Author’s response to reviews

Title: Perceptions of consent, permission structures and approaches to the community: a rapid ethical assessment performed in North West Cameroon.

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Version: 2
Date: 2 August 2014

Author’s response to reviews: see over
Dear editor,

We have the pleasure to submit the revised version of our manuscript entitled "Perceptions of consent, permission structures and approaches to the community: a rapid ethical assessment performed in North West Cameroon". The authors would like to thank the reviewers for their very useful comments and suggestions which allowed them to improve the manuscript. All the reviewers’ concerns have been addressed and the corrections effected in the text.
Reponses to comments raised by Reviewer 1

<table>
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<th>Comments</th>
<th>Responses</th>
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| **Major Compulsory Revisions**  
1. At present the paper suggests in the background, methods and discussion section that decisions about research participation may be made by on behalf of competent adults by other adults, such as community leaders and heads of family. While is this primarily a report of a social science study, it is important to recognise that this is a problematic assertion. International guidance and regulation recognises the role of others in the consent process, for example as gatekeepers to communities, but consistently holds that consent to research cannot be given by others on behalf of competent adults. This paper should contextualise its discussion on this topic within the international policy and debate and may either wish to make the controversial claim that proxy consent on behalf of competent adults is acceptable in this context (cultural relativism) or highlight the issues that researchers may encounter when reconciling international guidance with local cultural norms for decision-making. | We realise that some of the findings relating to proxy consent may be controversial and have given more thought to how this is discussed. We have tried to distinguish gatekeeping permission structures from consent given on behalf of another adult, and have added a section on this in the Discussion (page 16, lines 26ff). |
<p>| <strong>Minor Essential Revisions</strong> | |
| <strong>General comments:</strong> | |
| 2. There are multiple typos and grammatical errors to be corrected (there are three in the abstract for example – Background is not spelt correctly and the clauses ‘transcribed and coded following themes’ and ‘Respondents held relatively sophisticated understanding of consent’ need correction). The paper needs careful proofreading. | The typos and grammatical errors have been corrected and the manuscript proofread by third parties for polishing. |
| 3. In many places in the m/s spaces are missing and words have run together but this may be an artefact of the submission system. | We think that this is an artefact of the submission system since these spaces do not appear in the manuscript uploaded. |
| <strong>Background section</strong> | |
| 4. Page 3 paragraph 1 The opening sentence the description of the consent process assumes that it results in consent to take part in research (rather than declining to take part). | The sentence has been adjusted and now reads “The informed consent process is one of communication between researchers and potential study participants resulting in a decision about whether to take part in a given piece of research or not [1, 2].” (page 3, lines 1-3). |
| 5. Page 3 Paragraph 2 second sentence – If stating that in some communities it is usual for male members of the family to make decisions on | References have been included (page 3, line 9). |</p>
<table>
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<tr>
<th>Number</th>
<th>Paragraph/Section</th>
<th>Original Text</th>
<th>Revised Text</th>
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<tbody>
<tr>
<td>6.</td>
<td>Page 3 paragraph 2 third sentence</td>
<td>See the comments immediately above and in the section on major compulsory revisions – these three references do not provide unqualified support for this sentence but discuss the problems that arise in such circumstances.</td>
<td>We have rephrased this to read &quot;In other settings, community leaders, chiefs or elders take on a ‘gatekeeping’ role and determine access to whole communities by researchers [6, 8, 11, 12].” More appropriate references have been added. P3 lines 9-11.</td>
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<td>7.</td>
<td>Page 3 paragraph 2 fourth sentence</td>
<td>Please clarify the point here – arguments have been made that information sheets and consent forms should not be borrowed from other settings, and that they are often incomprehensible for participants in the settings for which they were developed. As such, claiming that participants are insufficiently educated to understand them begs the question of why they should be expected to do so.</td>
<td>We have revised this to read “In addition, research participants may not have the scientific literacy to understand information sheet templates developed in more developed countries, [14, 15], thus the way in which information on the potential risks and benefits of research is provided must be refined.” (p3, lines 13-15).</td>
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<td>8.</td>
<td>Methods</td>
<td>In the methods section it would be useful to know why there are such discrepancies between numbers of females and males in the IDIs and the effects this may have had on the data.</td>
<td>We have explained this discrepancy in the Methods section: “The disparity in the number of males and females was due to the fact that most health workers, community leaders and NGO members were men, and women were mostly interviewed as community members.” (page 6, lines 13-15).</td>
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<td>9.</td>
<td>Methods</td>
<td>More details about the analysis would be welcome. For example what theories informed the coding, how were the main themes arrived at – where they inductive or deductive?</td>
<td>We have described the analysis in more detail – “Interviews were transcribed anonymously, and interviews conducted in Pidgin were translated into English. Translation was done by experienced social scientists. To check for consistency, some of the interviews collected in Pidgin were translated twice by different people and the two English versions compared. Comparison showed good agreement. Close reading of the text was followed by coding based partly on themes identified in earlier research, and partly allowing themes to arise de novo. An inductive approach was used with themes of the latter type.” (Page 7, lines 8ff).</td>
</tr>
<tr>
<td>10.</td>
<td>Results</td>
<td>Need to be consistent with references for quotes (some say FGD, some don’t mention source of data.</td>
<td>This remark has been taken into consideration. The source of the data has been added to all references for quotes.</td>
</tr>
<tr>
<td>11.</td>
<td>Results</td>
<td>If I understand the Study Participants section correctly only a single researcher was</td>
<td>The researcher gave his approval to be quoted in the paper despite being</td>
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interviewed. The researcher is quoted a couple of times and is relatively identifiable as the only person in that category. At my institution the staff who monitor data issues have requested that we ensure that categories of participants have a minimum of 4-5 persons to limit the chances of individuals being identified. Alternatively your researcher may have reviewed and happy to be quoted in this relatively identifiable manner, or the likelihood of his identifiability may have been covered in detail in the consent process for this research and consented to.

possibly identifiable through being the sole researcher interviewed.

Authority Structures in the Communities

12. In the first paragraph under this heading you mentioned that most respondents favoured the argument that consent to research should first be given by the Fon. Coming back to the issue discussed earlier about voluntariness and proxy decision-making, and the points made in some of the papers you cite, are you sure that the Fon is being asked to consent (i.e. give proxy consent on behalf of competent adults) or is the role more of a gate-keeper or similar role where the research is reviewed and assent / permission is given to discuss it with the quarter head and others. You refer to the Fon’s permission (rather than consent) later in the paper (page 12).

You are right that the correct English word here is “permission”. However, some respondents used a word corresponding more closely to ‘consent’ in the original language – we have tried to clarify this issue in the discussion. (page 16, lines 26 ff).

13. The term ‘quarter head’ is first given in a quote and should be explained there.

Correction effected (Page 10, lines 10-11).

14. The quote where the final sentence is ‘Questions will be addressed but to you and not to the others’ is not entirely clear to me. Is the father talking about himself in the third person earlier in the quote and then in the second person in this final sentence?

We went back to the recording. It is the father talking about himself in the third person. The sentence has been adjusted to read “Questions will be addressed but to you [the father] and not to the others.” (Page 10, line 17).

Sensitisation processes

15. The second quote in this section raises a very important issue regarding what health workers see as their role in providing information which is then not addressed in the paper.– ‘to make them participate…so that most of them will make the right decision. When I do like that about 97% of the population participates. Only a few will refuse’. I think if this issue is being raised (the role of information provision being seen as ensuring the ‘right’ decision to participate is made) then this needs to be addressed.

We agree this is an important issue, and have commented on this in the Discussion –“In this study in North West Cameroon, where there is no patient association and health research is not as well established as in Kilifi, the trusted groups are community leaders and the formal health system. It is therefore vital that members of these groups have a clear understanding of the nature of informed consent. Comments by a health worker in an in-depth interview suggested that he saw his role as maximising participation rather than facilitating a decision-making process. Training of members of both groups is clearly important if the trust placed in each is not to be misused.”
**Discussion**

16. I'm not sure that the statement 'this relatively sophisticated understanding of consent may be explained by previous involvement … and contrasts with studies in communities in Kenya and Ethiopia…' can be justified. The cited studies discussed barriers to understanding of specific research protocols may have been replicated in this context if this study was conducted with participants or prospective participants in a particular study, rather than community members being asked general questions about consent. This REA was conducted prior to a genetic study aiming at demonstrating the genetic basis of podoconiosis, very much like that in Ethiopia. The study context was therefore very similar to that in Ethiopia, and the questions on consent arose during the REA as they had in Ethiopia.

17. Paragraph 2 of the discussion focuses on voluntariness, the following two paragraphs discuss different issues and then voluntariness and authority structures are returned to. I think it would be useful to bring the discussion of voluntariness together in a single place and have made comments about how the topic may be addressed above. The discussion of voluntariness has been brought together in a single place as suggested (page 16 line 12 – page 17).

**References**

18. Reference 14 might usefully be updated to Bull SJ, Farsides, B, Tekola Ayele, F. (2012) Tailoring information provision and consent processes to research contexts: the value of rapid assessments. JERHRE, 7(1): 37-52. This reference (now 23) has been updated.


20. I think this paper would be strengthened by a brief consideration of the limitations of this study. We have added a paragraph on study limitations on page 18.

**Discretionary Revisions**

**Results**

**Authority Structures in the Communities**

21. The phrasing 'However, some women expressed the opinion that the decisions taken by men … Nevertheless they acknowledged' sounds as if this may have been a grudging admission – was that the case? Or might it equally be

We have altered the phrasing as suggested (Page 11, lines 3-5).
appropriate to say ‘Some women …However they noted …’

<table>
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<tr>
<th>22 Information requested when approaching the community</th>
<th>We have added a substantial paragraph discussing this on page 15 lines 20ff.</th>
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<td>This is stated to be a very important area where advice may be given to researchers about what issues to cover in consent processes, but is only given a paragraph. Might it be usefully expanded with further insights into views? Likewise could it be considered in more than a single paragraph in the discussion section. Alternatively, perhaps this topic could be omitted if there isn’t room to develop it further.</td>
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## Reponses to comments raised by Reviewer 2

<table>
<thead>
<tr>
<th>Comments</th>
<th>Responses</th>
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<tbody>
<tr>
<td><strong>Major Compulsory Revisions</strong></td>
<td></td>
</tr>
<tr>
<td>1. For full appreciation of the paper, the English version of the semi-structured interview guides should be provided to the reviewers as complementary information.</td>
<td>The revised version of the paper has been submitted alongside the English version of the semi-structured interview guides.</td>
</tr>
<tr>
<td>2. The modalities of translation and back translation of the Pidgin version of the semi-structured interview guides should be briefly described</td>
<td>Translation was done by experienced social scientists. To check for consistency, some of the interviews collected in Pidgin were translated twice by different people and the two English versions compared. Comparison showed good agreement. We have added a statement describing this on page 7, lines 10-11).</td>
</tr>
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<td>3. It should be confirmed that the decision to use verbal consent has been approved by the relevant ECs (by the way, there is apparently a slight contradiction here between the use of verbal consent and the statement in the discussion that “in most of the communities the participants were comfortable to give written consent”). The way verbal informed consent was documented should be specified (e.g., audio recording? Signature by the person administering the consent?)</td>
<td>The decision to use verbal consent was given by the Cameroon National Ethics Committee and the Research Governance and Ethics Committee of Brighton &amp; Sussex Medical School. For the present study, verbal consent was obtained from participants and digitally recorded. We have added a phrase describing this on page 6, line 5.</td>
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<td>4. Some more details should be given on the sampling of study participants. This is also important to show that the sample was representative of the community and that there were no major selection bias (e.g., people with previous exposure to agricultural or health research could have volunteered to participate, so resulting in a group with a better knowledge of research than the average).</td>
<td>A purposive sampling strategy was used for the recruitment of health workers, NGO members and community leaders while a stratified random sampling was used for the recruitment of community members based on pre-defined inclusion criteria for enrolling participants. A sentence describing this has been added on page 6, line 9.</td>
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<td>5. The authors should describe how audiotapes were transcribed/how data were coded or anonymized, and how participants’ confidentiality was ensured (which maybe especially relevant in this study, since some sensitive opinions on hierarchical structures have been expressed)</td>
<td>Interviews were transcribed anonymously, and interviews conducted in Pidgin were translated into English. Codes were then developed based on the different themes that had previously been developed from hypothesis. We have explained this more clearly on page 7 under ‘Data analysis’.</td>
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<td>6. Some parts of the paper may give the</td>
<td>This was a point identified by both</td>
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impression that REA aims at providing information with the ultimate objective of “obtaining” the informed consent, rather than for conducting an appropriate consent interview at the end of which the participant will either accept or not (e.g. “gaining informed consent”, “successful recruitment”). If this is not the case, these parts could be reworded.

This issue has been addressed by adding a section on desire to know about potential risks into the Discussion (page 15, lines 20ff) – “Respondents did not specifically mention a desire to know about the potential risks related to research. They seemed to be more interested in the benefits and importance of the research and other issues such as confidentiality and duration of research than the potential related risks. Nevertheless, they emphasized that they wanted to be given full information about the research. Underestimation of the potential risks attached to research, particularly for a clinical trial or genetic research, would weaken the informed consent process [1-4]. Informed consent presupposes that subjects are well informed about the study, the potential risks and benefits of their participation and that it is research, not therapy, in which they will participate [32]. More studies aiming to investigate the perceptions of community members about the potential risks they think could be associated to research are encouraged in our setting.”

<table>
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<th>7. Some parts of the results’ section may give the impression that it is taken for granted that any research will be beneficial, e.g. respondents emphasize the “benefits” but do not mention the “risks” of a research (underestimation of potential risks attached to a research, e.g. to a clinical trial with an investigational medicine, will per se weaken the informed consent process). Some parts of the results’ section also shows that getting the chief’s approval will very often result in general agreement to consent. If a priori trust in hierarchies generally pushes/encourages people to consent to research, then the chiefs’ capacity to critically appraise a research proposal is key to avoid community exploitation by “bad research”. Similarly, if a priori trust in health staff encourages people to consent to research, there is the risk of therapeutic misconception. These aspects could be addressed in the discussion more in-depth, because they may weaken the informed consent procedure in practice, despite a good theoretical knowledge.</th>
</tr>
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<tr>
<td>This issue has been addressed by adding a section on desire to know about potential risks into the Discussion (page 15, lines 20ff) – “Respondents did not specifically mention a desire to know about the potential risks related to research. They seemed to be more interested in the benefits and importance of the research and other issues such as confidentiality and duration of research than the potential related risks. Nevertheless, they emphasized that they wanted to be given full information about the research. Underestimation of the potential risks attached to research, particularly for a clinical trial or genetic research, would weaken the informed consent process [1-4]. Informed consent presupposes that subjects are well informed about the study, the potential risks and benefits of their participation and that it is research, not therapy, in which they will participate [32]. More studies aiming to investigate the perceptions of community members about the potential risks they think could be associated to research are encouraged in our setting.”</td>
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<th>8. The limitations of the work have not been clearly stated. For instance, this paper describes community perception around informed consent, authority structures and approaches to the community, but it does not look at other local knowledge’s and beliefs that may have an impact on the perception of a research, such as beliefs about taking blood/tissues, nor at the community perception of “research” and related concepts. This may be due to the fact that this REA was not linked to a specific study, but it should be acknowledged in the text, and the authors could specify if they are planning to further look at it in additional research.</th>
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<td>Information on other issues such as the community perception of ‘research’ was gathered but will be presented in a separate manuscript since this one is already long. Both reviewers brought up the issue of study limitations, so we have added a section on these to the Discussion (p18).</td>
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9. The reference of the Helsinki Declaration is very outdated. Please correct by putting the most recent one (2013)

The reference to the Helsinki Declaration has been updated (reference 4).

**Discretionary revisions**

1. Some of the challenges mentioned in the background may be considered ubiquitous and not specific to resource-poor settings, even if they are exacerbated for externally-sponsored studies in developing countries (e.g. poor understanding of the informed consent may be ubiquitous because the language of the consent is not adapted to lay people, or due to therapeutic misconception; but this will be exacerbated in poor contexts by illiteracy/poor formal education).

This part of the paper has been reworded taking into account the comments

2. In the background, ethnicity is mentioned together with linguistic features as a factor that may have an impact on the informed consent procedure. Is this impact due to “ethnicity” as such, or rather to the cultural and socio-economical characteristics of a given group?

Ethnicity and linguistic issues are mentioned as factors that may have an impact on informed consent, based on the assumption that each ethnic group has its characteristic culture and language. In information provision for example, we notice that certain scientific words do not have exact or direct translation in the local spoken language and that poses a barrier in the understanding of the research protocol or information sheet.

A few tables summarizing the main findings per theme could greatly improve the readability of the study findings

A table has been provided summarizing the main findings per theme and is found on page 24.
Interview guide

Rapid Ethical Appraisal Prior to Study of Genetics in Podoconiosis

Information Sheet

My name is …………………. I am working with a study team from the Institute of Tropical Diseases and Environment, Buea. The topic of our study project is ‘Rapid Ethical Appraisal Prior to Study of Genetics in Podoconiosis.’

The study is a collaborative study with investigators from the Institute of Tropical Diseases and Environment, Buea (Jonas Arnaud Kengne, Prof Samuel Wanji) and Brighton and Sussex Medical School/Sussex University (Dr Gail Davey).

The objective of the study is to explore issues and concerns associated with ethical issues in general and informed consent in particular to genetic research requiring the collection of biological samples in Cameroon. At the end of the study we aim to find out how research is understood in Tubah and Ndop districts; to discover community perceptions surrounding who should give permission for genetic research within the family and to explore understanding of informed consent for medical or genetic research. Finally, the findings will be used as input to the upcoming project which aims to investigate the genetic basis of podoconiosis in Tubah and Ndop districts. We also believe that the outputs of this study will be useful to future researchers planning biomedical research in Cameroon.
Rapid Ethical Appraisal Prior to Study of Genetics in Podoconiosis

Consent Form

Hello and welcome to this session. My name is ___________ and I am working with a study team from the Institute of Tropical Diseases and Environment, Buea.

The study team is currently undertaking a Rapid Ethical Appraisal Prior to Study of Genetics in Podoconiosis in Cameroon. We are doing this interview to learn from your experiences, perceptions and knowledge about conditions related to ethics and research related to genetics. You were invited because we think you have sufficient knowledge and experience about what we are trying to know. We are having similar interviews and discussions with scientists/researchers; field workers; and the community of Tubah and Ndop districts.

I will ask you very general questions being interested in all your ideas, comments and suggestions. There is no right or wrong answer. All comments—both positive and negative—are welcome. Whatever you say will not make us feel good or bad or affect us in any way. So feel free to give frank and honest answers.

You have probably noticed the voice-recorder. If you don’t mind, I will record the interview. The purpose is to ensure I don’t miss anything you said. Since people often say very helpful things in these interviews and I can’t write fast enough to get them all down, I prefer to use voice-recorder.

We won’t use any names in our reports. All comments are confidential, used for research purposes only. If you wish to discontinue the questionnaire at any time, you may. However, all the information you give us is highly valuable to the study.
community Interview Guide

(Patients plus community members)

Thanks for agreeing to take part and explain who you are.

Introduce reason for the interview.

Please tell me a bit about yourself?

This community?

A. Questions that will elicit information about community and personal views on podoconiosis

As you know we are trying to understand more about podoconiosis. Would you be happy to tell me about your illness? Would be happy to tell me what you know about this disease?

Can you get treatment for podoconiosis?

What do you understand about the treatment you can get for podoconiosis?

B. Questions to elicit information about the research we are going to do.

What do you think research is?

Is there a difference between research and health care?

Have you ever participated in research?

Can you tell me about your experience?

Prompts
  • Way treated
• Consent process
• Information provided
• What happened after research etc.

How do you think a study team should approach this community?

How would you feel if you were asked to participate in such a study?

What would put you off being part of such a study?

If you were interested, what kind of information would you want before making a decision?

How should this information be given to the community?

C. Genetic studies

What do you think ‘genetics’ means?

Why do you think genetic studies might be important?

Who should give consent in a genetic study?

How should these people be approached?

Play this section a bit by ear – some focus groups and some individuals – in a way piloting consent process and seeing what issues come up.

Would you prefer written information?

Are you happy with signing a consent form?
Do you mind other people knowing about your disease and studying your body?

Do people want to know the results of studies they have been part of?

How should a study team tell this community the results of a study?
Healthworker Interview Guide

Please tell me a bit about your background and training, and how you came to be doing this kind of work?

What do you understand by ‘research’?

Have you asked people from this area to consent to research before?

Explain that you are particularly interested in the PROCESS of consent, that is, what they think should happen prior to someone agreeing to participate and once they have done so.

If yes:

We are interested in consent in the context of biomedical research.

How well do you think this community understands the idea of research?

How would you explain the dominant models of decision-making in this community?

Do you think people in this community can reach free and voluntary decisions about healthcare/research?

Please tell me a bit more about your experiences with previous consent processes with this community:

Prompt:

- Identification of recruits
- Publicizing of research opportunity
- Stages (approach, inform, engage, consent, enrolment)
- Providing information
- Checking understanding
- Assessing voluntariness
- Beliefs and false beliefs
- Privacy, confidentiality

Are there any common problems with getting consent from members of this community?
Have you experienced these problems?

How did you try and overcome the problems?

Were you happy that you had the resources and the skills needed to overcome the problems?

**Shift the discussion to look specifically at the genetic study**

How easy do you think it is for participants to understand our interest in genetics?

Are there special problems with understanding and information provision?

What do you think is the most important information to be provided about a research study like this?

What do you think participants would most want to know about this kind of study?

Do you think that genetic research poses any other specific problems or risks not encountered in other research settings?

Why do you think people would participate in this kind of study?

**Concluding questions:**

What kind of information will make the consent process easier for you to conduct?

How do you think we should tell the community about the study results?

Are there any other issues we haven’t covered that you’d like to discuss?
Researchers/Scientists Interview Guide

Thank the participant for giving their time, give them an idea of how long you will take, what recording you will do, get permission for recording and presence of the other her person and introduce them. Describe our project....Anonymity and confidentiality.

**Introductory questions** – biographical, experience, training, role in the project

What do you hope to achieve in this project?

(Demonstrate your knowledge of the protocol by alluding to recruitment needs and then say something like, “Could we talk for a while about consent in quite general terms?”

How would you define consent? (What do you see as the purpose of the consent process?)

When designing consent processes in the past what did you think were the most important aspects?

*Possible prompts*
- Information – what’s the most important information to be provided?
- Communication – What’s the best way to provide information about research?
- Voluntariness, non-coercion, non-inducement – Is it possible to make sure the decision is free and voluntary?
- PROMPT: Economic constraints / social constraints
- Why do you think people are participating?
- Therapeutic non therapeutic distinction - Do you think they understand they are participating in research not healthcare?

**Can we move to speaking abut the community that will be involved in this project?**

Have you worked with this community before?

Are you aware of any colleagues having worked with them?

Do you think research in a developing world context raises different issues to the same research being carried out elsewhere?

*Possible prompts*
- Cultural issues and diversity
- Language and literacy
- Poverty
- Gender issues
- Cost benefit analysis
- Knowledge infrastructure
- Social representations

Do you think this project will raise any particular issues in relation to recruitment?

Possible prompts
- nature of study i.e. genetic
- nature of the samples
- nature of community
- prevalent decision making procedures
- previous experience of participant group

Where would you or do you seek guidance on these issues? (How would you address these issues?)

What do you find most useful when trying to address these issues?

For this or previous projects were you under any particular obligations due to funders’ requirements, ethics committee requirements or regulations?

If Yes,
Do you consider these requirements to be well informed and/or reasonable?

When gaining consent from your participants, do you feel that you and your team are able to operate to a standard that would satisfy you, were you to be a research participant in this project? When conducting consent processes:

- What issues arise?
- What parts go well?
- What parts concern you?
- How do you address these problems?

If they say NO

Why is that?
What if anything would enable you to change that?

Do you have good reason to believe that you have captured what is important to the people you will be recruiting, as they may not share your concerns and may have rather different interests and priorities?

**AND finally**, is there anything else about consent processes that we haven't raised?

What else, if anything, would you like as a researcher to help you design consent processes?

Would you like feedback from this study?

**Rounding off comments and thank you.**