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(A wholly independent, volunteer, non-profit, tax-exempt organization,
incorporated under the laws of the State of New York)
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Science and Technology Directorate
U.S. Department of Homeland Security

VIA Federal eRulemaking Portal: <http://www.regulations.gov>

In re: U.S. Department of Homeland Security, Notice and request for comment,
Docket No DHS-2011-0074, 76 Fed. Reg. 81,517 (2011):

Request for Review and Comment: “The Menlo Report: Ethical Principles Guiding Information and Communication Technology Research” (“Menlo Report”) for the Department of Homeland Security (DHS), Science and Technology, Cyber Security Division (CSD), Protected Repository for the Defense of Infrastructure Against Cyber Threats (PREDICT).

These comments respond to the Department of Homeland Security request for review of and comment on “The Menlo Report.” On balance, the report is dubious legally and ethically. We note at the outset:

- This report is under consideration by Homeland Security at a time when: The Supreme Court of the United States has found unanimously that warrantless, sustained Global Positioning System monitoring of a suspect’s vehicle violates the Fourth Amendment to the Constitution, and justices have urged Congress to enhance reasonable expectations of privacy; the European Union is bolstering its already strong privacy protections; and the Department of Health and Human Services has encountered privacy-based objections to loosening of human subjects research protections.
- Homeland Security should not pre-empt these very important national discussions or imply possible endorsement of the Menlo Report, given the Constitutional and ethical significance of personal privacy and the report’s possible ramifications.
- The Menlo Report runs counter to Homeland Security’s own statutory mandate and to U.S. commitments under international law.

Citizens for Responsible Care and Research, Inc. (CIRCARE) is the oldest human research protection organization in the United States and is entirely independent. We advocate conscientious research. We are private citizens dedicated to effective protection of human subjects in behavioral and biomedical research. Our board members and officers are from science, law, research policy, ethics, medicine, nursing, social work, education, and care-giving. Some have been voluntary subjects of research. Experience represented in our board and officers includes governmental and academic Institutional Review Board membership and chairmanship and university faculty in national and international law and ethics of human subjects research. We serve without pay. CIRCARE receives no support from industry or government.

The kinds and extent of research contemplated in the Menlo Report pose serious threats to personal privacy and may be illegal, and the consequences of disclosure of personal information identifiable to the individual can be severe, even dangerous, and irremediable.

We are pleased that the Menlo Report drafters recognize these issues and acknowledge that how these issues are addressed has serious implications also for the broader array of interrelated biomedical, behavioral, and social research.

But the drafters argue for a rationale that would view some of this research as ethical and legal although neither ethical nor legal. The drafters seem loath to accept the possibility that some of this research should not be done. They recognize that ultimately very few individuals could not be identified or identifiable from data aggregated and refined by the techniques under consideration.

In order to justify what amounts to surreptitious collection and retention of data on individuals without their consent, without warrant, and on a massive scale, the drafters in effect would rationalize away the clear protective intent of applicable law and agency policy. They argue that, after all, there no physical harm can be expected. But they discount or ignore the fact that such activities would add to the growing vulnerability of identifiable and/or identified individuals to ever more consequential invasions of their privacy as more and more of their personal information is tracked and analyzed—without their express permission. Moreover, all this would be done without individual recourse to relevant information, let alone to remedy. Further, the drafters would alter the neutral role of Institutional Review Boards, the human subjects research ethics review entities specified in statute, to enlist them in facilitating these activities.

Moreover, because the Menlo Report is in aid of the researchers interested in carrying out this work, researchers in this field are likely to assert that the report, sponsored by Homeland Security, reflects the appropriate legal and ethical stance for all such research. Perhaps not intended as such, it nevertheless is an attempt to shield such research from effective ethics review, which is required by law.

The Department of Homeland Security should affirmatively disavow this report and should caution that insofar as it would weaken requirements for informed consent and for standards of ethical review it conflicts with law and agency policy.

For protection of human subjects of research that it sponsors or conducts, Department of Homeland Security organic legislation, Intelligence Reform and Terrorism Prevention Act, Pub. L. No. 108-458 § 8306, 118 Stat. 3638, 3869 (2004), defers to the Common Rule, 45 C.F.R. part 46, of the Department of Health and Human Services. See also Pub. L. No. 108-458 §§ 1061 et seq., evidencing legislative intent to safeguard personal privacy and comply with the Privacy Act, 5 U.S.C. § 552a, even in operational intelligence work involving information technologies. Homeland Security's implementation of its human subjects protection mandate is U.S. Dep't of Homeland Security, DHS Directive MD No. 026-05 rev. no. 00 (2007), Protection of Human Subjects, reiterating the Common Rule.

The legislative intent behind the Common Rule is protective:

Sec. 289. Institutional review boards; ethics guidance program

(a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an "Institutional Review Board") *to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.*

U.S.C. § 289(a) (emphasis added). The Menlo Report would have the IRB balance a project's ostensible public purpose against individual rights and facilitate the research under consideration here. That would put the IRB in violation of statute and regulations.

It is important to realize what rights are in question, inasmuch as the Menlo Report proposes research without the informed consent of the research subject. In addition to common law and statutory privacy rights, the applicable law includes rights guaranteed under the Constitution and under international law to which the United States is party.

The United States is a state party to the International Covenant on Civil and Political Rights, Done at New York December 16, 1966, entered into force March 23, 1976; for the United States September 8, 1992, T.I.A.S., 999

U.N.T.S. 171 (167 ratifications as of August 24, 2911), which provides in pertinent part:

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.* Int'l Covenant on Civil & Political Rights, art. 7 (emphasis added).

And:

1 . In time of public emergency which threatens the life of the nation and the existence of which is officially proclaimed, the States Parties to the present Covenant may take measures derogating from their obligations under the present Covenant to the extent strictly required by the exigencies of the situation

2. *No derogation from articles 6, 7, 8 (paragraphs I and 2), 11, 15, 16 and 18 may be made* under this provision. Int'l Covenant on Civil & Political Rights, art. 4 (emphasis added).

In other words, no public emergency exception is permitted (save where the intervention is for the direct medical benefit of an individual patient and no alternative is available).

“Non-consensual” scientific “experimentation is illegal in the U.S. Specifically, it would violate the Fourth Amendment’s proscriptions against unreasonable searches and seizures” and “the Fifth Amendment’s proscriptions against depriving one of life, liberty or property without due process.” U.S., Initial reports of States parties [to the International Covenant on Civil and Political Rights] due in 1993; United States of America (CCPR Human Rights Comm., State Party Report CCPR/C/81/Add.4, 1994), <[http://www.unhchr.ch/tbs/doc.nsf/\(Symbol\)/da936c49ed8a9a8f8025655c005281cf](http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/da936c49ed8a9a8f8025655c005281cf)> (last visited Aug. 24, 2011).

All U.S. Government departments and agencies long have been under Presidential order to implement the Covenant and other human rights treaties to which the United States is a state party. Exec. Order No.13,107, 63 WEEKLY COMP. PRES. DOC. 68,991 (Dec. 15, 1998).

The Menlo Report drafters would facilitate feasibility studies for what the Supreme Court now has forbidden law enforcement to do—employ information technology to track the behavior of individuals over extended periods without judicial warrant; see *United States v. Antoine Jones*, No. 10-1259, slip. op. (Jan. 23, 2012), 565 U.S. ____ (2012). The facts differ in that, while *Jones* involved direct tracking of an identified criminal suspect, some of the research contemplated in the Menlo Report involve indirect monitoring of many persons, perhaps hundreds of thousands, and derivation of actionable

intelligence. Conceptually, either activity is the same—surreptitiously gathering, aggregating, storing, analyzing, and using or distributing information on identified or ultimately identifiable individuals without legal cause, without warrant, without permission, and without due process of law.

The Menlo Report drafters’ ethics rationalization in part is that, after all, most Internet users surrender any thoughts of privacy when they decide to use Internet services. It is not as if they have practical choice, however. The Internet has become essential to participate in the economy, and direct regulation has lagged. To the extent that opting-out of being tracked is possible, it is often only by opening one’s computer to cookies generally. Agreements to use of Internet services are contracts of adhesion. As Justice Sotomayor made clear in *Jones*:

More fundamentally, it may be necessary to reconsider the premise that an individual has no reasonable expectation of privacy in information voluntarily disclosed to third parties. . . . This approach is ill suited to the digital age, in which people reveal a great deal of information about themselves to third parties in the course of carrying out mundane tasks. People disclose the phone numbers that they dial or text to their cellular providers; the URLs that they visit and the e-mail addresses with which they correspond to their Internet service providers; and the books, groceries, and medications they purchase to online retailers. Perhaps . . . some people may find the “tradeoff” of privacy for convenience “worthwhile,” or come to accept this “diminution of privacy” as “inevitable,” . . . and perhaps not. I for one doubt that people would accept without complaint the warrantless disclosure to the Government of a list of every Web site they had visited in the last week, or month, or year. But whatever the societal expectations, they can attain constitutionally protected status only if our Fourth Amendment jurisprudence ceases to treat secrecy as a prerequisite for privacy. I would not assume that all information voluntarily disclosed to some member of the public for a limited purpose is, for that reason alone, disentitled to Fourth Amendment protection. . . .

United States v. Antoine Jones, No. 10-1259, Sotomayor, J., concurring, slip. op. at 5-6 (Jan. 23, 2012), 565 U.S. ____ (2012) (citations omitted).

The Menlo Report drafters’ ethics rationalization in part is that there is no problem here because no physical harm is done. But the growth in scope and ability of data-mining is such that individuals might be suffer years or decades hence because of information and inferences about them from electronic files of which they have no knowledge and over which they have no control.

A requirement of informed consent would make it impossible to carry out the kind of research anticipated here, the Menlo Report drafters say. Their

solution is to do away with informed consent for this research. It is an approach neither lawful nor ethical.

The Menlo Report urges reinterpretation of the Belmont Report, which is the statement of regulatory intent under the Common Rule, to allow selection of research subjects because they are conveniently there, they should not have to be told of likely ramifications of participation, and they need not have a say in whether to participate. Belmont emphasizes research subject autonomy, balancing individual subjects' risk against individual subjects' likely benefits, and justice. Belmont emphasizes respect for persons. Menlo treats these persons as available because they have been suckered in the marketplace.

If the Menlo Report is endorsed, adopted, or accepted widely, its impact on the research world's trustworthiness and credibility will be far-reaching and adverse. Put in simplest terms, Menlo says researchers with government backing may snoop into people's Internet behavior and communications without individual, informed consent because the technology and Internet companies' privacy behavior enable them to do so. Public realization that this is so will severely undermine trust in all meritorious research. Trustworthiness depends, in Judge Cardozo's words, on "something stricter than the morals of the marketplace." The Menlo Report's positions are conducive to cynicism among researchers and potential and actual research subjects. That would be enormously harmful to conscionable and necessary research.

We will be pleased to be of further assistance.

Sincerely,

For Citizens for Responsible Care and Research:

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