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## CeSSRA Transcontinental Conversation Between IRBs

21 February 2008

### Proceedings of the Videoconference

Moderators:

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Cleveland: Patricia A. Marshall, Ph.D., Professor of Bioethics, CWRU, School of Medicine

### Discussion Summary:

On 21 February, CeSSRA convened approximately 35 IRB members and researchers in Kampala and Cleveland for a two hour videoconference on the general topic of the ethics of international research. Discussion covered issues of reciprocity/ cross IRB relations, local context review, social science research review, informed consent, and broader cross cultural considerations.

Below is a summary of each of these topics, as well as notes on specific participants' contributions.

### Reciprocity/cross IRB relations

Communication between IRBs was highlighted by the US-based participants as one potential area that sometimes has frustrating results especially regarding access to information (transcripts of review minutes) from international IRBs. However the 'International' participants noted that providing transcripts of minutes was not practical given the confidentiality implications and noted further that they normally would provide summarized extracts of the minutes and send them to the investigators. This type of information was deemed sufficient. And that they would encourage the US IRBs to request that information (preferably from the investigators, but also directly from the IRB if preferred) as supplementary information about the review process if the approval letter was deemed insufficient.

Another major challenge to reciprocity and sharing minutes is the cross cultural difference in what IRBs are looking out for in the review process. Because IRBs may be looking out for different points, the UG-participants pointed out that sending minutes of meetings may not necessarily answer the questions that the US-based IRB may be concerned with. The meeting was provided with several real-life experiences by some investigators including differences in ascertaining legal guardianship for minors and permission sought from husbands by women to participate in a study. The conference agreed that this was an area that would benefit from increased communication between IRBs via exchange of minutes even though that provided a challenge in terms of timing the minutes/meetings to reduce delays in the review process.

Related to timing of IRB approvals for international multi-sited protocols is the challenge of which IRB setting provided the primary approval when both IRBs demand to see each other's approval first. The potential of having one overall IRB approval, perhaps co-signed by both IRBs was suggested as a way that would reduce



the challenge of having two independent review processes. However, because some critical issues of interest to the IRBs differ by cultural setting, some participants argued that requiring independent approval from both sides be maintained even if it were possible to achieve review in both settings and minutes shared within the same time or with a short turnaround/feedback period.

### **Local Context Review**

Related to the above discussion on reciprocity, local context review generated exciting debate regarding differences in expectations and process undertaken to achieve it. The US-based participants explained the methods they use to achieve local context review but acknowledged that it was sometimes very difficult to achieve it especially for certain geographical areas (Papua New Guinea, Kenya) where the resources and capacity had not quite evolved as in Uganda. A suggestion that a local Investigator on the protocol should serve as a local context reviewer was discouraged as a potential source of conflict of interest.

The Uganda-based participants raised some reservations about the process especially citing how difficult it would be to achieve local context review depending on who qualified to conduct it. In response, the first method used by the US-based UH IRB was the reliance on 'locals' who resided in the US but were born and bred in the 'local' cultural context and went through a vetting system to ensure they were qualified to perform the duties. The response from the UG-participants raised concerns about the cultural authenticity of such 'locals' as well as the potential that they may have agendas against the researchers/protocols under review which would compromise their impartiality in the review process. In response the UH-based IRB indicated they were comfortable with their careful, strong vetting process to ensure no people with agendas were involved in the local context review.

A third option raised by the UG participants was the possibility of considering a CAB does play a role in the local context review process. However the conference was told of an experience when a US-based IRB refused to consider the views of the local CAB as replacement for local context review. It should be noted that this example was raised mainly in response to the complexity of some issues within the process of achieving informed consent that are discussed in detail below.

### **Social Science Research**

This discussion opened with the observation that social science research is reviewed by biomedically dominated IRBs especially in Uganda. And that this raises the question of whether the review is sometimes unfairly harsh particularly in respect to rigorous 'scientific' review.

The UG-based social scientist participants further suggested that perhaps social science research should have its own IRB. However one challenge highlighted was whether there would be enough social scientists in the country or qualified enough to serve on the IRBs. Moreover the UG-based participants noted that even on the biomedically dominated IRBs, there were few social scientists on the boards. Participants recommended that more training of social scientists should be encouraged as a way to increase the number available to serve on IRBs.

The CASE IRB members mentioned that their IRB is not only exclusively made up of social scientists but have also taken specific consideration to review social science protocols including having a community representative, conducting seminars and offering a template/s to guide preparation of IRB materials.

The conference agreed that it was important for IRBs to aim at striking a balance between sound scientific methodology and protection of human subjects when reviewing protocols regardless of if they were social science or biomedically oriented ones.

## **Informed Consent**

The discussion commenced with Prof. Marshall's observation of three key components of informed consent namely: voluntarism, confidentiality, and the assumption that people understand what they're signing. However in reality as field work progresses those assumptions frequently come into question.

One main challenge pointed out by the conference was that the language requirements reflected in the consent forms from a US perspective were not only difficult to achieve but sometimes not applicable in the international settings. Further, because of the numerous requirements for informed consent the forms were generally considered very long and tedious to implement. UG-based participants even noted that at times the length of the forms and the complexity of the language hinders rather than facilitates understanding the material.

Another suggestion raised was the possibility of using the CAB to determine informed consent especially in contexts where language limits translation of complex scientific concepts or literacy levels limit capacity to achieve individual informed consent.

One interesting issue for future consideration that arose was what would be the appropriate length of a form to obtain informed consent.

UG-based participants observed that informed consent remains a challenge in poor international settings because of illiteracy and/or inability to read/write English language, translation challenges which include loss of meaning as concepts are translated from "science" to English to Local languages', and poverty of participants.

## **Cross-cultural considerations**

The CASE IRB participants noted that they make consideration for cultural differences in consent processes and have a template with guidelines that allow for requesting a waiver of written consent, getting oral consent or leaving out some parts of the informed consent that are deemed irrelevant to the cultural context. However the CASE IRB members noted that investigators do not usually seek to use these guidelines.

One suggestion that arose was whether IRBs could be willing to accept community consent. However the meeting was informed that while community consent or family consent cannot substitute for individual consent, there are certain contexts where it can be applicable. Many guidelines agree that regardless on whom or which people you rely on for consent or information you cannot take away the importance of an individual having an opportunity to give individual consent.

An important issue raised was how to deal with the challenge of what happens when research/protocol that has been providing care ends? It was noted that for many international contexts it may be very difficult for participants to separate between research and care due to poverty. Time did not allow for further discussion of this point.

## Transcript:

Welcome and introductions from the Pls, format issues, and participant introduction.

McGrath: Suggestion to bump procedures, as we are already behind time

Wabwire-Mangen: Thinks human subjects protection vs. scientific review is a very important issue to discuss, and maybe we can come back to it in the end.

Rwabukwali: yes, later

Marshall: Reciprocity has been an issue in multi-sited projects when many IRBs review the same protocol, particularly a challenge with international work.

Cola: IRBs want to move efficiently, secondary to the protection of human subjects. In the US, many institutions have reciprocity already, for efficiency to save investigators from multiple reviews. International reviews require local context review of protocols. The keys to making this run smoothly are efficiency, reciprocity, and the sharing of information between IRBs. A problem has been getting information from international IRBs.

Marshall: What kind of information?

Cola: We would like to have meeting minutes

Rwabukwali: Which level IRBs are the ones with reciprocity? Are they national, university-based, regional, etc? How can we go about creating a system like that here?

Ecuru: UNCST goes back and forth with other IRBs and researchers often reach a stalemate between IRBs; dialogue might help to improve this. But instead of waiting until there is a problem, the dialogue should begin early in the process of review, and IRBs should be collaborating from early on. UNCST encourages interface with local IRBs at the institutional level, not the national level.

Kityo: Please clarify in Cleveland what you mean by local context review? This is an efficient way to do things? Projects within Uganda allow and accept approval from other IRBs in the country. Has never had a formal request for dialogue between IRBs, though no one would refuse to discuss issues. Even at the national level, there is no approval without local approval first.

Cola: Reciprocity in the US is between institutions. Local context review is a processes which uses people who are experts on a location as reviewers to understand cultural norms. Potentially a different way to do the same things is to use information from the local IRB to do a context review. This requires meeting minutes to qualify potentially for local review. The key is timing for efficiency, to make sure notes are available before US IRB meets.

Marshall: Is there a precedent for IRBs to share their meeting minutes?

Cola: This has started with a group in Papua New Guinea, and they are able to use the information as local review.

Marshall: Interesting; they share transcripts, which is a summary of issues from the meeting.

Kamya: Will information given from local IRBs always be accepted for local context review? Gives the example of a cohort of HIV positive children and the requirement of consent from a legal guardian. The definition of guardian is different cross-culturally, and in this case the US institution would not accept the local definition of legal guardian.

Ibingira: Sharing of information should be encouraged, and required for either side. Some issues with this are in cultural definitions across institutions- for example, consent or standard of care. Would prefer to have home institution review the protocol first.

Wyza: As Alice and Sandra know, Ugandan IRBs want Case approval first, and vice versa. There is sometimes a tension between comments of the different IRBs. Both want to have the other approval first- they all want the same thing.

Rwabukwali: Why not use the local co-PI for local context review? Why use a person who has left the country?

Simon: Local context review occurs the way it does because IRBs have scarce resources. The people used may not be the best. We should think about local context review as a gold standard- what would be best? Maybe a community advisory board is best at the local level for review, instead of an institution. Don't limit options because of resources.

Erdey: Has had experience as both investigator and member of IRB. In many countries, has found Case approval easier to get than local approval. Part of this is financial- US funds cannot be released without approval. IRBs are careful with selecting someone to conduct local context review, the people really are experts. The new model in Papua New Guinea, where IRB members are used to do local context review, is being piloted and may be good for the future.

LaMantia: Local investigators cannot be used for local context review because of a conflict of interest.

Wabwire-Mangen: We should get the chairs of IRBs to talk to each other. Minutes taken by IRBs might be different, because the issues discussed are different. Agrees that investigators should not be the ones to do review, but is uneasy with who is doing the reviewing. Chairs of IRBs talking to each other is preferable to address cultural issues.

Ochieng: During the review, we write minutes and then send sections of those to investigators for comments. The comments then should act as minutes and can be communicated to the home IRB. Sending out full meeting minutes would be a violation of privacy.

Rwabukwali: Moving on to social science research. Many studies are done in collaboration with social scientists, but the reviews are often conducted by medical IRBs, why? Maybe there should be social science specific IRBs? Sometimes the comments from medical IRBs are irrelevant to the research being conducted, in social science the most important issue is how people behave. Social scientists are at a disadvantage because of the standard of review. Is it possible to be reviewed by peers?

Neema: Am the only social scientist on a medical IRB. Spends lots of time justifying methods as the token social scientist. Separate IRBs would be best, though medical IRBs also consider important issues.

Kityo: Thanks for suggestion of social science IRBs. Sometimes other types of research like basic sciences also suffer. It is true that there are few social scientists on IRBs and in general. Maybe the key then is to train IRBs on key issues of what makes social science different? People's backgrounds give them bias.

Sanchez: Is part of an IRB which only reviews social science protocols, because the same issues do not always apply. The goal is still human subjects protection. Also, have online training for education about ethical concerns.

Greksa: Am the chair of the social science IRB just mentioned. Most research that they review is minimal risk, except for issues of confidentiality. For cultural context review, always prefer to use local IRB. The local IRB needs to have an FWA for this, which is true in Uganda. This assures minimal risk to participants in research. Regarding minutes from IRBs, the issues are different because many things are not discussed explicitly which may be an issue for another IRB.

Farkas: Human subjects protection vs. scientific review- the science may affect the protection of human subjects and a balance in the review process is important to be true to protection.

Kakande: UNCST requires a team of certain members on each IRB, so there cannot be one that is pure social science. So how do we review social science protocols? Wants evidence. One insisted on using a hypothesis, though not needed for that work. There is a need for a minimum standard of issues to review social science protocols, regardless of the IRB composition. Also need more social scientists in general.

Ecuru: As Nelson said, there are national guidelines from UNCST regarding IRBs, but does not have objection to social science IRB—it just needs to be arranged logistically at an institutional level. Likes having a mix of reviewers.

Rwabukwali: I rest my case

Ibingira: The goal is protecting human subjects, their privacy, confidentiality, and rights. The issues relevant in reviewing research are true even for social science review.

Marshall: Informed consent is the key for ethics in research. Has three main components: communication, understanding, comprehension to ensure the potential for voluntary participation. Documents used for obtaining consent assume that people have the capacity and understanding to participate, though in doing research, these assumptions are questioned. What are some issues you have faced in reviewing and implementing consent?

Simon: In South Africa, has been forced to use language in consent forms that doesn't make sense in the local context. HIPAA has added to this.

Sanchez: IRBs take culture very seriously in reviewing protocols, even those without written languages, they require a verbal script and culturally appropriate language. The ideal of informed consent in the US is not always applicable across settings. "we understand"

Marshall: Even in the US there are still issues. For example, a study may have a 14 page document, which is hard to understand and this is a big problem when applied to reality. Who can provide permission for someone

else? In a genetic study in Nigeria, many women in urban (20%) and rural (50%) areas required their husbands consent for participation.

Rwabukwali: The process is cumbersome and the issues of consent are old issues. What constitutes consent? Few people actually achieve this and the process needs to be shortened. Jargon makes the process more difficult.

Wabwire-Mangen: The complex language of consent is legal and medical. Who is the consent for? Gives example of a study where the consent was longer than the instrument, due to US requirements. Given advice from a CAB, they prepared a short consent document more appropriate for the context. The US IRB however would not back down and they had to attach the simple, shorter form to the original long consent.

Neema: Translational issues are difficult, because some words don't change well, especially in back-translation. For example, the word "risk" has been translated into Luganda to mean "danger" and had to be changed. Sometimes one word takes an entire paragraph to translate.

Ibingira: Agrees with others. What should be the duration of the consent process? And how can we put into practice these ideas?

Ochieng:

<<technical problems and loss of connection>>

Ochieng: Regarding consent, education is a challenge because translation to local language is hard. You have to translate from Science to English to Luganda. There is also a conflict between research and medicine. Research participants are also patients, and recruitment can be potentially coercive. Says standard US consent documents are 15 pages, and have jargon, but half of a page is too little for all of a study's information. Consent differs between the individual, families, and the community.

<<more technical problems>>

Marshall: Consent clarification between the group and individual. Western views prioritize the individual and assume capacity for understanding. According to international guidelines of CIOMS, Helsinki, Nuffield, etc. regardless of who else is involved, the individual still needs to agree. Gives example of HAPMAP in Kenya and Nigeria, where there is community engagement and consultation, not consent because that is from individuals.

Rwabukwali: That is an issue for the future.

Greksa: Regarding social science research, there is a template available for consent forms. However, that can be changed or there are waivers for written consent. Though this is not often done by researchers and sections are still included even if they are irrelevant. IRBs need information from the local context to change the forms, but it can be done.

Rwabukwali: Standard of care involved in health research can be coercive. Poor people want care. How do we make the care sustainable? What is the responsibility of the researcher?

Ochieng: In the research versus care dilemma, there are lots of cross-cultural issues. Especially poverty and educational status are big issues and need to be considered in protocols and consent. For example in language, things like a virus may not be locally understood after translation.

McGrath: Time to wrap up. To summarize the big topics:

Conversation between IRBs is a fruitful exercise. E.g. guidelines can be shared.

There is a need to explore avenues for improving the consent process

IRBs have evolved so much over time but in general share common goals especially the protection of subjects while ensuring good research is conducted.

Will send out more information regarding reviewing of social science research

New Ways forward- different from old consent. Lots has changed in the past 20 years. But we all share the same goal of protecting human subjects. Thank you.

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