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**Social dynamics of biomedical research in a sub-  
Saharan African country.  
Patterns of participation in clinical research at the  
Medical Research Unit of the Albert Schweitzer Hospital  
at Lambaréné, Gabon.**

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## DEDICATION

I dedicate this dissertation to my dear Yannick Doucka Nziengui  
and our wonderful son Dilan Emil  
who have been there for me  
as constant source of love, support and strength  
all the time.

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### LIST OF ABBREVIATIONS

|                |   |
|----------------|---|
| <b>AMANET</b>  | African Malaria Network Trust Initiative                            |
| <b>ASH</b>     | Albert Schweitzer Hospital  |
| <b>AVAREF</b>  | African Vaccine Regulatory Forum Initiative                         |
| <b>CAB</b>     | Community Advisory Board  |
| <b>CERIL</b>   | Comité d'éthique régional indépendant de Lambaréné                  |
| <b>CIOMS</b>   | Council for International Organization of Medical Sciences          |
| <b>CIRMF</b>   | Centre International de Recherche Médicales de Franceville          |
| <b>EDCTP</b>   | European Developing Countries Clinical Trials Partnership           |
| <b>ERC</b>     | Ethical Review Committee  |
| <b>GCP</b>     | Good Clinical Practice  |
| <b>GHI</b>     | Global Health Initiative  |
| <b>ICH-GCP</b> | International Conference on Harmonization on Good Clinical Practice |
| <b>IRENSA</b>  | International Research Ethics Network for Southern Africa           |
| <b>MRU</b>     | Medical Research Unit   |
| <b>NRA</b>     | National Regulatory Authority                                       |
| <b>PABIN</b>   | Pan African Bioethics Initiative                                    |
| <b>SARETI</b>  | South African Research Ethics Training Initiative                   |
| <b>UNESCO</b>  | United Nations Educational, Scientific and Cultural Organization    |
| <b>URM</b>     | Unité de Recherche Médicales  |
| <b>USS</b>     | Université de Science de la Santé                                   |
| <b>WHO</b>     | World Health Organization   |

# 1 INTRODUCTION

## 1.1. Clinical research in sub-Saharan Africa

The poor regulation of biomedical research activities before the Second World War led to repeated abuse of human beings involved in experimental processes. After the 2<sup>nd</sup> world war several guidelines for ethical conduct of clinical research have evolved with the ultimate aim to ensure the safety and well-being of research participants. Ethical requirements focus on the informed consent of potential participants as precondition to conduct clinical research. Country-based ethical review boards with respect to local legal regulatory rules have been established to oversee and validate the ethical value of clinical research processes. Ethical principles were primarily formulated and evaluated in the wealthier countries and then - in the context of transnational research - assigned to be “cross-culturally valid, relevant and applicable” (Tangwa 2009a). However, implementation of health research ethics and international standardized guidelines in particular local social, economic and cultural contexts raise major challenges.

### 1.1.1. Transnational research: need for regional and global networks for scientific and ethical regulation

Following the millennium 2000 goals announcement, the funding landscape of tropical disease research has extended. Further, the establishment of partnerships between research organizations of developed and developing countries to promote health research in Africa improved significantly (Kuepfer and Burri 2009). This contributes to the development of several research centers qualified to conduct transnational trials. Ethical and regulatory frameworks have been developed as well, with the goal to take into account local contexts of African countries.

- The leading ethical guideline: ICH-GCP

The International Conference on Harmonization on Good Clinical Practice (ICH-GCP 1996) which set up quality standards for the design, the conduct and report of clinical trials is being implemented and disseminated in sub-Saharan Africa; research sites try to

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comply with the ICH-GCP standards for the design, conduct and reporting of clinical trial (Kuepfer and Burri 2009).

- Specific ethical guidelines to address issues in poor settings

Subsequently, numerous ethical and regulatory challenges were encountered and are continuously addressed through additional guidelines, frameworks and networks. The Council for International Organization of Medical Sciences guideline for biomedical research involving human subjects (CIOMS 2002) in collaboration with the World Health Organization (WHO) as well as the National Bioethics Advisory Commission (NBAC 2001) and the Nuffield Council on Bioethics (Nuffield Council on Bioethics 2004) are such specific guidelines and frameworks that focus on requirement like the availability of the successful treatment to participants after trial completion (Kilama 2009b).

- From guidelines to local ethical bodies and ethically conducted research: challenges in sub-Saharan Africa settings

Structurally, the translation of guidelines to functional bodies and daily activities are the main hurdle in establishing ethically conducted research in Africa. Ethical review institutions like independent Ethical Review Committees (ERCs) and National Regulatory Authorities (NRAs) are still not available in all African countries, and when they exist, they are often not fully functional. The first African ethics committee was established in South Africa in 1967 (Kass et al. 2007) whereas 36 % of the WHO African Region countries still had no ethics committees in 2005 (Kuepfer and Burri 2009). There is a broad agreement, that local ERCs can best represent the cultural and social values of the local population and act as a link between community and research centers. However, many ERCs are not yet operating as they should. For example, due to lack of funding and infrastructure, lack of regulation, conflicts of interest among the members, limited formal academic training in ethics, lack of standard operating procedures and independence (Kass et al. 2007, Kuepfer and Burri 2009 and Loff 2002). Several initiatives to either create or improve the commitment of ethical bodies have been reported. The Pan African Bioethics Initiative (PABIN) Conference, which was held in Libreville Gabon in 2002, called for the creation and capacity strengthening of



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existing committees (Effa et al. 2007). Similar initiatives and conferences were organized to check the status of implementation of national research bioethics committees in the sub-Saharan African region to determine the existence of National Ethics committees in the different countries. To date, less than half of the sub-Saharan African countries report the existence of an ERC (Kirigia et al. 2005, Nyika et al. 2009 and Rwabihama et al. 2010).

Currently, increasing efforts are initiated to create available frameworks and supportive ethical settings for clinical research in sub-Saharan Africa with numerous initiatives including refined guidelines in consideration to the local contexts. There are two main approaches that emerge in relation to global scientific production to come up to a more “locally adapted ethics”. First of all, the refinement of guidelines and enforcing of regional and national review processes to protect the rights of research participants and to consider interpersonal relationships more centrally. Secondly, to concentrate on how to ensure that the engagement is directed towards the improvement of local health care settings and the wider interests of the whole population (Molyneux and Geissler 2008). These two approaches may apply to the current situation in sub-Saharan Africa where scientific, medical and ethical contents of clinical research involve each other and are being developed.

### 1.1.2. Ethical challenges to conducting biomedical research in sub-Saharan Africa

Obtaining informed consent is the central procedure to initiate clinical research. The informed consent procedure is defined as “a process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subjects’ decision to participate. The process is documented using a written, signed and dated informed consent form.” (ICH-GCP 1996)

However, many reports point out some issues at obtaining informed consent in developing countries, and especially in regions like sub-Saharan Africa (Bhutta 2004). The social, economic and cultural contexts of sub-Saharan African countries present structural challenges for the daily application of the ethical gold standards of a

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voluntary and free participation from an autonomous person. On a daily basis, Africans deal with low income, low or no education and poor access to health care. In these contexts participation to research could be driven by the willingness to have access to ancillary cares that are free of charges during clinical trials. Therefore, the frontier between disinterested participation and coercion or inducement is not clearly cut. Numerous studies have been published over the last decade showing the limitations and even inadequacy of informed consent procedures as requested by the referring guidelines (Fitzgerald 2002, Flory and Emanuel 2004, Hill et al. 2008, Krosin et al. 2006, Minnies et al. 2008, Molyneux et al. 2007, Pace et al. 2005, Lema et al. 2009 and Dawson and Kass 2005).

### **Limitation of informed consent procedures and other main ethical concerns**

- Vulnerability of local populations in sub-Saharan Africa

The Declaration of Helsinki (WMA 2004) as the leading international regulatory document on clinical research describes vulnerability in six of its articles. Furthermore the CIOMS International Guidelines for Biomedical Research Involving Human Beings (CIOMS 2002) clarifies what means to be a vulnerable person: “*Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interest (...), they may have insufficient power, intelligence, education, resources, strength or other needed attributes to protect their own interests.*” The Good Clinical Practice guideline (ICH-GCP 1996) specifies them as “*Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate.(...) Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.*”

According to the above definitions, sub-Saharan African populations are commonly considered as vulnerable because they often belong to socio-economically and medically disadvantaged groups involved in research projects. Therefore, they are more susceptible to undergo coercion and joining a study with some expectation of access to

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health care and free medical treatments which would otherwise not be available (Tangwa 2009b). Moreover, non-participation may be experienced as some kind of deception and greater trouble than joining. However, there is broad agreement that marginalized vulnerable groups should not - as a precaution - be excluded from research so that there is no possibility for them to benefit from research.

We remember that research ethics is based on four fundamental principles which are autonomy, beneficence, non-maleficence and justice (Beauchamp and Childress 2009 and Tangwa 2009a). The principle of justice is to ensure equal distribution of benefit from any research. This is where ethics committees have to protect vulnerable human beings from harm, coercion or dependence when they join medical research projects (Smith 2008). During the first AMANET Health Research Ethics Workshop in Kisumu (Kenya), discussion centered about this ethical issue and the “Kisumu declaration of moral integrity and noble intent” was set up to join all investigators doing research with potentially vulnerable populations with the aim to maximize participants’ benefits and avoid harm and coercion (Tangwa 2009b).

### - Risk of rumor

In some contexts – even until today - risks of rumors seem to be more considered than concerns about side effects of the investigational research product. The rumors circulating are mostly about blood-taking and organ stealing. The blood samples and organs are supposed to be collected for research and later sold or otherwise used as for example material benefit of western scientists. Further rumors concern the taking of photographs and death of children after trial as a result of witchcraft or the idea of people serving as guinea pigs for human experimentation (Gikonyo et al. 2008). Geissler and Graboyes closely examined the major ethical rumors about health research in Africa over the last twenty years. Following their observation, the purpose and meaning of these rumors are related to the dimension of social relations and encounters between the first white colonial medical researchers operating in Africa (Geissler and Pool 2006, Graboyes 2010). The concerns of some local people can partially be associated with the traumatic history of colonialism. Even if they are rooted in the past, they are still present in many African countries until today. In order to perform ethical research it is therefore necessary to look behind the rumors as a symptom of potentially

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problematic relationships between the research community and the investigators. An open dialogue is needed between the participants and researchers and should be part of the scientific investigation (Geissler and Pool 2006).

- Standard of care during and after the conduct of clinical trials

The trend towards increasing biomedical research activities over the last decade is a response to the urgent need to challenge the disastrous burden of infectious diseases and the general purpose to improve health systems and health care access in poor regions. Indeed, the availability of products after clinical trials done in low income regions as well as access to health care during participation in clinical research, present significant ethical challenges. More currently, ethical concern arises from the debate about standards of care, as the Declaration of Helsinki requires control groups to receive the "best" current treatment, which is not always the local one. When research is conducted abroad, human subjects must receive protection equal to that in the sponsoring country as required by the referring guidelines, but unfortunately this is not always respected in reality (Angell 1997).

Further concern is expressed about how to make results available to the local population and community after the end of the trial (Kilama 2009a). Ancillary care that includes every medical care that is provided to study participants during a clinical trial and which is not part of the scientific research investigation (Brownsword et al. 2008), plays an important role wherever research is conducted in settings with limited health care access. Giving ancillary care as a benefit and compensation for the participants could potentially coerce, influence or induce participants' decision and thus interfere with the principle of impartiality, autonomy and free consent (Klitzman 2005). The CIOMS guideline argues that "although sponsors are, in general, not obliged to provide health care services beyond what is necessary for the conduct of research, it is morally praiseworthy to do so" (CIOMS 2002).

- Therapeutic misconception

Closely linked to the ancillary care obligation is the problem of "therapeutic misconception" which is understood as the confusion or misunderstanding of research and routine medical care by study participants (Lema 2009). Individual benefit from

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clinical care is often confounded with collective benefit which future individuals may get through research. Therapeutic misconception is not the same as the incapability to understand the nature of the study. The origin of therapeutic misconception is primarily based on the patient-doctor relationship and the natural belief of subjects that doctors will do nothing to harm them. Secondly some researchers, being aware of the simplification of recruitment procedures, avoid speaking and explaining study procedures and designs to potential participants because they fear that this could generate worries leading to refusal (Lidz and Appelbaum 2002).

Therapeutic misconception is reported from most of the research institutions in sub-Saharan Africa as one of the most frequent misunderstandings (Molyneux et al. 2005b).

### - Trust and mistrust

At least, elements of trust and mistrust in health research institutions and the relationship between the researcher and the potential participant, which play an important - but often under-estimated - role in sub-Saharan Africa health research. Especially researchers from Kenya and the Gambia have closely examined the social and inter-individual relationships between local communities and the research teams. They identified broad trust in the institution based on observation, experience with the research unit as well as good quality of health care, but little understanding of the institutions' research aims (Molyneux et al. 2005b, Geissler et al. 2008, Gikonyo et al. 2008 and Masiye et al. 2008). They also describe how the social relationships with the trial community interfere with the formal ethical principles required from study protocols. The research institutions are often considered rather as a providing health care center than a research center. Participation in clinical research might be conceived as being based on an exchange of blood samples for free, high-quality medical care and other privileges like free transport to the research center.

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- Beyond ethical concerns

Others outline that ethical clinical research is mainly dependent on the researchers and research activities which are considered to be the determining driver when it comes the question whether research is carried out properly or not (Nyika 2009). Interestingly, the process seems to be shared and better understood, if the following conditions are met: investigators should be experienced, interviewers should be skilled, fieldworkers and study staff should be trained; during training sessions, enough time should be spent on the informed consent process and multiple informed consent sessions should be carried out, instead of one single information meeting. Further, the use of different media and discussions in target groups seem to attain better understanding of the community about the research project (Fitzgerald 2002, Flory and Emanuel 2004, Hill et al. 2008, Krosin et al. 2006, Minnies et al. 2008, Molyneux et al. 2007, Pace et al. 2005 and Lema et al. 2009). This may suggest the existence of some dynamic and social incorporation of activities related to clinical research. Some interesting results of Ghanaian studies showed that most of the participants understood the nature of research. This finding contradicts to major findings throughout the literature concerning ethics on informed consent in developing countries. It was probably linked to such potential dynamic integration of research purposes due to the activity of the research center over the years and the fact that many of them had at least previous contacts with research center (Oduro et al. 2008).

### 1.1.3. Recent development on biomedical ethics in sub-Saharan Africa

- Community engagement

Over the last decade the need for community engagement and the establishment of Community Advisory Boards (CABs) especially in low-income settings was increasingly recognized and considered as a panacea to overcome the ethical dilemma of clinical research in developing countries. The overall aim of community involvement is to form a collaborative partnership between researchers and participants. This should be accomplished by trying to understand community perception of ethical research requirements and ensuring that participants and their communities are regarded and treated as stakeholders as well as equal partners in biomedical research (Molyneux et al. 2005a). Involving the community has been emerged as a requirement to start

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community-based research in addition to ethical regulation and informed consent with the aim to attain community acceptance (Nyika et al. 2010). Since then several authors, predominantly those from Kenya, have been worked on this topic. They tried to find out how to involve and engage communities best, in order to reach a better collaboration between researchers and the study population to ensure that research harmonizes with the needs of the community and makes it more ethical. Most of them suggest a gradual process of informed consent, which includes the following steps: Primarily it is important to get the permission from the community, then a discussion should be held with community elders, then with the heads of families and finally a discussion with the potential participant should take place. Additionally it was shown that obtaining community permission and consent facilitates the individual consent (Diallo et al. 2005, Dickert and Sugarman 2005, Doumbo 2005).

Building up community communication through community engagement and consultation as well as collaborative partnerships with the aim to integrate research findings into national health care systems, gives the community "ownership" of the research. Such efforts have contributed to more protection and empowerment of the communities, instead of or in addition to formal ethics, which are based on international principles (Kilama 2010, Tindana et al. 2007, Marsh et al. 2008). In some countries CABs have therefore been established as an example of community engagement in international research "safeguarding the interests of local populations, through the establishment of a solid foundation that supports relationships based on trust and engagement with community members" (p.243) (Marshall & Rotimi 2001).

In Tanzania for instance, a continuous interactive, multi-method informed consent process was successfully established with good results of comprehension and message retention among the participants. Efforts such as the implementation of comprehension checklists, engagement with community representatives and stakeholders, using different media at multiple times, involvement of different health professionals, discussions at community and clinic level had been realized. Still, it remained unclear to what extent people participated after having outweighed risks and benefits due to the informed consent or because of other reasons such as trust, individual benefits or a combination of both (Vallely et al. 2010).

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Although there is great potential of community engagement, the success of an established community involvement program is based on how researchers and participants really work together on a daily base. Challenges and difficulties arise for instance from the choice of representatives of the community, the decision of topics to be discussed, financial resources and independence of the bodies, low attendance rate of members, and how to adopt and take into account the views of the community in protocols (Shubis et al. 2009, Marsh et al. 2010, Nyika et al. 2010). Reality is more complex because every community is different and opinions among the local population can diverse. Therefore in any given research environment individual decisions have to be failed to give the research activity sense in the specific context (Vallely et al. 2009). The Setting up of a community engagement body or a community advisory board without the willingness and openness to form a true partnership and to come into dialogue with the trial community, could lead to what is described in the literature as “window-dressing” by critics concerning community engagement (Quinn 2004, Strauss et al. 2001). However there is broad agreement that communities should and want to be integrated in the planning, conduct and application of universal ethical values in research activities (Molyneux et al. 2005a, Upshur et al. 2007).

### **1.2. Current leading methodological approach and the need to learn about dynamics and changes**

Having summarized the most important ethical considerations for clinical research in sub-Saharan Africa, it is evident that the ethical concerns reported are true and challenge the ethical validity of the research being conducted in Africa. However, two major dimensions and levels of the social environment - time as well as the socio-economic and cultural contexts - were considered to a limited extent in most research concerning the ethics of biomedical research in poor countries. The exclusion of time and the complexity of contexts may present difficulties in fully accessing and understanding the dynamics and power of conflicting situations faced by the research actors. The dominant paradigm with respect to bioethics in the field of human health research is the implementation and evaluation of multilateral efforts for improving compliance to international ethical requirements, such as informed consent. In terms of methodology, most biomedical and social science researchers investigated the capability



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of potential participants to “understand” the nature of clinical research activities in order to obtain voluntary consent from an autonomous subject who has no personal interest. The current approaches employed in learning about the social component of biomedical research could be extended by additional paradigms and methodological approaches dealing with the dynamics and complexities of the social dimensions of clinical research.

### **1.3. Bioethical principles and social sciences**

“Principlism”, which means accordance to certain universal standards, is still the mainstream approach in bioethical research. The main topic addressed so far in the biomedical ethics research conducted in developing countries focuses on how to comply better with international ethical principles and guidelines as well as with related dilemmas such as therapeutic misconception and the trust/mistrust of research institutions. Following the requirements of international bioethics, most participants involved in clinical research within the sub-Saharan region are commonly considered vulnerable because of their poor socioeconomic background. In practice, this may lead to an ethical impasse because the main methodological approach involves a static correlation of the poor socio-economic conditions of sub-Saharan Africa with the compliance to ethical principles. Nevertheless, the simple and exclusive application of these principles risks ignoring time and movement in the social, economic and cultural contexts; it could lead to what Corrigan designates as “empty ethics” (Corrigan 2003). The critics of applied ethics advise against isolating bioethics from everyday practice.

In contrast to the current top-down approach of principlism, a more bottom-up approach paradigm is growing in the field of health ethics. This paradigm would focus on the experiences of researchers, field staff (Hedgecoe 2004) and, particularly, research participants.

With respect to ethical regulations and guidelines, a more ethnographical approach is emerging in the field of transnational research. Such an approach could integrate ethics into the society and social experiences of the actors in a better way. This would include investigation at the micro-social level as well as deeper observation of the different interpersonal relationships between stakeholders and of collaboration processes in the

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context of biomedical research in sub-Saharan Africa. Ethnological research focuses on the exploration of the trial community as a whole. It examines social relationships at the field level among trial participants, the wider interests of the community and the research teams. In addition, it considers the relationships between research teams and policymakers at the national level (Molyneux and Geissler 2008). For instance, local fieldworkers may form a link between the research centre and the participants because they often integrate themselves into the lives of local community members and families and become crucial members of social networks (Molyneux et al. 2009). The social relationships established between the different actors in clinical research may eventually facilitate the understanding of ways to fulfil formal ethical requirements.

The engagement of participants with medical research centres in sub-Saharan Africa often comprises a kind of social practice. Joining a study project largely implies a social relationship rather than disinterested, autonomous and isolated participation in a clinical trial (Fairhead et al. 2006). Therefore, ethical research should result in the benefit that questions are situated more socially in addition to previous reflections.

### **1.4. Paradigm and study problems**

The dominant paradigm of “principalism” and its related methodological approaches have contributed to address the main ethical concerns and challenges that may hinder the conduct of clinical research in sub-Saharan Africa. Besides the identification of dilemmas, however, the ethical conduct of research and access to healthcare may both be part of the same social objective (Kelly et al. 2010) - i.e. improving access to medical care. A paradigm shift is being advocated increasingly through suggestions that ethical values and individual interests - such as access and quality of healthcare - are not mutually exclusive. In this work, we assume that individual experiences are often embedded in group activities and structures, and that they later generate new groups and activities in a dynamic manner. We will apply such a paradigm in the current work to understand how clinical research activities as well as related ethical principles and guidelines can affect a particular community. Such a movement could eventually lead to social change, resistance or its occurrence within the same society. A pilot qualitative study using in-depth interviews was conducted among researchers at the Medical Research Unit (MRU) of Lambaréné. The study highlighted the variable perceptions of

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research participants in the area. Contexts like poverty, rural conditions and poor access to healthcare may represent the leading motivation for enrolment in clinical research. On the other hand, participation in research may appear to be a more complex decision when local contexts, perceptions regarding the research and individual constraints are considered. A quantification of interviews suggests variable perceptions: senior researchers perceive the participation of the community in research at Lambaréné as being more complex while junior researchers feel that the limited socio-economic resources of the inhabitants of Lambaréné are a key driver of participation in research. The present work aims to understand the perceptions of the local population of Lambaréné regarding clinical research activities. In order to do so, we investigated interactions at the micro-social level between the different actors involved in clinical health research projects. We were particularly interested in the perspectives of the study participants and used the informed consent procedure as a model for these interactions. Furthermore, we examined whether and how inter-individual relationships and individual motivations may impact the emergence of a potential community of research participants.

### 2 METHODS

#### 2.1. Study setting

Since 1992, the MRU of Lambaréné has enlarged its research activities significantly and is accessible for about 35.000 inhabitants living in the main town of the area (Lambaréné) and in the villages alongside the national road number 1 of Gabon. This includes a study area of about 100 kilometres south and 80 kilometres north of Lambaréné. Health care system in Gabon is characterized by a weak availability of drugs, weak institutional frameworks, the non-implication of the communities in the handling of health care problems and insufficient financial resources. All this is reflecting the limited health care access particularly in periphery regions (Stratégie de Coopération de l’OMS avec les pays, 2008-2013, Gabon).

In Gabon, the high infant mortality is particularly due to malaria (28.3 %), acute respiratory infections (10.7 %), diarrhoea infections (8.8 %) and neonatal infections (35.1 %). A vaccination program was established in 1978 but its realization is still very limited with a weak vaccination coverage of 44 % in 2006 (Stratégie de Coopération de l’OMS avec les pays, 2008-2013, Gabon). Additional information about Gabon is provided in the annexe section.

Especially, the idea of free medical treatment and primary health care access for every ill person in need is still important for the community of Lambaréné – as held a view in the period of Dr. Albert Schweitzer’s work. The Albert Schweitzer Hospital (ASH) represents a primary health care provider with cheap or even free medical investigation and treatment that contrasts to most of the other health care institutions in the country.

Lambaréné (GPS Coordinates: 10.24039, -0.70155) as an urbanized town contrasts to the surrounding villages along the main national road 1 to Libreville in the North and Fougamou in the South. Farming and agriculture are the main activities of families in the rural provinces. There are particularly remarkable differences in terms of disease prevalence in rural regions in contrast to urbanized areas. For instance, there is a higher prevalence of helminth infections in the rural provinces putting pressure on those populations to receive medical care.

The MRU of the ASH in Lambaréné was established in the early eighties to understand and study major causes of disease burden in the Gabonese population with the aim to gain knowledge in the pathophysiology and in the treatment of infectious diseases in sub-Saharan Africa. Since then, the MRU has become a leading research centre in the sub-Saharan African region. The health research activities of the MRU of Lambaréné mainly concentrate on malaria as it is still one of the most common causes of infant mortality and morbidity in sub-Saharan Africa. The studies on malaria include basic epidemiology, new medical compound investigation and up to phase III malaria vaccine multicenter trials. Additionally the MRU works on the so called Neglected Tropical Diseases like schistosomiasis and other helminth infections, but further also investigates in allergenic studies and more recently on tuberculosis.

A core group of research scientists and local field workers has emerged and the MRU has achieved a high international reputation for its interdisciplinary research activities. Today the MRU interacts mainly with collaborators, research institutions and universities from Germany, the Netherlands, the United Kingdom and Austria as well as multiple national and transnational networks (Ramharter et al. 2007). With the achievement of several qualifications, the site has gained support from multilateral partnerships as well as international grants and funding in the context of multicenter clinical drug and vaccine trials.

## **2.2. Study design**

This study is a quantitative research based on series of questionnaires conducted among research participants in Lambaréné. The questionnaires are designed to describe the research participants as well as the patterns of participation into experimental procedures among inhabitants of Lambaréné. The questionnaire survey was performed semi-openly (closed question and open question type) approaching three main themes: The first theme of the questionnaire includes the description of the relationships and social interactions between the study participant and the study site and staff in the context of a particular research study and across research projects. In order to better understand procedures such as informed consent in transnational health research projects, participants' perception and attitude of informed consent procedures is

interrogated through the survey in the second theme. The interviewees are also asked to describe the best information model from the communities' point of view.

In the third theme, parents are asked to describe the practices of health care in their community. They are asked to write about their experience and perception of hospital facilities, the interest of preventive medicine, blood sampling, self-treatment and auto medication, traditional treatment, resources dedicated to health, source of funding, expectations for a better health care and the need for new drug and vaccine development to reach better health care.

### **2.3. Study implementation**

During the construction phase of the questionnaire survey (see annexe) several amendments had been necessary to deplete sources of error. Finally a previous draft of the questionnaire was delivered to some study participants before study onset in order to detect if questions could be well understood.

The questionnaire survey was performed in French being the working language of Gabon. A local fieldworker assured that all questions could be well understood by the parents and translated and back-translated into the local languages if this became necessary.

All study site members were made familiar with GCP guidelines and obtained a GCP certificate after a training workshop. Interviews and questionnaire surveys were conceptualized and conducted by a research team including one independent sociologist, one ethicist with a philosophical background and one clinical investigator with a background in sociology.

Beside questionnaires, observation of the informed consent procedures was conducted. During sessions and discussion between trials investigators and participants, a member of our social research team observed the sessions. We did direct observation on informed consent procedures and practices of health care in the community.

### **2.4. Study population characteristics**

Study population involves mothers who had enrolled their children in a malaria vaccine clinical trial between 2006 and 2011 which was conducted at the MRU of Lambaréné.

Parents who involved their infant/children in a research project at the MRU were recruited from two malaria vaccine candidate trials in clinical phase II or III. There were also some parents who had already joined several study projects at the medical research unit and who had thereby already gained experience with the study staff and the research activities of the centre. A total of 70 participants were asked to answer the questionnaires. They were selected based on the above characteristics.

### **2.5. Study period**

Questionnaire surveys with participants were performed from May 2010 to February 2011. Observation was done from October 2009 to August 2010.

### **2.6. Conduct of questionnaire**

The questionnaire survey with voluntary parents was mostly performed at the parents' house. For the recruitment of study participants, the study team fieldworker organized contact in three house visits by telephone.

On the first visit, the objectives and procedures of the study were explained to the participant and they were asked about their interest for participation in the study. The informed consent form was handed out with the first part of the questionnaire survey. The participant was told to read the informed consent information paper and to get familiar with the first part of the questionnaire survey.

After 2-3 days, the study team visited the participant again and the informed consent was signed if they are willing to participate. A copy of the signed informed consent sheet was later made at the MRU and handed out on the following visit. The completed first part of the questionnaire was collected for data entry at the medical research centre and the second part of the questionnaire survey was handed out to the parents to get familiar up to the last visit few days later. On the last visit the second part of the questionnaire survey was collected and controlled for completeness and parents were given the possibility for questions and were asked about problems they had faced with the questionnaire survey form. Participants filled in the questionnaires.

## **2.7. Ethical considerations**

The study was submitted and reviewed by the local Ethics committee of Lambaréné (CERIL). Only participants who signed the informed consent were enrolled. Study participation was on the base on the voluntariness without any special beneficial compensation and no disadvantages that would follow non-participation. The study participants were informed about their right to withdraw from the study at any moment without having to give any justification.

The study was performed according to the international GCP standard and all data were treated confidentially. Apart from the questionnaires which were filled in with the parents, no sample was taken or any other invasive procedure was performed.

## **2.8. Data management**

All data obtained from study participants were filled in a questionnaire survey form and controlled for completeness and conformity by study team members. The data was transcribed in an electronic data base for further analysis once the questionnaire survey was completely finished.

## **2.9. Analysis of questionnaires**

To describe the patterns of participation into experimental research by people living in Lambaréné and their interactions with health care systems, descriptive statistics were performed. The frequency of a particular perception and behaviour was calculated and reported in tables. No inferential statistics were used in this study.



## RESULTS

### 3 RESULTS

The response ratio is about 100 % (71/71) for the first theme of the questionnaire survey (3.1.). This part includes 18 questions of which 10 are closed questions and 8 of them open questions.

The response ratio of the second theme (3.2.) is about 98.6 % (70/71) including 37 questions of which 30 are closed questions and 7 of them open questions.

The response ratio of the third theme (3.3.) is about 97.2 % (69/70) and includes 28 questions with 16 closed questions and 12 open questions.

#### 3.1. Human interactions in clinical research in Lambaréné

##### 3.1.1. Contact with the research site and research staff

For half of the study respondents, first time acknowledgement of the MRU activities (36/71) occurred through the communication strategies of the research institution including face to face contact with the staff of the MRU or media coverage.

##### *Illustration Ia*

Interestingly, to one third (21/71) of our questionnaire respondents, interactions between family members, friends and neighbours provided information about the spectrum of the MRU's activities. *Illustration Ib*

More than 80 % (63/71) of the study participants had positively perceived the bandwidth of the research centres' activities.

##### 3.1.2. Perception of research staff by research participants

Involvement in clinical research as volunteers increases the favourable perception of the research site and activities. Among our interviewees, 97 % (69/71) reported convenient interactions with the members of the research centre. Notably, the research staff is in most of the cases (90 %) mentioned by name, for example "I know Dr. M., Dr. J. and fieldworker E." *Table 1*

Within this number, it is remarkable that 51 % (36/71) of the interviewees listed several categories of research staff by name, for example investigators and fieldworkers.

## RESULTS

### 3.1.3. Interactions between research staff and research participants

In consequence of research participation, volunteers apparently develop some ties with the research team. Reference to professionalism of the research activity (including study specific procedures, medical practices and availability of health care) seems for almost 3/4 of the respondents the main researchers' value. Additionally, research participants expressed to have friendship ties with the research site members for about 11 % of our respondents.

Beside perception of the research site and the whole research team, ties and preferences with individual research staff were reported from 37 % (26/71) of our respondents. However, inter-personal ties may be mobilized by participants when anxieties or incomprehension to study procedures occurs.

Confidence on the researchers as health professionals and personal relationships between participants and particular researchers seem to be the basis of favourable perception of the site. Confidence to the researchers' professionalism is the main driver.

#### *Table 2*

Reference to professional abilities of researchers is preferred by participants when they want to address concerns and questions. Inter-individual interactions between participants and researchers do not seem to be primarily linked to the positive perception of the site and whole team as about 60 % of our interviewees had no preference for a particular researcher. *Table 3*

### 3.1.4. Interactions and relationships among research participants

More than half of the interviewees (58 %) mentioned acquaintanceship to other study participants of a same study. The contacts were either specified by name (27 %) or without name (31 %). 24 % (17/71) of the respondents stated that there is nobody they know among the other study participants. *Table 4*

The formation of friendships among study participants joining different research activities was reported from about 66 % (47/71) of the interviewees.

Inter-individuals relationships around participation into clinical research activities had been established as 83 % (59/71) of the respondents reported known relatives who had joined studies.

## RESULTS

Among them, 62 % (44/71) stated that it was either their family, neighbours or friends or someone else in the community who joined research projects at the MRU, too. Community driven participation means that there was more than one of the following category of acquaintances (family, neighbours, friends and someone else) who joined research activities in their environment.

Individual driven participation was reported for 10 % of our respondents. We further observed that the majority of those participants who showed acquaintanceships to other study participants also expressed confidence to the research site which is mainly related to the professional skills of the research site. *Table 5*

### 3.1.5. Building up long term relationships between the research institution and the community

A single participation in a research project was reported from 61 % (43/71) of the interviewees. About 40 % (27/71) of them have already joined research activities in the past. The link with the MRU lasts up to 5 years for about 80% of our respondents. Participants that are engaged for more than 5 years are about 16 % (11/71) of the respondents. *Table 6*

Interestingly, continuous participation to clinical research activities with the MRU applied to 66 % (47/71) of the respondents. These participants have ever been in linkage to the MRU since their first encounter.

Others reported discontinuous engagement with the MRU in 24 % (17/71). Decoupling followed a period of study participation and - at a later date - newly participation in research activities. Unique encounters with the MRU were only reported in about 8.5 % (6/71) of the interviewees.

Professional interactions with the research site and individual researchers seem to be related to ongoing assemblies with the MRU as already demonstrated in Table 6. The majority of our respondents who were characterized by continuous encounters with the MRU also expressed confidence to the research site which is mainly due to professionalism. *Table 6 and 7*

After the experience with the research staff and the research activities of the MRU, 89 % (63/71) of all respondents expressed interest in further participation. Only 8.5 % (6/71) had no desire for future study participation.

## RESULTS

### 3.2. Informed consent process

#### 3.2.1. Participants' understanding of research purposes and research procedures

The fact being voluntary participant in an experimental process was quite well shared by our interviewees. For instance 67 % (47/70) of the respondents reported that their child received an experimental product. *Table 8*

Invasive research procedures were reported and especially blood sampling and vaccine jab were the most kept in mind. Importantly, there were 41.5 % (29/79) who were not able to name or describe the study that their child had joined.

#### 3.2.2. Participants' perception of informed consent procedures

The encounter with the research staff before study onset was kept in mind by 93 % (65/70) of the interviewees and multiple meetings were reported from 60 % (45/70). It is remarkable that all of the respondents (70/70) remembered that they had received “some kind of documentation” representing the informed consent paper.

The act of signing the informed consent paper was remembered in 97 % (68/70) of the interviewees. More than half of the participants acknowledged to have received more than one documentation sheet as part of the informed consent process (there were several documents). *Table 9*

The majority of the interviewees, about 69 % (48/70), did not remember the name of the documents. Nearly half of the respondents did not read all of the informed consent form and 17 % (12/70) did not read anything at all. *Table 10*

The perception of the informed consent documents was divided into a general positive perception in almost half of the cases (45.5 %). To the other half of the respondents, perception of informed consent documents were either negative or more complex (too long and too complicated for example). *Table 11*

Overall 93 % (65/70) of the interviewees had a positive perception of the informed consent process as a whole (including for instance meetings with research staff, discussion of the research purposes and procedures).

## RESULTS

### 3.2.3. Informed consent procedures and the context of participants in Lambaréné

At least 34 % (24/70) of the respondents stated that there was no recall on study objectives and study procedures during the study period. Repeated explanation was given in about 63 % (44/70). *Table 12*

Nearly all of the interviewees supported multiple information sessions and repeated explanations. *Table 13*

Propositions by our participants for a better understanding of research purposes and better acceptance of research procedures were given in 88.6 % (62/70). The propositions on how to keep the participants informed sufficiently during the entire period of the study about research objectives and methods, ranged from recall sessions, discussion and community meetings, ongoing contact to research staff to more frequent calling and house visits.

### **3.3. Biomedical research and public health**

#### 3.3.1. Practices of health in the community

Attending the health care facilities was identified as the first modality to manage health problems and diseases in the community of Lambaréné as stated by 94 % of our respondents. Access to health facilities is the unique mode for more than 80 % of participants to get medical care and solve health problems. Alternatively, traditional medicine and self purchase of drugs are reported as practices for nearly 1/4 from the interviewees.

Concerning the perception of the health care system, 90 % (62/69) of our interviewees have favourable opinion of their encounters with the research staff. Waiting and blood sampling are the most common reported inconveniences. The ASH has a good reputation in the community of Lambaréné, harmonious experience was reported in 87 % (60/69) of the interviewees. There is another state hospital in Lambaréné which is not known all over the community of Lambaréné, 42 % (29/69) of the interviewees had never had any experience at all with this hospital. Half of the interviewees (51 % i.e. 35/69) stated that they are also used to go to the local dispensaries. *Table 14*

## RESULTS

Self-medication was mentioned in 35 % (24/69), even if in most cases it was the doctor who prescribed medication. *Table 15*

The public health sector provides medication for only about 18.8 % (13/69) of the respondents. Private financial provision was declared from about 45 % (31/69). Medication that is provided from the public health sector together with private financial provision applied to 27.5 % (19/69) of our interviewees. *Table 16*

38 % (26/69) reported that they do not purchase medication easily. The main reason was financial limitations, followed by local lack of the required medical products. *Table 17*

### 3.3.2. Health care needs in the community

Even if the majority of the interviewees (77 % i.e. 53/69) evaluated that their children are adequately medically addressed, however 20 % (14/69) were not satisfied with the current health care in their environment. Remarkably 77 % (53/69) were persuaded of medical treatment to improve their children's health. *Table 18*

Concrete ideas how to improve the medical care of their children and themselves were given in 58 % (40/69) of the interviewees. Among them 39 % (27/69) enumerated practical suggestions on public health. About 19 % (13/69) mentioned that this should become through ongoing health research efforts to achieve better health care.

Note that this question was an open question type. There were also some of the interviewees who stated that they had no idea how to improve medical care and some did not answer to the question probably due to lack of comprehension or no idea as well. *Table 19*

Even if there were only 16 % (11/69) of the respondents who were not satisfied with the existing medical treatment of their children, the majority among them (36.4 %) estimated that it was by means of health research to minimize the number of cases of illnesses. After this, 23 % estimated through improvement of the public health sector and 18 % quoted suggestions including both (through endeavour on health research and public health). 18 % had no idea how to minimize the cases of illnesses even if they disagreed about the sufficiency of existing drugs and medicines.

Noticeably 77 % (53/69) were convinced that there is a need for new drugs and medicines to successfully treat the major diseases in the community, e.g. malaria, upper respiratory infections and diarrhoea. *Table 20*

## RESULTS

Among them who were positive about the need for novel drugs, the majority identified by means of health research (33.5 %) to advance. 17.5 % listed the improvement of the public health sector and 16 % had no idea how to proceed. *Table 21*

Development of new vaccines is a need for 83 % (57/69) of the interviewees. *Table 22*

### 3.3.3. Community perception of research

Considerably nearly half of the interviewees (45 % i.e. 31/69) described a realistic pathway of clinical drug and vaccine development. *Table 23*

The awareness of the necessity for new drugs and vaccines was widely spread among the respondents. Nearly all of them (93 % i.e. 64/69) affirmed that it is beneficial to investigate on new vaccine development.

The majority of the interviewees (87 %) elucidated personal and collective benefit as drivers for endeavours to search for new medical products. Personal benefit was enumerated in 26 % (18/69), collective benefit in about 29 % (20/69), and personal as well as collective benefit in about 32 % (22/69) of the respondents. *Table 24*

77 % (53/69) expressed a good feeling knowing their child to be involved in an experimental study. *Table 25*

Prior to the participation to the research project, 42 % (29/69) of the respondents had already had a positive perception of the MRU's activities. 35 % (24/69) had never made experience with the MRU and 16 % (22/69) stated that they had negatively thought of the research centres' operations. 59.5 % (41/69) affirmed that joining a research project at the MRU changed their thinking about health research activities in general. *Table 26*

Among the interviewees who affirmed the changing on their perception of the MRUs' activities, the majority enumerated access to high qualified health care (41.5 %) to be the main reason. This followed a better acceptance and adoption of research activities in general (29 %). For 24.5 % of the participants, both research and better quality of health care lead to this change of perception. *Table 27*

Health research showed some positive impact on human being life for about 58 % of the respondents. Clinical research procedures as a manner to improve public health applied for 20 % of the interviewees. For 12 % of the interviewees, research contributes only to advance science. For 7 % of our respondent, the benefit of research activities is targeted at both, the public health care sector as well as health science. *Table 28*

### 4 DISCUSSION

The present study intends to describe the patterns of participation in clinical research of the population of a low-income region in sub-Saharan Africa. Using a questionnaire, we focused on the perceptions of participants in ongoing and completed trials regarding clinical research procedures and the functioning of health systems.

Inter-individual interactions and relationships between research participants and the research site and staff seem essential for understanding how clinical research principles and procedures are being integrated by the entire population. The conduct of research procedures and activities as well as their integration within broader health concerns and solutions may take place through the constitution of social networks among the different actors, including participants, their relatives and researchers.

Within these networks, principles and procedures seem to be shared, understood and challenged dynamically.

#### **Building the identity of research participants in the community of Lambaréné**

##### Community perception of informed consent procedures

Our study participants are familiar with the general principles and aim of informed consent procedures, including the acknowledgement of being part of an experimental process, the concept of voluntary participation, the act of signing a consent form and the description of the main study procedures.

However, a third of the respondents forgot or failed to understand the key principle of the acknowledgement of participation in an experimental process before enrolling a child in the research project. The quality of informed consent in sub-Saharan Africa was broadly assessed and misunderstandings were often reported throughout the literature (Fitzgerald 2002, Krosin et al. 2006, Pace et al. 2005, Minnies et al. 2008). Moreover, the high burden of disease and the otherwise limited access to healthcare for the local population have been identified as the prior motivation for research participants in sub-Saharan Africa to join research studies. Thus, in poor socioeconomic contexts, the role of individual participants in the informed consent process is often over determined due to basic needs and expectations. Obtaining informed consent is far more challenging



## DISCUSSION

when research is carried out in the developing world. There is broad agreement that the more complex endeavours are indispensable in a poor socioeconomic context in order to create better understanding (Hill et al. 2008). Therefore, as recommended by nearly all of our respondents, face-to-face meetings, verbal exchanges and continuous information sessions are essential during the course of their participation, in addition to formal documentation, to ensure that the participants are well informed throughout the health research project (Fitzgerald et al. 2002, Flory and Emanuel 2004, Hill et al. 2008, Minnies et al. 2008, Oduro et al. 2008).

Beyond the assessment of participants' competencies, it may be relevant to understand how the one-third of respondents who misunderstood the objectives of the research studies in which their children participated interacts with the remaining two-thirds and with the broader local community. This could improve understanding of how change occurs at the individual or social levels with respect to the integration of the informed consent process with overall clinical research purposes and procedures (White 2008).

### From an ethical impasse to a less-determined participant

Besides general trust in the research institution and the occurrence of acquaintanceships and friendships with other participants, the observed ties to particular research staff characterized our interviewees' participation in clinical research. Isolated participation was uncommon. Most of the research participants have interactions and relationships with relatives who had previously been involved in a research project. Interactions and relationships between individuals associated with the research institution and individual participants as well as those among relatives, neighbours and other participants in the community represent potential influencing factors in the decision-making process (Agnandji et al. 2012).

Thus, obtaining informed consent in such settings may not primarily involve trust in scientific and ethical purposes and requirements. Instead, trust is based on social interactions with individual actors involved in the clinical health research process. This appears to be the dominant explanation so far in the literature. It usually leads to an ethical impasse and a statement of unethical research (Geissler et al. 2008, Gikonyo et al. 2008, Kelly et al. 2010, Masiye et al. 2010, Molyneux et al. 2009, Molyneux et al. 2005a, Molyneux et al. 2005b).

## DISCUSSION

Alternatively, the individuals and groups exposed to clinical research through both, social relationships and scientific and ethical frameworks, may themselves break the dilemma of dissociating from a less-determined and misunderstood participation in research. This paradigm has been examined to a negligible extent thus far. Hence, it would be beneficial to elucidate more comprehensively how individuals and groups dynamically integrate scientific and ethical resources in relation to their environment.

### **The social dynamics of biomedical research in Gabon**

#### Social networks around participation in clinical research activities

Our findings reveal some ingredients that strongly suggest the existence of social networks centralized by the clinical research activities. Attempts to characterize the relationships between participants and investigators showed human interpersonal relationships and a confidence based mainly on the professionalism of the researchers. Relationships have been established primarily between research participants and the researchers, and seem to extend to the broader community. Hence, research purposes and procedures may be shared within the community. Such community-based interactions regarding the research may later evolve into relationships with some (partial) independence with regard to the initial participant-researcher relationships. In other settings similar to Gambia and Kenya, social interactions with the trial community as daily ethical practice are essential for making ethical principles realistic. Principles and practices - formal ethics and moral ethics - should function complementarily for ethical research to be carried out successfully (Geissler et al. 2008, Molyneux et al. 2009).

Therefore, relationships are essential for an effective application of the international formal ethical guidelines; relationships play an important role in the informed consent process as well as in the overall research purposes and procedures (Marsh et al. 2010).

However, there is hardly any research on the way that principles and practices work together in the real world. Our interviewees showed the complexity of social networks - including of human components like researchers, participants, neighbours and relatives of study participants - and of the organizational framework of research such as ethical and regulatory guidelines as well as access to medical care and health systems. These

## DISCUSSION

components are active on a daily basis. There are also more distant components, including research partners, sponsors, ethical and regulatory bodies, and scientific paradigms. Social networks form an operational structure around the clinical research activities, and may represent a valuable and essential target. Thereby, we can learn about change, dissemination and resistance to research in our study area as well as in similar settings.

### Community participation in clinical research

Overall, participation in a research project leads to a positive perception of research and active opinion, including favourable impressions or reserve about study-specific procedures like informed consent. Interestingly, participants with a positive perception of the study seem to be more compliant with ethical guidelines and requirements. This may suggest that, in the broader community, such research participants are active in supporting the dynamic integration of research purposes and procedures through their social networks. Our findings show a trend towards better understanding of general research purposes and conduct at a research centre in Ghanaian settings than in other regions (Oduro et al. 2008). However, these findings may be biased by access to healthcare being highly improved during the research project. The improved access to healthcare may lead the same participants to become 'priority' participants and to enrol themselves repeatedly in new studies in order to maintain access to healthcare. Other research studies in similar settings discuss how research participants expect and desire continued relations as well as the ongoing insurance of quality healthcare (Geissler et al. 2008). Surprisingly, the literature reported the determinant factor of access to healthcare as a leading factor in ethical dilemmas and the ethical impasse. Unfortunately, there is little existing research on any potential change. Our findings suggest that there may be a dynamic change through interactions and relationships within the social networks we have previously described.

## DISCUSSION

### **Emergence of a medical research centre in Gabon**

#### Healthcare needs in Gabon

Like many other sub-Saharan African countries with a poor socioeconomic background, Gabon has a weak healthcare system with limited access to primary healthcare. The WHO reports insufficient drug availability, weak institutional frameworks, and - particularly in the peripheral regions - difficulties in the handling of public healthcare problems and financial limitations (Stratégie de Coopération de l’OMS avec les pays, 2008-2013, Gabon). Hence, the majority of the population has to make private financial endeavours to obtain access to medical treatment. The absence of required medical products in local pharmacies poses a further problem to the easy procurement of medication.

The widespread awareness of community members regarding the need for new drugs, medical products and investigation for new vaccine development is broadly acknowledged to work successfully against major diseases in the community. A remarkable finding in our study was that investigation on biomedical research and efforts to upgrade the public healthcare sector were identified as the main methods required to improve local healthcare settings.

#### Access to quality healthcare during the research process

To some extent, participation in research and confidence in a research centre in sub-Saharan Africa is attributable to access to the high quality of health services during the entire study period in Lambaréné and similar settings (Greco and Diniz 2008, Molyneux et al. 2005a, Geissler et al. 2008, Gikonyo et al. 2008, Fairhead et al. 2006, Lidz 2002 and Molyneux 2004).

Better medical care was appreciated considerably and was identified as the major change that co-occurred during participation in the study. Access to healthcare, beyond dilemmas like therapeutic misconception, represents a social resource and component of the social networks centralized by clinical research activities. Over time, such a resource may potentially lead to a shift in thinking and gradually support the change towards higher acceptance and adoption of biomedical research purposes.

The phenomenon of therapeutic misconception in poor socioeconomic contexts and elsewhere cannot be denied; however, better healthcare through participation in research

## DISCUSSION

projects could also represent a kind of resource. Greater focus on this aspect could ensure a wider integration of research needs, purposes and conduct in a community.

### Research as benefit and conflict for the community

About two-thirds of our interviewees believe that beyond their individual benefit, there is a collective interest in conducting health research in the community of Lambaréné. Our findings contrast with the widely reported predominance of individual benefit, which implies a prior motivation for participation and not the desire to contribute towards solving a major public health problem (Molyneux 2004, Gikonyo et al. 2008, Krosin et al. 2006, Lema 2009, Lema et al. 2009, Masiye et al. 2008 and Fairhead et al. 2006). All of our participants acknowledge individual benefit. We show that a community in sub-Saharan Africa, given certain social and economic conditions, can potentially become aware of collective interests. This may have occurred dynamically through the emergence of social networks. Such an assumption needs further investigation and a longitudinal study design as well as a larger sample that includes those who are resistant to participating in research.

### **Implications of our findings on social science research**

Given the nature of such dynamic social networks around clinical research activities, we expect that this perspective will boost understanding about how change occurs and how a society can integrate research purposes and processes. This suggests that, over time and in terms of participation in research projects and the resulting relationships, some change may occur progressively and dynamically. This is a call for social science to conduct further investigations that may lead to a change in perceptions regarding research within social networks and the broader community (White 2008, Bès and Grossetti 2003, Grossetti and Godart 2007).

### 5 SUMMARY

The ethical debate on biomedical research in sub-Saharan Africa gives the impression that scientific production in poor socioeconomic contexts naturally involves an “ethical dilemma”. Throughout the literature, this debate mainly concentrates on the research participants’ competence and compliance to transnational scientific and ethical requirements.

This study intended to describe the patterns of participation in clinical research of the population of a poor region in sub-Saharan Africa. Using ethnological and quantitative approaches, we focused on the perceptions of the participants of ongoing and completed trials regarding clinical research activities and the functioning of health systems. The frequency of a particular perception and behaviour was calculated and reported in tables.

Inter-individual interactions and relationships between the research participants and the research site and staff seem essential in understanding how the entire population is integrating clinical research principles and procedures.

The performance of research procedures and activities as well as their integration within broader health concerns may take place through the constitution of social networks among the different actors, such as study participants, their friends and relatives, and the researchers.

A paradigm shift towards research questions and methods that are neither limited in time nor restricted to conform to international standardized guidelines and regulations would facilitate understanding of biomedical science implementation and production in sub-Saharan Africa.

## 6 ANNEXE

### 6. 1. Additional information about Gabon

The MRU of Lambaréné is situated in the Moyen Ogooué, one of the nine provinces in Gabon in Central Africa. *Figure 1 and Figure 2*



**Figure 1: Landscape of Gabon in Central Africa**



**Figure 2:** <http://www.who.int/countries/gab/en/>

Gabon has a total population of about 1.5 million inhabitants. 73 % of the population lives in urbanized regions, more than half of the population lives in the capital Libreville and the economic centre Port-Gentil according to the WHO report on Gabon (Stratégie de Coopération de l’OMS avec les pays, 2008-2013, Gabon). Life expectancy

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is about 60/64 (m/f) years and the probability of dying under five years per 1000 live births is about 69 reported from the World Health Organization. *Figure 3*

|   |                  |
|---|------------------|
| Total population  | <b>1,475,000</b> |
| Gross national income per capita (PPP international \$)                 | <b>12,400</b>    |
| Life expectancy at birth m/f (years)                                    | <b>60/64</b>     |
| Probability of dying under five (per 1 000 live births)                 | <b>69</b>        |
| Probability of dying between 15 and 60 years m/f (per 1 000 population) | <b>321/262</b>   |
| Total expenditure on health per capita (Intl \$, 2009)                  | <b>513</b>       |
| Total expenditure on health as % of GDP (2009)                          | <b>3.5</b>       |

**Figure 3: statistics on Gabon**

<http://www.who.int/countries/gab/en/>

Lambarene has become well known and popular because of the ASH. It is situated only a few kilometres in the south of the Equator on the Ogoué River, it is surrounded by the rain forest and counts approximately 26.000 inhabitants. Lambaréné is the economic, administrative and medical centre of the province and the fifth biggest town of Gabon. It is situated 250 kilometres in the south of Libreville. The town of Lambaréné is divided into three parts because the river running through it is split into two river branches. The landscape of the province is characterized by the central African rain forest and its tropical climate with a high humidity and middle rainfall duration of 140 days per year with a middle temperature of 27°C throughout the year (Stratégie de Coopération de l’OMS avec les pays, 2008-2013, Gabon). The big rain season is disrupted by a dry season ranging from July to September. Throughout the province there is a great ethnical diversity, principally the Punu, Eshira, Fang, Akélé and Myènè. Lambaréné as an urbanized town contrasts to the surrounding villages along the main national road 1 to Libreville in the North and Fougamou in the South. The rural villages in the province are characterized by little houses. Farming and agriculture are the main activities of the families. Animals, such as sheep, dogs and chickens, live in close contact with the population.

Following the WHO report on Gabon, the alphabetization rate is about 72 % and the school enrolment rate about more than 90 % from 6 to 14 years and even equal between boys and girls. It is remarkable that there are only 68 % of attending students between 15 to 19 years (Stratégie de Coopération de l’OMS avec les pays, 2008-2013, Gabon).



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Nevertheless, the educational level of the population in the Moyen Ogooué region where the MRU is situated reflects the diversity between urban and rural areas in the province. While inhabitants of Lambaréné have great chance to attend a certain educational level, everyday life in the rural regions is concentrated on agriculture and farming even though there are some schools alongside the national road 1.

### **6.2. Ethical framework in Gabon**

The MRU has contributed to the creation and strengthening of the national ethical and regulatory review structures. The progress that was made over the last few years involving human beings in clinical research activity in Gabon through the establishment of ethical frameworks, offers great potential for transparent, professional and safe health research conduct in the country.

The quite recently established National Bioethics Committee for research of Gabon cooperates with the three main Gabonese research institutions which are the USS Libreville (Université de Science de la Santé de Libreville), the URM Lambaréné (Unité de Recherche Médicales de Lambaréné) and the CIRMF Franceville (Centre International de Recherche Médicales de Franceville) as well as several Gabonese hospitals and ministries. The MRU of Lambaréné has importantly been involved in the establishment of the Local Ethics Committee in Lambaréné (CERIL) and the National Bioethics Committee of Gabon with the support and through multiple grants from the AMANET, the EDCTP, training support from the Vienna School of Clinical Research and the Government of the Republic of Gabon. There were also other partners as the WHO, the United Nations Educational, Scientific and Cultural Organization (UNESCO) and the Institute Pasteur of Dakar who supported the initiative.

Today the National Bioethics Committees work comprises the review and proven of clinical trial protocols, advise on ethical considerations, involvement in the formulation of new recommendations as well as public health education (EDCTP 2009). There is also a NRA body of clinical research in Gabon which was subsequently established with the help of numerous initiatives such as the AVAREF assisted by WHO and national initiatives like the Gabonese National Ethics Committee and the “Centre National de la Recherche Scientifique et Technologique” of Gabon.

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### 6.3. Questionnaire (French version)

Numéro d'étude ES :

Age du parent:

Sexe:

Profession:

Nombre d'enfants qui sont suivi à l'URM : *(premier/deuxième... contact avec la recherche ?)*

Domicile:

Nom d'étude:

#### **Thème 1 : Relation entre le chercheur et le participant**

1. Comment et où avez vous entendu parler du laboratoire de recherche pour la première fois ?
  - Amis
  - Voisins
  - Famille
  - Radio/télévision
  - Personnel du labo de recherche
  - Autres : \_\_\_\_\_
2. Quels sont les gens que vous connaissez au labo de recherche ?
3. Comment était la première rencontre avec les gens du labo?
4. Avez-vous participez à une ou à plusieurs études ?
  - J'ai participé à une seule étude.
  - J'ai participé à plusieurs études.
5. Vous rappelez-vous des noms de ces études ?
6. Racontez nous en quelques mots comment l'étude s'est passée ?
7. Vous venez au labo depuis combien du temps ?
8. Est-ce qu'à un moment vous n'êtes plus venue au labo ?
  - Non, depuis la première rencontre je suis toujours venue.
  - Oui, je ne suis plus venue pour un certain temps.  
Après cette période, vous êtes encore revenu au labo ?
    - oui
    - non
9. Aujourd'hui, les gens du labo de recherche sont devenue qui pour vous ?
  - Ils sont devenus des amis.
  - Ils sont des personnels qui s'occupent de notre sante.
  - Ils sont devenus des gens à qui j'ai confiance.
  - Ils sont des gens qui font du mal.
  - Ils sont des gens qui font peur.
  - Autre chose : \_\_\_\_\_.

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10. Quand vous ou votre enfant est malade, est-ce qu'il y a une personne qui vous aide plus que les autres ? Vous avez une préférence des gens quand vous venez au labo ?
- Oui
  - Non
11. Pourquoi cette (ces) personne (s) ? La personne a quoi de particulier ?
12. Quels sont les gens qui vous écoutent quand vous avez des problèmes, des questions ou de craintes ? Vous vous adressez à qui ?
13. Est-ce que les rencontres avec les gens du labo sont bonnes ?
- Oui
  - Non
14. Quand vous venez au labo, est-ce qu'il y a toujours quelqu'un qui vous reçoit ?
- Oui
  - Non
15. Quels sont les gens que vous connaissez entre les autres participants ?
16. Autour de vous, est-ce qu'il y a des gens qui viennent aussi au labo ?
- Non
  - Oui, ce sont
    - Des amis
    - Des voisins
    - Des membres de notre famille
    - Autre monde :
17. Depuis que vous venez au labo, êtes vous devenu amis avec d'autres participants ?
- Oui
  - Non
18. Après vos expériences avec le labo de recherche, est-ce que vous souhaiteriez participer encore à d'autres études ?
- Oui
  - non

### **Thème 2 : la perception du processus du consentement éclairé selon le participant**

19. Avez-vous (ou votre enfant) reçu un médicament ou un vaccin ?
- J'ai reçu un médicament
  - J'ai reçu un vaccin
  - je ne sais plus
20. Vous (ou votre enfant) a reçu par la bouche au une piqure ?
- Par la bouche
  - Une piqure
  - je ne sais plus

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21. Avez-vous (ou votre enfant) donné du sang ?
- Oui
  - Non
22. Qui vous (ou votre enfant) a amené a participer ?
- mon parent
  - mon ami
  - mon voisin
  - un chercheur m'a contacté
  - je suis venue moi même.
23. Avez-vous parlé avec un chercheur avant de commencer l'étude ?
- Oui
  - Non
24. Combien de fois ?
- une seule fois
  - plusieurs fois
25. Ou ?
- à la maternité
  - à l'hôpital Schweitzer ou Régional
  - A la maison
  - Au labo de recherché
26. Est-ce que vous avez reçu un document ?
- Oui
  - Non
27. Vous avez reçu un ou plusieurs documents ?
- un seul
  - plusieurs
28. Si vous avez reçu plusieurs documents, lequel était le plus simple, le plus intéressant ?
29. Pourquoi ce document vous a plu ?
30. Vous rappelez vous du nom de ces documents?
31. Avez-vous lu tous les documents?
- Oui
  - Non
32. Avez-vous lu une partie des documents?
- Oui
  - Non, j'ai rien lu.

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33. Comment était le document ?

- trop long
- Clair
- Trop compliqué
- Intéressant

34. Est-ce qu'on vous a expliqué le document ?

- Oui
- Non

35. Combien de personnes vous ont expliqué ?

- 1 personne
- 2 personnes
- Plusieurs personnes

36. Qui l'a mieux expliqué ?

- Le médecin qui m'a reçu au labo
- La personne qui est venue à la maison

37. Comment a t'il fait ?

- Il m'a montré des images
- Il a fait un dessin
- Il a lu avec moi
- Il a expliqué avec des mots simples

38. Avez-vous signé le document ?

- Oui
- Non

**Après la signature du document, est-ce que vous saviez:**

39. Que vous étiez libre de participer (ou de faire participer votre enfant) ?

- Oui
- Non

40. Qu'on allait prendre du sang plusieurs fois ?

- Oui
- Non

41. Qu'on donne un médicament ou un vaccin qui est encore en étude/en expérience (n'est pas encore en pharmacie) ?

- Oui
- Non

42. Que le médicament ou le vaccin peuvent donner des effets sur votre santé ou la santé de votre enfant ?

- Oui
- Non

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43. Que le médicament ou le vaccin peut être bien pour votre santé ou la santé de votre enfant?
- Oui
  - Non
44. Vous rappelez-vous du nom du médicament ou du vaccin que vous ou votre enfant a reçu au laboratoire de recherche ?
45. Combien de temps a duré l'étude ?
46. Que les résultats des études précédentes chez les animaux et les hommes étaient favorables ?
- Oui
  - Non
47. Vous vous rappelez du nombre des participants ? Donnez le nombre !
48. Que vos informations (ou de votre enfant) sont gardées entre les gens qui travaillent pour l'étude ?
- Oui
  - Non
49. Qu'un ou plusieurs comité d'éthique ont donné leur d'accord sur l'étude ?
- Oui
  - Non
50. Que les autorités de régulation (ministère de la santé au Gabon), ont autorisé l'étude ?
- Oui
  - Non
51. Que les résultats de l'étude sont vérifiés par un comité de surveillance de la sécurité des participants ?
- Oui
  - Non
52. Que l'étude peut être interrompue si les chercheurs ou les autorités pensent que le médicament ou le vaccin peut être dangereux pour vous ou votre enfant?
- Oui
  - Non
53. Est-ce que l'on vous a rappelé toutes ces informations pendant l'étude ?
- Oui
  - Non
54. Pensez-vous qu'on doit vous le rappeler plus souvent ?
- Oui
  - Non
55. Qu'est-ce que vous pensez de ces informations ?
56. Comment peut-on mieux vous informer ?

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### Thème 3 : recherche clinique et pratique sociale

#### **a. La pratique des soins a Lambaréné**

1. Où soignez-vous vos enfants et vous-même quand vous êtes malade ?
  - Au dispensaire le plus proche de chez vous ?
  - A la pharmacie ?
  - A l'hôpital général ?
  - A l'hôpital Schweitzer ?
  - partout
  - je ne vais pas souvent dans les hôpitaux ou dispensaires
  - Autre part? Précisez
  
2. Avez-vous toujours eu l'habitude d'aller à l'Hôpital pour vous faire consulter ?
  - Oui
  - Non
  
3. En général comment cela se passe t'il ?
  - bien
  - je n'aime pas l'hôpital.
  - ils ne travaillent pas bien.
  - l'accueil est mauvais, le docteur et les infirmières sont mauvaises.
  - Le docteur et les infirmières qui s'occupent des enfants ou de moi-même sont gentils
  - je préfère aller hors de Lambaréné pour me soigner.
    - où ?
    - à Libreville ?
    - à Bongolo ?
    - autres :
  
4. Quand vous êtes à l'hôpital, qu'est-ce ce que vous détestez le plus ?
  - attendre
  - voir l'enfant se faire piquer ou être piqué soi même
  - autre ? précisez
  
5. Que pensez-vous de l'hôpital Schweitzer ?
  
6. Que pensez-vous de l'hôpital Régional ?
  
7. Avez-vous l'habitude d'aller dans les dispensaires ?
  - oui
  - non
  - si oui, lequel ?
  
8. Si vous ne partez pas a l'hôpital, comment faites-vous pour vous soigner ?
  - Je vais chez le Nganga.
  - J'utilise des médicaments traditionnels.
  - j'achète des médicaments chez les commerçants au marché.

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9. Tous les médicaments que vous prenez qui vous les prescrits souvent ?

- Le docteur
- Je les achète directement à la pharmacie
- Un parent, un ami me les conseille
- Autre

10. De façon général, comment faites vous pour acheter vos médicaments ?

- J'ai une assurance maladie
- Je paie avec mon argent
- Je demande de l'aide aux voisins, aux parents, aux amis
- Autre. Précisez.

11. Est-ce que vous vous procurez facilement des médicaments?

- Oui
- Non

12. Si non ou se pose le problème ?

### **b. Attente d'une meilleure qualité de soins**

*Dans les questions suivantes, dites tout ce que vous savez sur les soins que les enfants et les adultes reçoivent à Lambaréné et au Gabon en général (pas seulement les soins au cours de l'étude de l'enfant ou de vous-même).*

13. Pensez vous que les enfants sont bien soignés ?

- oui
- non

14. Doit- on améliorer la façon de soigner les enfants ?

- oui
- non

15. Comment peut-on améliorer les soins par exemple du paludisme, de la toux, de la diarrhée ou autre maladie ?

16. Etes-vous satisfait des médicaments qui existent pour soigner ces maladies?

- Oui
- Non

17. Si non, que pensez-vous qu'on doit faire pour diminuer le nombre de fois que vous/votre enfant a le palu/ la toux/ la diarrhée ou une autre maladie ?



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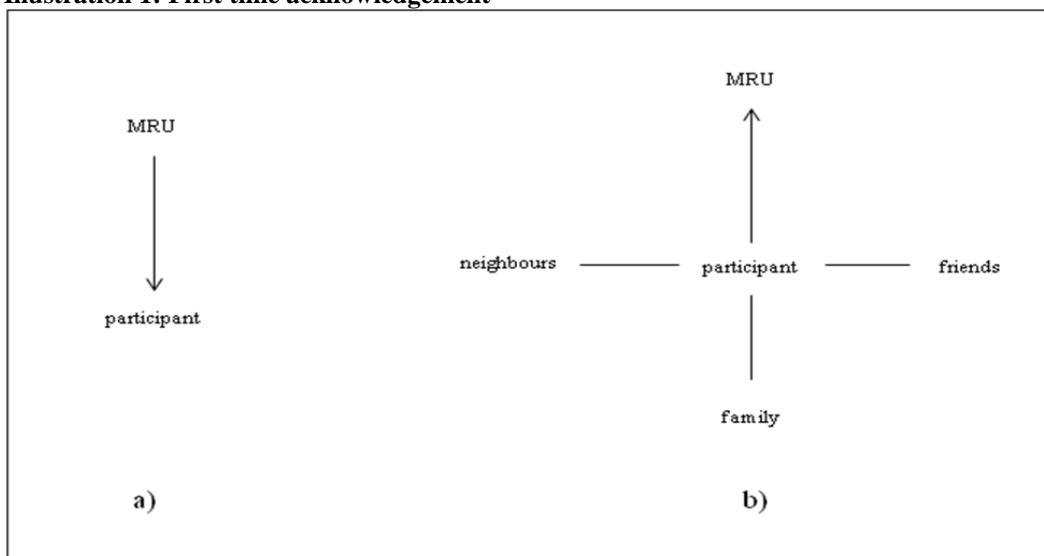
### c. L'idée de la recherche

*Dans cette partie, nous sommes intéressés par ce que vous pensez de la recherche médicale et si selon vous la recherche médicale sert à quelque chose.*

18. Comment les médicaments se retrouvent-ils en pharmacie ?
19. Pensez-vous qu'il faut de meilleurs médicaments pour soigner le palu, la toux et les autres maladies des enfants ou de vous-même ?
  - Oui
  - Non
20. Si oui, comment faire pour cela ?
21. Les vaccins permettent que les enfants ne tombent malades ou ne tombent gravement malades, pensez-vous qu'il faut plus de nouveaux vaccins?
  - Oui
  - Non
22. Le labo de recherche participe à avoir plus de nouveaux vaccins, pensez-vous que c'est utile, est-ce que ca sert à quelque chose?
  - Oui
  - Non
23. En quoi cela est-il utile/ sert à quelque chose ?
24. En participant à une étude pour qu'un nouveau vaccin ou médicament soit disponible, quel est votre sentiment ?
25. Avant que vous ne participiez aux études, comment voyiez-vous ce qu'on fait au laboratoire de recherche?
26. Est-ce que le fait de participer ou de faire participer votre enfant aux études à changer quelque chose dans votre façon de voir le travail de la recherche ?
  - Oui
  - Non
27. Si oui, qu'est ce qui a changé ?
28. Qu'est ce que vous pensez du travail de la recherche aujourd'hui ?

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**Illustration 1: First time acknowledgement**



**Table 1: Acquaintanceship to study staff**

|  | Response frequency (%) |
|--|------------------------|
| 1 person                                 | <b>17 (24%)</b>        |
| >1 person, one category of staff         | <b>11 (15%)</b>        |
| >1 person, different categories of staff | <b>36 (51%)</b>        |
| non-nominative                           | 5 (7%)                 |
| No answer                                | 2 (3%)                 |
| Total                                    | 71 (100%)              |

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**Table 2: Inter-individual relationships between participants and researchers**

|  |                                 | Do you have preferences with research staff?<br>Why do you prefer this particular person? |                            |                            |                          |                             |
|--|---------------------------------|---|----------------------------|----------------------------|--------------------------|-----------------------------|
|  |                                 | Professional relationship   | Personal Relationship      | No Preference              | No Answer                | Total                       |
| <b>How do you perceive Research staff?</b> | Contribution of professionalism | <b>10</b><br><b>(19 %)</b>  | <b>12</b><br><b>(23 %)</b> | 28<br>(54 %)               | 2<br>(4 %)               | <b>52</b><br><b>(73 %)</b>  |
|  | Friendship                      | 1<br>(12.5 %)   | 1<br>(12.5 %)              | 6<br>(75 %)                | 0                        | <b>8</b><br><b>(11 %)</b>   |
|  | *others                         | 1<br>(9 %)  | 1<br>(9 %)                 | 8<br>(73 %)                | 1<br>(9 %)               | <b>11</b><br><b>(16 %)</b>  |
| <b>Total</b>                               |                                 | <b>12</b><br><b>(17 %)</b>  | <b>14</b><br><b>(20 %)</b> | <b>42</b><br><b>(59 %)</b> | <b>3</b><br><b>(4 %)</b> | <b>71</b><br><b>(100 %)</b> |

\* others: not specified confidence; no answer

**Table 3: Attachment figures among the research staff**

|  |                                 | Which person do you address in case of any troubles? |                            |                          |                             |
|--|---------------------------------|--|----------------------------|--------------------------|-----------------------------|
|  |                                 | 1 research staff                                     | several research staff     | * <sup>2</sup> others    | Total                       |
| <b>How do you perceive Research staff?</b> | Contribution of professionalism | <b>20</b><br><b>(38 %)</b>                           | <b>29</b><br><b>(56 %)</b> | 3<br>(6 %)               | <b>52</b><br><b>(73 %)</b>  |
|  | Friendship                      | 1<br>(12.5 %)  | 7<br>(87.5 %)              | 0                        | <b>8</b><br><b>(11 %)</b>   |
|  | * <sup>1</sup> Others           | 5<br>(46 %)  | 4<br>(36 %)                | 2<br>(18 %)              | <b>11</b><br><b>(16 %)</b>  |
| <b>Total</b>                               |                                 | <b>26</b><br><b>(37 %)</b>                           | <b>40</b><br><b>(56 %)</b> | <b>5</b><br><b>(7 %)</b> | <b>71</b><br><b>(100 %)</b> |

\*<sup>1</sup>others: not specified confidence; no answer.

\*<sup>2</sup>others: research staff and other persons; no answer

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**Table 4: Acquaintanceship to study participants**

|  | Response frequency ( %) |
|--|-------------------------|
| Nobody                                     | 17 (24 %)               |
| <b>1 person (specified with names)</b>     | <b>6 (9 %)</b>          |
| <b>&gt;1 person (specified with names)</b> | <b>13 (18 %)</b>        |
| <b>specified without name</b>              | <b>22 (31 %)</b>        |
| Question misunderstood                     | 5 (7 %)                 |
| No answer                                  | 8 (11 %)                |
| <b>Total</b>                               | <b>71 (100 %)</b>       |

**Table 5: Participation and interactions with research staff**

|  |                                 | Are there other people in your environment who join the MRU? |                                 |                                |                          |                             |
|--|---------------------------------|--|---------------------------------|--------------------------------|--------------------------|-----------------------------|
|  |                                 | No   | individual driven participation | Community driven participation | No answer                | <b>Total</b>                |
| <b>How do you perceive research staff?</b> | Contribution of professionalism | 6<br>(11 %)  | <b>30</b><br><b>(58 %)</b>      | <b>13</b><br><b>(25 %)</b>     | 3<br>(6 %)               | <b>52</b><br><b>(73 %)</b>  |
|  | Friendship                      | 0  | 6<br>(75 %)                     | 2<br>(25 %)                    | 0                        | <b>8</b><br><b>(11 %)</b>   |
|  | *others                         | 1<br>(9 %)   | 8<br>(73 %)                     | 0                              | 2<br>(18 %)              | <b>11</b><br><b>(16 %)</b>  |
| <b>Total</b>                               |                                 | <b>7</b><br><b>(10 %)</b>                                    | <b>44</b><br><b>(62 %)</b>      | <b>15</b><br><b>(21 %)</b>     | <b>5</b><br><b>(7 %)</b> | <b>71</b><br><b>(100 %)</b> |

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**Table 6: Duration of participation and interactions with the research staff**

|  |                                 | Duration of participation  |                            |                          | Total                       |
|--|---------------------------------|----------------------------|----------------------------|--------------------------|-----------------------------|
|  |                                 | up to 5 years              | >5years                    | Not specified            |                             |
| <b>How do you perceive Research staff?</b> | Contribution of professionalism | <b>42</b><br><b>(81 %)</b> | <b>9</b><br><b>(17 %)</b>  | 1<br>(2 %)               | <b>52</b><br><b>(73 %)</b>  |
|  | Friendship                      | 5<br>(62.5 %)              | 2<br>(25 %)                | 1<br>(12.5 %)            | <b>8</b><br><b>(11 %)</b>   |
|  | *others                         | 10<br>(91 %)               | 0                          | 1<br>(9 %)               | <b>11</b><br><b>(16 %)</b>  |
| <b>Total</b>                               |                                 | <b>57</b><br><b>(80 %)</b> | <b>11</b><br><b>(16 %)</b> | <b>3</b><br><b>(4 %)</b> | <b>71</b><br><b>(100 %)</b> |

\*others: Not specified confidence; no answer.

**Table 7: Continuity of engagement and interactions with the research staff**

|  |                                 | Did you disrupt your participation at any time? |                            |                            |                            | Total                       |
|--|---------------------------------|---|----------------------------|----------------------------|----------------------------|-----------------------------|
|  |                                 | Continuous contact                              | Discontinuous contact      | Single contact             | No answer                  |                             |
| <b>How do you perceive Research staff?</b> | Contribution of professionalism | <b>32</b><br><b>(62 %)</b>                      | 15<br>(29 %)               | 5<br>(9 %)                 | 0                          | <b>52</b><br><b>(73 %)</b>  |
|  | Friendship                      | 8<br>(100 %)                                    | 0                          | 0                          | 0                          | <b>8</b><br><b>(11 %)</b>   |
|  | *others                         | 7<br>(64 %)                                     | 2<br>(18 %)                | 1<br>(9 %)                 | 1<br>(9 %)                 | <b>11</b><br><b>(16 %)</b>  |
| <b>Total</b>                               |                                 | <b>47</b><br><b>(66 %)</b>                      | <b>17</b><br><b>(24 %)</b> | <b>6</b><br><b>(8.5 %)</b> | <b>1</b><br><b>(1.5 %)</b> | <b>71</b><br><b>(100 %)</b> |

\*others: not specified confidence; no answer.

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**Table 8: Consciousness of experimental process**

|            | Response frequency (%) |
|------------|------------------------|
| <b>Yes</b> | <b>47 (67 %)</b>       |
| <b>No</b>  | <b>21 (30 %)</b>       |
| No answer  | 2 (3 %)                |
| Total      | 70 (100 %)             |

**Table 9: Quantity of informed consent documents**

|                      | Response frequency (%) |
|----------------------|------------------------|
| <b>One</b>           | <b>31 (44 %)</b>       |
| <b>More than one</b> | <b>39 (56 %)</b>       |
| Total                | 70 (100 %)             |

**Table 10: Lecture of informed consent documents**

|            | Response frequency (%) |
|------------|------------------------|
| <b>Yes</b> | <b>38 (54 %)</b>       |
| <b>No</b>  | <b>32 (46 %)</b>       |
| Total      | 70 (100 %)             |

**Table 11: Quality of informed consent documents**

|                            | Response frequency (%) |
|----------------------------|------------------------|
| <b>Positive perception</b> | <b>32 (45,5 %)</b>     |
| <b>Negative perception</b> | <b>16 (23 %)</b>       |
| <b>complex perception</b>  | <b>18 (25,5 %)</b>     |
| No answer                  | 4 (6 %)                |
| Total                      | 70 (100 %)             |

**Table 12: Recall of information during study period**

|            | Response frequency (%) |
|------------|------------------------|
| <b>Yes</b> | 44 (63 %)              |
| <b>No</b>  | <b>24 (34 %)</b>       |
| No answer  | 2 (3 %)                |
| Total      | 70 (100 %)             |

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**Table 13: Need for recall of information during study period**

|              | Response frequency (%) |
|--------------|------------------------|
| <b>Yes</b>   | <b>63 (90 %)</b>       |
| <b>No</b>    | <b>6 (9 %)</b>         |
| No answer    | 1 (1 %)                |
| <b>Total</b> | <b>70 (100 %)</b>      |

**Table 14: Alternative medical attention**

|  | Response frequency (%) |
|--|------------------------|
| <b>Traditional medicine</b>                                    | <b>22 (32 %)</b>       |
| <b>Non-professional drug purchase</b>                          | <b>16 (23 %)</b>       |
| <b>Traditional medicine and non-professional drug purchase</b> | <b>2 (3 %)</b>         |
| No answer  | 29 (42 %)              |
| <b>Total</b>   | <b>69 (100 %)</b>      |

**Table 15: Prescription mode of medicine**

|                                      | Response frequency (%) |
|--------------------------------------|------------------------|
| <b>Medical professional</b>          | <b>44 (64 %)</b>       |
| <b>Self-medication</b>               | <b>10 (14.5 %)</b>     |
| <b>Medically and self-medication</b> | <b>14 (20.5 %)</b>     |
| No answer                            | 1 (1 %)                |
| <b>Total</b>                         | <b>69 (100 %)</b>      |

**Table 16: Reception of medicine**

|   | Response frequency (%) |
|---|------------------------|
| <b>Public health sector</b>                   | <b>13 (19 %)</b>       |
| <b>Private funds</b>                          | <b>31 (45 %)</b>       |
| <b>Public health sector and private funds</b> | <b>19 (27.5 %)</b>     |
| Others  | 2 (3 %)                |
| No answer                                     | 4 (5.5 %)              |
| <b>Total</b>                                  | <b>69 (100 %)</b>      |

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**Table 17: Uncomplicated purchase of medicine**

|            | Response frequency (%) |
|------------|------------------------|
| <b>Yes</b> | <b>42 (61 %)</b>       |
| <b>No</b>  | <b>26 (38 %)</b>       |
| No answer  | 1 (1 %)                |
| Total      | 69 (100 %)             |

**Table 18: Need for improved infant care**

|            | Response frequency (%) |
|------------|------------------------|
| <b>Yes</b> | <b>53 (77 %)</b>       |
| <b>No</b>  | <b>14 (20 %)</b>       |
| No answer  | 2 (3 %)                |
| Total      | 69 (100 %)             |

**Table 19: Mode of improvement of infant health care**

|                        | Response frequency (%) |
|------------------------|------------------------|
| <b>Public health</b>   | <b>27 (39 %)</b>       |
| <b>Health research</b> | <b>13 (19 %)</b>       |
| No idea                | 13 (19 %)              |
| No answer              | 16 (23 %)              |
| Total                  | 69 (100 %)             |

**Table 20: Need for new drugs and medicines**

|            | Response frequency (%) |
|------------|------------------------|
| <b>Yes</b> | <b>53 (77 %)</b>       |
| <b>No</b>  | <b>14 (20 %)</b>       |
| No answer  | 2 (3 %)                |
| Total      | 69 (100 %)             |

**Table 21: Mode how to proceed for new drugs and medicines**

|  | Response frequency (%) |
|--|------------------------|
| <b>Public health promotion</b>                     | <b>12 (17.5 %)</b>     |
| <b>Health research promotion</b>                   | <b>23 (33.5 %)</b>     |
| <b>Public health and health research promotion</b> | <b>5 (7 %)</b>         |
| No idea  | 11 (16 %)              |
| No answer  | 18 (26 %)              |
| Total  | 69 (100 %)             |



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**Table 22: Need for investigation on new vaccines**

|            | Response frequency (%) |
|------------|------------------------|
| <b>Yes</b> | <b>57 (83 %)</b>       |
| <b>No</b>  | <b>11 (16 %)</b>       |
| No answer  | 1 (1 %)                |
| Total      | 69 (100 %)             |

**Table 23: Pathway of drug and vaccine development**

|                           | Response frequency (%) |
|---------------------------|------------------------|
| <b>Realistic idea</b>     | <b>31 (45 %)</b>       |
| <b>Non-realistic idea</b> | <b>5 (7,5 %)</b>       |
| <b>No idea</b>            | <b>32 (46,5 %)</b>     |
| No answer                 | 1 (1 %)                |
| Total                     | 69 (100 %)             |

**Table 24: Benefit of new medical products**

|  | Response frequency (%) |
|--|------------------------|
| <b>Personal benefit</b>                | <b>18 (26 %)</b>       |
| <b>Collective benefit</b>              | <b>20 (29 %)</b>       |
| <b>Personal and collective benefit</b> | <b>22 (32 %)</b>       |
| *others                                | 9 (13 %)               |
| Total                                  | 69 (100 %)             |

\*others: advantage non-specified; no idea; no answer.

**Table 25: Perception of participants involved in an experimental process**

|                            | Response frequency (%) |
|----------------------------|------------------------|
| <b>Positive perception</b> | <b>53 (77 %)</b>       |
| <b>Negative perception</b> | <b>6 (9 %)</b>         |
| No idea                    | 5 (7 %)                |
| No answer                  | 5 (7 %)                |
| Total                      | 69 (100 %)             |

**Table 26: Change of perception during participation**

|            | Response frequency (%) |
|------------|------------------------|
| <b>Yes</b> | <b>41 (59,5 %)</b>     |
| <b>No</b>  | <b>25 (36,5 %)</b>     |
| No answer  | 3 (4 %)                |
| Total      | 69 (100 %)             |

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**Table 27: Description of change**

|  | Response frequency (%) |
|--|------------------------|
| <b>Better acceptance of research activities</b>              | <b>12 (29 %)</b>       |
| <b>Better quality of medical care</b>                        | <b>17 (41.5 %)</b>     |
| <b>Better acceptance of research and better medical care</b> | <b>10 (24.5 %)</b>     |
| No answer  | 2 (5 %)                |
| <b>Total</b>   | <b>41 (100 %)</b>      |

**Table 28: Current perception of health research activities**

|                                   | Response frequency (%) |
|-----------------------------------|------------------------|
| <b>Simple positive perception</b> | <b>40 (58 %)</b>       |
| <b>Public health</b>              | <b>14 (20 %)</b>       |
| <b>Health research</b>            | <b>8 (12 %)</b>        |
| <b>Public health and research</b> | <b>5 (7 %)</b>         |
| No answer                         | 2 (3 %)                |
| <b>Total</b>                      | <b>69 (100 %)</b>      |

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### 9 DEUTSCHE ZUSAMMENFASSUNG

Die ethische Debatte über klinische Forschung in Regionen Afrikas südlich der Sahara vermittelt den Eindruck, dass Forschung in ärmeren Ländern ein unabdingbares „ethisches Dilemma“ mit sich bringt. In der Literatur bezieht sich diese Argumentation hauptsächlich auf das mangelnde Verständnis seitens der Studienprobanden gegenüber klinischen Studien, wodurch international gültige ethische und wissenschaftliche Anforderungen nicht erfüllt werden könnten.

Die vorliegende Studie hat das Ziel, die Einstellungen und Einschätzungen zu beschreiben, die Studienteilnehmer einer ärmeren Bevölkerung Afrikas klinischen Forschungsprojekten entgegenbringen. Mithilfe von ethnologischen und quantitativen Ansätzen haben wir uns darauf konzentriert, zu erfassen, wie klinische Studien und das Gesundheitssystem von den Studienteilnehmern, die an Impfstudien teilnehmen, wahrgenommen werden. Hierzu wurde die Häufigkeit einer bestimmten Wahrnehmung oder eines bestimmten Verhaltens berechnet und in Tabellen dargestellt.

Persönliche Interaktionen und soziale Beziehungen zwischen den Studienteilnehmern untereinander, aber auch gegenüber dem Forschungsteam und der Forschungsabteilung scheinen unerlässlich zu sein, wenn man herausfinden will, wie klinische Forschung und die dazugehörigen Vorgänge von der Gesamtbevölkerung aufgenommen werden.

Die Darstellung von Forschungsabläufen und die damit zusammenhängenden Aktivitäten und deren Bezug zu anderen gesundheitlichen Themen kann durch den Aufbau von sozialen Netzwerken zwischen den beteiligten Parteien, z.B. den Studienteilnehmern, ihren Freunden und Verwandten und dem Forschungsteam erleichtert werden.

Ein Paradigmenwechsel in Bezug auf die relevanten Forschungsfragen und -methoden, die weder zeitlich befristet, noch auf international standardisierte Richtlinien beschränkt sind, würde dazu beitragen, dass biomedizinische Forschung und deren Umsetzung in Regionen Afrikas südlich der Sahara, besser verstanden und aufgenommen werden kann.

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