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Consent to Research in Madagascar: Challenges, Strategies, and Priorities for Future Research

Elysée Nouvet, Simon Grandjean Lapierre, Astrid Knoblauch, Laurence Baril, Andry Andriamiadanarivo, Mihaja Raberahona, Chiarella Mattern, Lorie Donelle and Jean Rubis Andriantsoa

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Article abstract

The ethical conduct of research in any setting hinges on the voluntary and informed consent of research participants. Working towards consent that is truly voluntary and informed, however, is far from straightforward, and requires attention to contextual factors that may complicate achievement of this ideal in specific research settings. This paper is based on Madagascar's first "Consent complexities in health research in Madagascar" workshop, held in Antananarivo, Madagascar, in October 2018. It identifies a number of challenges encountered by individuals responsible for the conduct or oversight of health research in Madagascar related to informed and voluntary consent. Key challenges identified included: adaptation of consent tools into local dialects and for limited literacy populations; perceived acquiescence of potential participants regardless of actual preference based on cultural norms; perceived time pressures within tight project timelines to collect data as quickly as possible, limited time for consent processes; fears and taboos related to specific research procedures or topics; and, uncertainty about how best to approach and verify the validity of individual consent in contexts where traditional leaders' influence is conventionally sought out and respected. Potential strategies for responding to each of these challenges are proposed, as are key questions meriting further study.

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Consent to Research in Madagascar: Challenges, Strategies, and Priorities for Future Research

Elysée Nouvet[a], Simon Grandjean Lapierre[b,c,d], Astrid Knoblauch[b,e], Laurence Baril[f], Andry Andriamiadanarivo[g], Mihaja Raberahona[h,i], Chiarella Mattern[b], Lorie Donelle[j], Jean Rubis Andriantsoa[k]

Résumé

La conduite éthique de la recherche, quel que soit le contexte, dépend du consentement volontaire et éclairé de ses participants. Cependant, assurer un consentement volontaire et éclairé est loin d'être facile, et nécessite une compréhension des facteurs contextuels qui peuvent compliquer sa réalisation dans des contextes de recherche particuliers. Cet article est basé sur le premier atelier sur les « Complexités du consentement à la recherche en santé à Madagascar », qui s'est tenu à Antananarivo, Madagascar, en octobre 2018. Y sont présentés différents défis liés au consentement libre et éclairé auxquels font face les personnes chargées de la mise en œuvre ou de la surveillance de la recherche en santé à Madagascar. Les défis clefs identifiés lors de l'atelier comprennent : la traduction et l'adaptation des protocoles pour usage en dialectes locaux et auprès de populations peu scolarisées; l'acquiescence perçue des participants à la recherche, conformément aux normes culturelles, et qui pourrait masquer leurs préférences réelles; les contraintes de temps engendrées par des échéanciers de recherche serrés qui allouent peu de temps à la collecte de donnée, et donc aux processus de consentement; l'existence de craintes et de tabous par rapport à certaines procédures ou certains sujets de recherche; et l'incertitude quant à comment approcher et comment s'assurer de la validité du consentement individuel dans des contextes où l'avis des chefs traditionnels est communément cherché et respecté. L'article propose des stratégies pour faire face à ces défis et des questions devant faire l'objet de recherches plus poussées.

Mots-clés

éthique de la recherche, consentement, Madagascar, recherche sur la recherche, santé mondiale, Afrique subsaharienne

Abstract

The ethical conduct of research in any setting hinges on the voluntary and informed consent of research participants. Working towards consent that is truly voluntary and informed, however, is far from straightforward, and requires attention to contextual factors that may complicate achievement of this ideal in specific research settings. This paper is based on Madagascar's first "Consent complexities in health research in Madagascar" workshop, held in Antananarivo, Madagascar, in October 2018. It identifies a number of challenges encountered by individuals responsible for the conduct or oversight of health research in Madagascar related to informed and voluntary consent. Key challenges identified included: adaptation of consent tools into local dialects and for limited literacy populations; perceived acquiescence of potential participants regardless of actual preference based on cultural norms; perceived time pressures within tight project timelines to collect data as quickly as possible, limited time for consent processes; fears and taboos related to specific research procedures or topics; and, uncertainty about how best to approach and verify the validity of individual consent in contexts where traditional leaders' influence is conventionally sought out and respected. Potential strategies for responding to each of these challenges are proposed, as are key questions meriting further study.

Keywords

research ethics, consent, Madagascar, research on research, global health, Sub-Saharan Africa

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INTRODUCTION

Voluntary and informed consent to research participation constitutes a universal minimum ethical requirement of research involving human participants (1,2,3). This requirement cannot be understood outside the history of widely publicized and less widely denounced human rights abuses in the name of research. This history precedes but includes in the 20th century: Nazi scientists during World War II forcing concentration camp prisoners to take part in inhumane and often fatal experiments (4,5); intentional infection with active Hepatitis of disabled minors at the Willowbrook School in New York State in the 1950s and '60s towards developing a vaccine (6); nutritional experiments on indigenous minors in Canadian residential schools that denied already malnourished children in control and treatment groups adequate nutrition (7); and the infamous Tuskegee experiments that left African American "volunteers" to suffer and in many cases die from treatable syphilis in the name of scientific "natural"

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observation until the 1970s (8). These “scandals”, while initially framed as anomalies, are today understood to have been possible and indeed justified within deeply engrained and long-standing systems of values and discrimination that have normalized the routine neglect, abuse, exploitation, and dehumanization of racialized, indigenous, disabled, institutionalized, and other socially constructed minorities (9,10). The importance of research ethics governance in general, and commitments to voluntary and informed consent in particular, cannot be understood outside this history of abuse and unequal treatment in research of socially marginalized and less powerful groups.

While none today would deny that informed and voluntary consent are non-negotiable in scientific research, normative interpretations of this requirement and the practices and processes intended to uphold consent have become a focus of increasing discussion and critique from researchers working in global health contexts (11-14). Core to normative research ethics’ definition of valid or meaningful consent to research are a number of presumptions about how humans everywhere should and can affirm their rights to participate in research or not. The very notion of autonomous decision-making is for many at odds with how they make decisions: i.e., it is informed by their sense of connectedness and obligation to others and/or in consideration of the impact of their decision on others and their community (11-15). Power imbalances between healthcare professionals and the general population, and norms of deference linked to gender, age, class, or other differences may also affect perceptions and actual framings of what it means to voluntarily participate in research (13,16-18). Ensuring voluntariness may be further complicated in high poverty contexts, where those approached for participation in research may have high need or desire for the income, healthcare, social recognition, or other benefits that participation may bring (19-23). Lack of familiarity with the concept of health research as distinct from healthcare or limited literacy may also complicate communication of consent information, adding to the challenge of ensuring that potential participants understand a research project prior to consenting (16,17,19,24).

A growing number of scholars and organizations have stressed the importance of attending to cultural and/or community differences in expectations and standard processes for conducting ethical research in different settings (1,11,12,25-28). Doing so can better equip these stakeholders to engage in research activities in ways that account for such differences, reduce misunderstandings, and inform the tailoring of research processes to best uphold commitments to core research ethics principles. This paper identifies a number of “consent to research” complexities and challenges identified by individuals involved in the conduct or oversight of health research in Madagascar. It is the outcome of the first “Consent complexities in health research in Madagascar” workshop, held in Antanarivo October 10, 2018, co-organized by Western University, the Madagascar National Biomedical Research Ethics Committee (CERBM), and the Institut Pasteur de Madagascar (IPM). Several proposals for addressing such challenges, including ideas for further research identified by workshop attendees, are discussed. Until now, there has been no Research on Research (RoR) to identify and better understand particularities to the ethical conduct of research in the context of Madagascar. This workshop, and the discussions on consent complexities it generated, are timely, if not overdue. Health research activities are on the rise in Madagascar, as in many African countries. With such expansion comes responsibility: for those involved in research in the country, it is important to reflect on existing practices and develop adjustments, if and where needed, to better protect research participants and the ethical integrity of research in the country. While focused on the Malagasy context, it is anticipated this paper and the workshop methods it describes will be of value to research stakeholders in other national settings.

CONTEXT AND METHODS: THE “CONSENT COMPLEXITIES IN HEALTH RESEARCH IN MADAGASCAR” WORKSHOP

Several of the authors (EN, SGL, AK, LD) were funded through a Canadian Institutes of Health Research (CIHR grant #15610) grant to explore complexities of consent and compensation in global health research. EN and SGL met with the CERBM in August 2018 to learn more about identified research needs related to consent in the country. Members of the CERBM felt consent posed an important challenge, especially in the context of work with rural populations. The CERBM suggested that a workshop with other individuals with experience conducting research in the country could be a fruitful way for the CERBM and the Canadian researchers to learn more about consent complexities in the country. The workshop was not designed as a study, but as a first step towards identifying consent-related research questions for the Malagasy context. It was facilitated by EN and SGL, with the agenda approved by the President of the CERBM in advance. The request to develop an article based on workshop discussions came from attendees themselves, who regarded the exercise as valuable for its affirmation and clarification of several key challenges faced by researchers, and to further reflections on how these might be mitigated in the future.

Workshop attendees: sampling strategy

We recognize that the perspective of actual participants in research is crucial to clarifying complexities of consent in any context. For this workshop, we had a limited budget, limited capacity for participants, and could not agree on a recruitment strategy that would allow meaningful and diverse representation from this key stakeholder group. On this basis, a decision was made to focus recruitment on individuals involved in the conduct or oversight of research. Invitations to attend the workshop were sent to all contacts of the IPM and the CERBM, including healthcare centres, universities, private research institutes, non-governmental organizations (NGOs), and all members of the CERBM. These organizations were asked to identify one or two individuals with direct experience engaging in consent processes with patients or community members in the context of research in Madagascar.

Thirty-three individuals from 15 organizations attended the workshop. These included individuals with a range of research experience, i.e., junior researchers working primarily on the front lines of data collection, experienced social scientists and epidemiologists, clinician researchers, and expert members of the CERBM. Organizations represented at the workshop included: the National Institute of Public Health, the University of Madagascar, Antananarivo Hospital Centers, the Malagasy Academy (l'Académie Malgache), the Institut Mérieux, several NGOs (Action Against Hunger, Actions de Terrain, Intégration, Autonomie – ATIA, Professionals for Fair Development – GRET, Médecins du Monde, Population Services International Madagascar), and private and public scientific institutions (Centre d'Infectiologie Charles Mérieux, Institut Pasteur Madagascar).

Structure and documentation of workshop discussion

In keeping with our primary objective of learning more about challenges to meaningful consent experienced by health research-investigators and regulators, the workshop featured small group discussions followed by a synthesizing exercise.

Small group discussions

Following a brief overview of the plan and objectives for the day, workshop attendees were invited to form four groups of approximately eight individuals. To ensure a diversity of perspectives in each group and to promote cross-organization learning, attendees from the same organization were asked to join separate groups. Each group was asked to identify a volunteer to take detailed notes on the discussion, with an understanding that notes would be fed back to the larger group. Small group discussions were organized in three timed blocks (30 minutes each). The first discussion block invited attendees to share those challenges related to consent that they regarded as the most common or important to troubleshoot. In the second block, attendees were asked to identify normative expectations for consent processes that were not challenges, in their experience. The final block asked attendees to describe strategies they had used in response to challenges experienced, and to identify what further research or resources might facilitate navigation of consent complexities in the country, moving forward.

Synthesizing exercise

The final hour of the workshop involved regrouping the attendees to discuss and begin to develop consensus on key complexities and recommendations. In three rounds corresponding to the three small group discussion blocks, each group presented a summary of main points raised in their discussion. One of the workshop facilitators (EN) tracked the points raised by each group on a flip chart, asking attendees to confirm the accuracy of these notes as she proceeded. All attendees had the opportunity to add to challenges, norms, and recommendations for next steps identified by members of other groups as their colleagues presented them, and these comments were also recorded on the flip chart. A summary of the workshop was prepared in the days following the workshop, based on the large group discussion recorded on flip chart notes. This report was circulated to all workshop attendees for their review, to provide the opportunity for additional suggestions and comments, and to ensure it represented an accurate record of key points raised in the workshop. Small suggestions on wording were obtained in this process. The revised report forms the basis for the present article.

Ethics

We did not obtain ethics approval for the conduct of this workshop, as it was not conceptualized as research, but rather as an intersectoral consultation aiming to advance sharing and understanding of consent challenges in the country (see Appendix 1: Invitation to workshop letter). It was thus framed as such. Verbal consent was sought and obtained from all workshop attendees at the workshop regarding an eventual submission for publication of a summary of the workshop discussion, following a request from attendees that we pursue this avenue.

RESULTS: IDENTIFIED CHALLENGES TO INFORMED CONSENT IN MADAGASCAR

Workshop attendees had no trouble identifying several complexities of consent in the context of Malagasy health research. These fell into two main categories: 1) challenges related to consent form preparation for national review and local use; and 2) challenges of ensuring meaningful consent of research participants during data collection. Specific challenges within these broader categories are presented below, along with potential mitigation strategies and avenues for future research and dialogue (Table 1).

Table 1: Challenges to informed consent in the Malagasy context and suggested strategies and research questions for addressing these

Challenge areas	Underlying structural factors	Proposed mitigation strategies	Proposed avenues for future research and dialogue
1) Consent form preparation for national review and local use			
Language and clarity Protocols developed in French, English, or other languages must be translated into Malagasy and from Malagasy into local dialects. Technical terms may not have local-language equivalents or may be unfamiliar to participants. Attempts at explaining or paraphrasing terms adds length and complexity to documents/conversations.	• Tension between desire for concision and clarity, and for thoroughness and accuracy. • Tension between formal ethical norms and local norms and realities.	• Feasibility studies, development and dissemination of training on how to develop (clear, appropriate) consent documents. • Anthropological fieldwork by researchers and trainees, to develop clearer understanding of potential participants' day-to-day lives. • Development and dissemination of "sample" consent documents, in local languages, that demonstrate effective information sharing. • Development and dissemination of "sample" visual and audio-visual tools to support effective information sharing.	• What specific items or aspects within consent discussions and forms represent the most consistent challenges to informed consent in specific studies? Are there patterns in the challenges to the understanding of consent discussions across or within Malagasy participant populations? • What terms, analogies, or paraphrasing are being used to explain terms that have no equivalent in local dialects, if any? Are these effective in increasing Malagasy research participants' ability to provide informed consent (do these increase understanding)?
2) Optimizing meaningful consent during data collection			
Pressure to consent Politeness norms in some Malagasy communities prioritize agreement. If invited, participants may not feel comfortable declining to participate in a study.	• Tension between formal ethical norms and local norms and realities.	• Anthropological fieldwork by researchers and trainees to develop clearer understanding of communication norms in research communities. • Giving participants enough time to reflect on their decisions about participation.	• Would providing more time to participants for their decision-making result in more individuals expressing a preference not to participate? • What amount of time (hours? days?) would be sufficient to reduce the influence of norms of politeness on decisions to partake in research (assuming these do influence consent to research in at least some Malagasy communities)?
Addressing taboos Key research procedures and topics may be the subject of taboos (e.g., blood samples, discussions of sexuality). Researchers may feel uncomfortable addressing, or uncertain of how best to address, such topics.	• Tension between formal ethical norms and local norms and realities. • Lack of material, institutional, and educational support for Malagasy researchers.	• Development of pre-deployment training for frontline researchers, that focuses on making explicit expectations and fears about taboos.	• Are there respectful and sensitive ways of discussing topics that relate to taboos?
Addressing concerns about signatures Participants may feel uncomfortable signing consent documents, whether or both because they are unable to read these documents themselves, and/or in light of local histories in which rights were ceded by signing documents.	• Tension between formal ethical norms and local norms and realities. • Lack of material, institutional, and educational support for Malagasy researchers.	• Development and dissemination of training materials outlining alternative means of documenting consent. • Development and dissemination of "sample" consent documents that allow participants to choose between different means of documenting consent.	• What (various) meanings and implications does the act of signing carry in rural Madagascar? • What alternate means could be acceptable for documenting consent?
Individual consent Given norms of respect for chiefs' and families'/communities', researchers may feel uncertain that potential participants' choices genuinely reflect personal preferences.	• Tension between respect for collective/community and individual decision-making.		• How can Malagasy ideals of respect for the community, family, and for chiefs be reconciled/balanced with health research ethics norms that emphasize individual decision-making?

Time limitations Researchers may face limited time to engage in consent processes. Participants may not have time for consent forms and discussions that explore, clearly and in comprehensible terms, all categories of information normally required by REBs. Deciding what information to prioritize may be difficult.	• Tension between desire for concision and clarity, and for thoroughness and accuracy.		• What aspects and dimensions of consent documents should be prioritized? • What level of detail would best serve to inform potential participants without overwhelming them?
Ability to ask questions Participants may not feel free or comfortable asking questions of researchers. In the absence of questions, researchers may have difficulty assessing participants' understanding.	• Tension between respect for collective/community and individual decision-making. • Tension between formal ethical norms and local norms and realities.	• Anthropological fieldwork by researchers and trainees, to develop clearer understanding of communication norms in research communities. • Develop and share strategies for strengthening trust between researchers and potential participants. • Ask participants to explain key information in their own words, as a means of assessing their understanding and to elicit questions.	• Do potential or confirmed participants truly feel hesitant to ask questions of researchers? On what bases? How does hesitancy intersect with social position, gender, or other factors? • What methods can serve to gage potential or confirmed participants' understanding of research projects and terms of participation?
Concentration Consent and information conversations may include topics or occur under conditions that are distracting to researchers and/or participants.	• Lack of material, institutional, and educational support for Malagasy researchers to identify and assess the ethical significance of participants who may seem distracted during consent processes.	• Anthropological fieldwork by researchers and trainees, to develop clearer understanding of potential participants' day-to-day lives.	• Are there particular topics, research procedures, or conditions that participants would define as limiting their ability to process and participate as fully as possible in consent processes?

Challenge area 1: Consent form preparation for national review and local use

Preparation of consent forms was stressed as a challenge by a number of workshop attendees. Research in Madagascar is almost entirely funded by non-Malagasy based institutions and agencies. This implies multiple ethics approvals of the protocol and study instruments: from non-Malagasy partner institutions, as well as from the National Ethics Committee in Madagascar (the CERBM). Many international partnering institutions recommend and expect the adoption of specific language in consent forms as a condition for their approval of protocols. A first complexity of consent is related to internationally funded research in Madagascar, and the need to adapt study protocols that include non-Malagasy institutional language preferences for the Malagasy context.

Consent forms often need to go through multiple translations: into French sometimes, into Malagasy, and then, into Malagasy dialect(s). The latter occurs in the field via translators, if (as is often the case), researchers are not versed in the local dialect spoken by potential participants but also because Malagasy dialects do not have standard written forms. For limited literacy populations – a significant demographic in Madagascar research – it is expected that all consent form components will be verbally explained to potential participants. Some scientific and medical terms have no equivalent in standard Malagasy or dialects. Workshop attendees noted a tension between the desire to create forms that are as concise as possible so that these can be read to research participants in their entirety, and the need to explain concepts through a series of words or sentences because there is no equivalent term in the target language or dialect.

Echoing a recurring theme in the literature (29,30), many attendees were uncertain as to the level of detail they should include in consent forms. A few wondered if it was important, for example, to name funders, or the particular bacterium in a bacteriological study. They expressed worries that such detailed information could confuse and reduce, rather than increase, potential participants' understanding of a study. Both junior and senior researchers worried about "cut and paste" approaches to consent forms that negated the importance of ensuring the language and information in forms were adapted to specific populations, participant education level(s), particular concerns, and prior exposure to information, studies, or methods. These practical complexities and concerns are well founded, and echo those raised by researchers and ethicists interested in the quality and challenges of informed consent in African clinical research (13,31-34). In a systematic review that looked at clinical research participant understanding for consent, across 21 African studies, over 50% of participants were found to have consented without understanding key concepts relevant to the study in which they volunteered (35). Seventy percent appeared unclear that they were even involved in research (35). In contexts of limited literacy and when working in languages that do not possess equivalent terms for key research concepts, supporting informed consent necessitates careful planning and innovation to adapt consent instruments and procedures (29,35,36).

Workshop attendees identified a dearth of opportunities for formal training on the drafting of protocols and consent forms as a factor complicating efforts to deal with these issues, especially for students and early career researchers.

Challenge area 2: Optimizing meaningful consent during data collection

Workshop attendees identified five key challenges to the ideal of informed and voluntary consent arising at the "field" level, during data collection. Three were understood as stemming from Malagasy cultural beliefs, norms, and socio-economic conditions, and as being more pronounced amongst research participants living in rural regions and with limited literacy. The remaining two pertain to conditions that may be more directly in the researcher's control.

A cultural norm of the Malagasy answering 'yes' even when they are thinking 'no'

One of the cultural norms that workshop attendees identified as challenging was the observed tendency of Malagasy peoples, whether or not in the context of research, to answer 'yes' even when they may be feeling or thinking 'no'. One attendee, a research assistant experienced in obtaining consent in the country, described this practice manifesting when, for example, they presented research to individuals in rural areas and some individuals agreed before they finished explaining what the study was about or involved for those who might enroll. In the assessment of workshop participants, the Malagasy may choose to express acquiescence, whether to follow norms of politeness or perhaps, sometimes, simply to help bring a tiresome line of questioning to a quicker end. This makes it more difficult to ascertain whether or not a participant's consent actually represents their preference.

Taboos and fear

Certain studies involve the collection of biosamples. While biosample collection may involve a wide range of biological materials, the collection of blood samples was highlighted by workshop attendees as being uniquely challenging in the Malagasy context. Fear of blood drawing was common, particularly in village settings, with the occasional result that once the procedure was mentioned, potential participants seemed to stop listening to any new information, even as they assured researchers to continue, and that all was fine. Workshop attendees expressed uncertainty about whether potential research participants' distraction due to this fear could undermine their ability to absorb information and thus provide informed consent.

Certain acts, including intentional removal of blood from the body, whether through donation or for biosample purposes, as well as speaking about sexuality, were noted as being taboo to many Malagasy participants. Whether or not respecting such taboos represented best practice in populations whose health needs required engaging these topics (e.g., through studies on causes of high teen pregnancy rates), was discussed without resolution. Some proposed the best way forward in such scenarios was to respectfully avoid talking about the taboos directly, for example, by framing a study about adolescent sexuality as being about adolescent activities. Others were uncertain that this aligned with a commitment to honesty and transparency in the provision of information to potential participants. The animated and unresolved discussions around what to do in the face of taboos highlighted an apparent division amongst workshop attendees: between those who felt ethically challenged reframing research in ways that would obscure the connection of this research to taboo practices or topics, versus others who regarded such reframing as respectful and pragmatically necessary. The latter perspective merits critical consideration. It does indicate an extractive approach to research, wherein a complexity of consent is reduced to being an obstacle to the researcher's agenda.

Fear and concerns around signatures

In many remote areas of the country, the arrival of "outsiders" in villages can recall unwelcome experiences related to mining or, dating further back, colonial government missions. These historical precedents can lead to (at least initial) associations of researcher "outsiders" with dishonest intentions and risks of harm. In workshop attendees' experience, learning about such histories and ensuring villagers understand how the intentions of researchers differ from those of past outsiders may be critical to not only building trust, but also to ensuring potential participants understand that they have the right to refuse without risk of harm. Some potential participants may trust researchers and find value in research projects while still distrusting the normative requirement of sealing the consent process with a signature.

Respect for leaders (les chefs)

The respect accorded to traditional leaders poses a particularly salient challenge to the ideal of individual consent in Madagascar. Norms of respect for (usually male) heads of households, traditional leaders such as kings, and elected leaders such as village chiefs, require research teams to seek consent from these individuals before approaching any of those for whom they are assuming the role of leader. The extent to which members of communities feel able to refuse (or accept) participation in a study once their leaders have given approval (or refusal) is unclear.

Time pressures

Noted by several attendees engaged in field-based data collection was the tension between time needed to engage in meaningful consent discussions with study participants, and limited time for data collection. Budgets can be lean, and daily or weekly expectations lived as quotas for questionnaire completion or collection of bio-samples put pressure on researchers to sometimes rush the consent process. Those being recruited do not have unlimited time either. Potential study participants were observed to tire and grow distracted or annoyed if consent forms and discussion were overly long or detailed.

Creating an environment conducive to questions and discussions

Time pressures and cultural norms can conspire to create situations where potential participants are reluctant to ask questions. Researchers explained feeling uncertain of potential participants' level of understanding when, after a lengthy explanation of a study, participants had no questions for them. Currently, researchers are uncertain whether a lack of questions or discussions prior to participants providing their consent indicates an actual lack of questions and concerns, reflects participants' fatigue in the face of lengthy study and participant explanations, or represents a situation where, for reasons unclear to the researcher, a potential participant has questions or concerns but is not expressing these. Researchers were not sure how to proceed in such scenarios. One attendee noted that they felt uncomfortable at the prospect of pressuring unwilling potential participants to speak up.

Researcher engagement in consent processes

Some workshop attendees who worked on teams in the field admitted that researchers themselves sometimes lack concentration during consent processes. Reasons for this included the time pressures just described, or researchers perceiving consent as a chore that one just had to "get done", prior to starting data collection. Whatever its cause, it was noted that researchers' lack of concentration could lead to accidental omissions of consent information, and limited attentiveness to potential study participants' questions or even apparent discomfort.

Challenges and complexities not identified in workshop discussions

Notably absent in workshop discussions was the limited choice of those invited to participate in research. This struck the first author (EN), and co-facilitator of the workshop, as worth underlining. She was primed to note such an absence based on her involvement with a World Health Organization working group dedicated to advancing good participatory practices in the conduct of clinical research and based on her long-standing interest in bringing under-recognized perspectives to bear on global health research ethics (37-41). A key theme in the literature on consent to research in sub-Saharan Africa centres on the challenge of ensuring voluntariness in the context of projects or studies that provide participants with free, valued, and otherwise inaccessible options for medical consultations, treatment, diagnostic tests, or even benefits such as food supplements (20, 36). Only one participant in the workshop briefly referred to the poverty of participants and their need for healthcare as a complicating factor for consent in the Malagasy context.

Many have argued for the importance of community input and collaboration in research ethics guidance development and oversight (26-28,31-35,37-39,42-45). Collaborating with members of researched populations for research ethics development and oversight has been advocated as part of broader commitments to minimize harm, decolonize research ethics, foster respectful researcher-participant relations, and avoid the objectification of research participants. There is a global move to advance evidence-based or practical ethics by listening to and recognizing the value of research participants' experience-based insights for guidance. No attendee in the workshop raised the possibility of involving community representatives in the development or improvement of informed consent processes, forms, or research ethics training more generally. No attendee suggested that further research on decision-making or consent processes and challenges in Madagascar could or should be developed in partnership with representatives from researched communities and localities.

The absence of calls for collaboration or engagement with individuals in researched communities is worth noting. This absence arose in the context of a workshop limited to individuals involved in recruitment, enrollment, and oversight of research in Madagascar; but that does not render it less significant. This absence may reflect prevalent understandings and approaches shared amongst those responsible for the conduct of research in the country. It may indicate prevalent understandings about how and with whose input best practices for the conduct of research could be advanced – in this case, without the involvement of participants. It may also reflect a dominant and uncritical conceptualization of research as an extractive endeavour, i.e., one that is organized around participant enrollment and data collection goals, and that engages with researched populations for the exclusive purposes of fulfilling research agendas without significant input from those populations. Such an extractive approach to research reduces consent complexities to pragmatic barriers. Histories, ongoing power relationships between researchers and those approached for participation, and social-cultural ideas and norms animating participants' engagement with research are seen as barriers to research in need of troubleshooting, rather than something to explore in dialogue with those being approached for research participation.

Several strategies were proposed in relation to the challenges encountered by researchers as they seek to support potential participants' consent decision-making. These are described below and fall into two main categories: *practical strategies* to address challenges related to consent, and *recommendations* for further dialogue and empirical investigation.

Practical strategies to address consent challenges related to protocol preparation, navigating cultural norms and taboos, and time pressures

There is a need, especially pressing for Malagasy students and junior researchers, for more training in the "how to" of formulating protocols and consent forms. Workshops focused on the preparation of consent forms, in particular, could help de-mystify the process and prepare researchers to thoughtfully engage with this, in both a pragmatic and respectful manner.

Pre-field anthropological training could orient researchers to the diversity within as well as across specific Malagasy populations and encourage them to be informed about prior activities by "outsiders", and therefore be ready to explain their

own presence and purpose in relation to these historical precedents. Related to this latter point, researchers could be primed to remain intensely curious in general, and attentive to relations of power, apparent discomfort, preconceived ideas, or conditions that could influence participants' abilities to understand and freely consent or refuse participation in research. Supervisors and educators could further emphasize the importance of being present, alert, and responsive to potential misunderstandings during consent processes, so as to ensure the quality and ethics of research.

Specific open-access tools that could be created include: a reference document with suggestions for translating scientific and medical terminology into Malagasy dialects, and audio-visual tools to support research participants' (especially limited literacy participants') understanding of study goals and methodologies. Researchers need to slow down when necessary to ensure potential participants have the time to ask questions and express concerns. One attendee recommended the strategy, described in the literature over 20 years ago (46) and which they found effective, of asking a potential participant to summarize the consent information just explained to them.

The National Biomedical Research Ethics Committee in Madagascar (CERBM) currently allows researchers to adapt consent processes in response to population needs or individual preference – for instance, by allowing limited-literacy populations and communities who might be wary of providing signatures to "outsiders" to provide their consent orally. If the experience of workshop attendees is representative, this flexibility is not widely known and rarely practiced in Madagascar. The creation of a Malagasy/French open-access document outlining when and why oral consent may be used, and with what risks and advantages, could help legitimize it as an ethically acceptable alternative.

Recommendations for further discussion and research

Overarching tensions highlighted in the workshop merit further discussion and empirical exploration in and of themselves, to support the development of best practice guidelines for the ethical conduct of research in Madagascar. No consensus was reached amongst attendees with respect to the challenge of determining how minimalist can be information shared in a consent process while remaining sufficient for consent to remain informed and thus valid. This challenge was clearly entangled with time pressures lived by all attendees: pressures to "complete" the consent confirmation process, collect data, and complete research. Some attendees seemed to hope that there might be a quick fix to the "problem" of long consent forms and consent processes. Such comments raise concerns: some front line health researchers may be engaged in poor practices by rushing consent processes. A number of senior and junior researchers noted as much, calling for a change to the research culture so that more time was expected and reserved for initial consent processes. Others questioned the feasibility of such a change, especially in a context where virtually all research is funded by international partners and projects that often have strict timelines. How to bring about this change in culture and norms, as well as the impact this could have on the quality of consent processes, remains to be seen.

Ensuring that the content and wording of consent forms is accessible to potential participants in accordance with their literacy level and cultural context is a known requisite of ethical consent to research participation processes (26). While workshop attendees recognized this need, no clear strategy for meeting it was identified. Procedures, such as for blood biosamples which are the subject of common fears and taboos, may need to be explained and addressed to a degree that potentially exceeds their place in a study. Further research, conducted within distinct and diversely located projects throughout the country, is needed to determine what constitutes culturally and contextually appropriate types and levels of information to support informed consent. As one attendee noted, research is needed to understand the specific impact on participant understanding and decision-making when more or less information is included.

The relationship between collective and individual consent also merits further research. Attendees remain uncertain how researchers might best enact their ethical responsibility to respect distinct cultural values and practices, while also ensuring – in accordance with this foundational research ethics principle – that individual participants' consent to research is voluntary. A review of key research ethics guidance shows that these provide little in the way of practical advice for navigating dual responsibilities to respecting values of individual and collective consent. Thus, for example, the latest CIOMS (1) stresses the importance of "showing respect for communities" and "ensuring community acceptance" of projects (1, p.25), while maintaining that community leaders' permission may "in no case […] substitute for individual informed consent" (1, p.35). The Canadian *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (42), a key reference point for Canadian co-authors on this publication, provides a good example of the possibilities – and limitations – of efforts to explicitly address or regulate these tensions. Since 2009, this guidance document has included a Chapter on research with aboriginal Canadian groups, developed under the leadership of and in consultation with aboriginal scholars and community members. This Chapter defines collective decision-making as an important cultural practice in many aboriginal communities that researchers working in these communities are ethically bound to respect but provides no guidance on how one might operationalize "collective decision-making as a complement to individual consent" (28, Ch.9). In sum, the challenge of ensuring individual consent while remaining respectful of collective decision-making and of leaders' authority is not limited to Madagascar. It is potentially present in all contexts where relational and collective decision-making and respect for family or community leaders' evaluation of the acceptable and unacceptable are dominant cultural practices. Workshop attendees agreed that deepening understanding of how chiefs and research participants understand the relationship between individual and collective consent would represent a valuable addition to Research on Research scholarship and research ethics guidance in the Malagasy context.

No workshop attendee raised issues related to the absence of representatives from researched communities at the meeting. It is not clear whether this reflects an actual lack of recognition for the importance of working with such representatives, but it may. Discussions with members of researched communities are needed to advance understanding of the consent complexities identified by workshop attendees and their ethical significance. Indeed, all further research on consent complexities in Madagascar ideally would be developed and implemented in meaningful collaboration with former participants to research studies in the country, or with individuals positioned to speak on behalf of researched populations. Such collaboration on the design of study questions, methods, and analysis of findings would have practical and ethical benefits. Notably, it could multiply insights on consent complexities and as a result strengthen research ethics guidance and localized strategies to further support informed consent to research in the country. Just as important, such collaboration enacts recognition that participants – as stakeholders who are directly affected by research processes – are well positioned to clarify what counts as ethical, respectful, and in this way "best" practice in a particular setting (47,48). Inviting input on study objectives and questions from members of researched populations also supports a shift away from an extractive approach to research that engages with participants for agendas that are established outside the purview of researched populations' concerns and priorities. How best to achieve increased engagement with members of researched communities in ways that feel non-extractive to these stakeholders will itself require dialogue with researched community representatives (48,49). Such invitations, at this point in Madagascar as elsewhere, will not necessarily be welcome or trusted. These will occur against a backdrop of colonial and neocolonial extractive research, dominant hierarchies of knowledge, and racial, economic, and social hierarchies; as such, it can be expected that invitations to "collaborate" from researchers from "outside" may be interpreted as attempts at exploitation (38,47-49).

CONCLUSION

There is nothing simple about ensuring free and informed consent to participate in most circumstances of biomedical research. Best practices for supporting voluntariness must also be developed in ways that enable reconciliation of universal principles for the ethical conduct of research with cultural practices and values that may at times appear or actually be at odds with these principles. The 2018 "Complexities of Consent in Madagascar" research dialogue initiative brought together representatives from a range of institutions and with a range of experiences in the conduct of research in Madagascar. Together, we identified key challenges, potential strategies, and questions in need of further exploration for supporting consent in this sub-Saharan African country. One workshop is insufficient to identify and troubleshoot all the complexities of informed and voluntary consent, even for a single national context. As previously noted, this workshop included a limited number of stakeholders, and it did not include actual research participants. Consultations or research with individuals and communities that have been invited to participate in research studies is necessary, if the complexities and challenges of consent in Malagasy contexts are to be described and addressed in ways that can inform "best practices" that resonate with both research participants and those in charge of studies. Anthropological studies can play an important role in advancing understanding of the lived experiences of those conducting research amongst diverse Malagasy populations as well as individuals approached for research participation. While we recognize that the workshop generated neither comprehensive nor empirically robust findings, the discussions are worth documenting and sharing. They illuminated numerous important issues related to informed consent processes in Madagascar health research that merit attention, notably in the form of capacity building, practical tools, and further research. The workshop discussions summarized here represent a first, if not conclusive step, in developing evidence-based context-specific strategies to strengthen consent and research ethics processes in Madagascar. More events through which researchers can share and collectively troubleshoot new and old concerns and challenges related to the application of research ethics principles will be important to developing shared best practices that are tailored to Malagasy contexts.

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APPENDIX 1: INVITATION TO WORKSHOP LETTER

Antananarivo, October 1, 2018

Subject: Invitation to workshop on challenges related to the ethics of consent to health research in Madagascar

Health research in Madagascar is conducted in accordance with international ethical norms and must be approved by the Bioemdical Research Ethics Board of Madagascar (CERBM) within the Ministry of Public Health of Madagascar. Ensuring the protection of participants in the context of clinical research within unique cultural and legislative contexts requires constant reflexivity.

The CERBM, researchers from Western University (London, Canada) and local researchers have deemed it important to discuss those challenges connected to the ethics of health research, and, more specifically, related to informed and voluntary consent, pertaining to Malagasy research participants. These discussions are financed by the Institutes for Health Research of Canada (CIHR).

The organizers wish to invite you to a workshop on the challenges of consent and the ethics of health research that will take place October 10, 2018, at the Institut Pasteur of Madagascar starting at 8:30 am. Les organisateurs souhaite vous inviter l'atelier de travail et de formulation autour

You and members of your organizations are invited to this workshop. Please note that those individuals to whom we are extending this invitation are primarily field researchers and researchers who are experienced in enrolling participants in health research projects.

In order to facilitate the organization of this workshop, please do confirm your intention to attend as well as the number of participants from your institution who will attend prior to October 5, 2018 by communicating directly by email xxx@pasteur.mg or by phone at (xxx xxxxxxx).

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