Statement from Ryan Spellecy, PhD, Associate Professor, Medical College of Wisconsin

These comments will focus on ethical issues surrounding the use of data for research, specifically medical research, as that is my area of expertise. While much of the following comments are applicable to uses of data for purposes other than research, I will clarify instances in which the applicability may vary, though that is most often a matter of degree and not of complete inapplicability. These comments will highlight the main areas of ethical concern in the use of data for research, analyze a fundamental ethical conflict in attempts to use data (particularly population data) for research that, quite frankly, might not be amenable to resolution, and suggest an alternative strategy that, while it may not avoid the ethical conflict completely, may be the best, most ethically defensible way forward regarding the use of data, both for research and other purposes.

The ethical concerns in the use of data for research are privacy and confidentiality. In research, privacy is commonly understood as pertaining to information about which an individual has a reasonable expectation that access is controlled by the individual, whereas confidentiality is commonly understood as pertaining to information that an individual has entrusted to another, with an *understanding* that the information will only be used for certain purposes. For the purposes of these comments, privacy and confidentiality will be defined as such.

Much of the ethical concern regarding the use of data in research stems from the "understanding" that existed (or did not exist) when the patient initially provided information to a healthcare provider in confidence. Medical research might involve data that was provided as part of the research study in question, for example, in a straightforward quality of life survey in cancer patients. In such a study, the understanding is that the data provided by the subject will be used for the research as defined by the informed consent process, and this is not controversial. Ethical concerns do arise, however, when the data was *not* offered by the patient with the understanding that it would be used for research.

A commonplace example is a patient who provides information to her physician during the course of her routine clinical care and later, that information (data) is accessed and used by a who obtains data from existing medical charts (a chart review study). This is done with Institutional Review Board (IRB) approval in a manner consistent with the Code of Federal Regulations that govern research, and without the patient's consent. In ethical terms, the patient provides her physician with information, often sensitive information, *in confidence* with the *understanding* that it will be kept *private*, and that information is then shared with a researcher the patient has never even heard of without her consent. In a strict sense, the patient's privacy has been violated, her confidentiality

has been breached, and this scenario occurs innumerable times every day across the United States…and importantly, it is not unethical. It is important, however, to recognize that we do violate privacy and we do breach confidentiality when we engage in such research, both so that we conduct such research carefully and minimize the possibility of data breaches, but also so that we think proactively about how to engage patients and communities to conduct such research according to the highest ethical standards.

The question of whether or not the patient consented to the use of her data for research is essential[1]. If she did, then it was part of the understanding under which she provided information in confidence and there is no violation of confidentiality or privacy. She need not even have full information concerning the research to be conducted, nor even information beyond that her data may be used for future unspecified research (with standard protections). This is because she may simply decide that it is consistent with her values to allow her data to be used for research. Perhaps one of her deep moral convictions is that people should help others, she sees such research as an instance of helping others, and so agrees to allow her data to be used for research. The specific ethical reason is not important. What is important is that competent adults do not need full and comprehensive information to make autonomous, informed choices(1). What is also important, ethically, is whether or not the patient or subject consents to the data use.

Consent is important because it is the primary means for upholding the Belmont principle of respect for persons (or respect for autonomy). Briefly, respect for persons in this situation requires that we afford a competent individual the opportunity to decide for him or herself whether or not to participate in research. It is her data that researchers wish to use and so the decision ought to be hers. Of course, no Belmont principle is absolute, and the Belmont report exhorts us to identify the relevant ethical principles and *balance* them against one another, and in this case, that principle is beneficence. The ethical consideration becomes whether or not the benefit of such data research outweighs the affront to respect for persons. This balancing, however, is not straightforward as respect for persons and beneficence in this case appeal to fundamentally different ethical concerns.

The Federal Regulations that govern research recognize this ethical tension. 45 CFR 46.116(d) contains a provision for waiving informed consent for research, such as research on data from clinical records. To grant such a waiver, an IRB must document

[1] While some institutions seek to address the issue of consent by including a notification that data might be used for research, two problems remain. First, these notices are often buried in a HIPAA privacy notice on in the clinical consent, and so are not read and consent is not genuine. Second, such an approach, if it really seeks to gain consent and not mere notice, would require the ability to not permit the use of one's data, which would introduce bias into the dataset.

that four conditions are met, the second of which is that the waiver or alteration will not adversely affect the rights and welfare of the subjects. The difficulty with this recommendation is it makes perfect sense to consider whether or not waiving the requirement for informed consent will adversely affect the welfare of potential research subjects. This is a simple application of beneficence, and is a simply risk/benefit calculation. What does not make sense is whether or not the rights of a potential subject will be adversely affected. While benefit and harm are terms that are amenable to considerations of degrees, rights are not. Rights are simply either violated or not. They cannot be "adversely affected." If an individual is denied his right to vote, we do not say that his rights have been adversely affected, as though his right was decreased. It has been violated. Rights simply do not admit of degrees as harms and benefits do. So, to attempt to balance one Belmont principle (beneficence) that admits of degrees and can be increased, decreased, balanced, or ignored, with another Belmont principle (respect for persons) that, at least in this case, is simply upheld or not, is futile.

It may be best to simply state that in evaluating such research, we recognize the great potential for benefit, the minimal potential for harm, and so are justified in waiving informed consent. However, it does not follow that we must then ignore respect for persons altogether. Rather, we might look to other models of research for examples of how we might engage key stakeholders and communities and involve them in the process in order to uphold respect for persons in a different fashion, one that shifts the focus away from rights.

There are two models of community engagement that might be useful to NCVHS in considering the use of ethical use of data; emergency research with an Exception From Informed Consent (EFIC) and Community Engaged Research (CER). EFIC and CER engage the community in different ways, and offer lessons both in what works well to engage the community, and what does not.

EFIC research invokes a specific regulatory framework (the "Final Rule," 21 CFR 50.24) that allows researchers to conduct research that is greater than minimal risk yet waives the requirement for informed consent, as long as certain requirements of the Final Rule are met. This research is conducted in settings in which consent is not possible (i.e. heart attack victims who are unable to provide consent due to their condition and cannot be proactively consented as it is unknown who will suffer a heart attack), yet the research is essential to advancing healthcare knowledge. This is important, as this is the only research that is greater than minimal risk that the regulations permit without informed consent, and so the additional safeguards become key (2-4). One of those safeguards is that the researchers, with approval and oversight from the IRB, must conduct community consultation for the research study. The point of community consultation is not to gain community consent or proxy consent. Rather, the point is to consult with the community and learn whether or not the community thinks that this kind of research ought to be done in their community and what changes, if any, should be made to the research plan to make it more acceptable to the community. This provides an ethical model for using data for research purposes without consent. If it can be established that, just as in EFIC research, consent is not feasible and the benefit is

great, a preferable, ethical alternative to doing nothing at all would be to engage the community in conversations about the research or use of data.

One last point of interest in EFIC research for community engagement is the different models of community consultation that have been employed in these studies. This has included querying a convenience sample, random digit telephone surveys, targeted focus groups, large community meetings/public forums, community advisory boards, or some combination of these methods(5-8)(9-12). These approaches all have their advantages and disadvantages, and the appropriateness of each approach will vary depending on the purpose of the research (i.e. if the research is focused on patients in status epilepticus, focus groups with epilepsy patients might be appropriate).

The other model of community engagement, CER, offers a method for engaging communities throughout the research process, unlike EFIC research. CER works with communities even to the point of identifying research priorities for the community, while EFIC research comes to the community with the research study already designed.

NCVHS should be commended as it already recognizes the importance of building relationships and trust with communities, as does a recent white paper from the American Medical Informatics Association(13). Specifically, the recommendations contained in the NCVHS report, *The Community as a Learning System: Using Local Data To Improve Local Health*, to involve community members in decisions about data use and fostering a sense of ownership are key. The challenge, however, is how to engage key stakeholders in the process in a manner that is not ad hoc or after the fact, but one that does so in the spirit of respect for persons. Developing plans and guidelines *before* engaging stakeholders will fail to involve community members in decisions regarding data use and will not foster a sense of ownership. In order to successfully engage stakeholders, it will be useful to look at a research model of community/academic partnerships called Community Engaged Research (CER).

While there are numerous excellent summaries of the ethical challenges that have arisen in CER(14-16), it is worth discussing a few of those lessons here, as CER has an established history of successful community/academic partnerships that are bi-directional and sustainable. Some of the key elements to a successful partnership include engaging the community early and throughout the process, both chronologically and in different roles (i.e. identifying concerns and needs of the community, employing community members as members of the research team, forming a community advisory council, etc.), and ensuring that the relationship is both bi-directional and sustainable.

Relationships that are bi-directional encourage respect for all parties, and acknowledge that the researcher has as much to learn from the community as the community does from the researcher. Two areas in which this is relevant to data use is in developing approaches to engage the community and understanding community perspectives on

risk. Community partners, members of the community as team members, or community advisory councils can be essential in understanding how to best approach the community. This might involve employing respected member of the community to recruit potential subjects or invite members of the community to a community forum, and in our experience at the Medical College of Wisconsin, community members simply provide access to the community that academics do not have. We have found this to be near impossible if the relationship is not grounded in respect for persons and, as a consequence, is bi-directional.

Sustainable relationships are also key. In CER, community groups quickly become sophisticated in the realities of research and when researchers come to the community, conduct their research, and leave, with no lasting impact or communication, community groups become less willing to participate in future research. However, if researchers invest in sustainable relationships and communicate the results of the research, community groups recognize the value of research and are eager to partner with academics to collaboratively solve the problems facing their communities.

In conclusion, the use of data for purposes other than the reason for which is was initially collected poses unique ethical challenges. Fortunately, there are examples, such as EFIC research and CER, that provide a model for conducting this important work in a manner that adheres to the highest ethical standards. While it may require that we change our focus and re-evaluate how we fulfill certain ethical commitments (such as respect for persons), it can be done if we engage the community in meaningful, bi-directional, sustainable partnerships.

References

1. May T, Spellecy R. Autonomy, full information, and genetic ignorance. *The Monist.* 2006 2006; 89(4): 466-481.

2. Kipnis K, King NM, Nelson RM. Trials and errors: Barriers to oversight of research conducted under the emergency research consent waiver. *IRB.* 2006 Mar-Apr; 28(2): 16-19.

3. Spellecy R. Unproven or unsatisfactory versus equipoise in emergency research with waived consent. *Am J Bioeth.* 2006 May-Jun; 6(3): 44-45.

4. Derse AR. Emergency research and consent: Keeping the exception from undermining the rule. *Am J Bioeth.* 2006 May-Jun; 6(3): 36-7; discussion W49-50.

5. Baren JM, Anicetti JP, Ledesma S, Biros MH, Mahabee-Gittens M, Lewis RJ. An approach to community consultation prior to initiating an emergency research study

incorporating a waiver of informed consent. *Acad Emerg Med.* 1999 Dec; 6(12): 1210-1215.

6. Dix ES, Esposito D, Spinosa F, Olson N, Chapman S. Implementation of community consultation for waiver of informed consent in emergency research: One institutional review board's experience. *J Investig Med.* 2004 Mar; 52(2): 113-116.

7. Lowenstein DH, Alldredge BK, Allen F, Neuhaus J, Corry M, Gottwald M, O'Neil N, Ulrich S, Isaacs SM, Gelb A. The prehospital treatment of status epilepticus (PHTSE) study: Design and methodology. *Control Clin Trials.* 2001 Jun; 22(3): 290-309.

8. Kasner SE, Baren JM, Le Roux PD, Nathanson PG, Lamond K, Rosenberg SL, Karlawish J. Community views on neurologic emergency treatment trials. *Ann Emerg Med.* 2011 Apr; 57(4): 346-354.e6.

9. Yarborough M, Fryer-Edwards K, Geller G, Sharp RR. Transforming the culture of biomedical research from compliance to trustworthiness: Insights from nonmedical sectors. *Acad Med.* 2009 Apr; 84(4): 472-477.

10. Kremers MS, Whisnant DR, Lowder LS, Gregg L. Initial experience using the food and drug administration guidelines for emergency research without consent. *Ann Emerg Med.* 1999 Feb; 33(2): 224-229.

11. Mosesso VN,Jr, Brown LH, Greene HL, Schmidt TA, Aufderheide TP, Sayre MR, Stephens SW, Travers A, Craven RA, Weisfeldt ML, PAD Trial Investigators. Conducting research using the emergency exception from informed consent: The public access defibrillation (PAD) trial experience. *Resuscitation.* 2004 Apr; 61(1): 29-36.

12. Contant C, McCullough LB, Mangus L, Robertson C, Valadka A, Brody B. Community consultation in emergency research. *Crit Care Med.* 2006 Aug; 34(8): 2049-2052.

13. Safran C, Bloomrosen M, Hammond WE, Labkoff S, Markel-Fox S, Tang PC, Detmer DE, Expert P. Toward a national framework for the secondary use of health data: An american medical informatics association white paper. *J Am Med Inform Assoc.* 2007 Jan-Feb; 14(1): 1-9. PMCID: PMC2329823.

14. Ahmed SM, Palermo AG. Community engagement in research: Frameworks for education and peer review. *Am J Public Health.* 2010 Aug; 100(8): 1380-1387.

15. Ross LF. 360 degrees of human subjects protections in community-engaged research. *Sci Transl Med.* 2010 Aug 18; 2(45): 45cm23.

16. Ross LF, Loup A, Nelson RM, Botkin JR, Kost R, Smith GR,Jr, Gehlert S. Human subjects protections in community-engaged research: A research ethics framework. *J Empir Res Hum Res Ethics.* 2010 Mar; 5(1): 5-17. PMCID: PMC2946318.