September 5th , 2008

Christie Hand
IRB Chair
Future Generations

Dear Christie,

I would like to thank you for the concerns raised during the review. I apologize for not being able to respond earlier. We were involved with the launching of another project at the sites. I have revised the applications and forms to address the concerns.

1. ***Complexity of the consent form:*** *Given the population to be interviewed, the IRB found that the consent form was unnecessarily complex. We believe that it can be simplified without losing its integrity*.

   I have modified the consent form to bring down the reading level. The Johns Hopkins School of Public Health's Institutional Review Board (JHSPH IRB) has given wavier for documentation of informed consent to all participants since this is a minimal risk study. Because of this, the consent document will not serve as a "consent document", but will be used as a guide to the consent discussion. I have modified the Research Plan to reflect the "Oral consent" which will be sought now. I will also be handing out an information sheet to all participants regarding the study.

2. ***Certain wording in consent form:*** *The respondent is asked to sign a statement saying, "I agree to participate in this research study and to answer the questions asked." This seems to contradict the requirement that participants be free to not answer any question or to drop out at any time. This might be corrected in the simplification of the consent form with the following wording: "I understand and accept the conditions of my participation in this study."*

   Because of the waiver to get documentation of informed consent sanctioned to us and the modification in research plan to get oral consent, this section has been modified. Now the interviewer will discuss the points in the consent form with the participant . He/she will also hand out an information sheet about the study. After the participant makes her decision, the interviewer will mark appropriately and sign the declaration at the end of the form.

3. ***Recruitment and training of interviewers:*** *Because the surveys will be carried out by village women interviewers, the IRB requests that you describe how these interviewers will be recruited, trained, and supervised, including the general content and process for that training. The training you plan to provide these interviewers needs to address all the issues of confidentiality and ethical treatment of human subjects that you have noted in your proposal. By all indications, this research will present minimal risk to*

the participants; however, the interaction between interviewer and participant is of utmost importance, and thus the issues of recruitment and training need to be reviewed by the IRB.

The research plan has been modified and a new section on training and supervision has also been added. A section on Monitoring and Supervision of Dr Manjunath Shankar has also been added.

4. ***Further explanation of confidentiality:*** *The proposal is clear that a system of coding to the master file will be used to preserve the confidential treatment of study participants' names. However, in the interest of complete privacy, the IRB would like to know why names cannot be omitted from all records. If maintaining a record of the names of respondents is essential, please describe why you require a record of names and how they would be used in the research.*

   The requirement for keeping the names comes from the organizational perspective. Future Generations Arunachal (FGA) has started a new initiative to revamp its Health Management Information System. As part of this we felt the need to keep the names and link it with some sections of the questionnaire like Social demographic characteristics since this will be common across the different FGA projects. This will avoid inconvenience to the participants since the same information will not be asked as part of other projects in future. Another reason is-for data quality purposes, we are planning to visit a sample of the households and verify the information. For this we need linking the names at least on a temporary basis.

   If the IRB feels that there is a strong need for complete privacy, we are ready to omit all names. We propose to have a small half page with the participant name -attached as a separate sheet to the consent form. As soon as the verification of data quality is done we will destroy the small half page document thereby de-linking it with all records.

5. ***Final versions of the data collection instruments:*** *Although sample questions were given for the qualitative phase of the study, the IRB was concerned that there was no final version of the questionnaire available for review, nor was the quantitative survey available. We do understand your need to wait until you have results from the qualitative data collection to help frame your survey questionnaire. It is important, though, for the IRB to be able to review the final versions of each of these data collection instruments. After the above concerns (#1-4) have been satisfactorily addressed, the IRB anticipates approving your research plan; however, we request that, as soon as final versions of both the qualitative and quantitative instruments are available, they be sent to me and I will forward them to the rest of the IRB members.*

   I will abide by your instruction and submit the final versions of the questionnaires before starting the field survey to the IRB.

I will further abide by all the decisions and suggestions that the IRB may give in future including those from annual reviews. I will submit revisions of research protocol , if any to IRB for prior approval.

I have attached both clean and with track changes versions of all the relevant documents for your kind reference.

I look forward to hearing from you.

Thanks and Regards
Manjunath

FutureGenerations/Graduate School
To Research, To Demonstrate, To Teach – How Communities Change

October 6, 2008

Dear Manjunath,

Thank you for the protocol and subsequent revisions which you have submitted to the Future Generations Institutional Review Board. We appreciate your thoroughness in complying with the standards set forth by the Office of Human Research Protection and our IRB. We are happy to approve your research protocol and look forward to staying in contact with you to ensure that all continues to go well.

Sincerely,

Christie Hand

Christie Hand, Chair
Future Generations Institutional Review Board

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