (Talk with IT team) ● Ensure the Data Management Plan describes how to: o Limit access of identifiable data to staff based on need o Encrypt files and devices storing confidential data o Store direct identifiers separate from other data as appropriate ● Ensure there is a data breach plan that is up to date and known by research team ● Ensure the data sharing strategy is assessed for re-identification risk and appropriate sharing strategy (public, restricted, or no access)

Appendix 2: Taxonomy of Vulnerability

TABLE 4.1: Taxonomy of Vulnerability for Study Participants[26]

Vulnerability	Definition	Potential Causes	Ethical Research Practice
Cognitive Vulnerability	The research subject does not have the capacity to deliberate and decide whether to participate in the study	Immaturity (through age, other cause), dementia, certain types of mental illness, disability; educational deficits and unfamiliarity with the language; situational mental distress/crisis	Mitigated through proper **Informed Consent**: plain-language, advance directives (where incapacity is anticipated), supplementary educational measures to ensure comprehension, and the proper use of surrogates and advocates
Juridic Vulnerability	The research subject is liable to the authority of others who may have an independent interest in the research subject's participation	Prisons and the military, where wardens and officers have legal authority over prisoners and enlistees; Children under the authority of their parents, Students subordinated to Professors, Institutionalized persons subject to the authority of custodians, women legally subject to their husbands;	Mitigated through proper **Informed Consent**: devise a consent procedure that will insulate the research subject from the hierarchical system to which he or she is subject. This is particularly challenging if the researcher/project team is a part of the hierarchical system (so program beneficiaries who are surveyed by their benefactors).
Deferential Vulnerability	The research subject exhibits patterns of deferential behavior that may mask an underlying unwillingness to participate	May be driven by social and political pressures to follow/defer to others despite own desire to not follow/defer *(often present with juridic vulnerability)*	Mitigated through **Sample Recruitment/ Screening** and **Informed Consent**: Inclusion Criteria/Sample Selection may require input of local informants or consultants to devise a process that eliminates as much as possible the social pressures a research subject feels. Informed consent mitigation same as above.
Allocational Vulnerability	The research subject is lacking in important social goods that will be provided because of participating in the research	When participation in the research can provide research subject a social good - money, housing, medical care, childcare, burial benefits, opportunities to benefit the community, freedom – that they otherwise do not have access to	Mitigated through **Sample Recruitment/ Screening** and **Compensation**: The Inclusion Criteria/Sample Selection may require input of local informants to determine whether or not the offering of research participation may introduce undue influence; Project Teams must also carefully consider Compensation packages to limit their under or over-value and may need to consider not just their research sample, but also neighboring communities /individuals/households that are excluded and may feel resentment for the exclusion.
Infrastructural Vulnerability	The political, organizational, economic, and social context of the research setting does not possess the integrity and resources needed to manage the study	Research subjects have access to research requirements (phone, transport); Project teams have access to research requirements (skills for specific biomarker tests, psychological tests, etc.; electricity, transport, safety)	Mitigated through **Study Design**: The study design/protocol should be carefully reviewed for local context and cultural sensitivities.
Medical Vulnerability	The research subject has been selected, in part, because he or she has a serious health-related condition for which there are no satisfactory remedies	When (i) illness is severe and (ii) no safe, effective, and otherwise satisfactory treatments are available, patients can be primarily driven to participate based on false hope for benefits	Mitigated through **Study Design** and **Informed Consent**: Given the interests and aspirations of both parties (and the poor bargaining position of the research subject) work toward fair division of the benefits and burdens of cooperation and design the study to maximize the likelihood of subject benefit based on medical intervention found to be safe and effective; communicate benefits and their probabilities for success through Informed Consent.

[26] This reference is extracted from Hoces de la Guardia and Sturdy (2019) and adapted from NBAC 2001.

Appendix 3 Adverse Events Reporting – Actual Risks and Potential and Actual Harms from Intervention and Study

Risk Description	Harm Description (Potential and Actual)	Date(s) occurred	Who was notified and when?	What was the response(s) and when?