Beyond Nazi War Crimes Experiments: The Voluntary Consent Requirement of the Nuremberg Code at 70

The year 2017 marks both the 70th anniversary of the Nuremberg Code and the first major revisions of federal research regulations in almost 3 decades.

I suggest that the informed consent provisions of the federal research regulations continue to follow the requirements of the Nuremberg Code. However, modifications are needed to the informed consent (and institutional review board) provisions to make the revised federal regulations more effective in promoting a genuine conversation between the researcher and the research subject.

This conversation must take seriously both the therapeutic illusion and the desire of both the researcher and the research subject not to engage in sharing uncertainty. (*Am J Public Health*. 2018;108:42–46. doi:10.2105/AJPH.2017.304103)

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See also Annas and Grodin, p. 10; Wilensky, p. 12; Crosby and Benavidez, p. 36; Shuster, p. 47; and Grodin et al., p. 53.

The Nuremberg Code set the standard for every subsequent attempt to regulate human experimentation. Its first principle remains, 70 years later, its most important: the requirement of the voluntary, competent, informed, and understanding consent of the human subject. Anniversaries provide an opportunity to reflect and to explore how subsequent events and discussions have affected our understanding of critical documents like the Nuremberg Code. The Code was a product of a war crimes trial, and a summary version of the Code was quickly adopted as an explicit requirement of the Geneva Conventions of 1949 and the International Covenant on Civil and Political Rights (ICCPR) in 1966; it is a norm of customary international law.[1] As important as it is to classify human experimentation without consent as a potential war crime and a crime against humanity, it is in the context of domestic civil law and ethics that Nuremberg's consent requirement has been most influential.

It has been 70 years since the Nuremberg Code was authored, and federal research regulations are, in 2017, receiving their first major revision in almost 30 years. The consent provisions of the revised federal research regulations follow the requirements promulgated by the Nuremberg Code. Of course, research has changed over the past 70 years, and federal regulations reflect changes that the Nuremberg judges did not (and often could not) take into account in drafting the Nuremberg Code.

Changes include procedures to permit children (and other populations incapable of consenting) to be used in research, the public's increased approval of medical research, as reflected in National Institutes of Health budgets; and new technologies for conducting research, including genomic information technology. Although there are strong arguments for modifications, the consent provisions of the revised regulations can be characterized as a memorial to the Nuremberg Code. Born in a war crimes trial, the Nuremberg Code remains at the center of legal and ethical guidance for all legitimate research involving human beings.

THE VOLUNTARY CONSENT REQUIREMENT

Contemplating the Nuremberg Code in 1992, Elie Wiesel—a Holocaust survivor and the Holocaust's most influential memorialist—wrote that the Nazi doctors who were tried at the Doctors' Trial for murderous concentration camp experiments did not see their victims as human beings, but as abstractions. In his words:

> This is the legacy of the Nuremberg Tribunal and the Nuremberg Code. The respect for human rights in human experimentation demands that we see persons as unique, as ends in themselves . . . we must not see any person as an abstraction.[2(pix)]

Wiesel's words were used 20 years later by Rebecca Skloot as an epigraph for her powerful best-selling book *The Immortal Life of Henrietta Lacks*. Skloot continues the Wiesel quotation: "Instead, we must see in every person a universe with its own secrets,

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with its own treasures, with its own sources of anguish, and with some measure of triumph."[3(pxiii)]

Surgeons took a sample of Henrietta Lacks's cervical cancer tumor for research without asking for her consent in 1950. No one at the hospital even told her family about this. Lacks died shortly thereafter, but her cells lived on in research laboratories around the world. As both Wiesel and Skloot underline, it is much easier to abuse people we do not see as fully human. The protection against treating people as abstractions who we can use and abuse with impunity is, as declared by the judges at the Nuremberg Doctors' Trial in 1947, the doctrine of voluntary, informed consent. This doctrine requires researchers to confront their human subjects directly, to talk to them, and to treat them as unique individuals.

The Nuremberg Code consists of 10 principles that constitute basic legal and ethical rules for research with human subjects. The first principle, the consent principle, is unique among them. Not only is it placed first, but unlike the other 9, each of which is limited to a single sentence, the consent principle is followed by 2 detailed explanatory paragraphs:

> *The voluntary consent of the human subject is absolutely essential.*
>
> This means that the person involved should have legal capacity to give consent; should be so situated as to be able to *exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion*; and should have *sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision*. The latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the *nature, duration, and purpose of the experiment*; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
> The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity. (emphasis added)

The text highlights a number of basic concepts. The first is the nature of a "volunteer." All the deadly Nazi experiments reviewed by the judges in the Doctors' Trial, including the freezing and high-altitude experiments, were performed on prisoners in concentration camps. There was considerable testimony at the trial, especially from US medical expert Andrew Ivy, about whether prisoners could ever "volunteer" for experiments. The judges concluded that it was possible but that the ability to refuse was crucial. This is reflected in making voluntary consent not only first but "absolutely essential" and by principle 9, the right to withdraw. To underline the voluntary requirement even more, the consent principle stresses that the individual must be able to "exercise free power of choice, without any intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion."

After voluntariness, the Code highlights "legal capacity to give consent," combining the elements of information and understanding: the human subject "should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." The required information includes "the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment." These points have sometimes been summarized simply as requiring that consent be voluntary, competent, informed, and understanding.[4]

Because the Code was enunciated by US judges sitting in judgment of Nazi physicians who were accused of murder and torture of concentration camp inmates, physicians did not immediately see the Code as applicable to them.[5] The World Medical Association, for example, adopted its own code, the Declaration of Helsinki, which was written by physicians (rather than judges) for physicians. The judges, nonetheless, believed they were writing a code for the future that could help prevent a repetition of the horrors of the murderous and torturous concentration camp "experiments."[6] That the international community agreed with their assessment can be seen in 2 documents that drew content from the Nuremberg Code: the Geneva Conventions of 1949 and the ICCPR (drafted in the early 1950s and in effect in 1966). The Geneva Conventions, for example, assume that prisoners of war simply cannot provide voluntary consent to medical experiments and so prohibit them from being used in nontherapeutic experiments:

> No prisoner of war may be subjected to physical mutilation or to medical or scientific experiments of any kind which are not justified by the medical, dental or hospital treatment of the prisoner concerned and carried out in his interest. (Article 13)

The ICCPR is similarly unequivocal in Article 7:

> No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.

The Geneva Conventions apply only during wartime, whereas the human rights requirements of Article 7 of the ICCPR apply in both war and peace.

The prosecutors at Nuremberg spent much of their post-Nuremberg lives trying to establish "a permanent Nuremberg" court to try war crimes and crimes against humanity. This effort ultimately became the International Criminal Court, which opened in 2002. Among the crimes over which the court has jurisdiction are "grave breaches of the Geneva Conventions" (including biological experiments) and "torture or inhuman treatment, including biological experiments." That the United States has yet to formally join the International Criminal Court remains a human rights scandal.

Oversight of human experimentation has primarily been predicated not on international criminal law but on local peer review in an ethics and domestic civil law context. With the publication of Henry Beecher's 1966 article on abusive post-Nuremberg experiments in the United States, the movement toward federal regulation of human experimentation began.[7] The Nuremberg Code was the touchstone for defining ethical norms; nonetheless, federal

regulation ultimately relied heavily on 2 procedural mechanisms not even mentioned in the Doctors' Trial or the Nuremberg Code: review boards and a written consent form. And, as my colleague Leonard Glantz has stressed, when the original federal regulations were adopted in 1974 and revised in 1991 (the last time before the 2017 revisions), they reflected 2 major departures from Nuremberg: (1) they addressed medical institutions that sponsored research, rather than physicians and scientists who actually conducted research; and (2) their protections were primarily procedural (including the review board and forms) rather than substantive.[8]

THE 2017 FEDERAL REGULATIONS

Revisions in the 1991 "common rule" were proposed in 2011, a revision of the revision proposed in 2015, and final rules issued in 2017.[9] Proposed revisions sought to accomplish 4 major things: treat biospecimens like people, reduce the types of research covered by the regulations, use a single institutional review board (IRB) to review research conducted at multiple institutions, and improve the informed consent process. All but the first were adopted.

The proposal to treat human tissue samples like people was simply a category mistake (biospecimens are not people) and was rightly rejected. The proposal was that consent should be sought for research on identifiable biological samples under the theory that private medical information could be obtained from the samples during the research. That large collections of tissue samples were being compiled for research purposes (especially genomic research) is true, but this was new only in scale. The privacy issues had been discussed at least since the 1970s—during which time there was no serious discussion suggesting that the federal research regulations were the proper way to regulate them.[10,11]

Just as public outrage over the Tuskegee Syphilis Study strongly influenced the development of the original federal regulations on human subjects research in the early 1970s,[12] the wide publicity generated by the story of Henrietta Lacks in the years after 2010 influenced attempts to treat biospecimens like people.[13,14] But the proposal to treat cells as people was always reductionistic and misguided. Henrietta Lacks was a person and her cells were not.

The second proposed change was to reduce the types of research to which the regulations applied. Nuremberg was focused on potentially lethal experiments (some with death as the endpoint) that risked life and limb and were better classified simply as murder and torture. There has been considerable complaint over the past 20 years that the mission of IRBs in reviewing research has suffered from "mission creep" (by including more and more kinds of research activities) and that measures are needed to rein in the growing mandate of IRB review.[15] In response, the new regulations specifically decree that some activities are not research for the purposes of the regulations, for example, "scholarly and journalistic activities," public health surveillance, use of biospecimens by criminal justice agencies, and national security activities. Other research is simply exempt from the regulations, including educational research, benign behavioral interventions, secondary research on biospecimens, demonstration projects, and taste and food quality evaluation. There is nothing in these subject matter limitations that the judges at Nuremberg would object to.

The third major proposal concerns IRBs, which are relevant to informed consent because the IRB must approve the form and process informed consent takes. The proposal calls for a single IRB review to be sufficient for research conducted at more than 1 institution. Although IRB review was not required by the Nuremberg Code at all, doing away with the requirement for all but 1 institution involved in a multicenter research trial could gut the review requirement of any real meaning. This is because the structure of the regulations requires holding the individual institution "responsible for safeguarding the rights and welfare of human subjects."[9(p7265)] The single IRB requirement risks replacing ethics with efficiency and can be justified, if at all, only in no or very low risk studies.[16]

On the other hand, a single, national IRB that had a majority public representation and met in public could usefully (and efficiently) set and enforce rules for extreme and unusual human experiments—experiments that local IRBs have no expertise in.[17] Examples might include xenografts, the artificial heart, and human gene editing. Another useful reform would be a requirement for the majority of the IRB members to be representative of the public (appreciating that this proposal has little current support and will require considerable effort and funding) rather than the current requirement that IRBs have at least 1 member who is not "affiliated with" the institution.[17] Under existing regulations, all members of an IRB but 1 could have an inherent conflict of interest because they can be employed by or affiliated with the institution. The judges at Nuremberg would not likely have approved this anti-accountability mechanism.

NEW APPROACHES TO INFORMED CONSENT

Seventy years after Nuremberg, it would be surprising if there were no proposals to modify our informed consent practices—and there have been. Some proposals are designed to address what we might call "consent form bloating," in which more and more information is added to forms that IRBs spend most of their time reviewing and that human research subjects spend little, if any, time trying to read and understand. No forms are required by the Nuremberg Code, but today there is often little left of informed consent other than forms. These forms get longer and longer and more and more complex. The reason is simple: they are designed to protect the institution, not the research subject.[18] In so doing, they undermine autonomy rather than protect it. The model everyone is familiar with is the 75-page disclosure form that you must accept before you can open a specific app on your smart phone or computer. Virtually no one reads these "consent" documents, and we have all become used to simply "accepting" their terms.[19]

We know that informed consent is a process, not a form. But can we escape our current

form mania? My colleagues Leonard Glantz and Michael Grodin and I have previously suggested that the only way to make sure the consent process involves an actual conversation between researcher and subject is to eliminate written forms altogether and replace them with an audio or video recording of the consent process.[20] There is no realistic way of sharing uncertainty or constructively dealing with the therapeutic illusion (that research is treatment) without direct conversation. The revised regulations do not adopt this highly controversial proposal. Rather they make a few modest changes—each of which could move in the right direction but require strong IRB and researcher support to make any real difference to the quality of consent.[21]

The first is commonsensical but insufficient: the information supplied to the human subject "shall be in language understandable" to the human subject. Although an improvement over the 1991 version, this still falls short of requiring, as Nuremberg does, that the subject actually understand the information, which is necessary to be able to make an "understanding and enlightened decision." Operationalizing this requirement would require at a minimum some form of confirming the subject's actual understanding, such as a series of questions about risks and alternatives (and quizzes are sometimes part of an informed consent process today). Second, the subject "must be provided with the information that a reasonable person would want to have . . . and an opportunity to discuss that information." This is also a commonsensical statement, but it requires good faith implementation and oversight to be meaningful.

Third, the

> informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject . . . in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Like "understandable," the concept of "comprehension" did not appear in the 1991 version.

If taken seriously, this requirement could spark a radical overhaul of current practices. Consent forms could no longer aim to simply catalog information with a view to protecting the research institution from charges of inadequate disclosure but must instead detail key information that would lead a person to say yes or no to being a research subject. Key information should be seen by IRBs as what the law has termed "material" information: information (like a risk of death or serious bodily harm) that would lead a person to accept or reject a treatment (or, in this case, a research protocol). This suggested interpretation seems reasonable considering the sentence immediately following in the regulations:

> Informed consent . . . must be organized and presented in a way that . . . facilitates the prospective participant's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

The fourth consent change is the introduction of a novel concept that was seen as necessary to permit certain kinds of research on biospecimens to be conducted efficiently: broad consent. The idea is that individuals can consent in advance to research in the future without knowing exactly what it is if they are provided with "a general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens." A statement that the subject "will not be informed of the details of any specific research studies that might be conducted" must also be included, assuming this is true.

"Broad consent" is, of course, a misnomer. What is proposed is planned uninformed consent, more like a waiver of rights. This waiver was seen as necessary precisely because biospecimen research does not fit into the rubric of human subject research. This is not unreasonable in the realm of privacy protection (even genomic privacy protection) or in the treatment context. However, in the research context, the concept of broad consent tends to undercut the meaning of informed consent, suggesting that it need not be taken seriously if it interferes with the efficient conduct of research.

The new regulations continue with a list of 8 "elements of informed consent" that are unchanged from the 1991 regulations but supplemented by additional privacy concerns for research on personal information and biospecimens. There are 3 new "additional elements of informed consent":

> (7) A statement that the subject's biospecimens . . . may be used for commercial profit and whether the subject will or will not share in this commercial profit; (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects . . . ; and (9) For research involving biospecimens, whether the research will . . . include whole genome sequencing.

These reflect a fascination with the amount of information gleanable from genome sequencing and with the privacy of that information. The first 2 can be seen as Henrietta Lacks oriented, because of the wide criticism of the fact that neither she nor her family was compensated in any way for the use and commercialization of her cell line. Likewise, no attempt was ever made to inform her family of any information gleaned from her cells. My own view, perhaps not widely shared, is that both of these should be rights, instead of waivers of rights. Research subjects should routinely share in profits (understanding that profits will be rare and record-keeping challenging), and researchers should be required to disclose individual results to research subjects "when clinically relevant" (unless the subject prospectively waives this right.).[22]

REVISED REGULATIONS AND NUREMBERG CODE

The revised regulations were issued in haste on the last day of the Obama administration and without adequate time to consider the comments on the 2015 proposed changes, especially those related to biospecimens. Biospecimens never became an issue at Nuremberg, primarily because Josef Mengele escaped Europe before the trial. His genetic studies using twins (including his collection of eyes) were not part of the trial.[23] Nonetheless, some genomic research, and some research on biospecimens, can be placed in the same category as Holocaust-related Nazi racial research.[24]

The statement at the beginning of the new regulations is more directly applicable to how they should be interpreted by the federal departments and agencies

to which they apply. Whether they apply to a particular activity should be made "consistent with the ethical principles of the Belmont Report." It is relatively astonishing that the new regulations are justified almost exclusively on the assertion that, since 1991, "the volume and landscape of research involving human subjects have changed considerably. Research with human subjects has grown in scale and become more diverse" but that interpretative guidance is to be sought in a document that is widely acknowledged to be out-of-date.[25] Belmont does, however, get us explicitly back to Nuremberg. The first paragraph of the 1979 Belmont Report reads:

> Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes intended to assure that research involving human subjects would be carried out in an ethical manner.[26]

Of course, the Nuremberg Code only opened the Belmont Report, which consisted primarily of identifying 3 principles of research ethics: autonomy, beneficence, and justice. In reflecting on the Belmont Report 20 years later, in 1999, Al Jonsen quoted Jay Katz, perhaps the world's leading expert on informed consent, as saying:

> Even if the Nuremberg Tribunal had been aware of the tension that has always existed between the claims of science and individual inviolability . . . I hope it would not have modified its first principle, namely, the voluntary consent of the human subject is absolutely essential. It is this assertion that constitutes the significance of the Nuremberg Code then and now. Only when that principle is firmly put into practice can one address the claims of science and the wishes of society to benefit from science.[27]

Jonsen continues in his own words, "The Belmont Report affirms that view."[27] Katz always admired the judges at the Doctors' Trial for insisting on informed consent. He also knew how difficult it was to engage physicians and research subjects in an actual conversation that acknowledged that research was not treatment (rejecting the therapeutic illusion) and that both research and treatment were filled with uncertainties.[28] Today we continue to admire the judges and their code—but must also heed Katz's warning that actually obtaining voluntary, informed consent requires a meaningful conversation between researcher and subject, and engaging in this conversation remains a major challenge.[29]

It seems fair to conclude that although the Belmont Report is almost 40 years old, its adoption by the 2017 rules is a reaffirmation of the informed consent principle of the Nuremberg Code as a necessary (although not sufficient) and primary requirement for ethical human experimentation—and as our primary protection of human dignity. In this sense, the informed consent provisions of the 2017 federal regulations can be seen as a memorial to the Nuremberg Code, albeit a memorial that is still under construction. That memorial will be complete only when Nuremberg's consent principle is taken seriously and made meaningful by researchers who strive to meet the ethical standards of the Nuremberg Code to promote human rights and human dignity. AJPH

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