

# Overt Communication or Covert Rhetoric: A Study of American Medical Informed Consent Forms

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## ABSTRACT

*Informed consent forms are a sine qua non in today's biomedical research. This article explores the rhetoric of ten informed consent forms approved by the United States Food and Drug Administration and an American mid-western university, and how researchers addressed bioethical concerns. Results show that the forms contain a strong apodictic logic congruent with the values enshrined in the canonical codes. Researchers, however, took precautions to distance themselves from the process of consent lest they be accused of influencing subjects. The report signals the need for vigorous technical communication research.*

**Keywords:** bioethics, informed consent form, rhetoric, technical communication, trial

## 1. INTRODUCTION

Informed consent forms (hereafter ICFs) are a *sine qua non* in today's biomedical research. They are communication documents between a subject-patient and physician-investigator that result in the patient's authorization or agreement to undergo a specific medical intervention. As Corrigan (2003: 768) avers, "The need to secure a patient's fully informed consent prior to medical intervention for treatment or research purpose is increasingly heralded as an ethical panacea counteracting the potential danger of paternalistic and autocratic practices".

ICFs derive their strength from US federal and international regulatory codes such as the Nuremberg Code which fundamentally holds that the voluntary consent of the human subject is absolutely essential (Pence, 2000; Annas & Grodin, 2008). This principle of participant autonomy is considered in the bioethics literature a prerequisite against manipulation, exploitation and coercion from what Corrigan terms "autocratic paternalism" in the medical community, and against a repetition of dastardly acts of years gone by committed in the name of medical research.

Research on informed consent has been extensively conducted from myriad perspectives—medicine (Pindyck *et al.*, 1993; Hill *et al.*, 2008), law (Wettstein, 1983; Mclean, 2004), nursing (Spindel & Suarez, 1995), bioethics (Jonsen & Miller, 2008, Lo & Garan, 2008; Walker, 2012), sociology (Appelbaum, 1982; Corrigan, 2003; Mazur, 2006), and psychology Benson *et al.*, 1982; Mattehew, 2008). As of 2003, the subject had recorded over 4,000 empirical reports (Sugarman, 2003). Informed consent has also been well theorized in such notable works as Faden and Beauchamp's (1986) *A History and Theory of Informed Consent*. Nonetheless, we know too little concerning the rhetorical deconstruction of the consent form as a communication

document. As Segal (2005) rightly affirms, “rhetoricians bring critical procedures that are both theoretically rich and historically informed to bear upon medicine’s complexity” (p.156).

But Corrigan’s (2003) sociological inquiry of empty ethics in informed consent resonates well with my focus. Situated in England, the study found that subjects had an elusive and less active understanding of ICFs, and also express different expectations about doctor care. On the strength of his findings, the author concludes that there ought to be a close consideration of the informed consent framework so that research subjects could make what he terms “valid informed decisions”. Studies have also shown that the text provided by IRBs in informed consent forms falls short of the IRB’s own readability standards (Davis *et al.*, 1998; Joffe *et al.*, 2001; Melo-Martins, 2008; Paasche-Orlow *et al.*, 2009). According to these authors, although ICFs are supposed to be easily read even by persons with low literacy, factors such as local literacy rates, level of research activity, and federal oversight could influence ability.

These problems are exasperatingly complex in psychiatry. In a study of therapeutic misconception in psychiatric research, Appelbaum and colleagues (1982), for example, report a great deal of therapeutic misconception among psychotic patients. Others also simply misconstrued the rationale of the experimentation, and were rather dismayed at the prospect of enrolling in the trials. Similar findings are chronicled by Benson (1982) and Sankar (2004) in which they claim that therapeutic misconception does quite often occur irrespective of the subject’s educational or social standing, or education given to would-be subjects prior to the intervention.

So too it is among minority and captive populations such as prisoners. Although it cannot be denied that the checkered history shared by these populations could itself fuel reticence in enrolling in trials, same could be said of their poor and low levels of education which in turn makes it difficult for them to understand the consent process. Studies have found that subjects have sometimes expressed misgivings about consenting to participate in trials (Emanuel *et al.*, 2008; Jonsen & Miller, 2008). Despite the rich literature, not much has been written concerning the rhetoric of the informed consent form in biomedical research. As McTear and King as (cited in Sankar, 2004). note, the language of informed consent is complex and multilayered, and prone to the kinds of miscommunication that are routine among people of notably different backgrounds or occupations

Major institutions such as the World Health Organization (WHO), American Medical Association (AMA) and the US Department of Health and Human Services (DHHS) all stress that the language of the informed consent should reflect the language of a local student of class 6th/8th grade (Melo-Martins, 2008; Paasche-Orlow *et al.*, 2009). As a communicative genre, the ICF is supposed to articulate, *inter alia*, such procedural and ethical considerations as the nature and purpose of the proposed treatment or procedure; the risks and benefits of the proposed treatment or procedure; the ability of a subject to withdraw from the trial if thought unfit to continue; the benefit of the trial and assurance of confidentiality and non-maleficence.

To be sure, most ICFs consist of two parts: the information sheet and the consent certificate. While the former details the necessary medical information needed by subjects prior to making their decisions, and is solely the obligation of the researcher(s) to so do, the latter, on the other hand, serves as evidence of the contractual agreement. The consent certificate also

serves as a testimony that speaks to the voluntary and/or altruistic tendencies of the human subjects enrolled in a trial. In fact, violations of the terms and conditions contained in ICFs could result in law suits, as they could result in harmful risks and untold pain to research subjects.

## 2. THE PRESENT STUDY

In filling this gap, I borrow from Segal's (2005) conceptualization of medical rhetoric in order to examine the rhetorical strategies deployed by clinician-investigators in their effort to convince would-be subjects to enroll in trials. Although she writes in the context of medical journal articles, Segal notes that "researchers are alienated from subjects...not only as a feature of style in medical writing, but also as a feature of rhetorical invention" (p. 92). Drawing on the Aristotelian model, she holds that the gamut of logical, ethical and pathetic appeals is, *writ large*, present in medical communication.

Following Segal, I investigate the extent of persuasiveness found in ten ICFs approved by the United States Food and Drug Association (FDA) and an American university which I will label as Mid-Western University (MWU) on ethical grounds. More important, the study analyzes how the rhetoric of the consent forms highlights such ethical concerns as participant autonomy, voluntariness and minimal risks vis-à-vis subjects' decisions to participate in the trials. Questions such as what rhetorical strategies are employed in the informed consent forms, and how do these strategies enhance the ethical considerations in the forms drive my inquiry.

In the next sections of this paper, I offer a vignette of the communicative genre of the informed consent form (ICF) in order to serve as a tableau for my analysis of the data. Consequently, I discuss the nature of the corpus used and the methods of collecting it.

## 3. THE DATA

As already pointed out, the data set for the present study comprises ten approved ICFs, three each by the FDA and MWU's Institutional Review Board. The forms were obtained from the official websites of the two institutions. These institutions were selected for two chief reasons. The US FDA is the official and mandated body that regulates most drug and food-related biomedical experiments in America while also the university in reference conducts highly technologically driven human-centered research in the US.

Though the number of consent forms here does not in any way speak to the issue of representativeness and therefore reliability of my claims, it was, nonetheless, felt that this choice is an effort at capturing both therapeutic and non-therapeutic trials. That is why the FDA-approved ICFs focus on therapeutic trials, those approved by the university mainly reflect the non-therapeutic. This set of consent forms thus provides an impetus for examining the rhetoric employed by biomedical researchers, and how they articulate issues of ethics in ICFs.

## 4. MAIN RHETORICAL STRATEGIES FOUND IN THE DATA

In line with the objective of the study, this section discusses the rhetorical strategies and their modes of instantiation in the informed consent forms (ICFs) under consideration. The analysis of the data brings to light two main rhetorical strategies: *logos* and *ethos* employed in varied configurations.

### 4.1 Logical Strategies Employed in the ICFs

Logical strategies were the most dominant, and the central argument in all the ICFs. In all the data, the investigators, first, attempted to define the nature of the experiment or disease under investigation (in the case of therapeutic experiments), and provided a comprehensive discussion of the nosology of the complication. In keeping with the ethics of biomedical research, most of the ICFs employed the rhetoric contained in requirement for the conduct of human research subject overseen by the Office of Human Research Protections (OHRP). This is seen in Table 1.

Table 1: Elements of informed consent in FDA and MWU trials (+ = Present, - = Absent)

Informed Consent Elements	FDA Trials		MWU Trials	
	Present	Absent	Present	Absent
Explanation of research	+	-	+	-
Risk/benefit assessment	+	-	+	-
Alternative treatment	-	+	-	+
Statement of confidentiality	+	-	+	-
Statement of voluntariness	+	-	+	-
Right to withdraw	+	+	+	-

Interestingly, the *logos* employed in these forms pay close attention to the kind of disease under investigation. This is how the experiment on the FDA influenza vaccine ICF couched its introduction to the trial:

*Influenza (flu) is a respiratory disease caused by influenza virus infection. The types or strains of influenza virus causing illness may change from year to year, or even within the same year. People who get flu may have fever, chills, headache, dry cough and muscle aches, and may be sick for several days to a week or more. Most people recover completely. However, for some people, flu may be especially severe, and pneumonia or other complications including death, may develop.*

Contained in this excerpt is powerful rhetoric, one which impresses on the audience the need to enroll in this trial because influenza is a commonly infectious disease, and so needs to be combated. Notice that the designers of this ICF end this section by making a reference to death. This certainly increases the logico-pathetic effect of their appeal. That is, flu is subtly dangerous because it has the power to kill.

So, given that enrolling in studies of this kind is useful, the investigators had to go to great length to insure their subjects of conducting good science or research (See Table 1). Indeed, the inclusion of the risk/benefit ratio is carefully presented to persuade would-be subjects of only minimal risks. This portion of the consent form contains many linguistic hedges: (a) adverbs, e.g. “possibly”, “generally”, “usually”, “only” and “may be” (b) nominals, e.g. “mild reactions”,

“mild side effects” and “a possibility” and (c) the modal putative verb, e.g. “could occur”. It does not, however, exclude the possibility of death.

With respect to benefit, explicit statements about direct compensations accruing to the subjects are meticulously managed. In many instances, researchers alluded to educational values or scientific knowledge, and sometimes altruism as the overall benefits of the trials. Below is an example:

*There will be no direct benefit to you because your tissue may not be used for some time after you donate it and because research can take a long time. However, it is hoped that the results of research on your tissue and tissues from other patients will provide information that will help other patients*

(MWU Use of Tissue Research)

But this was not always the case especially in therapeutic trials such as the one below:

*The benefit of the pellet is that will release the naltrexone over a long period of time. This means that you will not need to take naltrexone orally each day while the implant is active (which may be up to 60 days or more) (FDA Naltrexone)*

One other way of presenting the logic in the forms was by the use of passivization. As a grammatical property of language, passivization, especially the agentless type, allows writers to exclude themselves from the activities they describe. When applied to ICFs, this principle accords the designers to obviate all kinds of personal mood, biases and emotions attached to the protocol just so they could present the ICF in the best possible, objective light (Sankar, 2004). In fact, all the sentences in the data were conveyed passively especially in respect of the investigators’ effort to explain the consent process to subjects. And although the opening sentence of the ICF for the “Naltrexone Maintenance Therapy with Pellet Injection” trial starts thus “*This document confirms **our** conversations concerning your medical problems,*” (emphasis added), all the subsequent sentences are rendered in the passive voice.

This researcher-subject distancing lends the ICFs an aura of authority, and an escapist route from liability as subjects could hardly vent their frustrations on a single individual in cases of therapeutic misconceptions. The following examples will throw more light on the issue:

The implant **will be inserted** under the skin. An antiseptic **will be applied** first to clean the area. Then, a local anesthetic (Xylocaine) **will be given**. I understand that I may feel burning when this happens. Then, the pellet will be inserted. Afterwards, the wound **will be bandaged**. (emphasis added, FDA Naltrexone)

In the above example, it is clear that the agent of the actions of inserting, applying, giving and bandaging, though implied, is not categorically stated in the statements. Semantically, we reckon that the writer may not want to be identified with the conditions described, but squarely places these conditions at the doorstep of the subject. Ethically, this may not sound good because researchers must show care and concern for their subjects and also share in the responsibility the research imposes as enshrined in the Hippocratic vow. For example, the story would have been different if the above excerpt were written thus:

We will insert the implant under your skin. We will apply an antiseptic first to clean the area. Then we will give you a local anesthetic (Xylocaine). I understand that I may feel

burning when this happens. Then, we will insert the pellet. Afterwards, we will bandage the wound.

In this instance, we see who the agent is, and know for sure the activities performed by the actor. It is, then, ethically not misleading to demand a level of fairness and accountability from them in the discharge of their duties. Even so, upon a second look the revised statement still contains some ethical bias. Notice how the shift of responsibility is transferred from the researcher to the researched: “*I understand that I may feel burning when this happens*”. To many ethicists such questions as, “What is the significance of this semantic shift? Why does the sentence not read as ‘When we do this, you may feel burning’, for example, not stated?” should not go unanswered.

Interestingly, in discussing the subjects’ role in the experiments one experiences a shift in grammatical voice from passive constructions to active ones. This rhetorical move is a well intended one in as much as it emphasizes the voluntariness of the would-be subjects to participate in the trial, and that they are not under any compulsion. This effort reflects the first principle of the Nuremberg Code which affirms that “the voluntary consent of the human subject is absolutely essential”. Furthermore, it is in this section that subjects are expected to claim to have had full knowledge of the consent process, and had sought clarification on any issue that may have slightly disturbed them prior to appending their signatures on the forms. Here are some examples:

*I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.* (MWU, emphasis added)

*I have read the above information about the influenza and influenza vaccine and I have had a chance to ask questions. I understand the benefits and risks of influenza vaccination and request that the vaccine be given to me or the person named below for whom I am authorized to sign.* (FDA, emphasis added)

Indeed, the motivation behind this grammatical choice is to compel subjects to critically assess the responsibilities of wanting to enroll in the trials in recognition of the fact that the practice of medicine and surgery is not an exact science.

#### 4.2 Ethical Strategies Employed in the ICFs

Three kinds of strategies were deployed by the designers of the consent forms: (a) educational status, (b) institutional affiliation or logo, and (c) disclaimers.

In many of the consent forms from Mid-Western University, investigators explicitly mentioned that they were either faculty or graduate students conducting research for either an award of a higher degree (MS or PhD) or for the sake of gaining scientific knowledge. Researchers also provided their contact addresses as well as office telephone numbers to subjects should they be in need of any clarification:

*If you have any questions about your rights as a research subject, you may contact the Mid-Western University Institutional Review Board (IRB) by mail at [Address], by phone at [ ], or by e-mail at [ ].* (MWU)

Unlike their counterparts at the University, clinician—investigators hardly divulged any personal information relatable to their profession. On the contrary, they often used their institutional

affiliation and/or its logo as the standard of their authority or credibility. The Influenza (flu) Vaccine and Naltrexone trials, for example, embossed their ICFs with their logos on the top left corner of their front pages.

Another strategy of *ethos* found in the data was the use of disclaimers. These were of two kinds: (a) direct disclaimers and indirect disclaimers. Direct disclaimers were commonly associated with FDA—approved trials than with MWU—approved studies. It must be pointed out that the rhetorical effectiveness of this strategy is that it, first of all, it establishes the authority of the investigator(s) as person(s) who may have thoroughly assessed the risk/benefit ratio and is/are capable of reporting on anticipated risks. Secondly, the disclaimers serve as a legal framework barring them from any charges that could be pressed against them by disgruntled subjects. The following excerpt from the Naltrexone therapeutic trial is handy:

*The authority granted under this paragraph 4 shall extend to remedy conditions that are not known to or could reasonably be anticipated by the above physicians and medical professionals at the time the therapy is commenced (FDA).*

Even more manifest is the following from the same trial in which they squarely direct the subject to accept this obligation prior to the commencement of the trial:

*I am aware that the practice of Medicine and Surgery is an exact science and I acknowledge that no guarantees have been made or implied to me as to the results of the procedure or my satisfaction with the results; nor are there any guarantees against unforeseeable and/or unexpected results (FDA).*

But understandably, researchers would always insist on a higher enrollment than encourage would-be subjects to withdraw from trials.

Indirect disclaimers, on the other hand, were to a large extent pathetic. They evoked a kind of fear in the subject. In this case, researchers try to caution subjects of the possibility of danger in the event of which they the researchers should, however, not be held liable to the charge. It is not clear how the use of fear in the forms could function as a stimulus to subjects. Such statements as, “*If I start using heroin again, I understand I could die if I took my usual dose of heroin right away*” (FDA Naltrexone), does one thing: they reinforce the innocence of investigators in the outcome of the unlikely. It is also probable that pronouncements of such magnitude would make subjects comply throughout the trial, and thus receive treatment in the case of this therapy.

## **5. Conclusions**

### **5.1 Major Findings**

It is increasingly clear from the analysis that the rhetorical argument advanced in the informed consent forms approved by the Food and Drug Association and Mid-Western University’s IRB hold central five key principles. These include voluntary participation, subjects’ confidentiality and risk/benefit assessment. The rest emphasize explanation of research protocol, and alternative treatment. The main difference, between the two institutions, however, is that MTU-approved ICFs go a step further to remind subjects of their rights to withdraw from the trials should they experience discomforts. This ethic, in fact, is contained in the canonical codes. All the same, researchers presented these values using passive constructions that served the purpose of detaching their personal biases and emotions from the so-called scientificity of their trials. They

also resorted to hedging devices such as adverbials, modals and nominals in order to establish the risk/benefit ratio of their argument given that biomedicine is not a precise science.

It was also found that clinician-investigators employed three main strategies to establish their *ethos* in the consent forms. While ICFs from MWU contained the academic, personal addresses and institutional affiliations of the investigators, many FDA-sanctioned consent forms, on the other hand, had the logos of their mother institutions embossed on them as the symbol of authority and status. Moreover, FDA ICFs contained disclaimers pointing to what they want their subjects should know about the trials prior to their consent to enroll in the experiments.

Finally, the analysis points to the minimal use of *pathos* in the informed consent forms approved by both Michigan Tech and FDA. Clearly, none made explicit statement to the use of compensation or inducement as stimuli to the consent process. They, however, made explicit appeals to the altruistic and deontological instincts in their subjects. But it should also be noted that in some ICFs by the FDA, investigators categorically cautioned subjects about potential threats like death.

## 5.2 Implications of the Study

The research, at least, bears three visible implications. First, the concept of researcher-subject distancing is an ethically disturbing one, and needs serious attention. If this practice is continued, it will be anathema to the ethos of the medical profession as all loyal practitioners are taught to believe in the dictum “The primary care of my patient will be my concern”. Distancing oneself from the unlikely outcomes using disclaimers suggests that clinician-investigators do not care much about the welfare of subjects, even when this many not always be true. Again, such a practice brings to mind the question for whom the consent form is really designed. Is it meant to shield the investigator or the investigated? As O’Neil (2003: 4) points out, “Since the point of consent procedures is to limit deception and coercion, they should be designed to give patients and others control over the amount of information they receive and opportunity to rescind consent already given” .

Another issue worth considering is the linguistics and rhetoric of the informed consent form. According to Wright (2012), consent tools for health research generally are designed without contextual or linguistic factors in mind. In other words, Wright and others are of the view that the language used in designing ICFs has to be improved for their dearth concerning ethics. The use of agentless passive constructions, for instance, is a case in hand. The present study, therefore, resonates with the need for rigorous research in rhetoric and technical communication to ascertain the accessibility and usability of ICFs among differing audiences. It cannot be taken for granted that many people, however literate they are, could decipher the relevance of certain linguistic choices made in the forms and the legal implications they have. Moreover, the use of technical vocabulary and medical jargons obscures readability and comprehension of the consent forms, for example, in the Ghanaian context, where the majority are not literate ( Sarfo, 2012).

Akin to the above is that ethicists and health communicators need to question the nature of the rhetoric employed in ICFs for biomedical research. For example, is the rhetoric truly persuasive or regrettably coercive and manipulative? Are the forms neutrally informative or negatively coercive? What kind of language could be seen as neutrally informative since all kinds of discourses, as some have noted, are embedded in rhetoric? (Lunsford *et al.*, 2007) Only empirical research, I guess, can resolve this ethical complex. Moreover, are references to



excruciating pain and death appropriate and justifiable stimuli for consent? As one health communicator comments, it is not proper to remind patients of their terminal illnesses and that an error in a trial could cause their death, despite their emotional states and traumas. Will it not be emotionally burdensome and distasteful to remind HIV/AIDS patients of their trauma through consent forms designed in this manner? (Coker, 2012)

We gather from the analysis that this type of research certainly calls for a much more encapsulating work in the rhetoric and ethics of informed consent forms. One such promising area concerns research in the rhetoric of the ICF in developing countries such as in Ghana, West Africa. Mention should also be made of the need for ethnographic studies into the communication of informed consent forms focusing on both researchers and subjects.

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