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The Hydra

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Almost nobody favors long consent forms for prospective research subjects. Almost everybody thinks they interfere with informed consent's purpose—good decisions. Nevertheless, almost everybody believes consent forms have long been getting longer.

Years ago, Paul Appelbaum lamented the "tendency to cram ever more information into consent forms."[1] Weeks ago, Ilene Albala and her colleagues (one of them Appelbaum) reported in *IRB: Ethics & Human Research* that the length of one institutional review board's forms "increased roughly linearly by an average of 1.5 pages per decade. In the 1970s, the average consent form was less than one page long and often only a paragraph or two, but by the mid-1990s the average form had increased in length to over 4.5 pages." Similarly, "Baker and Taub demonstrated that the mean length of consent forms nearly doubled between 1975 and 1982. More recently, Beardsley and colleagues in Australia found that the median length of consent forms increased from seven to 11 pages between 2000 and 2005."[2]

Long forms are deplored on several grounds: That people will not read them. That even if people read them, they would not understand them. That even if people understood them, the forms would not promote better and might promote worse decisions.

For example, in a study of principal investigators, over half thought contemporary consent forms "unlikely to be read" or "incomprehensible." Onerous length and detail that reduced subjects' understanding were bemoaned. One researcher thought "most subjects skim through the incredibly long informed consents, believing that most of it is simply bureaucracy."

These concerns are well founded. First, long forms repel, confuse, bore, and distract. (It appears "that, in an educational context, people are unlikely to read entire documents that contain more than 1000 words, or about 4 pages."[3]) Furthermore, these forms compete for your attention with hundreds of other disclosures about innumerable matters. Who could—who would—study them all? Who reads credit card contracts, mortgage agreements, retirement account prospectuses, bank privacy statements, online purchase conditions, HIPAA warnings, insurance provisions, or rental car forms?[4] Not I. Not you. So, for example, the patients HIPAA blesses do "not appear to recognize, understand, or care about this complex law as it applies to research." They ask about disclosures "exceedingly rarely. For example, one academic health center reported that between 2003 and 2007, the institution received only 23 requests for accounting of disclosures, and none were from research."[5]

Second, in both research and clinical medicine even good forms and processes fail to achieve their educational goals. Even tested after optimal "consenting," patients correctly answer only a third to a half of the questions asked.[6] And even patients with "a relatively large variety of information sources" use incorrect information, so that fewer than half the breast cancer patients in one study understood treatments' survival rates, and fewer than a fifth understood recurrence rates.[7] The causes are many. For example, illiteracy and innumeracy prevent *many* people from reading *many* forms. (Roughly ninety percent of the people in one study had at least some college education, but 40 percent "could not solve a basic probability problem or convert a percentage to a proportion."[8]) Yet the simpler your language, the more words you need to explain your ideas, and the longer forms get.

Third, people can keep only a few things in mind when analyzing a problem. Miller's "magical number seven" is the classic estimate, and it is easily exceeded. For example, *Miranda* warnings are familiar, few, and short. Yet even with "verbal chunking" (combining data for easier storage) "the upper limit of information processing for Miranda warnings is likely less than 75 words,"[9] considerably fewer, that is, than the usual *Miranda* warning. And when anesthesiologists and nurse practitioners tried to educate their patients, they "vastly exceeded patients' short-term memory capacity."[10] Furthermore, integrating "different types of information and values into a decision is a very difficult cognitive process." Indeed, information can *decrease* the reliability of decisions. For example, the "reliability of the choices [of horse-racing handicappers] decreased as more information was made available."[11]

If long forms are widely and rightly condemned, why do they keep getting longer and wronger? Each form must be individually approved by a regulatory agency—an IRB. This gives IRBs a degree of authority over disclosure few regulators can match. So if things are going wrong, IRBs are the first place to look for a cause.

A study by William Burman (and others) provides a striking picture of how IRBs affect consent forms.[12] That study "evaluated the local review process

of two protocols from a multicenter clinical trials group." The twenty-five sites included "academic medical centers, Veteran's Administration Medical Centers, and public health departments chosen in large part for their experience in clinical research" and thus included "IRBs that are likely to be representative of large institutions oriented toward clinical research." IRB "review was a time-consuming process, requiring a median of 30 [range 10–48] hours of work by the local study site and more than 3 months of calendar time to complete." The IRBs did not require changes in the protocols, but they required a median of 46.5 changes in each consent form (range 3–160). (Only 1.5 percent of the changes "were thought to represent a need to fit specific local conditions.")

Most (85 percent) of the changes "did not change the meaning of the consent form," but they did change its quality. The forms got longer, the sentences got wordier, the active voice got scarcer, and the reading-difficulty level got higher (by a mean of 0.9 levels), so that 41 percent of the forms "had an inappropriately high reading grade level."

Furthermore, eleven percent of the changes actually introduced errors into the forms. Two-thirds of the forms "had an error of protocol presentation or a required consent form element." Many errors were minor, but over a quarter "were more substantive: deletions of significant side effects (e.g., the possibility of hepatotoxicity from rifampin and/or pyrazinamide), major errors in the description of study procedures (e.g., incorrect information on study duration), or the complete removal of a required section of the consent form (e.g., the right to withdraw from the study)."

If this is how IRBs review consent forms, no wonder an old IRB hand like Robert Levine thinks "there is no more expensive or less competent redaction service available in the United States than that provided by an alarmingly large number of IRBs."[13] But IRB members surely share the preference for concise consent forms. When a regulatory agency produces results neither it nor anyone else likes, there are deep-seated reasons. We will consider three: the federal regulations, the IRB incentive structure, and the IRB system's goals.

First, Appelbaum long ago cited "HHS Regulations . . . requiring that ever-increasing amounts of information be presented to potential research subjects."[14] Certainly they demand copious disclosures and invite IRBs to require more. Second, Vesuvian disclosure seems to protect IRBs and their institutions against lawsuits and Office for Human Research Protections retribution. Third, such disclosure seems to serve the IRB system's goals. The Albala study found that "discrepancies in the descriptions of risks between the consent form and the protocol" declined as forms' length increased. This might suggest that forms got longer because subjects needed more information. However, although these discrepancies "had ceased before the end of our study window, page length continued to increase, suggesting that greater attention to risks has not been the sole factor responsible for the increase in page length."

The IRB system's goal is not just reporting risks described in a protocol. It is, as Appelbaum said, "full disclosure." This is an ever-expanding category, since new topics (like conflicts of interest) and new risks (especially social, psychological, and "dignitary" risks) keep proliferating. And the goal is not just "full disclosure," but, as then-Secretary of Health and Human Services Donna Shalala announced, "maximal protection for all human subjects." Maximal means error free, since "even one lapse is too many." So in a 2,400-word article, Shalala used "ensure" nine times, "guarantee" twice, and "make sure" twice. The system must "guarantee" the "greatest possible protection for every human subject, in every clinical trial and at every research institution in the country."[15]

How are these utopian ambitions to be met? No doubt by yet more meticulous forms, but also, the Institute of Medicine "urge[s, by] a new approach to informed consent, one in which legal disclaimer and institutional self-protection are second to clear, simple, unclouded, unhurried, and sensitive disclosure that gives the potential participant all the information a reasonable person would need to make a well-informed decision, and the time to do so." So "consent should be an ongoing process that focuses not on a written form or a static disclosure event, but rather on a series of dynamic conversations between the participant and the research staff that should begin before enrollment and be reinforced during each encounter or intervention."[16] And so an ever-more elaborate form becomes embedded in an ever-more elaborate process.

But the giantism of consent forms is not just a product of the American IRB system. It is an international phenomenon. And it afflicts hundreds of other kinds of legally mandated disclosures. For example, the Truth in Lending Act of 1968 required lenders disclose interest rates and fees. Simple enough, perhaps, but soon the Federal Reserve issued Regulation Z to instruct creditors. That regulation, "while it did not salvage Truth-In-Lending's basic goals, did succeed in making the statute too complex to be complied with."[17]

Giantism—in short—is inherent in conventional disclosure mandates like informed consent. They aspire to equip novices to make well-informed decisions about complex questions. Yet while less may be more, less is not enough. For the reasons we've canvassed, lengthy disclosures are self-defeating, but shorter forms omit relevant facts. If there is a *via media* between too much and too little, it is elusive.

Even if that *via media* could be found, the institutional dynamics of mandating disclosure—like the fear of legal liability, the threat of political criticism, and ideological zeal—impel regulators past moderation into excess. Long and ever-longer consent forms (and processes) we shall have always with us until we ask more basic questions about these mandates than we have dared face. Until then, prospective research subjects will be told much and learn little.

1. P.S. Appelbaum, "Informed Consent: Always Full Disclosure?" in J.E. Sieber, *NIH Readings on the Protection of Human Subjects in Behavioral and Social Science Research:*