

# Visualize Everything

Lilly

Clinical Trial Visualization Redesign

<http://ctdesign.challengepost.com/>

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I give live links to my design. Entering these links would not reveal my identity, but clicking deeply into them possibly could if a person sought my identity but not otherwise.

Judges stay away from my identity per contest rules!

## Summary

**My recommendation for reviewing my design is to first read the bold text in each section, noting especially the “key features”. After getting through the document, back up to re-read entire sections of interest and considering verifying what I say by playing with the live version. Everything I propose is live and active now. There are 26 pages in this. Skip to the next page now!**

1. I did everything you asked to enter the challenge. I copied a checklist to the end of this document to show my thought process.
2. I asserted the Creative Commons license for both the informed consent document and the clinical protocol and uploaded them in an external repository (archive.org, a model non-profit repository) where anyone could access them – this is the base innovation of my design.
3. I converted the protocol and ICD from PDF to DJVU files and put them through optical character readers so that I could get text from them.
4. I uploaded the DJVU files to Wikimedia Commons, the media repository serving Wikipedia and all related projects, including Wikisource its archive.
5. I adapted a copy of the ICD to Wikisource. See this for the sample visualization. I copied this visualization to this PDF. This is how I think ICDs should look.
6. Once the ICD is in Wikisource anyone can rip, remix, and republish it with little effort in limitless ways. I made an example remix in as a Wikipedia article, which does not purport to be an informed consent document but does provide it and the protocol. There are several fundamental new privileges to engaging the consent process at this point, including guaranteed high search engine ranking for relevant queries, gaining the easiest conceivable accessibility that files can have on the Internet, and connection to legal guidance on remixing the source content.
7. After the fundamental advantages are established, there are some advantages which are implications of these. I showcase those in my design and describe theme here. Each one of fundamentally changes the nature of clinical research in ways that empower participants and benefit the research coordinator.
8. All live links are as follows:
  - a. [https://en.wikisource.org/wiki/PARAMOUNT\\_Eli\\_Lilly\\_Informed\\_Consent\\_Document](https://en.wikisource.org/wiki/PARAMOUNT_Eli_Lilly_Informed_Consent_Document)
  - b. [https://en.wikipedia.org/wiki/PARAMOUNT\\_trial](https://en.wikipedia.org/wiki/PARAMOUNT_trial)
  - c. [https://commons.wikimedia.org/wiki/File:PARAMOUNT\\_Eli\\_Lilly\\_Informed\\_Consent\\_Document.djvu](https://commons.wikimedia.org/wiki/File:PARAMOUNT_Eli_Lilly_Informed_Consent_Document.djvu)
  - d. [https://commons.wikimedia.org/wiki/File:PARAMOUNT\\_trial\\_Eli\\_Lilly\\_clinical\\_protocol.djvu](https://commons.wikimedia.org/wiki/File:PARAMOUNT_trial_Eli_Lilly_clinical_protocol.djvu)
  - e. I mention this interface - [https://en.wikisource.org/wiki/Page:PARAMOUNT\\_Eli\\_Lilly\\_Informed\\_Consent\\_Document.djvu/1](https://en.wikisource.org/wiki/Page:PARAMOUNT_Eli_Lilly_Informed_Consent_Document.djvu/1)
  - f. I mentioned this content but it is not mine - [https://en.wikipedia.org/wiki/Clinical\\_trial](https://en.wikipedia.org/wiki/Clinical_trial)

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# Visualize Everything

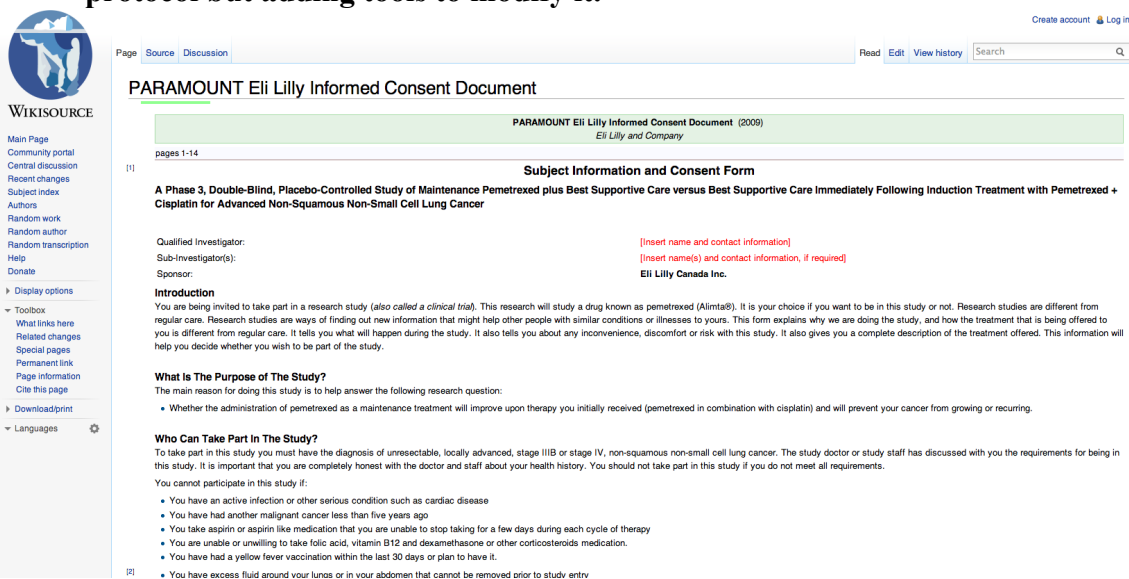
## A technical tour of the platforms used

I have a live version of the my design in the following “Wikisource” presentation of the informed consent document. This is included as an image partially shown below. If you like, see my design live in a sample manifestation at [https://en.wikisource.org/wiki/PARAMOUNT\\_Eli\\_Lilly\\_Informed\\_Consent\\_Document](https://en.wikisource.org/wiki/PARAMOUNT_Eli_Lilly_Informed_Consent_Document)

However, I would not expect anyone to recognize the design features here because it integrates dozens of basic tools related to communication and publishing. **I recommend that anyone who wants a quick grasp on this design to read through at least the bold text in each section because this design has background features which typically take hours to understand. I have working live designs for every feature I propose.**

### Key features of my live design:

- **I put the informed consent document (ICD) and protocol online for anyone to read, reuse, modify, republish, or do anything else with except claim copyright or fail to attribute the copyright owner.**
- **The content appears the same; I am giving back the content of the ICD and protocol but adding tools to modify it.**



**Figure 1 This is my fundamental design. The text is unchanged from the source document but lots of changes in the coding make it more adaptable, readable, accessible, and reusable.**

Here in this fundamental unalterable version, text is unaltered from the base document from the clinical researcher. The full file is with this package but if it is no bother, just check it out live. I did not adapt the protocol like this (only the ICD) but I intend to do so on my own time after the study is over. For now, you can have it back only slightly modified to be machine readable. It is with the other files in the submitted zip or online with everything else.

## Transcription base

This probably will seem subtle and strange at first look but it is really important – the documents for participants need to be machine readable unlike the documents Lilly gave. Doing this greatly empowers research participants as compared to the research coordinators for lots of forthcoming reasons. It also is the primary means of quality control and managing the authentication of official documents in public forums outside the control of the research coordinator.

### Key features of my live design:

- Humans and machines can more easily read plain text of the ICD.
- It incorporates library cataloging features and archiving practices.
- It authenticates official versions of documents and distinguishes them from derived versions and commentary.

In this challenge – and indeed in a lot of clinical research – for various reasons for the foreseeable future there are going to be problems with the public having access to “born digital” documents. The below is completely necessary and part of this visualization. See this in the image file provided or live if you like at [https://en.wikisource.org/wiki/Page:PARAMOUNT\\_Eli\\_Lilly\\_Informed\\_Consent\\_Document.djvu/1](https://en.wikisource.org/wiki/Page:PARAMOUNT_Eli_Lilly_Informed_Consent_Document.djvu/1)

The image shows a side-by-side comparison of a document on Wikisource. The left side displays the document with a proofreading interface, including a green validation bar and a structured layout with bolded section headers and red text for user input. The right side shows the original document as provided by Lilly, which is less structured and contains redaction codes like '[Insert name and contact information]'. The document title is 'Page:PARAMOUNT Eli Lilly Informed Consent Document.djvu/1'. The left side includes a sidebar with navigation options like 'Main Page', 'Community portal', and 'Download/print'. The right side includes a search bar and 'Read Edit View history' links.

Figure 2 This is a proofreading screen. My new formatting of the document is on the left and the original document is on the right. They look the same to humans but to computers they are very different. This screen helps humans check visually to see if the documents read the same.

On the right is the document which Lilly provided. This started as a PDF so was mostly useless for free communication except as something to be converted. I converted it to a DJVU file (a more free format) then put it through an optical character reader (OCR). On the left side I proofread and mastered the transcription while crowdsourced volunteer strangers “validated” the text (also known as “double key transcription”). Of course to benefit research participants Lilly could have made the document “born digital” instead

of as a simulated paper document put into digital medium but even still this “proofreading and validation” process has to happen as an authentication custom. A verification of source documents is necessary as protection measure backing the really radical modifications I propose.

## A remix – the first of many

Just for laughs – type in “PARAMOUNT trial” into your favorite search engine. See if a Wikipedia article appears – if so, I started that. With minimal effort an empowered person can make an attractive accessible forum for participant-targeted information. **I wanted the informed consent document to be intimately connected to absolutely every communication channel possible and the option of making it available through Wikipedia should be – among all other existing practices – part of any informed consent process.**

### Key features of my live design:

- It integrates the ICD into search engines.
- It integrates the ICD into all social media platforms.
- It integrates the ICD into practically every digital communication channel.
- It enables many forms of normal communication about clinical trials were not previously possible without a free public upload.

If you cannot find the Wikipedia article through a search engine then check the provided image file for the full page, or click through to the live version at [http://en.wikipedia.org/wiki/PARAMOUNT\\_trial](http://en.wikipedia.org/wiki/PARAMOUNT_trial)

The screenshot shows the Wikipedia article for "PARAMOUNT trial". The article text includes:

The **PARAMOUNT trial** is a clinical trial studying non-small-cell lung carcinoma (NSCLC). The trial was sponsored by Eli Lilly and Company. It was registered in November 2008 and was projected to end in September 2013.

PARAMOUNT found that maintenance therapy with pemetrexed for patients with advanced non-squamous NSCLC was an effective and well-tolerated treatment option in those patients who had not had progress after initial therapy with pemetrexed plus cisplatin.

**Study design** [edit]

**Name** [edit]

The full name of the trial is "A Phase 3, Double-Blind, Placebo-Controlled Study of Maintenance Pemetrexed plus Best Supportive Care versus Best Supportive Care Immediately Following Induction Treatment with Pemetrexed + Cisplatin for Advanced Non-Squamous Non-Small Cell Lung Cancer". Its common name is PARAMOUNT. Its ClinicalTrials.gov identifier is NCT00789373.

**Purpose** [edit]

The PARAMOUNT trial investigated whether treatment with a maintenance dose of pemetrexed would inhibit the growth of non-small-cell lung carcinoma and improve survival rates after first-line therapy with pemetrexed plus cisplatin.<sup>[1]</sup>

For patients with advanced non-small cell lung carcinoma (NSCLC), maintenance therapy is sometimes used when the initial chemotherapy does not lead to improvement.<sup>[2]</sup> An alternative would be administering a second chemotherapy if the disease progresses.<sup>[2]</sup> A significant number of patients do not survive long enough for a second treatment if their disease progresses.<sup>[3]</sup> When maintenance therapy is used it may or may not consist of a different drug than the initial chemotherapy.<sup>[2]</sup>

Studies prior to PARAMOUNT had shown pemetrexed, an antifolate, had been an effective therapy for patients with NSCLC when used either as an initial chemotherapy with cisplatin or as a maintenance drug when not part

On the right side of the article, there is a table titled "PARAMOUNT trial" with the following data:

PARAMOUNT trial	
other names	PARAMOUNT, NCT00789373
sponsor	Eli Lilly and Company
number of participants	939
start	November 2008
end	September 2013
primary completion	June 2010

Figure 3 An example Wikipedia article for a clinical trial. It links to both the informed consent document and the clinical protocol, but itself is only an encyclopedia article in compliance with Wikipedia guidelines.

I am not having a full conversation about the merits and problems of Wikipedia in this proposal at this time – contact me after the challenge. I will say that most Internet users consult Wikipedia at some point. A lot of people like it and find it understandable. This article links to the informed consent document and protocol. It is easy to find. It is going to exist forever. It has other characteristics. The problems are manageable and not a legitimate explanation for denying other rights.

### Conclusion of technical features tour

I could show more full images but the implications would not be apparent. **For most of the rest of this design presentation I will show visual details of the informed consent document and curate them.**

For maximum understanding, read this document while browsing live articles and click around with it.

## Tour of Features

### Creative Commons attribution tag

**Applying a free license to the informed consent document and the clinical protocol, thereby making them “open source” (a term for a freedom of information concept), is the fundamental change to the informed consent process in my proposal.**

**Research participant empowerment begins with allowing the research participant to discuss research.** Informed consent reform includes radically better access to discuss the informed consent document. After it was granted to everyone in this challenge, I applied a Creative Commons Attribution license to the original documents. This gave me the right to adapt them with software so that I could use them, republish them, and manually remix them.

#### Key features of my live design:

- **It has an open access license.**
- **Open access has a lot of implications – for details see for example Peter Suber’s book *Open Access*.**

Did all of you recognize the monumentality of applying a Creative Commons attribution license to the informed consent document (ICD) and the protocol for the PARAMOUNT trial? I have looked for some years for an ICD with an open access license. This is the first one I have seen. I think it is the only one which exists in English language. I expect that it might be the first one in the world, and the same might be true for the protocol.



Figure 4 This notice gives legal permission to share and remix media.

Once a document is open access it is open to the world and anything can be done with it. My submission for the Lilly Clinical Open Innovation Challenge is the conversion of the original source documents from PDF files to DJVU (“deja vu”) files. When I did this I also put the original files through an OCR (optical character reader) so that in the metadata for the file there is plain text embedded in a broadly-accepted standard that can be read by a lot more software than PDF. That is my base submission for the challenge - changing nothing about the source files but presenting them exactly as I found them in a natively free format (DJVU) and acknowledging their open access status. Since the files should be identical to casual readers if opened, I met the study requirements to present all the information from the original files because I only performed a conversion operation on them and am giving them back almost the way I found them.

However - supplementing that I also am proposing a reform of the concept of informed consent. Right now, “informed consent” is typically imagined as a single event in which researchers offer information in exchange for study participants’ consent. My



visualization is that informed consent should be a highly personal process designed by each study participant in which the entirety of the world's information is continually available to them to help them learn whatever they want about the study at any time and in any medium they like, irrespective of any "informed consent event" which the research coordinator may require. I imagine informed consent being a lifetime status in which even years after study ends, participants still can remember what they did in a trial and track whatever results may have come from it. At any time, participants can have communication channels to share thoughts on their experience in a trial and form whatever opinions and thoughts they like about the cultural institutions around clinical research. All interaction which any research participant wishes to conduct publicly or privately - whether anonymous or identified - whether with the research coordinator or with anyone else in the world who wishes to join the conversation - either at the time of the study or decades later - must be enabled and it all begins with the visualization of an open access license on the informed consent document.

I do have some other visualizations to present in addition to covering the base requirements. I draw on established applications of Creative Commons licensing, infrastructure of the Wikipedia project, the philosophy of the Open Knowledge Foundation, and the advocacy practices of Consumer Reports / Consumers International as I share my ideas. Anyone familiar with the work of those organizations will immediately understand what I am doing. If those organizations are new to a reader – please stay with me. I do my best to explain.

## An honest broker - Wikipedia

**Wikipedia is not necessary to this proposal, but I use it as an example because it is available to host and protect the ICD and protocol.** After the information is hosted, it can be distributed in a trustworthy way to other platforms including search engines, all social media platforms, email, repositories, paper print, and any other channel which can receive digital media. **Any equivalent platform could also work. In my model all communication has the ICD as the nexus of the discussion.**

### Key features of my live design:

- **Someone that is not the research coordinator becomes a primary distributor, keeper, and overseer of all public documentation of any given clinical trial.**
- **This “honest broker” would never receive personal clinical data from the research coordinators (so is not an honest broker in that sense of the word), but can be trusted to manage public or private communication on behalf of participants who want this. Currently it is practically impossible for research participants to contact each other.**
- **Wikipedia can do this but so can other platforms, and I choose Wikipedia arbitrarily.**
- **I am aware this causes privacy problems from the researchers’ perspective but people some people choose less privacy and that is their right to do so. The broker takes responsibility as a media channel – not the researcher, because the participants not the researchers choose the broker.**

The image visualizations I present are screenshots of design implementations either done or depicted as they would be done on Wikipedia. Wikipedia is an arbitrary platform which represents any simple, unadorned, familiar and well-liked presentation of information. A big part of Wikipedia’s success has been its lack of embellishment when presenting text and as I present it here, it appears more clean than an informed consent document but otherwise with minimal modification to the presentation of the base text. Wikimedia screenshots are Creative Commons licensed, by the way – see legal explanation in this document.

As a default practice unrelated to anyone’s visualization, some information on any clinical trial could be hosted or mirrored somehow on a Wikimedia project. For lots of reasons this ought not offend anyone and ought to please a lot of people.

## First connect all search engines to the informed consent process

### [PARAMOUNT trial - Wikipedia, the free encyclopedia](https://en.wikipedia.org/wiki/PARAMOUNT_trial)

[en.wikipedia.org/wiki/PARAMOUNT\\_trial](https://en.wikipedia.org/wiki/PARAMOUNT_trial)

The **PARAMOUNT trial** is a clinical trial studying non-small-cell lung carcinoma (NSCLC). The trial was sponsored by Eli Lilly and Company. It was registered in ...

**Figure 4** The above is an example search engine result. All communication channels, including search engines, should lead to information about any given clinical trial.

Imagine conducting an Internet search for any given clinical trial and finding the information one seeks immediately. When information is freely licensed it will tend to be more readily found than non-freely licensed content for lots of reasons.

The name of the trial in this challenge is “PARAMOUNT”. I cannot show live search engine results because search engine results pages (“SERPs”) are copyrighted, but try searching for “PARAMOUNT trial” yourself in your favorite search engine. See the Wikipedia article I made? For the foreseeable future that is going to remain the most accessible and popular source of information for participants who would imagine getting information about this trial through the Internet. Part of my visualization for this challenge is expecting any search engine in any language to lead to information to supplement the informed consent process. Furthermore, it is impossible to give informed consent in any clinical trial without empowering participants to ask questions about clinical trials on the Internet. A person’s own private Internet use habits are an essential part of the process of informed consent. They may not be satisfied with what they find on the Internet and it is not necessary for a clinical research to put all possible information on the Internet, but it is a requirement that all clinical researchers acknowledge the existence of the Internet and its implications for patient empowerment. Putting information on the Internet in a simple accessible form complements all other efforts to conduct informed consent and present the ICD. Research coordinators may put the ICD in an app, execute it alongside videos and interactive websites, or otherwise host in in their own impermeable and completely regulated walled garden, but whatever else happens, nothing replaces the research participants’ right to access the document how and when they like and to discuss it and the research where and with whom they choose.

### **Now connect it to every other kind of media**

Behind every Wikipedia article is a “talk page”, which is a dedicated forum for discussing the development of its Wikipedia article. The talk page is not a place for discussing the subject of an article and any such discussion is deleted on sight. Again, the use of Wikipedia as a platform is arbitrary and the model could be replicated anyway, but whatever else happens, having the option of a Wikipedia article and a talk page is an option which study participants ought to retain parallel to other options.

The advantage of a Wikipedia talk page (or any forum modeled after one) is that it is the collection point for all significant publications and documents describing the subject of an article. Especially for studies after completion or which are getting media attention at any time, this is the place that anyone can note any published statement about any clinical trial. This includes citations to all academic research, media descriptions for major studies which are publicized even before research is published, and other documents like the ICD if it is open access.

Also - such a forum is an appropriate venue for directing anyone who asks to all existing sources of information on a topic. Some other platforms which serve the same function could be Twitter, Facebook, any other social media platform, or any search tool in which the common name or ClincialTrials.gov identifier could be used as a search term. Could

tweeting about a clinical trial with ones friends be part of the act of giving continual consent? Could a Facebook post saying, “Hello family. I was thinking about participating in a clinical trial. What do you think?” be part of the informed consent process for those individuals who know the risks of publicly identifying themselves as a trial participant? Right now, integrating informed consent into people’s normal modes of conversation is not even possible because it is an illegal copyright violation to re-publish a consent document online and link to it in Facebook and Twitter. This stifles normal peoples’ normal conversation What is the standard response by clinical trial coordinators when patients say, “Can I post the ICD online? I want to see if any of my 1500 friends and followers have any comment on it.” The response should be, “The participant can discuss the trial with whomever they choose in whatever medium they choose, and we as researchers - while advising them of risks of breaking the confidentiality concerns we as researchers have to respect - support our participants in talking as much about their study participation as they would like to do.”

## Internationalization

The PARAMOUNT trial was an international trial which recruited participants in Australia, Belgium, Finland, France, Germany, Greece, India, Italy, the Netherlands, Poland, Portugal, Romania, Spain, Turkey, and the United Kingdom. Patient information was generated in all of these languages. My design right now connects to relevant lung cancer and clinical trial information for languages of all these places and future informed consent processes should do the same. All existing and future translations of information on every conceivable related topic connect to the ICD in my model.

### Key features of my live design:

- I connected the ICD to a platform to translate all content into all languages, and even now there is a lot of multi-language content connected.
- It enables research participants to communicate with each other across countries.
- It greatly balances research ethical practices across countries because now people in the same trial in different countries can talk about how each of their trials are conducted.

- [العربية](#)
- [Български](#)
- [Català](#)
- [Dansk](#)
- [Deutsch](#)
- [Español](#)
- [فارسی](#)
- [Français](#)
- [한국어](#)
- [Italiano](#)
- [עברית](#)
- [Lietuvių](#)
- [日本語](#)
- [Simple English](#)

If a person does not speak the dominant language in a given country, does that make them second-class in terms of their fair opportunity to participate in clinical trials. If the conduct of clinical trials is a benevolent act and if both the responsibilities and privileges of volunteering for a clinical trial are supposed to be available to all physically and medically eligible members of a community, then is it completely fair that inability to speak the local language is usually exclusion factor in the study recruitment process? The *Belmont Report* refers to a triad of rights including “justice”, which in that document refers to fair selection of research participants such that risks of participation and stake in the research are evenly distributed. My design incorporates internationalism to more fully achieve that justice.

**Figure 6 This is a partial list of Wikipedia translations for the article "clinical trial". My live version can do this too but right now I do not have translations.**

It usually is just logistically impossible to allow people to participate in a clinical trial if they do not know the language. However, it should at least be theoretically possible, and in any case people who do not need translated ICDs themselves may wish to do their own amateur translations of all or parts of an ICD to explain it to their friends and families if their peer support group does not speak the language of the trial.

Also - if a trial is multisite and multilanguage, is there any inherent reason why participants who wish should not read the existing ICDs of other languages? Human rights and dignity are universal, are they not? Could someone in India who received the

Hindi language informed consent document be also allowed to know of the existence of and read the equivalent English language document if they know English and wish to do so? Is there any reason why study participants in various countries ought not be able to - if they choose to reveal themselves - talk online with other study participants in other countries and compare their research participation experiences? There are lots of applications of internationalization; this has a lot of implementations.

Technically this is not difficult to execute with open platforms such as, for example, Wikipedia. Any given document can be tied with a library code to signal the existence of any other translations of a document, as well as all versions even through updates and revisions, and all of this can accommodate both official and unofficial translations with annotations. So for example, a research site could have an English document and translate it into five languages. All of these could be connected to each other in a free online library. The community may not like these translations or wish to annotate them, because for example, maybe the translations are localized and not exact or literal translations. As community demand existed anyone could produce these themselves and anyone should be able to moderate this. Wikipedia and its archive sister project Wikisource already do this; it is hard to explain but easy to demonstrate. See the translation menu image and visualize it as part of ICD.

## Connection to other resources

**One of the big remixes which have to happen in informed consent is granting potential participants the sum of all information in the world instantly on request in writing with documentation monitored by third parties overseeing exactly what is told and when. Currently the informed consent process does not promise this and is not working towards it, but my proposal demands it from the world and makes a thorough start at delivering it with available resources.**

### Key features of my live design:

- **It connects the ICD to every other informational resource on the Internet.**

The Belmont Report describes a research concept called “respect for persons”, and it defines this respect by saying that it means that research participants should be given all the information that they want about a study. I am interpreting fulfillment of “respect” as meaning a participants right to all extant public information which exists in the world, with information more closely related to the research being more deserved by right.

A tagline for advertising Wikipedia is, “Imagine a world in which every single person on the planet is given the sum of all knowledge.” The Wikipedia article for non-small cell lung carcinoma is already the world’s most consulted source of information on that topic (at worst, it is in the top 10 by popularity but is probably #1) so unless someone curates better information, it would not be unreasonable as a default action for a person to hyperlink technical terms in an ICD to Wikipedia article. What if every term in an ICD was hyperlinked to an encyclopedic summary explaining it, and every term in every one of those summaries was linked to summaries explaining them? Could someone print all of that information on paper and append that to the traditional paper ICD? My ICD is a million pages long printed and contains all public information about any connected field of research. No one will read it but at least the option is there.

The PARAMOUNT trial investigated whether treatment with a [maintenance dose](#) of [pemetrexed](#) would inhibit the growth of [non-small-cell lung carcinoma](#) and improve survival rates after [first-line therapy](#) with pemetrexed plus [cisplatin](#).<sup>[1]</sup>

[Figure 5](#) In this hypertext, there are links to encyclopedia articles on “[maintenance dose](#)”, [pemetrexed](#), [non-small-cell lung carcinoma](#), [first-line therapy](#), and [cisplatin](#). The original informed consent document did not offer further information on these concepts.

Would research participants like to browse the meanings of technical terms in an ICD? Perhaps this is uncertain, but definitely there is a huge body of data which supports the assertion that since the advent of Wikipedia there is a ravenous hunger emerging from unlikely people who for whatever reason really like spending their leisure time pouring over highly-specialized information jumping link to link in Wikipedia. Many kinds of filters could, for example, spider through the text of an ICD and hyperlink all terms to Wikipedia, PubMed, Mayo Clinic, or whatever anyone else desired. There really should be infinite options for any individual participant or anyone anywhere to remix any given ICD as they desire.

## Remixability

**There is no standardized informed consent process or informed consent document which fully serves the needs of all people. There really ought to be infinite variations of both and increasingly as time goes on research is becoming less ethical by retaining only a single informed consent option in an age when people are coming to require an endless personalized spectrum of options. Research participants have to design the ICD for themselves because only they can choose what information is necessary to help them make a decision about study participation. My model, in addition to connecting to all the available published information online, also offers study participants the opportunity to contribute and develop more media about the study. The “edit” button enables anyone to do anything! The contributive interactivity in many of my other feature proposals are inherent in the edit button!**

**Key features of my live design:**

- **It enables persons wanting information resources related to their study participation to signal their demand if this information does not exist.**
- **Anyone can provide that information in the forum in which the question was asked.**
- **Anyone can make or adapt any information they like in a way that it gets to people who are looking for it.**

Whatever else happens, there should be a moderated, base, official and authenticated version of the informed consent document which settles all concerns. Participants if they like should be able to travel the world and see whatever they like, but in the end, all official base versions of the ICD are in the research coordinator’s control.



**Figure 6** It is hard to explain how this works, but anyone can click the “edit” button and improve the any available research documentation according to continually enforced community guidelines.

Knowing that, advocates or empowered people should feel conscious of their option to refer likely participants for clinical research to a research coordinator even independently of the research coordinator. If someone feels that a health issue is important, for example, they ought to be able to adapt an ICD to make it accessible to their own community in their own internal communication. If that makes a mess when people come to join the study, then that is a problem, but instead of focusing on problems the attention should be on the right of communities to discuss health issues as they choose in their own way. After people get their rights then fix the problems; do not anticipate the problems that will come when people get their rights.



## Ending temporality

**Currently the informed consent process is, in practice, an event in a point of time. This practice became established because of resource limitations which are diminishing and it is time to start thinking detaching informed consent from any one point in time. My design makes it a continual process from which participants can withdraw consent at any time and also it connects the informed consent process to aspects of “return of results”, which is the principle that research participants deserve to enjoy benefits of study outcomes.**

### **Key features of my live design:**

- **The informed consent process ceases to be an isolated event in time.**
- **Participants become more aware that they can withdraw from the study at any time.**
- **The informed consent process becomes a never-ending chain of events which culminates in “return of results”.**

Study participants, after joining a study, remain participants in that study for life. Studies have no end and participants and their descendants should always be allowed to get information about the study even if a researcher closes active monitoring of the study.

One of the rights that study participants eternally retain is “return of results”. This is the right for people who have participated in a study to enjoy some of the benefits of it. One benefit which is essential is the right to be informed of study outcomes on request. There is not a good mechanism in place in current clinical research practices to deliver any explanation of study outcomes on request by participants. Connecting permanent anonymous Internet access to the ICD with updates on the outcomes of the research would fulfill “return of results”. My design perpetually is connected to all updates of a study and which is the hub through which all participants come for all information.

<sup>^</sup> Paz-Ares, L.; De Marinis, F.; Dediu, M.; Thomas, M.; Pujol, J. L.; Bidoli, P.; Molinier, O.; Sahoo, T. P.; Laack, E.; Reck, M.; Corral, J. S.; Melemed, S.; John, W.; Chouaki, N.; Zimmermann, A. H.; Visseren-Grul, C.; Gridelli, C. (2012). "Maintenance therapy with pemetrexed plus best supportive care versus placebo plus best supportive care after induction therapy with pemetrexed plus cisplatin for advanced non-squamous non-small-cell lung cancer (PARAMOUNT): A double-blind, phase 3, randomised controlled trial". *The Lancet Oncology* **13** (3): 247–255. doi:10.1016/S1470-2045(12)70063-3. PMID 22341744. edit

**Figure 7. My model generates academic citations from DOIs or PMIDs. Even when participants are presumed to be unable to understand the publications, all published information about all trials needs to be given to participants even years or decades later.**

## Crowdsourcing

It has always been the case that clinical research is supposed to be a relationship in which both researchers and research participants contribute to paying the costs of research and collectively enjoy the benefits. Researchers oversee all technical setup of the research, for example, and participants contribute their time and take risks of participation, and both enjoy developing products which benefit the community. Historically there was no reasonable way to invite the communities which provide research participants to join in overseeing the technical setup of research, and so research coordinators has nearly exclusive control over processes like execution of informed consent. **Because of new digital tools it is now becoming increasingly possible and more of an ethical prerogative to invite and encourage communities to take increasing responsibility for overseeing the technical aspects of research, and to feel as if the study design is lacking something when the community is not enthusiastic about hosting the research. My design both gives participants the idea to be bold about saying anything and the authority to make changes to the information they get if anything is inadequate enough to spur them to change things.**

### Key features of my live design:

- **Communities in which research is conducted, and not only research participants themselves, get greatly enhanced oversight into the clinical research process.**
- **Families, friends, doctors, and the social network of research participants are invited to talk about the trial in a way that can keep people anonymous or not.**
- **Anyone else interested can show up and with minimal effort make a substantial contribution based on existing crowdsourcing models.**
- **Having anonymous communication channels allows people to raise criticism which could never be done face to face in the context of participant/researcher relationships.**

It is necessary to get increased community involvement because individual research participants do not have free volition to give informed consent to participate in studies. In the traditional informed consent process, a single research coordinator presents an informed consent document to a single research participant who then may sign it to demonstrate informed consent. However - on the consenting side this has never been a decision only made by the individual research participant. When a research participant gives informed consent, that also is supposed to represent the consent of that participant's community to allow the research to happen in the community, and to take on the costs of having its community members assume study risks in expectation of using the benefits of the research to address community needs for health development. Because an informed consent document is not a legal business contract between two entities and is more of a quasi-legal document which research coordinators and their lawyers insist is not a contract, my design for an informed consent document design takes in consideration that informed consent can only be conducted within the goodwill of a community to allow it.

Informed consent documents by design need to be inherently created in such a way that permits oversight by the community in which the research is happening. The community has to be able to access the document, comment upon it, recommend changes, oversee how it is delivered, and talk amongst itself about the nature of the research it is hosting.

The research coordinators can never get community support for research without making research accessible to the community, and since informed consent document is the fundamental published interaction between any community member and the research team, the informed consent document must collect support from the entire community by a crowdsourced project. When the informed consent document exists in a form which can be shared online freely then that constitutes an great attempt at getting that community informed consent. Visualize informed consent coming from an entire demographic alongside every individual who signs an ICD.

Another aspect of crowdsourcing is receiving honest feedback and comments. Anonymous people on the Internet can say and do outlandish rude things that would never happen in the context of a personal relationship, even a casual one. Research coordinators are nice to research participants and for this reason, the feedback relationship is corrupted with the research

participants' respect for the human dignity of study coordinators. There is a problem the participant is unable to criticize the research coordinator with their savage best instincts. Research cannot always have a human face; it is a beast to be attacked when it is wrong and participants need a dehumanized communication channel to challenge without consideration of whose feelings they might hurt.

For example, the comments section at the bottom of any Internet news article are currently drawing out the most inhuman and insane primal instincts that can be expressed with a keyboard. Many individual comments are bogus but collectively these are indicators of complaints that people have always held but were inexpressible and uncountable before the advent of forums to act as communication channels to receive this bunk. My design for an informed consent document, while retaining all human face in the traditional process, also offers a channel for anyone to start a public discussion about presented information about a clinical trial and to call out information demands to the research coordinator while the requester cowardly hides in anonymity.

This, more than anything else in my design, expresses what the *Belmont Report* calls "beneficence". When the research coordinator actually sacrifices the primary defense of their own reputation to give research participants channels to say and do anything to them, anonymous, just as wildly as elsewhere on the Internet, it is as beneficent of a sacrifice and homage to participant rights as can exist. Good researchers enjoy – bad researchers beware!



**Figure 8 I am not going to show the forum for receiving complaints, but I will say that best practices for moderation encourage sharing pictures like this famous one to direct angry people to have some tea and chill out.**

## No cost and no disruption

Of all the changes proposed to informed consent above, none of them require the research coordinator to do anything in particular except apply that open access license to the informed consent document. After that happens, the coordinator could continue to do whatever they liked as they always have and not take any further action, and the community can visualize whatever they demand.

It is not certain that anyone would want to invest in any of these ideas and maybe any visualization pushed would not be appreciated.

**The reason why cost matters is that the informed consent document is not supposed to be controlled by the research coordinator. Anyone from the community should be able to give input into the research happening in their community without paying any money. Having input means being able to have deep free easy access to the development of research practices. I grant that.**

**Key features of my live design:**

- **The monetary cost of participation in discussing a trial is minimized to Internet access on any device, including mobile or limited computing devices.**
- **No features of this model necessitate changing any other part of existing informed consent practices.**

Also, cost can matter to research coordinators themselves. In the section above on “internationalization” I pointed out that this study, the PARAMOUNT study, was held in many countries. It is simply a fact that no medical research organization promises good research infrastructure into all countries equally, and some countries are privileged compared to others. This simply is not fair and all research coordinators have personal responsibility to ensure that all people get their human rights in medical research no matter which country they live in.

My model acknowledges regional variations in standards of care and research practices by letting everyone – regardless of geographical location – connect for free to all available resources. Anyone can volunteer to develop and translate existing resources. A goal for research has to be perfect fulfillment of rights for everyone.

## No sudden obsolescence

**Establishing an online text ICD which could be read or downloaded and shared freely would not go obsolete until text does and would serve as a base from which to develop anything else. My model does text right by minimizing filesize, maximizing readability including for bots (no PDF!), and being as if digitally native.** My model when propagated worldwide would not become outdated even if other new developments in informed consent document presentation came to be used.

### **Key features of my live design:**

- **Nothing in my model is likely to go obsolete and need to be discarded. If it goes obsolete then it can be abandoned and forgotten without formal process.**

Note also that the community has no requirements to comply with laws or anything else that concerns the research coordinator. If anyone finds it useful to create a Wikipedia article about a trial and lots of people go there for information then that is their business and not the responsibility of the research coordinator to monitor all public, published, and popular discussions about the clinical trial because the trial itself belonged to the community and never belonged to the sponsor anyway. Community discussion of an ICD is just that - discussion - and records of discussion can still persist even if any government says that the researcher's presentation of the ICD has to change.

## There are more benefits

It is really lame of me to say this, but there are more benefits that I am not describing. To learn more read about the work of the following organizations:

- Creative Commons, for legal licensing and implications
- The Wikimedia Foundation, for crowdsourcing theory
- The Open Knowledge Foundation, for demands for access to information
- Consumer Reports / Consumers International, for human rights of individuals when dealing with large organizations

I would be happy to talk to anyone after the challenge about making changes to the informed consent process. None of these organizations endorse this proposal or directly helped me in making it, although they all inspire me and I use their tools.

## Everyone can use this model

Although this proposal is being sent to Lilly, the open nature of it can be replicated by anyone as there is no proprietary development necessary to make this open concept work.

**Anyone can execute this at any clinical research organization, in any country, in any culture, and in any place in which the clinical research need not be made a secret from the community. It can be done on some or all studies and not affect practices for other studies.**

**The process is so open that I am going to execute an instance of it right now! See below!**

**Key features of my live design:**

- **It is a live design.**
- **No one needs permission from a clinical researcher to start talking online about trials.**
- **Demands for open access licensing can be made by anyone through an open letter process.**
- **I want open access licenses applied to every informed consent document in existence.**

1 October 2013

**To whom it may concern at Lilly,**

Eli Lilly conducts pharmaceutical research in my community. Since clinical research has certain risks, and since I feel and assert some responsibility as a citizen to participate in the safety and well being of members of my community, I would like to have a reasonable opportunity to oversee the research being done on members of my community.

I understand that as a primary written record of agreement, your organization shares informed consent documents with participants as part of the process by means of which you conduct the informed consent process. One might expect that the information which is given to research participants in the informed consent document constitutes enough written information to provide a basis from which a typical person can provide informed consent, because the informed consent document constitutes the written information you give in the informed consent process. Because there seems to be some relationship between this document and understanding a clinical trial, I think that my access to the informed consent document would also help me be able to become an informed partner in this research by giving my review and consent for this study to happen in my community.

I am writing to ask that I be provided the informed consent document describing the research study you are conducting in my community. Furthermore, as I would like to be able to re-publish and remix this document with my annotations and notes so as to be able to explain this research to peers in my community, would you to give me the informed consent document with Creative Commons-Attribution licensing (“CC-By”) so that I can have a legal way to do this which would not violate the copyright on this document?

Thanks for your reply in any case. If you can provide the ICD to me under these terms then I will share it broadly with everyone. If you are unable to share the document with me, then please also explain to me why you are unable to do so. I have shared the fact of my request with my community and a timestamped copy of it can be found at (this link shows my name so removed per challenge rules – your real letter is separate)

Thank you for your attention and thank you for conducting health research. I am the biggest fan of the advancement of open science!

yours,

(name removed per challenge rules – your real letter is separate)



## Checklist

*“Remember — your design must visually show ALL elements of the [Required Sections and Fields](#) document.”*

I meet this by returning to you – almost unaltered – versions of the informed consent document and protocol you gave me. That should cover all elements of the required sections if they were covered in these initially.

In addition to this, I did reformat the ICD in a different platform but my intent was to return it verbatim. The file conversion and upload is novel and an improvement, then the visualization happens when it is remixed anywhere. I put it in Wikipedia, Wikimedia Commons, and Wikisource.

*Create your design (Acceptable formats: PNG, JPG, GIF – non-animated, TIFF, PSD, AI, PDF, or HTML.)*

My design is this PDF with embedded PNG files. I am submitting this PDF, which contains the entirety of the entry, and additionally as separate files PNGs of all images in this PDF.

In addition, I have live versions of my entry hyperlinked in various places in this entry. Anyone can, as they like, check the live version, but conceptually the live versions are introduced in this PDF. Since I connected the live versions to other bodies of work, they are literally integrated with the Internet and hardly separable from it, but enough is explained in this document. Persons leaving this PDF run the risk of coming to see my identity. I do not think my identity is ever obvious or displayed in the links I give but it could happen against my intentions.

*Confirm you have read and agree to the [Official Rules](#) and are releasing your design to the public under the [Creative Commons Attribution 3.0 Unported License](#), then submit your design by completing the submission form.*

I read the rules and agree to them. I agree to the licensing. I make some extended and explicit explanations of how I do this in the “legal stuff” section below.

## Legal stuff

I give my agreement to release my design to the public under the Creative Commons Attribution 3.0 unported license.

In response to Rule 6

### *A. Language Requirements*

*All Submission materials must be in U.S. English.*

Uh-oh! I broke a rule! I asserted that ICDs for every language in which the study was conducted should be interconnected, and because of this, I demoed a multi-language interface. My graphic demonstrating this includes “submission materials” which are not in U.S. English. Please excuse me.

*(iii) The Design must not include any third-party copyrighted material or trademarks. The only exception is if the Contestant has written permission to use such material. The Administrator may require the Contestant to provide a copy of such permission upon request.*

I affirm that I take responsibility for displaying the Wikipedia and Wikisource logos in my design. These are copyrighted graphics and trademarks. I assert that I have written permission to use this logo, as the Wikimedia Foundation has mechanisms in place to encourage the Wikipedia community to use the logos for illustrative purposes in various ways. See

[https://wikimediafoundation.org/wiki/Trademark\\_Policy](https://wikimediafoundation.org/wiki/Trademark_Policy)

“Here are some of the things that you can do with the Wikimedia Marks that do not require our permission:

- distribute unchanged Wikimedia content, including appropriate attribution, for as long as you distribute them without charge or receipt of anything of value and do so in accordance with this policy”

Here are other associated permissions and terms:

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