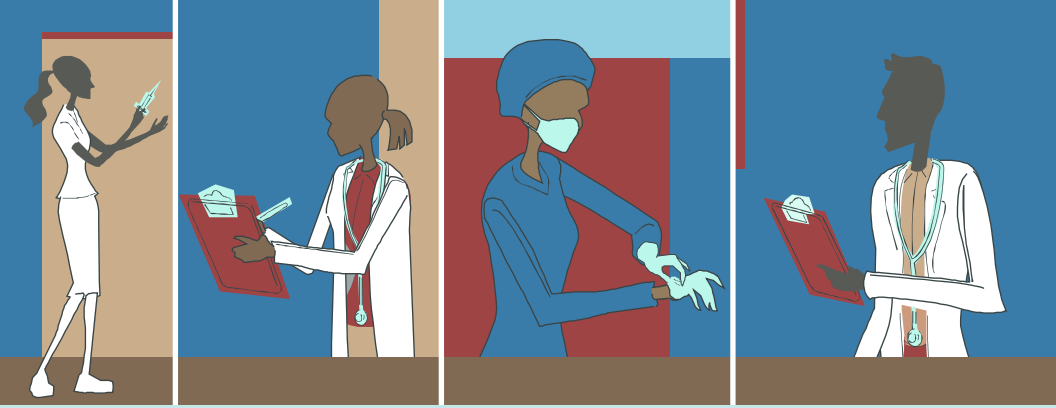

IMPAACT
International Maternal Pediatric Adolescent AIDS Clinical Trials Group

François-Xavier Bagnoud Center
University of Medicine & Dentistry of New Jersey

Community Advisory Board

Protocol Workbook

Protocol #: _____

Title:

_____

_____

_____

_____

CAB Member Name: _____

Key Contacts

Team e-mail:

_____

_____

Chair:

_____

Clinical Trial Specialist:

_____

Field Representative:

_____

Other:

_____

_____

_____

Protocol Team calls:

Day: _____

Time: _____

Protocol Review

Section 1: Schema/Study Design:

What is the main purpose of the study?

_____

_____

When this study is complete, how might the results effect HIV treatment?
(For example: "This study may improve treatment by correcting the dosing guidelines for abacavir in adolescents.")

_____

_____

Does this study seem to fit with the Mission of the IMPAACT network?

❑ Yes ❑ No

Comments or questions:

_____

_____

(Local or regional CAB representatives): **Is this study addressing a question your community thinks is important?**

❑ Yes ❑ No

(Community Representative on a Protocol Team): **Has this study been identified as one important to the overall community represented by IMPAACT research participants?**

❑ Yes ❑ No

Comments or questions:

_____

_____

[1] The mission of the IMPAACT group, which is worldwide in scope, is to significantly decrease the mortality and morbidity associated with HIV disease in pregnant women, children, and adolescents by:

- Developing and evaluating safe and cost effective approaches for the interruption of mother-to-infant transmission
- Evaluating treatments for HIV-infected children, adolescents, and pregnant women, including treatment and prevention of co-infections and co-morbidities
- Evaluating vaccines for the prevention of HIV sexual transmission among adolescents

What resource can you identify that will be needed to conduct this study and adequately support participants *(such as stipends for food or travel, phone calls, home visits, social worker or psychologists, peer support)***?**

What is the length of time needed to complete this study? *(Please note that the length of many protocols will depend upon when the last subject is enrolled. For example, if a protocol states that participants are to be followed on study for 24 weeks, the study will not end until the last participant to enroll has been on the study for 24 weeks.)*

What type of study is this?

❑ Treatment ❑ Prevention ❑ Clinical Management
❑ Vaccine ❑ Observational

What phase study is this?

❑ Phase I[2] ❑ Phase II[3] ❑ Phase III[4]

What is the study design?

❑ Blind ❑ Double-blind[5] ❑ Randomized[6]
❑ Control group[7] ❑ No control group
❑ Placebo[8] ❑ No placebo

Can this study be accomplished with a reasonable use of resources (time, money staffing)? *(In order to answer this question, think of whether or not you feel that time and money should be spent on this study. If it is a very important study for your community, spending money and time will seem worthwhile. If it is not very important to your community, then you may want to ask more questions about the resources that will be spent.)*

❑ Yes ❑ No Comments or questions:

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[2] The purpose of a **Phase I** study is to determine if the medicine is safe by testing it in a small group (5-30) of healthy people.

[3] If there are no serious safety problems in the Phase I study, the medicine is tested in a **Phase II** study looking at safety and efficacy in people with the disease being studied (more than 20 but fewer than 500 people).

[4] If Phase II results show medicine has no major safety problems and seems to work (be effective), researchers do a **Phase III** study looking at safety and efficacy in people with the disease being studied (Usually more than 100, and up to thousands of people).

[5] Double-blind means that neither the participant nor the researcher know which treatment has been assigned.

[6] **Randomization** is the process of computer assignment to a control group or a treatment group.

[7] The **control** group receives the standard treatment not the experimental treatment.

[8] **Placebo:** A dummy pill. A pill that looks exactly like the experimental medicine, but that contains no medicine at all.

What is the target population?

- ❑ HIV-exposed infants
- ❑ HIV-infected adolescents
- ❑ Breastfeeding women and their infants
- ❑ HIV-negative individuals at risk of HIV-infection
- ❑ HIV-infected infants or children
- ❑ Pregnant women
- ❑ Other _____

Section 2: Eligibility Criteria

Can you identify any potential problems with recruitment or retention of study participants or with adherence to the study requirements?

❑ Yes ❑ No

Comments or questions:

Are the eligibility criteria clear and understandable?

❑ Yes ❑ No

Comments or questions:

Do the exclusion criteria exclude only subjects who must be excluded to protect their health or to protect the ability of the study to clearly answer the research question? *(No one is being unfairly excluded from this study)?*

❑ Yes ❑ No

Comments or questions:

If qualified, would you participate in this study or enroll your child in the study? Would you recommend others who qualify to participate?

❑ Yes ❑ No

Comments or questions:

Do you think people at your site will want to participate in this study?

❑ Yes ❑ No

Comments or questions:

Section 3: Schedule of Evaluations

Is the number of research visits reasonable and manageable for a majority of the target population from your community?

❑ Yes ❑ No

Comments or questions:

Do you have any concerns that the requirements for the study place an unnecessary burden on participants? *(such as the number of visits required, length of study visits, number of blood draws, vaccinations, other tests and evaluations)?*

❑ Yes ❑ No

Comments or questions:

_____

_____

_____

Are you concerned about the impact of reading any questionnaires or surveys on participants? *(Consider in terms of length of time needed to complete, literacy level, poorly worded questions, or questions that may be very uncomfortable or disturbing to participants?)*

❑ Yes ❑ No

Comments or questions:

_____

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_____

Is there anything in this study that would discourage enrollment by a specific group? *(eg minorities, teenagers)*

❑ Yes ❑ No

Comments or questions:

_____

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_____

_____

_____

Do you have any concerns about stigmatization of study participants?

❑ Yes ❑ No

Privacy of study participants?

❑ Yes ❑ No

Comments or questions:

Section 4: Informed Consent

What are the potential benefits of participating in this study? Do the potential benefits to participants seem greater than the potential risks?

❑ Yes ❑ No

Comments or questions:

Are study risks for participants acceptable?

❑ Yes ❑ No

Comments or questions:

Are the following elements of Informed Consent clearly written and understandable?

- Purpose of this study ❑ Yes ❑ No
- Participation is voluntary ❑ Yes ❑ No
- Alternatives to participation ❑ Yes ❑ No
- Risks of participation ❑ Yes ❑ No
- Benefits of participation ❑ Yes ❑ No
- Numbers of participants in this study ❑ Yes ❑ No
- Method used to determine treatment assignment (randomization) ❑ Yes ❑ No
- Will the participant and the clinician know what treatment has been assigned? ❑ Yes ❑ No
- Required study visits and evaluations ❑ Yes ❑ No
- Person in charge of participants care while in study ❑ Yes ❑ No
- Length of study ❑ Yes ❑ No
- What will happen in the event side effects occur? ❑ Yes ❑ No
- Whether all test or evaluation results will be shared with the participant ❑ Yes ❑ No
- What will happen if the treatment fails? ❑ Yes ❑ No
- What will happen if the participant changes his/her mind about participating in the study? ❑ Yes ❑ No
- Privacy and confidentiality ❑ Yes ❑ No
- Whom to contact in the event of a problem or question about the study ❑ Yes ❑ No
- Disallowed medications ❑ Yes ❑ No
- Requirements for birth control? ❑ Yes ❑ No
- What will happen in the event of pregnancy (if applicable)? ❑ Yes ❑ No

Comments or questions:

Section 5: Other Issues

Does the community need more education about the study and the Informed Consent process?

❑ Yes ❑ No

Comments or questions:

_____

_____

_____

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_____

Do you have any ideas about what is needed in order to prepare the community for this study?

❑ Yes ❑ No

Comments or questions:

_____

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Notes

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Version 1.0 May 2007