From informed consent to negotiated consent: an approach of research among unevenly developed countries?

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Medical and scientific research, decidedly international nowadays, necessitates a multicultural approach with a social justice perspective. Through collaborations between countries with uneven development levels, the terms of the consent, designed by the industrialized countries, raise a number of challenges. It appears important to reflect in depth on the ethics of the consent collection and to think the ability of individuals to make choices, locally, during their participation in biomedical research, when it is led by partners from countries with different culture and economic development.

Introduction

Biomedical research objectives can be considered as universal: to promote the development of knowledge and allow the sharing of their achievements. However, in many cases, the research does not bring direct benefits to the participants and the communities they come from. It even frequently presents risks that may be misunderstood by people who are involved in the studies. In order to protect the rights and interests of those involved in the research, the World Medical Association (*Association Médicale Mondiale*, AMM) has adopted in 1964 the Helsinki Declaration, *"Ethical principles applicable to medical research involving human beings"*, that it has later repeatedly reworked (updated last in 2013), to take into account the growing internationalization of research. The Council of International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) have developed in 1982 international guidelines, in order to "indicate how the ethical principles applicable to biomedical research on human subjects, as defined in the Helsinki Declaration, could be followed by effects, particularly in developing countries, given their cultures and socio-economic conditions, national legislation and terms of administration and management of these countries." These guidelines were revised in 2016[2] to better integrate the development of translational research in developing countries and the "big data" phenomenon.

[2] CIOMS, *International Ethical Guidelines for Health-related Research involving Humans*, 2016

According to the Helsinki Declaration, the mechanism at the heart of the protection of individuals involved in a research is free and informed consent. People engaging in a clinical research protocol hope that their participation will be associated with or followed by care not available otherwise. But studies show that they often overestimate this possibility. More studies are needed to understand why this overstatement is common and how it can be an obstacle to informed consent[3]. In the areas of poverty, without well-established scientific research culture, the rules are generally applied without deliberation, whereas informed consent is a model of participatory and deliberative decision. The implementation of research projects in partnership among unevenly developed countries requires redefining informed consent in context and to strengthen the deliberative process where the researcher and the subject participating in the study agree on a shared goal making sense to each of the actors. Then we can speak of a "negotiated consent." "The trajectory of the consents is at the same time linguistic (there is a certain type of message), political (the backgrounds and interests co-exist), anthropological (there is question to review the relationship to the other in a context of research and fragility), and economic (the research commits a lot of material resources and sometimes indicates differences in the levels of income and life)." [4]

In his "capabilities" approach[5], translated in French by "*capabilités*" [6], the economist and Nobel Prize for Economics winner Amartya Sen proposes to improve people's lives in developing their capacity to meet their basic needs. Capability is the concrete possibility for a person, beyond its socio-economic determinism, to choose different functioning combinations. This approach will serve as a reference frame in our reflection on consent in areas of the world where choice and autonomy remain valid options, even if a community approval step is sometimes a prerequisite for individual consent[7].

Article 25 of the Helsinki Déclaration of the Wolrd Medical Association

"The participation of persons able to give informed consent to medical research must be a voluntary act. Although it may be appropriate to consult family members or officials of the community, any person capable of giving informed consent may not be involved in research without his or her free and informed consent".

Admitted by all, the autonomy principle requires that anyone capable of discernment as to his personal choices, be treated in the respect for her or his self-determination faculty. Yet its

[3] Lynn A. Jansen *"Mindsets, informed consent and research "* Hastings Center Report 44, 2014
[4] Jean G. Bidima, *Du consentement éclairé au « consentement négocié en Afrique : points de suspension, ouvrons les guillemets*, oral presentation during the 4th day of the yearly Ethics Committee meeting, see the full text in Appendix 1
[5] Amartya Sen, Development as freedom, Oxford University Press, Oxford, 1999
[6] Mylène Botbol-Baum, *Pour sortir de la réification de la vulnérabilité, Penser la vulnérabilité du sujet comme capabilité*, in *Travail et care comme expériences politiques*, UCL Presses Universitaires de Louvain, October 23 2017, p51-63 https://www.academia.edu/34955175
[7] Diallo Dapa, Doumbo Ogobara et al., *Community permission for medical research in developing countries*, Clinical Infectious Diseases. 2005, vol. 41, no. 2, p. 255-259, https://archive-ouverte.unige.ch/unige:85364

implementation is not always simple. The increasing scientific complexity of research projects and the variety of contexts can be sources of vulnerabilities. The capacity to consent can thus be hampered by the lack of understanding of scientific methods and the asymmetry of knowledge and power between researchers and research participants. The written consent, if it formalizes the situation in terms of procedure, is sometimes artificial, or even inappropriate. It does not guarantee an “ethical security” for individuals if they do not have the capacity to deliberate on the rules and adapt them to their needs and their beliefs.

The provisions on the enforcement of the consent are therefore meant to evolve, to better take into account both the current scientific issues and the concern for people’s autonomy. In the face of the plurality of cultures and socio-economic contexts, there is a need to go beyond the debate between ethical universalism and cultural relativism, to build research projects combining local and international requirements. The challenge is to create an inclusive universal standard, that develops in the discussion, in order to respect the plurality of values.

The purpose of this note is the study of the main challenges faced by the research teams in the collection of the free and informed consent to biomedical research. The note explores the provisions that would improve the validity of the obtained consent in research projects conducted in partnership among unevenly developed countries, offering an evolution towards a "negotiated consent". Issues of the future of personal data and the collected samples, as well as sharing the benefits of research, will be addressed. It will be approaching the subjects’ capability, in a joint reflection among the INSERM Ethics Committee, the Advisory Committee on Deontology and Ethics (*Comité consultatif de déontologie et d’éthique*, CCDE) of the IRD, and the “Souths” researchers, based on a dialogue between biomedical and social sciences[8].

[8] A-M Moulin, Editorial of the second Newsletter of INSERM Ethics Committee (https://www.inserm.fr/recherche-inserm/ethique/comite-ethique-inserm-cei/lettre-information-comite-ethique)

I – Promote the capabilities to give one’s consent

The consent collection is nothing without the shared information allowing this consent to be free and informed. If obtaining a written and signed agreement is needed, the information must come first. The latter must be given primarily by oral communication including the elements of the written document for discussion. It's the time spent with the voluntary subject to participate in a research project, and the quality of the exchanges, which will enhance her or his ability to give truly informed consent. Transparency of information and the availability of documentation from all biomedical research partners are essential.

The support of one’s economic and social destiny is a challenge on a daily basis for each of us, given the variability of available information and individual differences of perception and understanding of this information. What happens to one who engages in a biomedical study participation?
In his capability approach, based on human development as concrete freedom, Amartya Sen proposes to institutionalize two interrelated principles: i) the free decision-making capacity before the consent, and ii) the principle of democratic development, inspired by the description of the injustices that indicate a negotiated solution of justice. Sen first raises the question of whether people to whom a research project is proposed are really seeking it.

So the goal is not the transformation of individual values, considered from the sole perspective of the investigator, but more widely the promotion of the concerted improvement of the life conditions in context. This approach according to Sen takes very seriously the participatory dimension of consent and the affirmation of individual choices. It transforms the consent project into a negotiated project. In the capabilities approach, the development of the autonomy of the actors and society become inseparable. For example, women's literacy is associated with their capacity to consent, but it also has an effect on social and family norms. It allows better fertility control and a fairer resources distribution.

As indicated in the report of the UNESCO International Bioethics Committee on 'big data', the autonomy enjoyed by the individual in the exercise of her or his self-determination contains seven dimensions[9]:

i. The individual has the capacity to access the information, understand it, evaluate it, and put it into practice.
ii. She/He has information on the subject, both understandable and relevant.
iii. She/He has a choice between several solutions (act or abstain, or choose among several possibilities).
iv. Her/his values, preferences, and attitudes are taken into account in the decision and act.
v. She/He can make decisions and act on her/his own without any external or internal constraints.
vi. She/He can choose a goal and the means most appropriate to achieve it (formation of the will).
vii. Action refers to a conscious act or a conscious refusal to act.

It is important to note that in many traditional societies, the participation of a person to a research project, regardless of their social status, requires beyond personal consent, an agreement of his family - father, mother, aunts, uncles, big brothers, big sisters, etc.

The international bioethics symposium in Brasilia[10] allowed bioethics discourse to be re-appropriated by emerging countries like Brazil and India, but also by many African intellectuals. Sen's approach has also influenced the United Nations Development Program (UNDP) for which human development implies the freedom of people to live the life of their choice[11].

[9] Mertz M.et al. 2016. Digitale Selbstbestimmung. Cologne Center for Ethics, Rights, Economics, and Social Sciences of Health. http://ceres.uni-koeln.de/fileadmin/user_upload/Bilder/Dokumente/ceres_Digitale_Selbstbestimmung.pdf
[10] International Congress of Bioethics Brasilia 2005, published in World Bioethics
[11] United Nations Development Programme, Human Development Reports, http://hdr.undp.org/en/humandev

Ethical system put in place by the San community [12]

The San community of South Africa is one of the oldest in the world and is of interest to the international scientific community. In the absence of a legal and ethical framework, multiple studies have been conducted on the Sans, with little regard and respect for this community. In response the Sans have recently set up an Ethics Committee and a "South African San Institute." The Institute is responsible for protecting and promoting the whole of the community, through:

- the dissemination of a Code of Ethics
- reinforcing the capacity of individuals
- community mobilization
- health and social development
- the promotion of rights
- the promotion of sustainable economic development, which is not at the expense of the cultural identity and heritage of the San people.

'Women who care' in Colombia [13]

The capabilities approach consisted, in a research project in Colombia, to rely on the traditional role of women who care within the family, giving them a social recognition, by training them in vector transmitted disease prevention. They went from a family role perceived as natural to the health management of the family. They are now recognized as health agents within the family and beyond, at the level of community and national public health institutions.

[12] Ewen Callaway, South Africa's San people issue ethics code to scientists, Nature 543, 475–476 (23 March 2017) doi:10.1038/543475a

[13] Nadia Lorena and Mylene Botbol-Baum, *« Addressing vector-borne diseases in rural Colombia and women capabilities »* Journal de Bioéthique 3, 2016

II – Meeting the challenges of informed consent

A number of challenges, not exhaustive, and proposals to allow free and informed consent, and a truly shared decision, are outlined below.

1) Put in place the practical conditions of free and informed consent

Obtaining consent attests to the fact that the researcher and promoter have sought and obtained the agreement of a person to participate in a research. It is the result of a reciprocal commitment in which everyone recognizes their role, rights and responsibilities. The obligations concern only the researcher and the promoter, but by consenting to participate in a research, the volunteer accepts its terms and conditions. The reciprocity of the commitment creates the conditions conducive to the exercise of the autonomy of the participant.

But the situations of people who are asked for consent are far from homogeneous. Socio-economic and cultural contexts often dictate the possibility of exercising autonomy and therefore require special attention in low-income countries.

"With good intentions, the pre-judged is disqualified in the cycle of communication of negotiated consent." In fact, "negotiated consent, since it takes into account the capabilities, narratives and imaginaries of the subjects in negotiation, cannot ignore the pre-notions and pre-judgments that frame any structure of understanding, of interpretation and negotiation.

“[...] Can one understand the other by eliminating pre-notions and pre-judgments during the negotiated consent process?” [14]. Of course not!

Individual and community

In many traditional societies, the individual is not commonly called upon to give his or her opinion in a totally independent way. In some communities, women are structurally in a relationship of dependency, relative to the spouse and to the whole family and community. The challenge then is to promote the expression of individual consent, while allowing the participation of a community word, which would constitute interference if it is unsolicited, and negligence if it is not proposed.

[14] Jean G. Bidima, *Du consentement éclairé au « consentement négocié » en Afrique : points de suspension, ouvrons les guillemets…see Appendix 1*

In many African countries, permission was traditionally requested from the village chief or a group of notables (Marabout, priest, teacher Trader...).

Urbanization has changed the usage somewhat, and there is currently a superimposition of diverse communities of affiliations and references, which requires a reflection on the choice of local interlocutors and from the researchers to know precise socio-anthropological details of the populations with which they work.

A Community advisory Council in Haiti

The GHESKIO Centers in Haiti have set up a Community Advisory Council (Conseil Communautaire Consultatif, CCC), a link between the institution of care and research and the community. It is composed of 23 members representing different sectors of national life: Religious (Catholic, Protestant, Voodoo), people living with HIV, volunteers who participated in pre-GHESKIO studies, press professionals, educators, Health workers, women's groups, academics, human rights associations. Prior to any study, GHESKIO executives present the study to the CCC – its interest and objective, its participants, its risks and benefits – to gather feedback from its members. GHESKIO executives keep the CCC well informed of all research projects and interventions and ask the CCC about the potential interest of the population to participate.

Oral and written Tradition

In the world, the given word retains great value and there is often a distrust, of old, vis-à-vis the written words[15]. The written word refers to the paperwork of State and administration, which creates a mistrust on the part of the users. The written word appears more like a blank seal granted to an authority, and a commitment for which retraction is difficult, rather than a protection of the signatory. Illiteracy and language barriers complicate this compulsory registration of a written record of free and informed consent which, if it formalizes the situation, does not offer a real "ethical security"[16]. Thus, the interview has in practice a greater importance for the commitment in the research than the signature. This point is regularly highlighted in the opinions and recommendations of the CCDE of the IRD.

[15] Aïssatou Mbodj-Pouye, *« Le fil de l'écrit. Une anthropologie de l'alphabétisation au Mali »*, Lyon, ENS-Ed. 2013
[16] Pape JW. Ethics Review Committees: Consideration in Developing Countries. Emerging Infect Dis 2001; 7:3.

A discreet and quiet place, fostering confidential exchanges between researchers and potential participants in the research, is necessary. The time allotted for explanations is a quality factor. It can vary depending on the people, but the essential point is the availability of the professional who is ideally introduced by a person of confidence, recognized by the person and her/his community.

Secular expert patients

Some research projects involve a mediator or a representative of the village, the clan, the community. "Nothing for us without us." With AIDS, the “Community Advisory boards” appeared. Several people living with HIV have formed "secular experts" groups, particularly in sub-Saharan Africa but also in Southeast Asia[17].

In Guinea, the survivors of Ebola were asked in the aftermath of the epidemic to intervene as mediators to healed people to encourage them to participate in PostEboGui, a study on the evolution of their health over time[18].

2) Managing conflicts of Interest

The interests of researchers, communities and individuals do not necessarily coincide. And the holders of power, whatever their origin, which differ according to the regions and the circumstances, can have a great influence on the decision-making capacity of the individuals subject to this power.

In the north and the South, consent refers to a potential conflict of interest between the researcher and the participant. The Director of a research programme, conducted in a context of international competition, has an interest in rapidly including participants in his study so that his project will succeed and be published. This allows him/her to justify the allocated resources and to build his/her scientific career plan, as well as that of his team and partners. However, s/he remains the first guarantor of the volunteers’ protection and of the data integrity. The other actors and partners in clinical research, and in particular the ethics committee, the Independent Supervisory Committee and the external evaluators, generally intervene in a second, later,

[17] Eve Bureau-Point, *Les patients experts dans la lutte contre le sida au* Cambodge *»,* Université de Provence, 2016

[18] Jean François Etard et al., Multidisciplinary assessment of post-Ebola sequelae in Guinea (Postebogui): an observational cohort study, Lancet Infectious Diseases, 2017, 17 (5), p. 545-552. ISSN 1473-3099

period in the event of a deviation from the protocol or a serious adverse event. The principal investigator is responsible for the proper and contextualized training of her/his teams in good clinical research practices and ethics, including aspects of inclusion and free and informed consent of participants to the study.

Inequality between partners engaged in international research, when the majority of research budgets comes from countries with strong economies (particularly in the vaccine and therapeutic trials), invites to evaluate, as soon as the project is developed, the existence of potential conflicts of interest between the different actors in the research (including the participants) and to try to provide a solution, prior to the start of the study.

There is a debate on the difference between preventive and therapeutic research interventions, with the consent, according to some authors, not being subject to the same requirements. This distinction is far from obvious. It is based for Calain[19] on the authors' intention and on a difference in the benefit/risk ratio and its perception. But it must also consider the perception of participants without alternatives. In a situation where the health system is failing, it may be preferable to distinguish between a clinical research team and a care team, and to clearly explain the difference to those involved in the research.

Two teams for research and care in an Ebola treatment center [20]

The extreme vulnerability conditions of people admitted to the Ebola Treatment Centre (ETC) necessitated a double team at the bedside of the patients for the collection of their consent during a therapeutic trial in Sierra Leone: the research team very mindful to respect the ethics of biomedical research, meticulously applying the rules of information and collection of consent; and the healthcare team, responsible for the respect of the patient's interest, with the goal of healing. These two teams, although in permanent communication, were totally independent. The rules of the ETC were clear: the care of the patient priming on the research.

[19] Calain P et al., Research Ethics and international epidemic response : *the case of Ebola and Marburg Hemorrhagic Fevers*, Public Health Ethics 2009, 2, 1, 7-29

[20] Christophe Longuet, Alex Salam, Jake Dunning, *« Recherche sur Ebola : une rencontre entre science et humanitaire »*, Alternatives Humanitaires, numéro inaugural, février 2016

3) Sharing scientific information

In the process of collecting consent, dialogue is an absolute necessity to clarify misunderstandings about biomedical research. It is useful to be aware of the following questions when sharing scientific information with research participants: the mistrust of research, the relationship between science and traditional knowledge, the simplification of complex scientific concepts. Translating a newsletter from one language to another often poses an additional challenge.

Mistrust of research

In low-industrialized countries, given the weakness of health systems, access to research is often seen, as we mentioned earlier, as an opportunity for access to care and promising therapies. At the same time, the feeling of playing the role of "guinea pig" on behalf of Northern researchers is often expressed. During the Ebola outbreak in West Africa, research and care teams were even accused of participating in an attempt to eliminate people orchestrated by the political power. Several factors come into play in the genesis and dissemination of such messages, among which the lack of clear, accessible scientific information understandable by all.

The information phase of potential research participants must enable the clarification of a number of sometimes sensitive issues: how to intelligibly explain technical features of trials such as randomization and placebo? How to render admissible the possible absence of direct benefit to the participant?

In the sharing of information now comes a new actor: the Diaspora established in the city, in Europe, in the USA, etc. It regularly exchanges with the communities through the new communication means (social networks, Internet). The villagers use it as a primary source of information considered informed and objective.

Individual consent should ideally take place at the end of a process of co-development of the research project with local communities and researchers from these communities. The independent ethics Committee of the GHESKIO Centers, established from 1982, decided that no vaccine or drug candidate study would be carried out in phase I in Haiti[21].

[21] Phase I trials correspond to the first administration of a drug in humans. Their main aim is to study drug tolerance and to define the administration dose and frequency.

The steps leading to informed consent in GHESKIO Centers in Haiti

In the GHESKIO Centers, three stages of pre-consent allow the consent phase per se to be reached. They are:

1. Elicit and determine the interest of individuals to participate in the clinical trial via information given in the waiting room or throughout the community.
2. Carefully inform the interested persons of the different stages of the study by social workers (number of visits, duration of the study, frequency and quantity of blood taking...). When a large number of volunteers must be recruited, this step can be done using a video designed for that purpose[22].
3. Evaluate the knowledge of volunteers through a standardized questionnaire that reviews all the steps of the study. The volunteer must obtain a score of at least 80 on 100 to be able to participate in the study[23].

The volunteers are then entitled to sign the consent form in Creole. Those who do not know how to read or write sign with a cross or affix a fingerprint, in the presence of an adult of the family and a member of the GHESKIO. Only the best informed and the most motivated are thus entitled to participate in the clinical trial (6 to 15% of the candidates) allowing a very small number of premature stops of the study.

Relationship between science and traditional knowledge

Faced with the temptation to impose everywhere the Western "scientist" vision, we must ponder on the place of other medicines in the international search. How can local knowledge be taken into account for a respectful and context-appropriate consent? This implies, among other things, a dialogue between traditional approaches and scientific approach, often invoked but difficult to achieve in practice, with very diverse interlocutors who have their own strategy and vision of care. Should the presence of a third party, an interpreter, a trustworthy person, an "opinion leader" be preferred?

What are the elements of choice and their consequences in terms of development democratization, according to Sen's expression? Several questions remain open in an evolving and intersubjective process.

[22] Joseph, P et al., The use of an educational video during informed consent in an HIV clinical trial in Haiti. JAIDS 2006; 42:588-591

[23] Fitzgerald DW et al., Comprehension during informed consent in a less-developed country. Lancet 2002; 360:1301-2

The simplification of complex scientific concepts

Theoretically, the information must be complete and understandable. There is still a need to take into account the uncertainties of science. The transmission of Ebola by sexual means is still poorly known, or the efficacy of an experimental vaccine is by definition not fully established, not to mention the difficulty in understanding the functioning of the immune system.

Although there is a willingness to "popularize" it, the information and consent note is still very often written in unintelligible scientific jargon, even for participants whose mother tongue is English or French. A meta-analysis on the understanding of information given to participants in clinical studies conducted mainly in middle-and high-income countries, showed a variable understanding of the different aspects of research: at best 75.8% for the freedom to withdraw at any time from the study to, respectively, 52.1% and 52.3% for randomization and placebo[24].

Access to the investigative physician for further explanations, as stipulated in the consent form, is often another challenge, given the very vertical doctor/participant situation in many countries, and the little availability of practitioners with overloaded diaries.

[24] Nguyen Thanh Tam et al., Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis, Bulletin of the World Health Organization 2015; 93:186-198H. doi: http://dx.doi.org/10.2471/BLT.14.141390

A tool to help mutual understanding [25]

"Focus groups" can be organized in the course of the development of a research protocol, in which potential participants, in small talk groups, interact with the project leaders on different aspects of the protocol. Everyone has the opportunity to express, in their own way, what they understand about the project, their place in it, and to suggest ways of improvement. For the researcher, his/her presence in these talk groups is a way to better understand the potential participants perspective, their culture, their beliefs and the benefits they expect from the research. The participation of volunteers in the development phase of the protocol improves the information and consent documents as well as the procedures for inclusion in the research project. Greater understanding and participation of volunteers are the expected benefits of this tool to help mutual understanding.

Translation of the newsletter

When sharing scientific information with participants from a country whose language differs, the translator must find the character of the words in the other language. But the loss of meaning can be great when translating and lead to major disputes. It is then necessary to allow that some passages of a text or a dialogue become food for thoughts for researchers and clinical trials candidates. The created dynamic allows the empowerment and autonomy of the subjects of low-economy countries. So the question here is what researchers and clinical trials candidates are doing to avoid disputes, disagreements and misunderstandings[26].

It is, however, more intellectually honest, and it seems to us more ethically acceptable to realize the difficulty, even the impossibility, of translating certain scientific concepts, for example those of molecular biology, into vernacular languages. In this context the understanding of the study cannot be considered as total. Researchers must then ensure that the understanding of the issues for the participant is sufficiently enlightened to allow a real choice to participate or not in the study.

[25] Roshan das Nair et al., Exploring recruitment barriers and facilitators in early cancer detection trials: the use of pre-trial focus groups

[26] Jean G. Bidima, Du consentement éclairé au « consentement négocié » en Afrique : points de suspension, ouvrons les guillemets…see Appendix 1

An example of information and consent form in Laos [27]

In Laos the National Ethics Committee requires that each research protocol be submitted to the Committee, both in English and Lao. The information and consent form should aim at simplicity and conciseness and use terms understandable by the research participants.

For example, in a research project on the detection of HPV and cervical cancer among women living with HIV, some terms, not existing in Lao, have been clarified in the information form and orally:

- HPV is the "germ" that causes cervical cancer.
- Cervical smear is a cervico-vaginal swab to look for cancer cells.
- Colposcopy is a microscopic examination of the cervix.
- The biopsy is the collection of a small piece of the cervix to look for cancer.

The term genotype exists in Lao. However, an oral explanation was needed to evoke the existence of high-risk carcinogenic HPV genotypes.

A major challenge in this study was the popular belief that touching cervical cancer aggravated the outcome.

4) Transferring personal data and biological samples

Use of personal biological data and samples

The European Directive 95/46/EC on the protection of individuals regarding the processing of personal data and the free circulation of such data defines personal data as any information relating to a person identified or identifiable directly or indirectly, by reference to an identification number or to one or more elements, specific to its identity. Personal health data are considered to be sensitive data requiring specific protection.

Biological samples can be obtained from individuals for the purposes of a research project, or from patients who have undergone diagnostic or therapeutic interventions, autopsy, organ

[27] Phimpha Paboriboune, Le projet de recherche clinique LaoCol-VP de dépistage du cancer du col de l'utérus chez la femme vivant avec le VIH, Ethics in research for international development: environment, societies and health in the countries of Greater Mekong region, International symposium, Vientiane (Laos), October 26-27, 2015

donations or tissue from living or dead persons, organic substances (including excrement, urine, sweat and saliva) or abandoned tissues. Once the biological samples are taken, they can be stored in biobanks and serve as research resources for many years.

Over the last twenty years, new issues have arisen related to the development of computer tools (international databanks) allowing the storage of "mass data" and whose potential for undue exploitation can fuel suspicion. The data is transformed into potentially usable knowledge for purposes beyond the initial aims of the project[28]. Therefore, how can the interests of research participants be best protected when sharing data and biological samples between countries with unequal development? How is the data flow? What is the fate of the samples taken?

The collection of biological samples in a research project leads to the discussion of the local representations of body integrity[29]. Blood is valued in all cultures and its subtraction is often regarded as a lessening of the vital force, even as an identity theft: the manipulations of the teams that carry out the samples can be considered suspicious. Simple stool, nail, skin and hair removals can be erroneously estimated by researchers as insignificant, whereas they can have a strong symbolic importance in the eyes of the interested parties. Since samples are not often maintained in good conditions in the South, they are frequently exported to the North, reinforcing the impression of theft and "vampirism". Strengthening local capacity to preserve samples would limit these rumors[30].

Genomics research is bringing new demands on the part of users, who wish in particular to obtain a clear view about the future of their samples and the access to information that might be revealed about themselves. The advertising of personalized predictive medicine thus leads more and more subjects in the Northern countries to claim genetic information as complete as the current means permit.

Such a claim is also legitimate in the countries of the South where genomic research has become a reality. According to Appelbaum,[31] there are several options in the consent for the return of information on unexpected findings ("incidental findings") in genomics research, including mandatory return if participants agree to receive information on unexpected discoveries and "outsourcing" for which participants receive their raw data and can submit

[28] Annecy Workshop organized by the Inserm Ethics Committee, the Mérieux Foundation and the GFBR, November 2015, https://www.inserm.fr/qu-est-ce-que-l-inserm/l-ethique-a-l-inserm/seminaires-du-comite-d-ethique/groupe-de-travail-recherche-en-sante-dans-les-pays-du-sud

[29] Doctors and Vampires in Sub-Saharan Africa: Ethical Challenges in Clinical Trial Research
Koen Peeters Grietens et al. The American Journal of Tropical Medicine and Hygiene, Volume 91, Issue 2, Aug 2014, p. 213 – 215 (http://ajtmh.org/cgi/doi/10.4269/ajtmh.13-0630)

[30] Louise White, Speaking with Vampires Rumor in Colonial Africa, Berkeley, University of California Press, 2000

[31] Paul Apelbaum, Erik Parens et al. ,“Models of consent to return of incidental findings in genomic research”, Hasting center, Report July – August 2014

them to an external source for interpretation. It is right to question the conditions for transposing these options in limited-resource countries[32].

5) Sharing benefits, understanding the risks of research

Sharing the benefits of research, including access to new treatments and vaccines, is legitimate but usually exceeds the actual opportunities for engagement of researchers and even proponents of clinical studies.

Individual and collective benefits

Researchers carry the responsibility to promote the sharing of the benefits of their research. They have to contribute to the development of the populations with which the research is carried out. The research eloquently dubbed "helicopter" or "safari" is a practice of another age, albeit hardly ancient, of a real looting of the resources of the Souths. In co-operation projects, it is appropriate to allow a fair distribution of the benefits of research. The community that accepts a clinical trial in its territory is waiting for two kinds of benefits: 1] a direct benefit for the volunteer who agrees to participate in the research, and 2] a collateral benefit for the family and the participant's community. Nevertheless, the individual and collective direct benefits of research are often minimal compared to the benefits represented by advances in scientific knowledge. And direct individual benefits are often less related to research results than to the care provided to participants during the research. Particular attention must then be given to the potential drift of excessive and undue incitement that could alter the research participant's ability to judge.

Researchers, doctors and other research actors have a moral obligation to increase the knowledge and skills, in the specific field of their intervention, in the countries participating in their study. Thus, the recent epidemic of Zika in Latin America, with its impact on pregnant women from the poorest environments, directly raises the problem of sharing the benefits of the undertaken research. How can we ensure, beyond studies, the circulation and transfer of research knowledge and results, positive or negative, to health authorities, professionals and the general public? Scientific information is a global public good; every people, country, must be able to access it. The dissemination of scientific publications through "open source" channels is thus a practice to be favored. The sharing of knowledge makes it possible to strengthen global health security and to respond more effectively to epidemics and health

[32] Engaging Māori in biobanking and genomic research: a model for biobanks to guide culturally informed governance, operational, and community engagement activities. Angela Beaton et al. Genetics in Medicine volume 19, pages 345–351 (2017) (doi:10.1038/gim.2016.111

disasters. It is important to underline these collective benefits in the information given to potential research participants.

Nagoya Biodiversity Conference [33]

The World Conference on Biodiversity in Nagoya (COP 10), held in Japan in October 2010, welcomed 18 000 participants. The Nagoya protocol proposed a better access to genetic resources and a more equitable sharing of the benefits derived from their use (biopiracy control). In the appendix to the draft Convention, a chapter dealt with "Elements of an ethical code of conduct to ensure respect for the cultural and intellectual heritage of indigenous and local communities of interest to conservation and sustainable use of biological diversity."

The issues raised at the Nagoya conference relate to intellectual property, prior approval and consent, intercultural respect, protection of individual and collective ownership, fair and equitable sharing of benefits, active participation of indigenous and local communities in research, gender parity, confidentiality of the given information, partnership, cooperation, full participation through a participatory approach, and reciprocity. These issues are also key issues for biomedical research where human data and samples are exchanged, with a legitimate expectation of equitable sharing of research spin-offs.

6) Allow for renewed choice

Consent is often seen as a must-have but time-limited step. In fact, consent must already be debated during the writing of the project and then rigorously implemented at the time of its realization. It entails obligations that may extend beyond the project period. This may require a renewal or specification. But iterative consent is burdened with difficulties: lost from sight, difficulty of questioning what has been decided, etc. At a distance from a research project, it seems difficult and costly to ask for a new consent, in case of reuse of data and samples for purposes other than those initially foreseen in the project. Several solutions are possible.

The consent à la carte allows a real choice between several options. It is a consent more precise than the ordinary consent which has the advantage of exposing, as clearly as possible,

[33] Decisions adopted by the Conference of the Parties to the Convention on Biological Diversity at its tenth meeting https://treaties.un.org/doc/source/docs/UNEP_CBD_COP_DEC_X_1-F.pdf

the various points of the program, concerning in particular the use of collected bodily samples and personal information.

Another option is that of the broad consent, open to the use of personal data and samples –referred to as a "meta-consent"— for another later use of the data. By giving his/her overall consent, the subject authorizes any form of research on its biological samples in a particular field. This option implies an excellent understanding by the subject of the implications of such a choice. It takes into account the evolution of scientific research –new issues appear, not foreseeable at the time of the study– and the increasing importance of data and sample banks, and their future exploitation for the discovery of new diagnostic and therapeutic tools. This open informed consent approach is used in Europe and recognized by the World Medical Association (AMM) and the Council of International Organizations of Medical Sciences (CIOMS).[34] This model also elicits a growing interest in developing countries, particularly in the area of genomics and biobanks. To address concerns about the misuse of biobanks, the publication of good practices in the exploitation of big data for research involving the collection of samples and data and their storage in biobanks is being conducted. Standardized recommendations and ethical charters are issued by international organizations, such as the research infrastructure dedicated to biobanks and biomolecular resources –Consortium for a European research infrastructure (BBMRI-ERIC) [35] and the OECD on human genetics research databases [36] . Recent improvements include: (i) the establishment of patient-representative committees to review the governance process of the biobank, including the use of the potential commercial value of the data; (ii) the implementation of a follow-up procedure, whereby patients are kept informed of the nature and long-term implications of the research carried out with their data, and may indeed refuse their consent. With sufficient guarantees, such as controls ensuring that the data will not be used to make a decision about the person or will not be used so that the person and/or the community are affected, the use of the global consent is suitable for research purposes that contribute to the public interest.

[34] Report of the UNESCO International Ethics Committee on Big Data and health, http://unesdoc.unesco.org/images/0024/002487/248724f.pdf
[35] Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium, http://bbmri-eric.eu/
[36] Guidelines on Biobanks and human genetics research databases, OECD, http://www.oecd.org/fr/sti/biotech/lignesdirectricesrelativesauxbiobanquesetbasesdedonneesderechercheengenetiquehumainebgh.htm

Three models of consent

Due to new ethical challenges related to health data and biological samples, CIOMS recommendations 11 and 12, revised in 2016[37], propose three models of consent:

- "Specific Informed Consent": when the future use of the data and samples collected in the research is known.
- "Broad Informed Consent": gives permission to all future reuse in research, but by specifying several points, such as the purpose of the databank, the conditions and duration of storage, the access rights to this database, the possibility to contact the databank or the biobank and to stay informed of the reuses.
- "Informed opt-out consent": in the absence of broad informed consent, data and samples are stored and used for research, unless the participant, owner of the data and samples, does come forward and calls for the end of their use.

An evolution towards better practices in the course of research [38]

The DIELMO project, named after the Senegalese village where it was launched in 1990, was aimed at a better understanding of malaria. It provides an example of improving practices in the course of research with, for example, the introduction of meetings with local communities during the project. A regularly renewed broad consent was used to recruit participants in the long-term clinical and parasitological monitoring project, while a consent à la carte or specific consents were used when projects not originally planned were organized.

In the "negotiated consent" which takes into account the community dimension of the African individual and thereby enables participation in the decision-making process by the privilege granted to the capabilities, we stress that this consent could consider how Africans organize the therapy."[39]

[37] International Ethical Guidelines for Health-related Research Involving Humans, Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), Guideline 11 "Collection, storage and use of biological materials and related data" et guideline 12 "Collection, storage and use of data in health- related research"

[38] Aïssatou Touré, Institut Pasteur de Dakar, Example of the DIELMO project, Annecy Workshop organized by the Ethics Committee of Inserm, the Mérieux Foundation and the GFBR, November 2015

[39] Jean G. Bidima, Du consentement éclairé au « consentement négocié » en Afrique : points de suspension, ouvrons les guillemets…see Appendix 1

Conclusion

The motivations to participate in biomedical research are often linked to the access to new treatments and the care it allows. In low-industrialized countries, the weakness of health systems can exacerbate expectations. The time for information and discussion between the researcher and the potential participant is a critical time when the autonomy of the person will be expressed through his or her free and informed consent to participate, or not, in research. The researcher has a duty to explain in a comprehensive and understandable manner the proposed project, including its potential risks, its individual benefits or lack thereof, and the expected advance for science and public health, local and International. In collaborations among countries with unequal development levels, a number of challenges can make free and informed choice difficult. Reinforcing the capacity of research participants in context is then a significant investment based on a vision of the quality of life that is both objective and subjective. It also requires to strengthen in advance the researchers ability to elaborate contextual and participatory research. It is a matter, from gained past experience, to evolve the free and informed consent to a negotiated consent that promotes the sustainability of the systemic effects of research, towards health development for the benefit of all, with concrete solutions in terms of justice and the quality of research and care.

The question of tact arises from the beginning of the scientific process, when the research objectives and participation in the common discussion are exposed. "Tact means to take into account the person with consideration and respect, by intervening in the auspicious time, in the propitious space and in the propitious way. With negotiated consent, despite the difference in culture, we have the requirement to build a common world. This requirement stems from the duty to produce norms, discursive practices and social utopias that put in motion people, communities, interests, misunderstandings, weighings, measures, words and decisions that bear and challenge."[40]

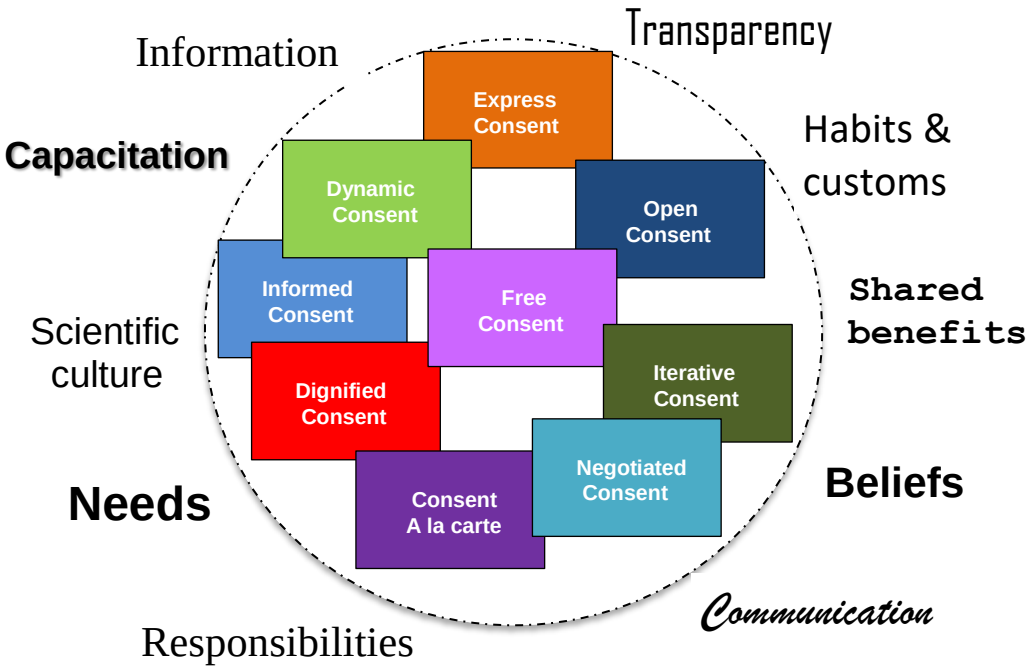
International biomedical research offers great opportunities for reciprocal development. It must be conceived in a joint ethical reflection ensuring a fair sharing of benefits.

To return to the etymology of the word consent: "to feel with the other" makes it possible to return to the gist of the consent approach. Many terms are associated with consent, as shown in the figure below: informed, dignified, dynamic, free, iterative, open, à la carte... We propose

[40] Jean G. Bidima, Du consentement éclairé au « consentement négocié » en Afrique : points de suspension, ouvrons les guillemets…see Appendix 1

to add the negotiated consent where the capabilities of the participants are taken into account to strengthen both the quality of the research and the quality of life of the research participant.[41]

[41] Aïssatou Touré proposes in Appendix 2 a comment to this note entitled « Du danger de la terminologie de consentement négocié dans le domaine de la recherche impliquant l'être humain. » [The danger of negotiated consent terminology in the field of research involving the human being]



Note: The oppositions North / South, industrialized country / weakly industrialized country, developed country / developing country, though they may be relevant in some specific cases, are far from reflecting the situations reality and complexity. These terminologies do not fully satisfy the authors of this note. However, asymmetry exists and it is important to take it into account when thinking about free, enlightened and negotiated consent.

Appendices

- Appendix 1 Comments of Jean Godefroy Bidima
- Appendix 2 Comments of Aïssatou Touré

FROM INFORMED CONSENT TO "NEGOTIATED CONSENT" IN AFRICA:

SUSPENSION POINTS, OPEN QUOTE...

Jean Godefroy Bidima

INTRODUCTION

Because *consent*, whether informed or negotiated, formulates itself as a linguistic activity, we will take the liberty of asking a few questions on the subject with the aid of the Jakobson's functions of language. As a reminder, Jakobson distinguishes six functions of language: 1/ *emotive* – relating to the Addresser (sender) of the message, 2/ *conative* – relating to its Addressee (receiver), 3/ *referential* – relating to the context, 4/ *metalingual* – relating to the code, whether or not it is shared by the message interlocutors, 5/ *phatic* – related to the *maintenance of contact* during the interaction, and 6/ *poetic* – which is *focused on the message* itself. We may, by analogy, consider the circuit of consent to comprise these various linguistic phenomena. Whether we are talking about the communication players who issue the consents, those who receive them, the various environments in which places are assigned and the roles, and for which we can evaluate the capabilities of those holding them, the codes from which the discourse is derived and their relevance, or the form of the consents itself – the consent trajectory is simultaneously ***linguistic*** (a certain type of message is involved), ***political*** (contexts and interests coexist), ***anthropological*** (about rethinking how we relate to others in a context of research and vulnerability) and ***economic*** (research uses lots of material resources and sometimes highlights disparities in lifestyle and income). If we are to ascertain what the southern countries want and more importantly how they can become real stakeholders in consent which not only is "***informed***" (imposed by the northern countries) and negotiated (with material resources and powerful rhetoric), but above all is measured (with the use of tact), we need to explore linguistic considerations, anthropology and ethics. We will focus on three elements of the document submitted for our attention[1]: the question of the

[1] This text is a response to the paper "*Du consentement éclairé au consentement négocié : Une approche de la recherche entre pays au développement inégal*" by the "Health Research in the Developing World" Working Group. This group brings together the Inserm Ethics Committee, the French Research Institute for Development Ethics Committee and experts from various developing countries. The document was presented by Dr. Christophe Longuet. In actual fact, my text is less of a response and more an extension of that submitted by Dr. Longuet. We would like to thank Dr. François Hirsch for his invitation.

insurmountable aspects of communication in negotiated consent (I), the ethical dimension of informed and/or negotiated consent (II) and the anthropological dimension of negotiated consent. But before we begin to quickly go through these, we will summarize the points that attracted our attention in the aforementioned document.

SUMMARY OF THE DOCUMENT

The document submitted to us highlights a paradigm shift. For the researchers conducting clinical trials it is no longer about going to Africa with the "informed consent" in a sealed envelope. The latter is often perceived as a methodology imposed from above with a rhetoric and enunciative mechanism that do not elicit the speech and movement of those who will undergo these therapeutic trials. With so-called informed consent, the African populations invited to participate in these trials have the impression of being "conned" and of being involved in an adventure in which they are mere "consumers" of such products as the consent paper needing signature and the ensuing clinical trial. Do they feel they have a place in the informed consent preparation process? Not really. This is because in the forms to be signed, the area reserved for the signature of the participants is usually small and found at the bottom of the page. The rest of the page is, we imagine, saturated with dazzling rhetoric that is too technical for those undergoing these clinical trials. With "negotiated consent", the participating populations enter into discussion with the researchers in order to find a common platform for negotiation. Here, physical contact, speech in its various modalities (sometimes intermittent, sometimes benevolent, sometimes adept), and the links between the trial researchers and target group members (*grassroots communities*, to borrow this expression from the era of single parties in Africa) precede any act of signature. What counts in this approach is not the act of signature as such but the mutual discovery between researchers and local populations. The major issue also resides in developing or discovering the capabilities (in the sense of Amartya Sen) of the populations during these negotiations. Shared speech, debated questions, requested explanations, errors of appraisal and the experiences of the various parties become conditions of intelligibility of what is in question. This negotiated consent process therefore represents a lengthy phrase which – whether linear or disjointed – always contains suspension points and quotation marks – the latter of which will open in the discussion that follows.

I-THE INSURMOUNTABLE ASPECTS OF COMMUNICATION IN NEGOTIATED CONSENT

1/ Prejudice

The process of negotiated consent, while recognizing the question of perception and the specific structure of orality, does not consider prejudice to be one of its founding elements. With good intentions, we disqualify prejudice from its communication cycle. Especially when it comes to the populations of the Third World, it is desirable to avoid prejudice during the consent process. Already ill-reputed in research, prejudice is also disliked in negotiation. In general, the heritage of Enlightenment philosophy and Cartesianism, preceded by religious struggles and exclusions of all kinds, convinced people of the legitimacy of eliminating prejudice from speech and chains of negotiation. Descartes, for example, distinguished the prejudices of haste and prevention which are judgments made before having reached the evidence presented clearly and distinctly. We often embark on conversation and negotiation with this in mind, shunning prejudice. However, we consider that prejudice is not something that consent is able to forgo, meaning that we need to change our understanding of this concept. It was the German philosopher Gadamer who, in his work *Truth and Method*, considered prejudice to form part of the fundamental structure of the situation of understanding and interpretation. *"The recognition that all understanding inevitably involves some prejudice gives the hermeneutical problem its real thrust […] And there is one prejudice of the Enlightenment that defines its essence […] the prejudice against prejudice itself […]"*[2] For Gadamer, we enter into situations of communication, comprehension and interpretation with existing ***preconceptions*** and ***precomprehensions***. Gadamer uses prejudice in the legal sense of prejudgment, namely the knowledge a judge has before reaching the final verdict. The judge must not stop at these prejudgments but rather – once the evidence has been gathered – confirm or abandon them. " *The history of ideas shows that not until the Enlightenment does the concept of prejudice acquire the negative connotation familiar today. Actually "prejudice" means a judgment that is rendered before all the elements that determine a situation have been finally examined. In German legal terminology a "prejudice" is a provisional legal verdict before the final verdict is reached […] Thus "prejudice" certainly does not necessarily mean a false judgment […]".*[3] Negotiated consent, because it takes into account the capabilities, utterances and perceptions of its participants, cannot forgo the *preconceptions* and *prejudgments* that form the framework of any structure of comprehension,

[2] Hans Georg Gadamer, *Vérité et Méthode*, Paris, Editions du Seuil, 1996, p291
[3] Ibidem, p291

interpretation or negotiation. The questions we could ask of the negotiated consent players here are: what is the place of these *preconceptions* and how do they evolve during the consent negotiation activity? What is it that ensures the transition from *prejudgment* to *judgment*? Which players, codes of interpretation and contexts work towards or against the success of negotiated consent? In other words, can we understand the person in front of us by eliminating *preconceptions* and *prejudices* from the process?

2/ Misunderstanding

In the negotiated consent process, the document submitted to us centers its concerns around the concept of ***dialog***. There is no question of imposing therapeutic trial models on the weakest without listening to or speaking with them. Speech is therefore a fundamental aspect of this process. Negotiated consent is when each player speaks. We could, in reference to Gérard Reach's book, *A theory of care*[4], say that negotiated consent has a diacritical dimension. It is a criticism of: a/ a paternalistic conception of patient autonomy – "I decide for you", b/ the informative model – "I tell you what I know", c/ the interpretative model – "I help you to define your preferences, we are in a situation of 'equals'"[5]. The fourth model – which for Reach is the deliberative model – in addition to proposing mediators, also enables speech and the circulation of speech with an objective to inform. What is important here is the concept of speech, which is an act signifying trial subject accountability and autonomy in the southern countries. But deep down, what does *speech* mean when one is economically and technologically weak? A question raised by Michel de Certeau is relevant here when it comes to consent negotiations involving African populations: "*Is there an equivalence between 'taking speech' and 'taking matters into one's own hands?'*"[6] The negotiation that takes place between researchers and those needing to know why they should accept or refuse therapeutic trials with their potential dangers and benefits, the mediators and village communities assembled to engage in dialog with the researchers beneath the gaze of Charters written by authors and approved by States so far removed from them, and finally the modalities of the discussion in which the spoken and written word and the gamble taken on future benefits cannot *forego conflict* as the submitted document states so clearly. Here, the first type of conflict could be what Jean-François Lyotard calls the "differend". "*A case of* ***differend*** *between two parties takes place when the "regulation" of the conflict that opposes them is done in the idiom of one of the parties while the wrong suffered by the other is not signified in that idiom.*"[7] And Lyotard establishes a marked difference between contention and differend: "*As distinguished from*

[4] Gérard Reach ; *Une théorie du soin. Souci et amour face à la maladie*, Paris, Les Belles Lettres, 2010
[5] Ibidem; p129.
[6] Michel de Certeau, *La Prise de Parole et autres écrits politiques*, Paris, Seuil, 1994, p38
[7] Jean-François Lyotard; *Le différend,* Paris, Editions de Minuit, 1983, p24-25

a litigation, a differend [differend] would be a case of conflict, between (at least) two parties, that cannot be equitably resolved for lack of a rule of judgment applicable to both arguments"[8]. Should conflict arise during the negotiated consensus process, *in which language will it be settled* and who will establish the discursive and political constraints? In the event of litigation, we can resort to the rule of law, but which law and with what legitimacy? In other words, if there is a conflict, what can we do to escape this differend in which a common rule of judgment is not found?

The second type of conflict after the differend is what the philosopher Rancière calls ***disagreement***. For Rancière, disagreement is not *misconstruction*, because the latter supposes that: "*one or other or both of the interlocutors do or does not know what they are saying or what the other is saying, either through the effects of simple ignorance, studied dissimulation, or inherent delusion.*[9] *Nor is disagreement some kind of misunderstanding stemming from the imprecise nature of words."*[10] Disagreement goes deeper, it is, Rancière tells us, "*a determined kind of speech situation: one in which one of the interlocutors at once understands and does not understand what the other is saying. Disagreement is not the conflict between one who says white and another who says black. It is the conflict between one who says white and another who also says white but does not understand the same thing by it or does not understand that the other is saying the same thing in the name of whiteness."*[11] And Rancière adds that with misconstruction and misunderstanding, we can proceed to "*language medicine*" that involves "*finding out what speaking means*"[12], but in the case of disagreement: "*contention over what speaking means constitutes the very rationality of the speech situation. The interlocutors both understand and do not understand the same thing by the same words."*[13] In other words, as with the differend, a *shared code of communication* – a sort of common language – is absent. The misconstruction at which intersect the various parts of the differend and the disagreement takes a medial pathway that often uses denial. Christine Servais and Véronique Servais, in their most enlightening article "*insiste(nt) sur le fait qu'être d'accord ne signifie en aucun cas se comprendre.* ["emphasize that being in agreement in no way means understanding one another.]

Plus précisément, le malentendu est "une divergence d'interprétation entre personnes qui croyaient se comprendre" (Robert, 1995).

[More precisely, misunderstanding is "a difference in interpretation between people who believed they understood each other" (Robert, 1995).] Catherine Coquio (1999: 21-22) who uses this

[8] Ibidem, p9
[9] Jacques Rancière, *La mésentente,* Paris, Galilée, 1995, p12
[10] Ibidem, p12
[11] Ibidem, p12
[12] Ibidem, p13
[13] Ibidem, p13

definition from the Dictionnaire historique de la langue française Robert (1995), in her lengthy introduction to the subject of misunderstanding, states that "conflit qui s'ignore ou ignore ses raisons, [le malentendu] est un scénario d'échange désirant et raté qui, à la faveur d'un langage (ou d'un sentiment) commun, protège l'insu d'une divergence pour faire durer un accord trompeur, ou un désaccord opaque".["conflict that ignores itself or its reasons, [the misunderstanding] is a desirous and failed dialog scenario which, in favor of a common language (or feeling), protects ignorance from difference of opinion to sustain a misleading agreement or a clouded disagreement.] D'où deux énoncés latents : mieux vaut bien s'entendre que se comprendre [Hence two latent statements: it is better to get along than to understand one another."] At this level of the negotiated consent process we can ask what is being done in practical terms between the researchers and therapeutic trial candidates to avoid differend, disagreement and misunderstanding? Speaking and showing agreement does not mean that we understand each other. What does *negotiate* mean with this possibility of having communication clouded by differend and misunderstanding?

3/ The passages

The document submitted to us states that the aim of negotiated consent is to privilege *deliberation*, whose mission is to enable the expression of both reason and affect. During *deliberation* we sometimes wish to conceal and use guile because negotiation does not erase mistrust. Mistrust we note in the legal precautions that we might take, meaning of the words that we might misinterpret and the various shifts in meaning. The question we are asking here is that of knowing whether, during discussion and deliberation, we can pay attention to the shifting of rhetorical registers.

Let us take a detour and examine the teachings of Aristotle in his work *Rhetoric*. He distinguishes three ways of using oratory: deliberative, epideictic and forensic. "*The deliberative kind is either hortatory or dissuasive; for both those who give advice in private and those who speak in the assembly invariably either exhort or dissuade. […] The epideictic kind has for its subject praise or blame. Further, to each of these a special time is appropriate: to the deliberative the future, for the speaker, whether he exhorts or dissuades, always advises about things to come; to the forensic the past, for it is always in reference to things done that one party accuses and the other defends; to the epideictic most appropriately the present, for it is the existing condition of things that all those who praise or blame have in view. It is not uncommon, however, for epideictic speakers to avail themselves of other times, of the past by way of recalling it [...].*"[14] What poses a problem for us in this case, and what Aristotle does not envisage, is that the *special ends* of these types of oratory can become blurred, the epideictic can influence the

[14] Aristote; Rhétorique, 1358b, *Oeuvres complètes*, Flammarion, 2014, p2611

deliberative[15]. For Aristotle, the *special end* of deliberation is "*expedient or harmful*"[16] and that of epideictic (praise or blame) "*the honorable and disgraceful*"[17]. How, in negotiated consent, can the parties ensure that the *deliberative* does not overlap the *epideictic*? How, in the definition of the *expedient* and *harmful* (deliberative), can we ensure that the oratories of the experts or host communities do not transform into *praise and blame* (epideictic) which can conceal a threat? What can we do so as not to activate the networks of culpability in this deliberative interaction? How can we remove insinuation and threat – if you do not accept these therapeutic protocols, you will be lost - from these deliberations? How can we avoid evoking such threatening insinuations as "whether you want therapeutic trials or you don't… it's up to you"?

4/ Translation

Translators and gray areas

When we hold debates on negotiated consent with groups of people, we use mediators to translate what some are saying in Beti, Doala, Fula, Manding or Lingala and others in French or English. It is therefore useful to reiterate the function of translations - in negotiated consent - which is not about going *from one meaning to another* in a rectilinear manner or even *from one language to another* while declaring loyalty to just syntax and vocabulary, but to bring into crisis the circulation of discourse, stage the meaning and bring into crisis the corporal performance. Translation is a political creation, not only because it restores to words their imprecise nature but also because it maintains a zone of turbulence between languages and attitudes. The Fulani writer Hampâté Bâ explains how, during the colonial period, interpreters and translators fabricated a policy of words, deceiving the colonial administrator and the African populations. Indeed, they would fabricate a discourse which was not that of the issuer of the message who, for his part, was under the illusion that it was being delivered. The interpreter also deceived the African populations receiving the discourse of the colonial administration. The translator therefore does not effect a binary construct from sender to receiver but maintains a third area, unstable, variable and opportunistic, which brings into crisis and challenges the circulation of discourse during the negotiation. How can negotiated consent, which restores speech to communities by favoring orality, rethink the question of translation which is not external to research and might come into play each time there are questions,

[15] This division of oratory by Aristotle has been challenged by linguists on various occasions. See Patrick Charaudeau & Dominique Maingueneau, *Dictionnaire d'Analyse des discours*, Paris, Editions du Seuil, 2002, p 284

[16] Ibidem, p2611

[17] Ibid, p2611

explanations, recommendations and prescription? The question is: *what about translation* in a situation of vulnerability?

And not forgetting the other question: *what does negotiate mean* in a period of vulnerability? Italian philosopher and semiotician Umberto Eco said that translation is the art of negotiating *par excellence*[18]. The problem with translation is not so much that of going from one text to another, or even from one cultural system to another, but that of negotiating within the possible worlds[19]. Translation as such a negotiation of meanings – how does it operate in a post-colonial context simultaneously loaded with history, the State and the phenomenon of economic and cultural globalization?

The untranslatables and the blurring of meanings

In translations, ***the untranslatables*** play the role of disruptors. The excessiveness of translation resides in wanting to be faithful but in a vocabulary and syntax of infidelity. The untranslatables show that languages are in a tenuous situation because they hold both ends of the string – on the one hand we want to know what is going on in the source language, but also, the interpretants and receptors are well aware that there is a remnant *that resists all translation*. The *remnant* is this element of resistance that all languages have towards the institutions – the same language which, paradoxically, is just as active in producing them. Here we must mention the research performed by the philosopher Barbara Cassin on *Heritage Untranslatables in Sub-Saharan Africa* [20] This research was conducted in order to save the world heritage of humanity, which concerns Africa most of all. Taking a different direction, we shall borrow from Emily Apter the expression 'Translation zone" (Paris, Fayard, 2015). How, during the consent processes, can we create *translation zones* which are not mere passages from one text to another but acts of *reflection* for the researchers and therapeutic trial candidates?

II-ETHICAL ASPECTS

The issue of negotiated consent brings into play various considerations concerning ethics; the production of standards, their dissemination, the principles and narrations from which they are derived, the relationships between the ethical standards and the religious and technological systems, the question of psychological powers in the production of consent, the way in which attention is utilized today, the *hubris* of improving human capacities, all of which could well have enriched the ethical questioning on negotiated consent. But what interests us will relate to a concept that often underlies ethics but

[18] Eco Umberto; *Mouse or rat? Translation as Negotiation*, London, Phoenix, 2004

[19] Idem in ; *Dire presque la même chose. Expérience de traduction*, Paris, Grasset, 2006, p54

[20] Cassin Barbara et Wozny Danièle; *Les intraduisibles du patrimoine en Afrique subsaharienne*, Paris, Demopolis, 2016

which thinkers such as the philosopher Baltazar Graciàn have theorized, that is to say tact. Used in the courts of kings and princes, tact is what weighs things up and evaluates distance and manner (of saying, doing, looking, smiling, responding, etc.).

The question of tact. In the circuit of negotiated consent, there is an attempt to pool speech through explanation, question and resumption. A chain of contact is established among the researchers, trial candidates, populations and laws. Problems relating to contact have as such supplanted the ethical question of tact. We sometimes thought of ***distance*** as being the condition for respecting others, we also considered proximity to be the essential element in respecting of the autonomy of the other. But what has often been forgotten is the ***manner***, tact. There is often agitation surrounding populations rendered vulnerable that omits tact. Tact itself combines with this concept of *kairos* which, as we know, simultaneously translates as the right time, place and manner. The question we could ask of the negotiated consent players would be that of the place of tact in the expounding of therapeutic objectives and the participation in shared speech.

In addition, the question of consent evokes that of the conversion of the viewpoints of colonial and colonized. How can we go from signs to subjects? How can we sweep aside the orders and usher in reciprocal respect between the interlocutors? The philosopher Leibniz established long ago the difference between *perception* and *apperception*. In the activity of "perception", the focus is on external subjects and objects. What we *apperceive*, is not what we perceive externally, *but our perceptive activity.* And according to Paul Valery, in perception we obtain information on our perceptive activity and not on the objects of perception. *Contact* is related to perception whereas *tact* is related to apperception. What is the role of *apperception* in the process of negotiated consent?

III-ANTHROPOLOGY

The anthropologist François Laplantine warns us that the search for models of disease and cure must involve a hermeneutic identifying the etiological and therapeutic models that correspond to our various perceptions of the disease; "*l'une des démarches qui doit, à notre avis, animer le chercheur dans son travail de construction de modèles de la maladie et de la guérison consiste à identifier, chaque fois qu'il se trouve en présence d'un discours émanant tant d'un malade que d'un médecin, le noyau de significations exprimés a partie d'une option étiologique et thérapeutiques*[", one approach which must, in our opinion, drive the researcher in his work to build models of disease and cure consists of identifying, each time he is in the presence of doctor or patient discourse, the core meanings expressed as part of an etiological and therapeutic option"][21]

[21] Laplantine François; *Anthropologie de la maladie*, Paris, Payot, 1992 , p 42,

Does negotiated consent recognize other types of medicine? Do we envisage conflicts between these therapeutic trials and others advised by traditional practitioners, revival churches, traditional pharmacopeias and local social taboos? By not omitting the clear-sightedness and transparency from negotiations, we can ask ourselves, *what is the place of belief* in this negotiated consent process?

The fiduciary

Of course, mention has been made of the fear of being used as guinea pigs. Indeed, in Africa, the novels written at the end of the First World War speak of Senegalese Tirailleurs who were unknowingly subjected to therapeutic trials. But on the historical level we also have other accounts. In his book: *Histoire de l'expérimentation humaine en France, Discours et pratiques, Paris, Belles lettres*, 2007, Christian Bonach recounts the Kerandel affair of the First World War. In 1915, Institut Pasteur director Emile Roux, with the approval of France's Undersecretary of State for Military Health, Justin Godart, wanted a combination vaccine against typhoid fever and paratyphoid infections. Under the initiative of Louis Landouzy, recounts Bonach, this combination vaccine was considered likely to have effects but those receiving it could not be informed[22]: "*Les essais de vaccinations commencent le 25 Février 1915 […] les vaccinations sont ensuite poursuivies sous forme d'autres essais sur les Annamites au camp Galiéni à Fréjus et sur les contingents Sénégalais[…] Le 13 septembre 1916, le médecin inspecteur Blanchard, en tournée d'observation des nombreux tirailleurs Sénégalais stationnés dans le Sud-Ouest de la France rapporte au sous-secrétaire d'Etat du ministère de la Guerre les conclusions de sa mission…(à savoir qu'il y a) un nombre important de malades parmi les Sénégalais, Soudanais et autres Africains qui, presque tous sont atteints des affections des voies respiratoires.*"

[The vaccine trials begin on February 25, 1915 […] the vaccinations are then continued in the form of other tests on the Annamites at camp Galiéni in Fréjus and on the Senegalese contingents […] On September 13, 1916, physician inspector Blanchard, doing his observational rounds of the many Senegalese Tirailleurs stationed in southwest France reports to the Undersecretary of State of the War Ministry the conclusions of his mission… (that is to say there are) a large number of patients among the Senegalese, Sudanese and other Africans almost all of whom are suffering from respiratory tract diseases.][23]. The physician Kerandel, with no real permission and for experimental purposes, performed pneumococcus vaccines/tests on over 1,200 Senegalese Tirailleurs in Fréjus, without testing on animals first[24]. Luckily, as it is

[22] Bonoh Christian; *Histoire de l'expérimentation humaine en France, Discours et pratiques 1900-1940, Paris, Belles lettres*, 2007, p292).
[23] Ibidem, p295
[24] Ibid, p p297

explained, Justin Godart put a stop to these experimental vaccines[25]. Other accounts confirm this poor reputation of therapeutic trials in Africa: the inoculation with BCG in Dakar and the experiments on the Congolese in Brazzaville[26]. These accounts fed fears to such an extent that simply talking about therapeutic trials and more particularly asking people to sign, even following negotiation, can only arouse suspicion. Another growing suspicion among Africans could involve asking why these therapeutic trials encountered in the West are not done there first and on the populations there? This question is considered to derive from a certain type of perception that is widespread in traditional Africa. Sometimes suspected of poisoning, the traditional healers always tasted the potions they gave to their patients so as not to be accused of poisoning by the patients' families. Because the populations undergoing the trials have no proof that those proposing the trials are testing them in the West, they can only be suspicious. The lack of response to this mistrust and the regrettable history of the unauthorized trials have damaged the *fiduciary relationship* between the African populations and the Western medical and research structures. The deterioration of this fiduciary relationship must also have other roots that only religion and other aspects of therapy in Africa make it possible to understand.

In "negotiated consent" which takes into account the community aspect of the African individual and which, by this very fact, activates participation in the decision process through the privilege accorded to capabilities, we report that this consent could take into account the way in which Africans *organize therapy*. The question remains, in negotiated consent, that of the identity of "*the organizer of this future therapy*"? There is also, at the basis of that, the disease types defined not by the patient alone, or even by the person treating them, but by the ***organizational chain of therapy***. As John Janzen suggests; in Lower Zaire "*The doctor-patient relationship has complex meaning when the therapy managing group has a prominent place in mediating that relationship. In this situation, Western practitioners who are trained to confer directly with the patient must learn to be sensitive to the family members who piece together the picture of therapeutic progress […].*"[27]
In the case of Lower Zaire, where there are, according to Janzen, two categories of illness (*Kimbevo dia Nzambi* – illnesses of God and *Kimbevo dia Muntu* – illnesses of man – we can observe that excluded from this classification are diseases caused by pathogens such as viruses – how can such negotiation of consent be organized when the communities are

[25] Ibid, p298
[26] ibid, p304-336
[27] Janzen John :*La quête de la thérapie au Bas-Zaïre*, Paris , Karthala, 1997, p27

so sure of their disease classification? Only an action within the *therapy managing group* – which can include Christian or Muslim clerics, traditional practitioners who certainly take the physical and individual causes of the disease into account, and also soothsayers – can help in making the negotiated consent a success. The negotiators and the patient's ethnic group alone cannot achieve good negotiation, because around the family group there are *other* players, remote players. We therefore need to identify, for each negotiation, not the ethnic group of the people who are to participate in therapeutic trials, but the "therapeutic group to which they belong". What links such a group? And what are the lines to cross or not to cross during the negotiations? In other words, how do these groups say the essential reference(in the meaning of Pierre Legendre) or the Big Other (as Lacan would say), namely, what in their group is the fundamental support of the edifice of representations? And how are expressed the *founding taboos* which can be more important for them than the individual therapy often proposed in these therapeutic trials?

CONCLUSION: NEGOTIATED CONSENT; A *LATERAL UNIVERSALISM*?

With the right conditions of transparency and equity, negotiated consent could become a form of a search and quest for a particular kind of universalism in this dialog. But this universalism is not one of arrogance in whose name dominant western cultures define their hegemonic relationship with the world. This arrogant universalism has "informed consent" as one of its avatars. This kind of imperial universalism that sets the framework and erects the hierarchies and priorities being in itself its foundation and purpose was qualified by Merleau-Ponty as ***overarching universalism***. And it could be said, in the colonial and post-colonial context, that it is a ***lead weight universalism*** that lands on you. This universalism, with its good intentions, its conventional indignations and its undisputed objectives has been the cornerstone of a patriarchal conception of the care relationship. Negotiated consent therefore has the merit of promoting what I would call in the wake of Merleau-Ponty a ***lateral universalism***; "*the equipment of our social being can be dismantled and reconstructed by the voyage, as we are able to learn to speak other languages. This provides a second way to the universal: no longer the overarching universal of a strictly objective method, but a sort of lateral universal which we acquire through ethnological experience and its incessant testing of the self through the other person and the other person through the self*[28]. Negotiated consent reminds us of two things: 1/ Despite the culture difference, we want to build a *common world.* From this ensues a duty to produce standards, discursive practices and social utopias that set in motion individuals, communities, interests,

[28] Merleau-Ponty Maurice; *Signes*, Paris, Gallimard, 1960, p 132-133

misunderstandings, thoughts, measures, speech and decisions that resonate and make people think. Negotiated consent, as with any negotiation, is the art of the therapeutic possibles. As Gadamer states, *"Without doubt clinical medicine – on which the greater part of modern medical research is built – is only one small area in comparison to the human task which falls to the healing arts as a whole"*[29]. This humanism that will ensue from the negotiations must also envisage the hypothesis of the *plain and simple refusal* of the populations to accept, following potential examination (of the geopolitical, commercial and human risk data), therapeutic trials. 2/ The last problem remains the viability of negotiated consent. African populations being proposed these trials must be able to properly examine the arcana of the various corruptions between their elites and the pharmaceutical companies. But also they must consider that the question of therapeutic trials is linked to Global Health issues by clarifying the fact that the demographic question is central to political, commercial, economic and religious challenges. Let us finish by returning to the Jakobson's functions of language described at the beginning of this paper: the ***senders*** of the consent messages, their ***receivers***, the ***channels*** used for these messages, the ***codes*** for recognizing and interpreting them, the ***contexts*** of the negotiation messages and the ***maintenance of contact*** between the messages represent various powers. These powers – idealistically speaking – will not be powers of some over others but, according to Hannah Arendt, ***the power of doing something together*** in this world which is so alien to us and yet so familiar. While we wait for Arendt's wish to come true, questions of power continue to be raised in terms of domination and struggle. And for negotiated consent to truly be a "lateral universalism" which remains a long-term objective, let us dare to look towards those in the northern countries who are proposing it to the southern countries. We will always ask those who come from the north with a new "product" to trade to adapt the traceability of the "negotiated consent" product and the conditions of its "display".Because we are "in business", we need to state the attendant economic interests and possibly initiate the practice of "negotiated consent". What do we really negotiate when it comes to therapeutic trials? Who organizes the negotiation and why? Who is doing the talking? Who is not? Who initiates and who follows? Who organizes things behind the scenes of the negotiation? Who writes the "score"? Who organizes the scene, the staging, the narration and the *denouements*? What is at stake here – money, profit or human lives? In whose interest is it to conceal the economic aspect of negotiated consent? Responses to or incipient reflection regarding these questions would remove all doubt of "negotiated consent" being at best economic staging with an ethical veneer, and at worst a form of "friendly pressure" on the most vulnerable. What might be our response to

[29] Gadamer Hans Georg; *Philosophie de la santé*, Paris, Grasset, 1998, p104

these remarks by Harriet A. Washington[30]? "*The use of poor people of color abroad by American scientists today enables researchers to escape both strictest scrutiny of institutional review boards and the gaze of FDA […] People are going overseas trying to do research in Africa […]. They are saying, 'we don't have to go through all that IRB stuff to study AIDS, sickle cell and other diseases. This questionable research is now going on in Africa […] because they are plentiful patients and the scientists are not subject to the same restriction they are subjected here. The Third World has become a laboratory for the West, and Africans have become the subjects of novel dangerous therapeutics…*"[31]

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[30] Washington Harriet A.; *Medical Apartheid,The dark h History of Medical Experimentation on Black Americans from Colonial Times to the Present*, First Anchor Books, New York, 2008
[31] Ibidem, p. 390.

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The Danger of "Negotiated Consent" Terminology in Human Research

Aissatou Touré

In the Memo of the Inserm Ethics Committee and of the French Research Institute for Development Ethics Committee entitled "**From Informed Consent to Negotiated Consent**", one word disappears ("informed") and another is added ("negotiated").
Before discussing its content, we feel it important to share our analysis of various concepts – one that reinforced our initial instinctual reaction to the potential danger to research ethics incurred by this epistemological shift.

The concept of negotiation

The concept of negotiation is far from covering an unequivocal reality. On the contrary, it designates a multifaceted reality in which it is a subject of uninitiated usage, on the one hand, and research in the fields of law, sociology and philosophy, on the other.
Our initial reaction was to consult the vocabulary specialists. The dictionary Larousse defines the French verb *négocier* – to negotiate – in two parts *i) Action de négocier, de discuter les affaires communes entre des parties en vue d'un accord et ii) Discussions, pourparlers entre des personnes, des partenaires sociaux, des représentants qualifiés d'États menés en vue d'aboutir à un accord sur les problèmes posés. [i) Act of negotiating, discussing shared matters among parties in order to reach an agreement and ii) Discussions, talks among people, social partners, qualified State representatives conducted in order to reach an agreement on the issues in question.]* (1)
What we take away from this is either the search for an agreement (with implicit benefit for each party) or the resolution of a disagreement, conflict or at the very least a situation of tension.
The *Perspectives Monde* website of the University of Sherbrooke offers the following definition:
La négociation est un processus de communication et d'échanges entre au moins deux parties dont l'objet concerne l'organisation d'une relation ou le règlement d'une problématique entre celles-ci. Le processus de négociation peut s'inscrire dans un rapport de coopération entre les parties ou dans un rapport de compétition. [Negotiation is a process of communication and discussion between at least two parties whose aim is to organize a relationship or settle a problem between them. The negotiation process can be part of a cooperative or competitive relationship.] (2)

Attempts to further elucidate the concept of negotiation led us to a highly complex observation which alone would justify the utmost care in its use.
As such, Catherine Kerbrat-Orecchioni (3) refers to the need to "négocier la notion de négociation" ["negotiate the concept of negotiation"]. While this author discusses more or less divergent uses of the term, her searches of fifteen issues of the journal *Négociations* show that the majority of uses fall within the definition made by Christophe Dupont (1994,p. 112): "Une activité qui met en interactions plusieurs acteurs qui, confrontés à la fois à des divergences et des interdépendances, choisissent (ou trouvent opportun) de rechercher volontairement une solution mutuellement acceptable. [An activity involving the interaction of various players who, when faced with both differences of opinion and interdependence, choose (or find it appropriate) to voluntarily seek a mutually acceptable solution.]"

What we take away from this definition is that the initial situation consists of a disagreement. In a research context, could we dare to evoke an initial situation of disagreement between the researchers and the community? We hope not.

Sophie Allain (4,5) exploring the contours of the concept of negotiation reveals its complexity. Allain reiterates the two meanings of the term by Christian Thuderoz, namely either an *activité sociale d'échanges visant à résoudre un litige ou à assurer une transaction économique [social discussion activity to resolve a dispute or ensure an economic transaction]* or *un mode particulier de décision consistant à déterminer collectivement des règles [specific decision-making method involving the collective determination of the rules]*. Allain for her part, suggests positioning negotiation along two perpendicular lines: one concerning the modes of treating situations of tension in the social arena and the other concerning the modes of organizing social relationships in order to treat these situations of tension (5).

Among these multiple viewpoints, the conceptualization that gets closest to what is understood by "negotiated consent" appears to be that of the collective determination of rules. But **while this approach appears reasonable in the researcher's approach to the community, does it not pose the risk of leading to "corruption" (in the corrosive sense) of the concept of individual consent on the basis of free will that is independent of the results of the "negotiation" with the mandators of the community** (even if this concept might make sense when it comes to taking an individual decision regarding participation in research, whatever it is)?

Can the concept of negotiated consent in the field of healthcare be extended to that of research?

The concept of negotiated consent in healthcare is an increasingly present issue, like those of shared decision-making or assisted consent.
These concepts have emerged with the interrogations of healthcare professionals in the face of difficult situations, such as patients refusing care or making choices that appear to oppose the therapeutic logic of the healthcare professional.
Rather than adopt the concept of consent to proposed treatment in the binary form of acceptance or refusal, an approach has developed based on the establishment of a negotiation space taking into account both the therapeutic fact and patient values and preferences, leading to a shared decision.
Alice Cortol from *Espace Ethique Région Ile de France*, shares her doubts as to just how much so-called "informed" consent applies in certain contexts of vulnerability or decreased cognitive function and the need in some cases to implement the conditions of "assisted" consent. (6). But above all it is the very concept of "consent" rather than the means of informing it that the author is questioning based on the principle that consent to treatment can only be characterized as free if there is an alternative for the patient refusing it other than "discharge against medical advice". While she considers the binary choice between consent and refusal to be coherent in research, she considers the concept of shared decision-making (which from some viewpoints can be understood as negotiated consent) as more likely to foster a care relationship (at the very least where treatment is negotiable – which is not always, particularly in a surgical emergency).

These scenarios involve the certitude of the healthcare professional to propose what they in all good conscience believe to be the most suitable treatment for their patient and the willingness of the patient with their own rationality rooted in their values and priorities. Various surveys reported in a French National Authority for Health document show great variability in the expectations and perceptions of the involvement of patients in the shared decision sometimes taken in the wake of a "negotiation" on the possible and acceptable treatment options (7)

Can we refer to the need to "negotiate" participation in a study? Is research systematically performed for the "good" of the patient? The answer to these two questions is obviously no – firstly due to the fact that there is (in principle!) no obligation to participate and then the very fact that the concept of research implies uncertainty as to its findings.

What does the concept of "negotiated consent" in the Memo of the Inserm Ethics Committee and of the French Research Institute for Development Ethics Committee cover?

The authors base themselves on the need to go beyond a passive application of the rules meant to govern the concept of "informed consent" and to evolve towards a deliberative process in which "*the researcher like the patient-subject consider that they "con-sent", in that they come to an agreement on a shared goal that is meaningful for each player*.
While the intention behind increased participant ownership of the research is laudable, the effective realization of this approach is just as much subject to questioning as the "informed" consent process being questioned by the authors.
There is no question of "con-sentir" in the etymological sense of "consentire" (to "feel together") when such asymmetry exists between the researcher (whether from north or south) with their knowledge and resources (needed to perform research) and the potential participant not necessarily in a position to refuse treatment possibilities or other benefits given their socioeconomic vulnerability, or not having the educational or linguistic level to fully understand the information given.
A phenomenon that the authors admit because they refer to the necessary process of **empowerment** with a view to improving the relevance of obtaining free and informed consent.
As much as the proposal of doing everything to increase the "capability" of the individuals for truly informed consent can only lead to the adherence of everyone, us included, we do refute the fact that this process can be a corollary/synonym of "negotiated" consent.
We are fully in line with the arguments made in the text and based on those of Amartya Sen, of the concept of development of autonomy of the players indissociable from that of the society in which they live.
Likewise, the various developments involving the challenges of informed consent appear to us to be totally relevant. In fact, we note as being particularly important and appropriate the conclusion of the necessary "*empowerment in the research participants context*" with as corollary the reinforcement of the researchers to "*prepare contextual and participatory research"*.

From “negotiated” to “empowered” consent?

Analysis of the Memo reveals that the argument focuses on the concept of empowerment rather than negotiated consent for which it does not clearly appear with whom and at what level this “negotiation” should take place: governmental, community, individual?
In the domain of healthcare, the concept appears relatively clear. In research, however, a certain number of gray areas need to be resolved if we are to avoid a dangerous slide into the “bartering” of research project adherence. This would not just run counter to everything this document is trying to do, but also risk the incitation to exploit vulnerability.

Therefore, given that it is about taking action in order to develop the autonomy to choose, why not simply adopt the term “empowered consent” as translation of the French concept of “consentement capacité” which to our mind best reflects the quintessence of this text?

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