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Infrastructuring Readability: Framing and Overflowing in Writing Assistant Software for Biomedical Research Informed Consent Forms

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Abstract

This article analyzes the development process of a software solution designed to assist researchers in writing biomedical research–informed consent forms. Funded by a Swiss ethics committee, the purpose of the software is to enhance the readability of such documents to improve

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biomedical research participants' understanding of the information disclosed therein and to reduce the editing work of research ethics committees. Drawing on an embedded ethnographic research, we show how concerns that emerge in ethics reviews shape ethics committee IT infrastructure and how, in turn, this infrastructure contributes to redefining research ethics. We demonstrate that while the software reinforces the biomedical framing of research ethics, it also generates unexpected overflows. By forming new collectives, this infrastructuring process furthers expertise on informed consent forms while giving rise to new areas of inquiry and redefining the issue of readability in biomedical research. Thus, we provide insights into the complex entanglements between research ethic, computer programs, and writing practices. We conclude by reflecting on the role played by our research team during the software's development and outline proposals on how ethnographic methods can contribute to make research ethics review accountable.

Keywords

Ethics committees, software, readability, research ethics, informed consent form, infrastructure

Introduction

At the time of our fieldwork in 2017, we were surprised to learn that research ethics committees (RECs) considered using digital tools for reviewing research protocols.¹ Such digital tools appear as further evidence that RECs are more concerned with bureaucracy than engaging in meaningful reflection on research ethics.² However, the seemingly counterintuitive character of such a venture illustrates the relative invisibility of the infrastructure of research ethics. Ethics review relies not only on standards, methods, and discourses, but also “boring things” (Star 1999): forms, meeting rooms, and computer platforms (Gagnon 1996; Hedgecoe 2009; Hoeyer 2009; Stark 2011; Hoeyer and Hogle 2014; Douglas-Jones 2017; Whelan 2018). Accounting for “the situated and practical work of designing, developing, building, transforming, maintaining, and using infrastructures” (Vinck and Oberhauser 2023, 457) is key to understanding how research ethics evaluation is framed and conducted. Moreover, the progressive implementation of large language models in informed consent forms (ICFs) requires a better

understanding of how computer programs, writing practices and research ethics come together.

In this article we analyze the development of software designed to assess the readability of ICFs. Based on research funded by a Swiss REC, we examine how concerns over the efficacy of ethics review frame software and how, in turn, unexpected overflows re-problematized the work of the committee that financed the project. We describe the key steps in the development of this piece of software to map the collectives that gradually emerged around the process. We then show how these collectives negotiated their expertise and contributed to redefining ethics in so doing. We emphasize how “infrastructuring” readability reinforced the influence of the biomedical perspective, while at the same time giving way to new perspectives on the discussion of scientific issues. In the conclusion, we discuss our enrollment in the project and offer suggestions on how ethnographic methods can contribute to make research ethics review accountable.

The Infrastructure of Research Ethics Review

Whether in the context of university research or clinical trials, formal research ethics review procedures rely on a set of documents designed to ensure adherence to essential ethical principles, particularly free and informed consent (Gagnon 1994a; 1996; Hoeyer and Tutton 2005; Hoeyer and Hogle 2014; Tutton 2007; Stark 2012; 2013; Whelan 2018). Among the numerous documents that researchers submit for review, REC members pay particular attention to ICFs. These often lengthy documents are intended to “inform” potential participants of research objectives, how the research will be conducted, and the risks that participation entails. ICFs are hybrid objects that serve as an interface among various—and sometimes partly contradictory—constraints, goals, and logics. ICF evaluation is a cornerstone of REC work because it is the only way for committees to assess the relation between researchers and participants (Gagnon 1994a; Gouilhers and Riom 2019; Gouilhers et al. 2022).

ICFs have received considerable research attention across different fields. In bioethics and public health debates, the readability of these documents and the capacity of research participants to understand their content has been the primary focus (Massé and Saint-Arnaud 2003). Bioethical principles state that only clear, comprehensive information renders people capable of meaningfully and ethically agreeing to participate in research and is thus a requisite for informed consent.³ Many studies, however, have pointed out that ICFs often contain overly complex phrasing and

esoteric jargon inaccessible to people without specialized knowledge (e.g., Bergler et al. 1980; Flory and Emanuel 2004; Manta et al. 2021). Researchers have suggested developing frameworks for assessing the quality of these documents and improving their content (e.g., Koyfman et al. 2009).

Social scientists have primarily considered ICFs in terms of their discursive dimension, often criticizing the principle of informed consent as the unfortunate consequence of both a deleterious bureaucratization of research (Dingwall 2008; Blee and Currier 2011) and neoliberalism (Corrigan 2003; 2004; Tutton 2007; Tutton and Prainsack 2011). Building on the work of Nikolas Rose (1999), some argue that the principle of free and informed consent embodies the ideal of rational individuals capable of making their own decisions with full agency once they have been informed. For instance, Oonagh Corrigan (2003) states that the empowerment of participants has become an “ethical panacea,” conceived by bioethics as the only meaningful “antidote” to medical paternalism. She shows that informed consent produces subjects of biomedical research, governed not by coercion but by their own subjectivities (Corrigan 2004).

If both perspectives contribute to a better understanding of ICFs and their underlying problems, they share a common premise: ICFs are given objects whose discursive qualities are ready to be evaluated. Nevertheless, the writing process and the overarching infrastructure that belie their production and evaluation are rarely taken into account. Building on the extensive science and technology studies (STS) literature on documents and writing (Smith 1984; 2001; Asdal and Jordheim 2018; Denis and Pontille 2019), we follow an alternative path. As argued by Hoeyer and Hogle (2014, 256–57), we suggest approaching ICFs less as a discursive or informational issue, but rather as a *practical* concern. Such a perspective raises original questions about the concrete organization of REC work (Douglas-Jones 2017; Hedgecoe 2009; 2012; 2014) and allows for the exploration of the textual infrastructure that these committees establish to carry out their evaluations (Stark 2011; Gouilhers and Riom 2019).

Laura Stark (2011, 245) has drawn attention to the essential role played by REC meeting minutes, which enact the opinion of the committee by invoking “‘The Board’ as the single social actor responsible for the decision.” Stark argues that minutes help committees make consistent decisions over time and develop their own way of reading and identifying problems in submitted research projects (see also Hedgecoe 2014). Stark’s (2012) ethnography emphasizes the collective nature of REC work and offers

insight into their organization. Her approach brings to light the bottom-up manner in which their ethics are developed: RECs do not simply apply principles; they also elaborate standards, making examining the work committees do all the more important.

Based on observations of Canadian REC meetings, Gagnon (1996) has shown that documents are central to the work of committees. He has analyzed how ICFs govern the encounters between researchers and participants: “More than a simple application of previously defined ethical principles, ethics review will appear as a complex dynamic, in which various mediations, detours, and procedures intervene and are interposed between the actors” (Gagnon 1994a, 143 our translation). Gagnon notes that REC control is effected through documents. These texts consolidate specific ways of thinking about ethics (see also Whelan 2018) and the practical administration of research projects by prescribing actions to researchers. Thus, both Stark and Gagnon call for a consideration of documents to capture how the work of research ethics review is concretely organized.

The readability of ICFs is a good example of the sort of problems surrounding RECs. Yet examining ICF readability as a merely technical issue with only marginal impact on ethical evaluations risks overlooking a key site in the politics of research regulation. Close attention to such “details” allows us to unfold ethics committees’ mundane work. In this respect, textual infrastructure not only supports RECs but also frames how research is reviewed. Here, the use of IT tools by RECs is not insignificant because it foregrounds the complex relations between computing practices and the law (Merigoux, Alauzen and Slimani 2023), and/or moral considerations (Jaton 2021).

Following the development of such an infrastructure provides a rare opportunity to examine what would otherwise be “invisible,” “part of the background,” and “ready-to-hand” (Star 1999, 380). In other words, observing the production of a writing assistant for ICFs and the uncertainties faced by the development team allowed us to untangle the complexity of REC work, i.e., how infrastructuring (Edwards et al. 2009) contributes to local knowledge about ethics reviewing, and how it frames procedures to render objective what is—and what is not—ethical. However, as Michel Callon (1998) notes, framing often provokes unexpected overflows that, in turn, re-articulate problems and solutions to these problems. Thus, we will consider infrastructuring—and its manifold framings and overflows—beyond infrastructure development, for its role in highlighting the surprises that emerge when new actors and expertise put the evaluation of research ethics to the test.

The Characters: A Swiss REC and an Ambitious Start-Up

Seeking to reconcile scientific progress with the development of moral values (Gagnon 1994b), while affirming patient autonomy (Rose 1999), bioethics broke new ground in the second half of the twentieth century (Rothman 1991). The United States and other Anglosaxon countries are often regarded in the vanguard of the emergence of research ethics regulations. It is still unclear, however, how ethical criteria circulate across national spaces and interact with local histories (Jacobs and Ljungberg 2021).

Switzerland offers an interesting case study in this respect for at least two reasons. First, the pharmaceutical industry occupies an important place in the national economy, and numerous public policies are in place to ensure the country's business-friendly climate (for example, on biobanking see Bühler et al. 2024). Second, the country's political organization is highly decentralized, and the healthcare system is not the responsibility of the national government but of the cantons. This organization gives RECs significant latitude to develop solutions in line with local institutional and political issues.

Swiss research regulations were slow to emerge and relied on complex governance arrangements involving public and private actors. Magaly Tornay (2021, 328) notes that "ethics committees and RECs...remained an elusive and moving target up until the 1990s, as did knowledge of their existence, composition, and modes of functioning. The landscape was heterogeneous, with various formats of ethical bodies coexisting." Only in 2011 did Switzerland adopt the Federal Act on Research Involving Human Beings (HRA), which came into force in 2014. As in other countries (see Corrigan 2003 for the UK, or Hoeyer and Hogle 2014 for the USA), legislation followed in the wake of major scandals, such as the VanTX case in 1999.⁴ The primary aim of the HRA was to bolster the attractiveness of Switzerland as a venue for biomedical research by facilitating research while preventing new scandals and avoiding legal proceedings (Gouilhers et al. 2022).

The HRA establishes seven cantonal research ethics committees grouped under the umbrella organization swissethics (Swiss Association of Research Ethics Committees). The main task of this public utility organization is to "coordinate the work of the cantonal Ethics Committees in order to assure the consistent application of the federal regulations regarding research involving humans."⁵ Research regulated under the HRA can only begin after obtaining express approval by a REC.

In 2017, one of these cantonal committees approached us in our capacity as social scientists to conduct research on ICFs. About forty people compose this REC, mainly medical doctors but also lawyers and researchers working within the biomedical field. A patient representative, a chaplain, and paramedics also hold seats on the committee. Members are all volunteers elected by the cantonal executive. The committee's weekly meetings are chaired by Professor Müller, president of the committee.⁶ He is a former chief medical officer at a university hospital and devotes part of his retirement to the committee. As president, he plays an important role in representing the committee and guiding its work.

Professor Müller made it his mission to improve the quality of ICFs submitted by research teams. As such, the committee undertook extensive work editing ICFs. At a dinner party in early 2017, Prof Müller met Mr. Darbellay, the CEO of Read-Easy, an ambitious Swiss start-up focused on textual analysis.⁷ Mr. Darbellay convinced Professor Müller of his company's ability to develop software capable of analyzing ICF readability. As Professor Müller told us during our first meeting, the software aimed to "objectively" locate evidence of a text's "poor quality," and empower researchers to rework their text to enhance readability.

Professor Müller financed this project using the REC budget, supplemented by fees paid by researchers to have their project evaluated by the REC.⁸ He secured additional financial support from the Canton's university hospital—his former employer—where he still has a strong network. However, for Professor Müller, the project was just a first step. A successful local trial would enable the development of a tool for use on a national scale. This would ideally offer a practical answer to the problems of ICF readability and—in turn—provide a new infrastructure for research teams, and contribute to a pro-research environment.⁹ The plan was straightforward: develop the software, test a beta version with a small group of researchers, and then present the results to the board of swissethics.

How We Got Enrolled

To advise and guide Read-Easy, Professor Müller planned to hire a team of researchers. He contacted Claudine Burton-Jeangros, who was engaged in the ethics committee within the Social Sciences School of her university. She quickly expressed her interest and approached two junior researchers (Solène Gouilhers and Loïc Riom) seeking short-term research positions. All three of us were interested in the opportunity to get an inside look at

the REC's work. In addition, we were intrigued by the ambitions behind the software.

We drafted a research proposal that combined our interests with Professor Müller's objectives. This is how we found ourselves "enrolled" in this venture. Here, by enrollment (Callon 1984), we wish to emphasize not so much the negotiation of the conditions of access to fieldwork and its hypothetical threat to objectivity. Rather, drawing on standpoint theory (Haraway 1988), we mean to emphasize how we made the problems of actors our own and vice versa (Hennion 2015). In the course of this research, we had to be there "for real" (Riom 2021), fully engaged with the concerns of Read-Easy developers and Professor Müller. Yet the enrollment was reciprocal, since our problematization also transformed the direction of the software development, as we will discuss.

We assisted the start-up developers for four months. We took part in weekly online meetings to discuss the direction of the software development process and the various problems that arose. Professor Müller and Mr. Darbellay were always present, as well as one or two other members of the start-up staff, depending on the issues to be addressed. In addition to Mr. Darbellay, the CEO, the start-up team included four part-time IT specialists responsible for the software interface, algorithms, and management. During these meetings, we took field notes and transcribed them into digital documents. We also conducted several ethnographic interviews with members of the Read-Easy team and a semi-structured interview with Professor Müller (recorded and transcribed).

We provided feedback to the developers and conducted tests on various versions of the software. For this purpose, we organized a preliminary test of the tool with five researchers working in large pharmaceutical companies using a questionnaire; two focus groups with researchers working at the University Hospital (with 11 participants in total); and three focus groups with (potential) medical research participants of various social backgrounds and ages (14 participants in this group). During the focus groups with researchers, we invited them to test the software themselves. We also asked them to share their experience writing ICFs and their relations with the REC. In the focus groups with research participants, we extensively discussed two specific ICFs selected by Professor Müller, one of which he rated as "very poor," and another which he had based on the REC's recommendations. Participants were asked to discuss the documents, but also to share perceptions of their medical and research experiences.

To better understand how the REC evaluates research projects, we also conducted observations at two of their regular meetings. On these occasions,

we had discussions with Professor Müller and other members of the committee. Moreover, we attended a joint training day held by two cantonal RECs. Finally, we analyzed a number of documents, including research projects submitted to the committee as well as the responses sent by the REC to the researchers, including recommendations and requests for revision of their ICFs. On these occasions, we were always presented as sociologists, and the aims of our research were clearly enunciated. Furthermore, Professor Müller was informed of our intention to write an article documenting our collaboration, although the cantonal committee did not review our research. Professor Müller decided that the REC was not competent to evaluate our research because it did not collect health data and therefore did not fall within the scope of the HRA. This conclusion illustrates the work of the president in framing the REC's field of action.

A Software Solution Made of Multiple Collectives

When we started our investigation, Professor Müller was enthusiastic about the software, which was still in prototype form and had everything to prove. Closely participating in its development allowed us to witness the emergence of multiple interconnected collectives by which the software was designed and brought to fruition. In this section, we describe this infrastructuring process through four questions that arose during the software development: (a) how should readability be measured?; (b) how do we define the software users?; (c) what is the software's field of application?; and (d) how should it be integrated into the REC ecosystem?

How Does One Measure Readability?

Assessing readability arose as a fundamental concern from the very beginning of the software development process. For Professor Müller, this evaluation had to be "objective" and incontestable in order to reinforce the committee's decisions and bolster its authority. Prior to our enrollment in the project, Professor Müller and the Read-Easy developers agreed on using the Flesch-Kincaid index.

The Flesch-Kincaid index is widely recognized as an effective tool for gauging the readability level of a text and is a common benchmark in the literature on ICFs (Holland et al. 2013; Sommers, Van Staden and Steffens 2017). Flesch-Kincaid was initially developed for the US Army to assess its manuals. The index's methodology breaks down texts into sentences, words, and syllables. The readability level of a text is then calculated

using the number of words per sentence and the number of syllables per word. The longer the sentences and words, the higher the score and the more complicated the text is deemed to be. The score is associated with a level of education (based on the US school system) required to comprehend the text. According to the index's criteria, readable texts are composed using short sentences, which corresponds well with the military instructions for which the index was developed.¹⁰ The methodology takes for granted a text's grammatical soundness, even though Professor Müller learned from editing ICFs that poor grammar is not uncommon. In addition, Flesch-Kincaid considers vocabulary choices only in terms of word length and not the frequency of their use.

The Flesch-Kincaid index raised questions within our team from the outset. First, this index was constructed in and for English-language texts, and its transposition into French is not easy. The CEO warned us: "It is very well developed in English, but for French, everything remains to be done!" French texts tend to score higher than English texts without necessarily being more difficult to understand. Since some French words are simple and common despite being long, how can the index be used effectively to alert users when a term should be replaced? The risk is that software based on this index would be of limited practical usefulness.

Another ICF problem identified in the literature is professional jargon. The first version of the software, which provided a general readability score (equivalent to a US school grade level) and highlighted sentences and words deemed too long, was quickly found to be inadequate. In response, Professor Müller asked the developers to ensure that the software could identify medical jargon; researchers often fail to recognize the relative incomprehensibility of esoteric terminology because they "are too much in [their] own world," as one of the interviewed researchers put it. As the software development progressed, a more qualitative logic took precedence over the quantitative logic of the index. Limiting the software to providing only a numerical assessment of text quality was insufficient. Researchers needed guidance on content, specifically on vocabulary choice. This took the form of a new feature that made recommendations for replacing jargon with more accessible terminology based on a lexicon programmed into the software.

Assembling a comprehensive lexicon of medical words was a complex task. One of the software engineers made us aware that if "the software was to be taught to detect problematic words," it needed to be "provided with adequate word lists." Professor Müller initially used lists readily available on the internet.¹¹ These lists, however, tended to include inappropriate

words. For instance, words like “objectif” (French for “unbiased” but also “goal”) were identified as problematic by the software, without considering their different meanings, thus undermining its credibility with users. When testing the software during a focus group, an anesthetist became angry: “There are a lot of words that come out in blue [i.e., that the software considers as problematic] that are not complicated! For example gynecology, the software says ‘which relates to women’s health,’ but this takes people for fools! I don’t want to change that word; it’s not right!”

Professor Müller continued to look for solutions. He asked the REC’s administrative staff to remove irrelevant terms manually from these lists. However, they had to carry out these tasks in addition to their daily activities, and it soon became clear that the scale of this task was monumental. Professor Müller came up with the idea of convincing swissethics to provide additional funding for software development: “This is where [our project] really matters. We need to make a convincing demonstration. We need their cooperation for the lexicon.”

While the developers could now rely on a better lexicon (although it still had a long way to go), the methodology underwent significant subsequent modifications to adapt to the specificities of French and to take into account vocabulary choice. The disapproval of long sentences was the only aspect of the methodology that went unchanged. This double translation—from English to French, and from military training to patient information—jeopardized the success of the software. It also raised questions—partly unresolved—about the relevance of the Flesch-Kincaid score, which remained in use throughout successive versions. Indeed, even if the latest version of the software’s interface no longer indicated words deemed too long, these evaluations were still used in the score calculation. Therefore, users encountered difficulties readily influencing the score of their documents. For example, one interviewee remarked: “I have improved my score, but I don’t really know how!” The solution was to redefine the assumptions made by Flesch-Kincaid about users’ skills.

A Software Solution to Control Quality or to Assist Writing?

From the outset of the development process, there was ambivalence between two possible visions for the software associated with two types of users. Was the software intended to be an infrastructure used by REC members to facilitate their evaluation of ICFs? Or did it aim to assist researchers in writing ICFs? These two versions also entailed different conceptions of the work of the REC and its relationship with biomedical research teams. These

questions opened the possibility of an expansion of the scope of the software and of more in-depth inclusion of researchers in the project's development.

Though Professor Müller's initial aim was to find a way to evaluate documents more efficiently and objectively, that the software could be used to help researchers improve their writing was always a matter of discussion. Over time, this option emerged as a solution to the difficulties described in the previous section. If the software could not identify problematic words, then the final decision had to be left to the writer. Ideally, the software would assist researchers before they submitted their protocols to the REC and thus contributed to Professor Müller's efforts to make the REC not just a supervisory board but also a practical resource for researchers in developing good practices. According to him, the REC needs to ensure the protection of research participants, while not making it too complicated to conduct research. As a former researcher, he is aware that if research conditions are too restrictive, clinical trials will be conducted abroad:

In the case of new drugs, e.g., new treatment options for a severe cancer, the question must be asked: What happens if we obstruct [the research process]? One of the consequences may be, and this has already happened, that this university hospital is not considered [to be part of the research]. If [a major pharmaceutical company] has 200 centers and one of them gives a shit and says, "The consent form is insufficient—please rewrite." [It may be more convenient for them] to look for a replacement for that hospital in Pisa or Milano, etcetera. Are we then depriving patients of a promising treatment? You have to ask yourself this question [as a REC]. (Professor Müller, interview)

Professor Müller's pro-research attitude may seem controversial, but his position emphasizes that ICFs need to be considered in a wider competition to attract innovative research projects, which ethics review helps to standardize and facilitate.¹² Therefore, he insisted on involving pharmaceutical companies. The first software testers he recruited were found through his network within pharmaceutical companies. From this point of view, a digital writing assistant could contribute to fostering an attractive ecosystem for research projects. Aware of the potential of these new alliances, Mr. Darbellay was also enthusiastic: "It's good news that β [a big pharmaceutical company] is involved. It's a private company and not an academic institution. They have efficiency needs."

The decision to develop a software solution to support researchers significantly expanded users' scope of action. In addition, the interface design needed to provide clear instructions not only for testing a text but also for

text editing. The Read-Easy developers utilized feedback from our focus groups to transform the interface to these ends. For example, based on our findings, they decided to highlight problematic passages in red instead of green, a color that some focus group participants found “confusing.” The click button’s design—it started the text analysis—was also improved because researchers had difficulty locating it.

Focus groups also raised unexpected questions. Many researchers hoped the software would clarify REC expectations for ICFs. They argued that writing ICFs is a significant undertaking despite its underappreciation and frequent delegation to junior colleagues. They also reported receiving limited support in their REC applications from their institutions, which leaves them feeling somewhat helpless. Finally, the scientists emphasized that research is only a small part of their job responsibilities, which are primarily clinical. Therefore, writing research protocols and ICFs is often an ad hoc task, which is undertaken—for many—only a few times during their career, and often outside of normal working hours:

I write [ICFs] in the evening or on the weekend, taking an old form and reworking it...But this example has to be recent enough to be up to date with the requirements of the swissethics models. After that, I try to translate what we do into language that is understandable [to patients] ...But it’s true that it’s often complicated, and that the software, particularly in regard to the length of sentences, could help improve the text and make it simpler and more accessible. (Anesthetist and researcher, interview)

More than additional control in ethical reviewing, researchers expected more support from the research ethics committees that approve their work. An epidemiologist interviewed admitted that he regularly asks his family to proofread ICFs to test their readability. “It would be a quicker way of checking readability than asking five people around you, two of whom are family members who are getting tired of it!” he argued. Interviewees envisioned the software as a new way of engaging with the REC. Indeed, the lack of direct access to RECs makes reviewing procedures and expectations difficult to understand. The possibility that the software could bridge the gap in understanding between researchers and RECs’ expectations was shared by Professor Müller and several researchers. Would the software become a way to overcome what researchers identified as an administrative burden? As the software development progressed, novel promises emerged. An updated interface suggested that a new relationship between research teams and the REC could be coded.

An All-Purpose Software?

As new promises for the software came into focus, another central issue arose: should the software be designed strictly for ICFs or should it be applicable to other types of documents? This question became particularly important when our team discussed the possibility—first raised in focus groups—of the software interface being based on swissethics generic ICFs models. Researchers would then simply “fill in” different sections following a template, which would fit well with turning the software into a writing assistant.

This option, however, would have reduced the flexibility of the software. It did not align with the developers’ hope that their product could accommodate a wide range of documents and thus be marketable to a broader array of clients. On several occasions, Mr. Darbellay stated the start-up’s goal: “It is good for us to anticipate a wider use of the software and therefore not make it too specific or complex!” He envisioned other markets: hospitals (to improve surgical consent documents), universities (to help researchers write abstracts), and government agencies (to evaluate various kinds of forms). This concern was echoed by Professor Müller. He hoped to demonstrate that the software could be used to improve the readability of documents designed not just for research participants but for patients more generally.

ICF readability requires taking a closer look at a new player in the matter: swissethics itself. Swissethics developed and made available to researchers its own templates for ICFs. The templates provide a pre-formulated structure that includes all mandatory sections, and even offers model sentences aligned with legal requirements that researchers could adapt in their ICFs. Yet according to the Read-Easy software, these stock phrasings scored poorly for readability. This observation, already noted in our initial tests, became even more striking during the focus groups with researchers, some of whom, irritated, pointed out that pre-formatted REC passages obtained the lowest scores in the documents: “what spoils my score are the sentences in the consent form imposed by swissethics!” remarked a researcher.

The reason the template model phrases scored so poorly is that they were written in legal language. They frame the legal status of both the researcher and the patients, but also of the various institutions involved, including RECs and swissethics. These observations shifted our attention toward how ICFs are read.

Since the project’s outset, we planned to involve research participants to ensure that the software addressed their concerns. At this new phase of the

software development process, we convinced Professor Müller to adopt a qualitative approach with focus groups rather than relying on a standardized questionnaire.¹³ We recruited participants through an initiative to improve patient engagement with the hospital. The initiative’s coordinator agreed to help us but insisted that her aim was not a one-off collaboration but a pathway toward greater patient engagement with all the hospital’s services. Professor Müller agreed to this principle and enrolled patients in the software development focus groups.

The focus groups with patients provided groundbreaking insight into the issue of readability. Patients were concerned by how the project, the research team, and the hospital presented themselves in IFCs—not so much by what they did not understand in the consent forms (Gouilhers et al. 2022). The documents were widely described as overly lengthy and not easily understandable, both in terms of the vocabulary use (e.g., “It’s gibberish!”) and—something that was not taken into account by the software—the structure of the texts, which was often described as “redundant” or “boring.” Moreover, some of the patients felt that the researchers were trying to “protect themselves” rather than inform participants properly, which generated mistrust.

These results highlighted a new challenge for the software: unlike US Navy manuals, IFCs are not intended to provide instruction. They establish a relationship between the researchers and the participants. For the software to be truly all-purpose, therefore, focus groups participants called for a much thicker understanding of readability. The software specifications were expanding beyond the problem of sentence and word length, causing the developers to worry. With the integration of patients, the aims of the project were shifting away from an “objective” measurement of readability toward a much more ambitious—and perilous—undertaking.

What if IFCs Were Not the Most Important Thing?

Listening to the focus groups, the scope of the software was expanded to address patients’ expectations. Patient feedback highlighted a previously underappreciated tension between two distinct logics inscribed in IFCs. On the one hand, forms are legal and administrative documents: they serve both as a “contract” between the parties and as a means of control for the committee. On the other hand, IFCs are relational objects. They serve as a basis for discussions between researchers and patients about their participation. Researchers told us that patients rarely read the documents. Usually, researchers explain the ICF content orally, selecting “in a

subjective way,” as one researcher said, the information to be delivered. The documents alone do little to convince patients to participate in the research. Both researchers and participants agreed that face-to-face contact is more important. “Patients don’t want to read! In practice, frankly, people don’t read, they trust us, and they sign!” added a research nurse.

Patients stressed that ICFs should provide a basis for discussion, which, in their eyes, remains the most critical aspect of the informed consent process. This is all the more true in a context of frailty related to health problems: “In the hospital, you are all screwed up, and then you are asked to sign [to signify that you agree to take part in the research]. You sign because you want to be taken care of and for it to go ahead.” In such a vulnerable moment, patients, as they themselves insisted, were looking for “humanity.”

Several patients also stressed the importance they placed on continuity in their relationship with researchers. They emphasized the need to be supported throughout the research process and to be able to ask questions. Other patients noted feeling anxious after reading certain passages. Some pointed out that poorly explained protocols, as well as the repetition of distressing medical words (e.g., “triple negative cancer”) leaves room for worry. This need for care in a research context articulated by patients resonates with what Annemarie Mol (2008) calls a “logic of care” as opposed to a “logic of choice.” Like the diabetic patients described by Mol, the patients we engaged with, and even some of the researchers, emphasized that being able to choose in a meaningful manner would require sound health and predictability surrounding outcomes. As such, patient participants called for a stronger commitment from researchers and a relational process adapted to the reality of the situations they experience. They pointed out that patients’ suffering bodies are often unruly, requiring a capacity for adjustment in a continuous dialogue.

Overall, focus groups enabled patients and researchers to articulate new needs and constraints. This resulted in two important decisions. The first was to develop new resources alongside the software to facilitate research. For example, the REC organized several events for its members and researchers focusing on ICF writing, during which we were invited to talk and make recommendations. The second decision was to assemble a group of patient-reviewers who would evaluate documents.

Conclusion

In this article, we examined the development of a software solution designed to review Informed Consent Forms and facilitate the work of Research Ethics Committees. We approached it as a process of infrastructuring that would

account not only for how infrastructure development reinforced a perspective on research ethics review, but also to capture “framing and overflowing” (Callon 1998) that emerged when new actors and kinds of expertise put the evaluation of research ethics to the test. Moreover, while its promoters hoped to find a technical and objective solution to close an ethical issue, the software development opened new questions about the care relationship between research teams and research participants, or the precariousness of research work.

The software was ultimately abandoned a little over a year after the end of our research contract. One might conclude that this failure did not produce much in the end—especially when it comes to ethics. We argue the opposite: the development of the software contributed to reframing the issue of readability. From a linguistic understanding that included only the length of words and sentences, readability became a much thicker issue at the intersection of research objectives, care practices, and patient affects. If the software contributed to the stabilization of ethics work centered on informed consent, it also made room for other forms of expertise (e.g., participants’ experience of reading, researchers expressing their own concerns), as well as possibilities to imagine new modalities for the practical organization of review work (e.g., a group of patient-reviewers, RECs providing support rather than mere oversight). We noticed during the focus groups that it was the first time that some researchers were discussing these matters “publicly.” These discussions gave greater visibility to concerns about readability and accessibility in informed consent practices, even if these tasks remain neglected and poorly funded. Furthermore, making more room for a “logic of care” (Mol 2008) rather than a “logic of choice” became part of the RECs’—and in particular Prof Müller’s—understanding of the situation.

Moreover, the software development process helped rethink, or rather unfold, the question of readability, emphasizing that the work of RECs is not abstract but, rather, rooted in an infrastructure. We show how this infrastructure involves an array of entities (i.e., researchers, committee members, pharmaceutical companies, participants, documents, indices) and organizes their relationships. The software contributed to reshape the identities of these actors. Our results underline that text processing software is not just algorithms but also interfaces that play an important part in framing users and practices. Furthermore, the development of the software put—at least for a moment—the identity of the REC to the test: should the committee be an oversight body or a support system for researchers? While being aware of the deleterious effects—on researchers and patients alike—of an overly restrictive approach to ethics, Professor Müller attempted to use the software to build a different infrastructure for the work of the REC.

The promise of using large language models for IFCs and research ethics is likely to raise these questions again. The findings of this project should help us approach the politics of such entanglements between digital tools, artificial intelligence, and writing practices, and their consequences on the organization of ethical work. More broadly, our results raise questions about the ways in which laws—here on biomedical research—are translated into computer programs (see also Merigoux, Alauzen and Slimani 2023).

To conclude, we would like to return to our role in this venture. What was our contribution? Our enrollment put us in a different position from those who criticize RECs from the outside. Our main contribution was to offer not critique but accounts of the difficulties encountered by test users of the software, the discussions within our team throughout different stages of development, and what the reading of ICFs truly entails. While the impact of ethics regulations on social science research—and particularly on qualitative work—has been the subject of numerous publications, the possible contributions of ethnography to ethics review procedures is rarely addressed. Like Florian Jaton's (2021) approach to algorithm design via "techno-moral graphs," our research demonstrates how the social sciences can contribute to reflecting about research ethics review. The heart of our contribution may lie in our attention to and accounting for the hesitations, framings, and overflows that are often rendered invisible by both promoters and detractors of ethics procedures.

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Notes

1. The release of ChatGPT in November 2022, along with the subsequent widespread interest in large language models, has significantly reduced the perceived absurdity of this idea.
2. Many authors subscribe to this view and have extensively criticized RECs for this reason (e.g., Bosk and De Vries 2004; Haggerty 2004; Boser 2007).
3. International recommendations emphasize this principle. See for instance “Declaration of Helsinki,” World Medical Association, accessed on February 22, 2022. <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>. In Switzerland, the HRA stipulates in article 16, paragraph 2 that “the persons concerned must receive comprehensible oral and written information on: (a) the nature, purpose and duration of, and procedure for, the research project; (b) the foreseeable risks and burdens; (c) the expected benefits of the research project, in particular for themselves or for other people; (d) the measures taken to protect the personal data collected; (e) their rights.” “HRA,” The Federal Council, accessed on February 22, 2022, <https://www.fedlex.admin.ch/eli/cc/2013/617/en>.
4. This Basel-based pharmaceutical company was found guilty of conducting clinical trials in contravention of several fundamental ethical principles (Sprumont and Béguin 2002).
5. swissethics, accessed on February 22, 2022, <https://www.swissethics.ch/en/ueber>.
6. Except for our team, all names are pseudonyms, including the start-up. To preserve confidentiality, the article does not specify the canton where our investigation was conducted.
7. Read-Easy had previously developed tools to analyze an author’s style or detect plagiarism.
8. These fees vary according to the project size and the type of research funding (public, private for-profit, or non-profit), with charges ranging from CHF200 to 7,000.
9. We learned later in our investigation that Professor Müller’s pro-research position is not shared by all REC presidents.

10. This point is detailed by Peter Kincaid and his colleagues in a 1975 report, which argues that the analysis should not be limited to the complexity of words alone but integrate the complexity of sentences too (Kincaid et al. 1975).
11. For instance, the developers used the medical news website Esculape who provided a list of medical terms and their definitions. See: “Dico medical,” Esculape, accessed on February 22, 2022, http://www.esculape.com/cherche/dico_medical.html.
12. Several authors have highlighted the role of industry and the market in formalizing research ethics (Tutton and Prainsack 2011; Mitchell and Waldby 2010).
13. With his medical research background, he prefers quantitative or experimental methods over qualitative approaches.

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