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The informed consent process: An evaluation of the challenges and adherence of Ghanaian researchers

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Abstract

This study assessed challenges faced by researchers with the informed consent process (ICP). In-depth interviews were used to explore challenges encountered by Investigators, Research assistants, Institutional Review Board members and other stakeholders. An electronic questionnaire was also distributed, consisting of Likert-scale responses to questions on adherence to the ICP, which were derived from the Helsinki Declaration and an informed consent checklist of the US Department of Health and Human Research (HSS). Responses were weighted numerically and scores calculated for each participant. The median score of the level of adherence to the informed consent process was 93%. Most of the respondents (60%) cited the lack of time for the ICP to be a challenge, with 65% indicating a lengthy consent document to be the main challenge with the informed consent document. Challenges with language and communication were the dominant theme among informants. Despite the high adherence of Ghanaian researchers and research assistants to the ICP, challenges are still prevalent, requiring diligent and continuous efforts in research implementation.

KEYWORDS
adherence, challenge, Ghana, informed consent, perception

1 | INTRODUCTION

Protection of the rights and welfare of human study participants and preservation of the integrity of research is mandatory in the conduct of research.[1] Central to this mandate is the informed consent, a process by which "a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate".[2] Birthed from a series of landmark research scandals such as the Nazi prisoner experiments and the U.S. Public Service Study of Syphilis at Tuskegee, the informed consent process (ICP) has evolved over the years to accommodate the contextual diversity of research, participant autonomy and preferences, and the dynamism of science and technology.[3,4]

When undertaking the ICP, sufficient information on all aspects of the research relevant to the participant's decision on whether to participate must be provided. This includes information about rights (covering the right to withdraw from research), the purpose of the study, procedures to be undertaken for data gathering, potential risks

[1]Hoverd, E., Staniszewska, S., & Dale, J. (2021). The informed consent process in health research with under-served populations: a realist review protocol. *Systematic Reviews*. 10(1):103.
[2]International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2016). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). Retrieved March 1, 2024, from https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf.
[3]Capron, A.M. (2018). Where did informed consent for research come from? *Jornal of Law, Medicine & Ethics*. 46(1):12-29.
[4]Bazzano, L.A., Durant, J., & Brantley, P.R. (2021). A Modern History of Informed Consent and the Role of Key Information. *Ochsner Journal*. 21(1):81-85.

and benefits of participation in the research, expected duration of the study, extent of confidentiality of personal identification and demographic data, among others.[5] Transparency, sufficient information and genuine opportunity to object are the conditions that validate the concept of informed consent.[6] Thus based on the information, a potential participant voluntarily confirms willingness or decline to participate in the research. The ICP is prerequisite to the enrolment of human subjects in any type of research; clinical (diagnostic, therapeutic, interventional), bioequivalence, social and behavioural studies.[7]

Research hinges on the trust and cooperation between the scientific community and the population of potential study participants.[8] Failure to carefully analyse and balance the goals of the scientific community with the needs and safety of the population may result in the exploitation of human participants, thus undoing years of progress in this area of research integrity.[9] The ICP is therefore harnessed as a tool to assess and maintain the integrity of research.[10] However, the rigour of the ICP lies mostly with the research team, with some oversight monitoring by applicable regulatory bodies and the Ethical Review Committee (ERC).[11]

Challenges in the ICP include language barrier, literacy, religious/cultural influences, misunderstandings/patient perceptions (therapeutic misconception, therapeutic misestimation, and therapeutic optimism), and consent for children and other vulnerable populations.[12] Particularly in poor-resource settings, unique challenges may be introduced into the mix- cultural context, health disparities, community consultation, potential mistrust of research, and decisional authority in consenting to research.[13]

A chasm exists between the theoretical ideals of ICP and what it accomplishes in actual practice, as many studies on ICP seem to be skewed toward participant-related challenges, an observation which is also notable in the Ghanaian landscape.[14] With ICP being centred on effective communication and genuine understanding by study participants, lack of a proper climate with barriers and challenges for informational exchange may compromise its quality.[15] There is therefore the need to thoroughly explore as well, the researcher-related challenges for a more holistic assessment of the process. Hence, this study aimed to investigate the issues encountered by researchers, and their adherence to the ICP in the Ghanaian context.

2 | STUDY METHODS

Qualitative and quantitative approaches were used for this study. We conducted in-depth interviews to explore and identify participants' challenges and used a survey to determine the level of adherence and associated factors.

Several institutional and government-based ethical review committees existing in Ghana appraise a considerable number of study protocols annually.[16] Review Boards may be put into three operational categories: Hospital-based, Academic based, and other Institutional based.[17] Using simple randomization, an ERC was selected from each category: Korle-Bu Teaching Hospital-Institutional Review Board (KBTH-IRB), the Noguchi Memorial Institute of Medical Research-Institutional Review Board (NMIMR-IRB), and the Ghana Health Service Ethical Review Committee (GHS-ERC), belonging respectively to the Hospital-based, Academic based, and other Institutional based categories. The study consisted of investigators and research assistants who had participated in health-related studies within the past five years, and had ethical approval for studies from the GHS-ERC, KBTH-IRB or the NMIMR-IRB.

As contacts could not be obtained from the ERCs, citing ethical concerns, investigators from known ongoing studies were approached for participation, and recommendations of other potential participants (snowballing). With the compiled list, investigators and research assistants were contacted and consent was procured. Questionnaires were then administered and returned electronically using Google Forms through participants' email and social media platforms.

The questionnaire had two parts. The first section collected information on background charcteristics of respondents, and the second part consisted of Likert-scale respones to questions on adherence to the informed consent process. The questions on adhereance were derived from the Helsinki Declaration (2013), and an informed consent checklist of the United States Department of Health and Human Research (HSS).[18] Background variables were age, role (researcher/assistant), level of education, and number of years in research. Outcome variables were adherence and challenges to the ICP. 'Adherence' was determined by a value obtained by numerically weighting the responses of the related questions. For each of the related eleven questions, participants chose 'Never'−1, 'Rarely'−2, 'Sometimes'−3, 'Mostly'−4, or 'Always'−5. Scores were obtained for each participant, median reported, and compared

[5]Beauchamp, T.L. (2011). Informed Consent: Its History, Meaning, and Present Challenges. *Cambridge Quarterly of Healthcare Ethics*. 20(4):515-523.
[6]Beskow, L.M. (2016). Lessons from HeLa Cells: The Ethics and Policy of Biospecimens. *Annual Review of Genomics and Human Genetics*. 17:395-417.
[7]Manti, S., & Licari, A. (2018). How to obtain informed consent for research. *Breathe*. 14(2):145-152.
[8]Beskow, op. cit. note 6, p. 2
[9]White, M.G. (2020). Why Human Subjects Research Protection Is Important. *Ochsner Journal*. 20(1):16-33.
[10]Manti & Licari, op. cit. note 7, p. 2.
[11]White, op. cit. note 9, p. 3.
[12]Nijhawan, L.P., Janodia, M.D., Muddukrishna. B.S., Bhat, K.M., Bairy, K.L., Udupa, N., & Musmade, P.B. (2013). Informed consent: Issues and challenges. *Journal of Advanced Pharmaceutical Technology & Research*. 4(3):134-140.
[13]Calia, C., Yucelli, S.N., Hoelterhoff, M., Amos, A., Chibwana, K., Kawale, P., Johnston, S., Magowan, R., Taylor, E., & Reid, C. (2019). The challenges and opportunities of informed consent in LMIC. *3rd European Congress of Qualitative Inquiry, Edinburgh, UK, Edinburgh, United Kingdom, 13 Feb 2019 - 15 Feb 2019*.
[14]Hill, Z., Tawiah-Agyemang, C., Odei-Danso, S., & Kirkwood, B. (2008). Informed consent in Ghana: what do participants really understand? *Journal of Medical Ethics*. 34(1):48-53.
[15]Beauchamp, op. cit. note 5, p. 2.
[16]Adu-Gyamfi, J. (2015). Ethical challenges in cross-cultural field research: A comparative study of UK and Ghana. *African Social Science Review*. 7(1).
[17]Owusu, S.A., Addison, G., Redman, B., Kearns, L., Amuna, P., & Laar, A. (2021). Assessment of the Operational Characteristics of Research Ethics Committees in Ghana. *Journal of Empirical Research on Human Research Ethics*. 17(1-2):114-128.
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among different subgroups of the background characteristics. Wilcoxon rank sum test and Kruskal-Wallis test were used to determine observable differences among the subgroups. Based on the possible maximum and the minimum scores, responses were categorized using a statistic tertile into 'high', 'moderate' and 'low' level of adherence. Proportions of indicated challenges faced by participants were reported. Data entry and analyses was done using Stata (16.1, StataCorp LLC, College Station, TX).

Key informant interviews included investigators, research assistant members of Ethical Review Committees, lecturers of research methods and members of ERCs. Data from in-depth interviews were collected on pragmatic grounds, while considering the maximum variation. Interviews were done with an in-depth semi-structured interview guide, and data obtained with a mobile phone recorder. Challenges and adherence to the informed consent process were explored through the interview, with focus on peculiar perceived reasons for non-adherence. Interviews were transcribed verbatim. Anonymized transcripts were then analyzed by two investigators. Transcripts were first read to gain meaning, and emergent themes identified and then coded. Study investigators met periodically to conduct interim analyses and determine if thematic saturation was reached. A limitation to the study is that it relied on the self-account of the interviewees since no verification mechanism was put in place to authenticate their responses.

Ethical approvals for the study were granted by the Ghana Health Service- Ethical Review Committee (GHS-ERC: 040/05/22), the Korle-Bu Teaching Hospital Institutional Review Board (KBTH-IRB- 00077/2022), and the NMIMR-IRB (CPN 051/21-22).

3 | RESULTS

3.1 | Background characteristics

There were 74 respondents to the questionnaire (response rate of 71.8%), consisting of 52 researchers and 22 research assistants (see Table 1). Most of the respondents (85.1%) had educational training beyond Bachelors or Diploma.

The mean number of studies the respondents had participated in within the past 5 years was 3.7, ranging from 1 to 20. The number of years of research experience did not correlate with the level of education (R = 0.09).

There were ten key informants consisting of 2 members from two different IRBs, 4 researchers from varying fields with a minimum of five years' experience, 3 research assistants, and one PHD candidate with experience in research. One of the researchers was also a teacher of research methods for Bachelors and Masters students, and another was also a journal reviewer.

TABLE 1 Background characteristics of respondents.

Variables	Number	Percent
Role		
Researcher	52	70.3
Research Assistant	22	29.7
Sex		
Male	42	56.8
Female	32	43.2
Age		
Young Adults (18-35 years)	47	63.5
Middle-aged adults (35-65 years)	27	36.5
Education		
Post-doctoral	11	14.9
Doctoral or equivalent	18	24.3
Masters	34	46.0
Bachelors or equivalent	10	13.5
Diploma/Vocational or equivalent	1	1.4
Years in active research		
Up to 3 yrs	45	60.8
More than 3 yrs	29	39.2

3.2 | Adherence to the informed consent process

From a minimum score of 33 and a maximum of 55, the median score of the level of adherence to the informed consent process was 51 (IQR = 46,54) or 93%, for the entire study population. Ninety-six percent of scores were within the upper tertile (high level of adherence), with the remaining four percent falling in the mid-tertile. The median adherence score did not significantly vary among the background characteristics of the study population as shown in Table 2.

The informed consent process is not undervalued, as explained by a 36-year-old key informant:

"Most often, I always try to go through everything because I take each patient or client as an individual and do it comprehensively from start to finish. In as much as it's time consuming, I try to at least hit on all the components either briefly or where necessary, I explain into detail."

Despite the high adherence to the ICP, its purpose may not always be clear, as one informant opined: *"…well you have to go through the entire process to get them to sign."* Citing a previous study as example, another informant highlighted the reluctance in emphasizing voluntary withdrawal and details of study risks to potential clients for fear of discouraging participation: "*…I am uncomfortable about telling them about the voluntary withdrawal bit. Reason being that sometimes it's very difficult even getting the respondents to participate in your study, and if you go ahead telling this guy that you (can) leave the study at any point in time, it's like you are not ready to reach your sample size.*"

3.3 | Challenges to the ICP

Explored challenges with the ICP as related to the research team, study participants, and the ICP document are shown in Table 3. With

TABLE 2 Adherence to the Informed consent process.

Variables	Median Adherence Score	IQR	Wilcoxon rank sum test/ Kruskal-Wallis test (P value)
Role			0.202
Researcher	50.5	(44.5,54.5)	
Research Assistant	52	(50.0,54)	
Sex			0.081
Male	50.5	(45,53)	
Female	52.5	(49,55)	
Age			0.769
Young Adults	51	(46,55)	
Middle-aged adults	51	(48,54)	
Education			0.632
Post-doctoral	54	(49,55)	
Doctoral or equivalent	50	(43,53)	
Masters	51	(46,55)	
Bachelors or equivalent	52.5	(47,54)	
Diploma, Vocational or equivalent	52	-	
Years in active research			0.569
Up to 3 yrs	50	(46,55)	
More than 3 yrs	52	(46,54)	

regards to challenges related to participants as experienced by respondents, failure to turn up for data collection after consenting was cited, as well as a perceived lack of interest and lack of understanding.

Generally, issues with language and communication were recurrent themes among key informants. While participant selection is sometimes limited by language barrier, translation of key elements of the informed consent form into the local dialects seems to challenge the process as pointed out by a respondent during an in-depth interview session: "*For our research it must be in one of the common local languages, so if you meet any person that can't speak any of these languages it becomes very difficult, and even with those, you have to be very fluent for the patient to understand*"

Reiterating this, another informant opined: "*It also becomes clear that we the people administering the consent are probably not well versed in the language because my assumption would be that, if we're going to do so in other languages then we have to use natives of those dialects and languages but we don't get that*".

Advancing the theme of language and communication as a challenge, another participant expounded with the following: *"…the greatest challenge would be how to translate the technical terminologies that explains the focus of the study to the participants or the respondents. You see, translating the scientific concepts in simple local language is sometimes very difficult…"* Illustrating this, the informant narrated, *"For instance, in a previous work on oral disease, research assistants at a point had to explain the difference between gum disease, oral ulcers and other oral mucosal changes which are all translated as 'enum akuro' (mouth sores), but they differ, you understand? So trying to coin a simplified term for complex concepts and terms in a scientific area or clinical areas can be challenging"*

Informants also recounted experiences where participants demanded monetary compensation as condition for their consent. Monetary demands had even been made outside the research period. *"You have some calling to complain that they don't have money and for some of them it can be really like harassing"*

In clinical-related studies, some participants explored benefits associated with their treatment. Particularly for researchers and research assistants who had to share their contacts, some of these demands were also made outside the research space: *"…so they think because they have your number they can call, some even call to discuss relatives or friends who have issues"*

There were incidents where participants had to seek approval from other people, such as spouses or children, in the case of the elderly. Some study participants also withdraw consent after the major clinical-based intervention had been delivered. *"One person in particular said he was backing out because he had come from far to have the surgery and he didn't think he was interested in any further communication about the follow up and all that, which was supposed to carry on for at least a year."*

TABLE 3 Challenges to the informed consent process.

Challenges	Number	Percent
Regarding the research team, which of the following have you experienced to challenge the informed consent process?		
Poor communication technique	43	58.1
Lack of time for the informed consent process	44	59.5
Inability to detect patient comprehension	37	50.0
Legal outlook toward the consent process	15	20.3
Regarding the participants, which of the following have you experienced to challenge the informed consent process?		
Anxiety and fear of procedures	47	63.5
Health status	16	21.6
Cognitive impairment	14	18.9
Denial of disease state or inclusion criteria	15	20.3
Religious reasons	21	28.4
Required approval from another person	44	59.5
Other	6	8.1
Regarding the informed consent document, which of the following have you experienced to challenge the informed consent process?		
Complex language	33	44.6
Medical terminologies	47	63.5
Legal nature	14	18.9
Lengthy consent document	48	64.9

3.4 | Training on ICP

All research assistants indicated that some training was offered for the study they participated in. Similarly, all researchers revealed that their research assistants were prepared for studies participated in. However, an informant suggested that selection of research assistants is based on experience. It was also evident from the research assistants interviewed that the level of training was dependent on the nature and demands of the study. Simple discussions and pilots were done for cross-sectional studies, whereas more rigorous training was done for more involving studies such as clinical trials.

3.5 | The IRB and the ICP

When applicable, the IRBs insist on assessing the material contained in the patient information sheets for every protocol. Various components of the informed consent form are also sought for simplicity and clarity. An IRB member indicated "*we scrutinize the information provided for the participant very well… and reconcile what is in there with what you propose to do*".

It is part of the mandate of the IRBs to supervise various aspects of ongoing studies including the ICP. All IRB members indicated, however that this role is not particularly pursued due to challenges with logistics and funding. One ERC member noted: "*…In fact all these six to seven years that I have been part of the Board, there's only once that we went to investigate events at a study site*".

4 | DISCUSSION

This study highlights the challenges faced by researchers with the ICP, projecting time for the process and communication, among other things, to be some of the most prevalent challenges. Despite these, the study also demonstrated adherence to the ICP to be high among Ghanaian researchers.

Stakeholders in the ICP include the research staff, ERC, institutions, funders (where applicable), participants, and regulatory bodies.[19] The perceptions of study participants on the ICP seems to have been extensively researched, with many of the studies undertaken in Ghana being community-based and small-scale research.[20] However, because of their role in the administration of the ICP, the research team is also strategically a choice subject in the evaluation of the integrity of the ICP. The perspectives of researchers and research assistants are not just important viewpoints, but an assessment mechanism which could point to areas that need attention in research. Our study's methods and findings therefore provide some insight in this regard.

Several studies have thoroughly discussed the elements of the ICP, and the variables that influence its understanding and quality.[21,22] Nathe and Krakow, for instance, underscore the simplicity, readability, length, quality, and the involved stakes as factors that affect the understanding of the ICP.[23] In practice however, challenges may exist despite sufficient measures put in place. Uncertainties exist on the practical application of some aspects of the IC, such as the scope and level of detail provided and the methods of disclosure, whether and how to assess comprehension, what constitutes necessary and sufficient understanding for valid consent, approaches to assessing persons' capacity to consent and steps taken when they lack that capacity, how to know when choices are sufficiently voluntary, and issues

[19]Nijhawan, et al., op. cit. note 12, p. 2.
[20]Heider, J.D., Hartnett, J.L., Perez, E.J., & Edlund, J.E. (2020). Perceptions and understanding of research situations as a function of consent form characteristics and experimenter instructions. *Methods in Psychology*. 2:100015.
[21]Kadam, R. (2017). Informed consent process: A step further towards making it meaningful! *Perspectives in Clinical Research*. 8(3):107-112.
[22]Heider, et al., op. cit. note 20, p. 11.
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concerning the documentation of consent.[24] Therefore, the research team requires training to find the balance between the theoretical construct and intended goals, and the practical application of the ICP. Although the rigour of the training was not assessed in this particular study, respondents indicated having had some training prior to the ICP.

In our study, prevalent perceived challenges among the researchers included poor communication technique, lack of time for the informed consent process, and the inability to detect patient comprehension. Challenges with language were also consistent among informants in this study as they discussed several opinions and experiences encountered in practice. Language and communication barrier is also a frequent theme in literature regarding the ICP.[25] With over 40 indigenous languages in Ghana, language used in both the consent process and the consent forms may primarily exclude non-English speakers if adequate preparation is not made. Beyond recruitment, it has been suggested that many individuals sign the consent form without fully understanding what they are signing.[26] Tight regulation of research IC has translated into increasing length, complexity, and incorporation of legal language, making them less likely to be read or understood.[27] Even where there is fair understanding of the ICP, this study suggests that important technicalities may be missed or misrepresented in the ICP. This observation was also noted by Forrow and Kontrimas,[28] Kadam,[29] and Flores et al.[30] Furthermore, the assessment of participants' level of understanding is another critical event that could be impaired by the language barrier. While there may not be a simple solution to the challenges with language and communication, it is crucial that research team members who take the informed consent are well trained and equipped to assess participants' understanding. The use of interpreters, illustrated information sheets and tailored audio-visual demonstrations may help mitigate the challenge of language barrier.

Study participant-related challenges are well documented in literature. Decision-making is influenced by sociocultural constructs, religion, education and economic status. Ghana has a hierarchical social structure, such that reverence and deference are accorded to persons in perceived positions of power (political, age, gender, et cetera) or wealth. Mfoafo-M'Carthy and Grischow[31] report the positioning of the researcher in a superior light by participants as a source of inequality in the interview process, potentially impacting the quality of consent and data obtained. Similarly in this study, many respondents opined that some study participants displayed fear, while others also required approval from another person before consenting. The cultural and social context of an individual plays a role in their understanding. Though variables like literacy might be easy to explain, participants' understanding of the ICP might have a complex association with several other variables such as religious influence, skewed individual perceptions,[32] and previous experiences. The high prevalence of participants requiring approvals from other people could also be accounted for by a social patriarchy system found in some communities,[33] and the perceived stakes of their participation.[34] Navigating through participant-related challenges requires some evaluation and identification of the specific source of fear or reservation. It is also proposed that participants are empowered to engage with researchers, and train local researchers to engage in culturally sensitive research processes.[35] Resilience from potential participants, despite making all information available is probably an indication for one to discontinue efforts at recruitment. Also, it is key that potential participants are adequately informed about the benefits and compensations with their participation. This information would help manage their expectations and sustained interest, should they be declined on request.

The challenge of withdrawing after being informed was also noteworthy in our study. Researchers are sometimes fixated on attaining their projected sample sizes, and as a result pressure their participants or downplay the ICP. Some researchers may even skip the process. This may mean placing sample sizes over the rights of research participants. Though effective communication may minimize the occurrence, it is key that researchers accommodate and understand the possibility of voluntary withdrawal during the ICP.

5 | CONCLUSION

Despite the reported high adherence to the ICP by our study participants, challenges such as poor communication technique, lack of time for the informed consent process, and the inability to detect patient comprehension are still prevalent, requiring diligent and continuous efforts in research implementation. It is therefore recommended that periodic evaluation of the ICP is done to direct mechanisms for improvement.

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[32]Nijhawan, et al., op. cit. note 12, p. 2.
[33]Princewill, C.W., Jegede, A.S., Nordström, K., Lanre-Abass, B., & Elger, B.S. (2017). Factors Affecting Women's Autonomous Decision Making In Research Participation Amongst Yoruba Women Of Western Nigeria. *Developing World Bioethics*. 17(1):40-49.
[34]Nathe & Krakow, op. cit. note 23, p. 11.
[35]Mfoafo-M'Carthy & Grischow, op. cit. note 31, p. 13.

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The authors declare no conflict of interests.

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