**PROTOCOL INPUT QUESTIONNAIRE\***

**PROTOCOL TITLE:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **DATE:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**REVIEWER NAME:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **Protocol Description and Background** | **Yes** | **No** | **Unknown** |
| Does the protocol, as written, include enough information and supporting material to allow full understanding of the study purpose, relevance, justification, and design? |  |  |  |
| *Brief comment:* |
| Do you agree with the justification for the proposed intervention? |  |  |  |
| *Brief comment:* |
| Do you think the study’s choice regarding a control arm, standard of prevention or care, or reference standard is appropriate? (Note: relevant issues to think about here might include use of placebo for the control arm or whether the standard of prevention or care or the reference standard is the right comparator.) |  |  |  |
| *Brief comment:* |
| Do you think the study seeks to answer an important question that will benefit the community? |  |  |  |
| *Brief comment:* |

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| **Locations Where Research Will Be Performed** | **Yes** | **No** | **Unknown** |
| Does the protocol include any information about plans for post-trial access to study drugs, diagnostics, or other investigational products in countries where the research is being conducted? |  |  |  |
| *Brief comment:* |
| Do you think people at your site would participate? |  |  |  |
| *Brief comment:* |

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| **Requirements of Study Participants** | **Yes** | **No** | **Unknown** |
| Are expectations of participants, including the length of participation, clear and fair? |  |  |  |
| *Brief comment:* |
| Does the protocol include information on forms of support participants will receive outside of the intervention under study (e.g., enablers such as transportation reimbursements, nutritional support, medical referrals, compensation for time off work, etc.)? |  |  |  |
| *Brief comment:* |

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| **Description of Research Risks and Benefits** | **Yes** | **No** | **Unknown** |
| Does the protocol adequately describe potential risks and benefits of the research? |  |  |  |
| *Brief comment:* |

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| **Eligibility Criteria** | **Yes** | **No** | **Unknown** |
| Does the protocol allow for the safe inclusion of vulnerable and/ormost-affected or high-risk populations? |  |  |  |
| *Brief comment:* |
| Is there anything in this study that would discourage or exclude the enrollment of a specific group or groups (e.g., women, men, adolescents, children, people living with HIV, people with diabetes, drug users, pregnant or lactating people, people over age 50, etc.)? |  |  |  |
| *Brief comment:* |
| Do you agree with that discouragement or exclusion and is it well justified? |  |  |  |
| *Brief comment:* |
| If you met the eligibility criteria, would you participate in this study? |  |  |  |
| *Brief comment:* |

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| **Description of Recruitment and Procedures** | **Yes** | **No** | **Unknown** |
| Does the protocol include and provide details on plans for engaging communities throughout the duration of the trial? |  |  |  |
| *Brief comment:* |
| Does the protocol specify plans for maintaining the confidentiality of participants? |  |  |  |
| *Brief comment:* |

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| **Procedures for Obtaining Free and Informed Consent** | **Yes** | **No** | **Unknown** |
| Are consent forms and study educational materials designed in a way that will be understandable and acceptable to participants? |  |  |  |
| *Brief comment:* |

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| --- | --- | --- | --- |
| **Results Dissemination** | **Yes** | **No** | **Unknown** |
| Does the protocol specify plans for dissemination of results to study participants and their communities? |  |  |  |
| *Brief comment:* |

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| **Other Impressions and Input** | **Yes** | **No** | **Unknown** |
| Does the protocol include any plans for sub-studies or evaluations that will address pragmatic concerns about implementing the intervention in a real-world setting (e.g., qualitative studies of patient experiences, cost comparisons between the intervention and the control, evaluations of adherence strategies, etc.)? |  |  |  |
| *Brief comment:* |
| Do you have any other suggested changes to the protocol? |  |  |  |
| *Brief comment:* |

*\*Adapted from the Protocol Input Questionnaire of the AIDS Clinical Trials Network (ACTG) Community Advisory Board (CAB).*