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A MOSQUITO IN THE OINTMENT: ADVERSE HIPAA IMPLICATIONS FOR HEALTH-RELATED REMOTE SENSING RESEARCH AND A "REASONABLE" SOLUTION

*Paul M. Secunda**

I. INTRODUCTION

Consider the following scenario: a researcher investigating the spread of West Nile Virus¹ in the United States seeks to determine whether increased precipitation levels in different geographical regions across the country correlate with (through a larger population of mosquitoes)² a higher frequency of West Nile Virus in humans.³ After gathering the relevant precipitation georeferenced data through remote sensing techniques,⁴ the

* Assistant Professor of Law, University of Mississippi School of Law. I would like to thank Joanne Gabrynowicz and Jacqueline Serrao of the National Remote Sensing and Space Law Center for humoring a novice and introducing me to the exciting field of remote sensing and space law. I dedicate this piece to my children, Jacob Ari and Isabella Julia, and to the betterment of their world.

¹ West Nile Virus is a vector-borne, viral infection that can cause inflammation of the brain. In certain cases, it can be fatal. For a general description of the characteristics of West Nile Virus, see generally WebMD Website, *Health Guide A-Z: West Nile Virus*, at http://my.webmd.com/hw/health_guide_atoz (last visited May 6, 2004) [hereinafter *Health Guide A-Z*]; see also Center for Disease Control and Prevention Website, *West Nile Virus*, at <http://www.cdc.gov/ncidod/dvbid/westnile/index.htm> (last visited May 8, 2004).

² West Nile Virus is spread by mosquitoes throughout North America. The first major outbreak was in New York in 1999. Mosquitoes obtain the virus by biting infected birds. See *Health Guide A-Z*, *supra* note 1.

³ This hypothetical is based, at least in part, on the work of four NASA students at the Ames Research Center who produced a risk map showing the potential risk of West Nile Virus being carried by mosquitoes in Monterey County, California. See SGE News, SGE: Ecosystem Science and Technology Branch of the Earth Science Division of NASA's Ames Research Center web site, at <http://geo.arc.nasa.gov/sge/news.html> (last visited Aug. 8, 2004) (news release regarding this study was first released on September 2, 2003).

⁴ "Remote sensing refers to satellite or aircraft technology used to observe the earth from distant vantage points. Cameras mounted on these platforms capture detailed pictures of the earth that can be employed for a range of business applications, such as

researcher still requires health information from numerous local hospitals and other health care providers and agencies to attempt to link the precipitation data with the number of West Nile Virus cases in a given location. Unbeknownst to our well-meaning researcher, he is about to face numerous procedural hurdles as he seeks access to this necessary health information for his research protocol.

Although the connection between this researcher's information-gathering conundrum and space law may not at first glance appear evident, this type of dilemma has important ramifications for space law in general, as remote sensing law has become an increasingly significant and emerging area within the field of space law.⁵ Indeed, over recent years, remote sensing has been utilized for a growing number of applications, including in the areas of public and human health research.⁶ It is this

identifying very early stages of diseased or drought-stressed crops in farmlands; managing forests, wetlands and fisheries; and measuring climatic or oceanic conditions." National Remote Sensing and Space Law web site, *About the Center*, at <http://www.spacelaw.olemiss.edu> (last visited Oct. 11, 2004). The data acquired from remote sensing research techniques is sometimes referred to as "geospatial" or "geo-referenced" data. *Id.* Geospatial data should become more available as NASA hopes to launch more than eighty missions between 1995 and 2010, carrying over 200 different instruments, providing measurements of many environmental change parameters, some for the first time. See SENSOR EVALUATION PROJECT: INTRODUCTION, CENTER FOR HEALTH APPLICATIONS OF AEROSPACE RELATED TECHNOLOGIES (CHAART), at <http://www.geo.arc.nasa.gov/sge/health/sensor/sensor.html> (last updated Aug. 2002); see also Louisa R. Beck et al., PERSPECTIVE, *Remote Sensing and Human Health: New Sensors and New Opportunities*, 6 EMERGING INFECTIOUS DISEASES 217, 217 (2000) ("These new capabilities will improve spectral, spatial, and temporal resolution, allowing exploration of risk factors previously beyond the capabilities of remote sensing."). Specifically, factors which will be able to be remotely sensed are: vegetation or crop type, deforestation, flooded forests, general flooding, permanent water, wetlands, and soil moisture. See *id.* at 222.

⁵ Generally, all nations have nonexclusive right to use space. See Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and Other Celestial Bodies, Jan. 27, 1967, art. I, 18 U.S.T. 2410, 610 U.N.T.S. 205 (entered into force on Oct. 10, 1967) [hereinafter Outer Space Treaty]. Remote sensing, in turn, has long been recognized as a permitted "use" of outer space. See CARL Q. CHRISTOL, *THE MODERN INTERNATIONAL LAW OF OUTER SPACE* 730-32 (1982).

⁶ The growing relevance of remote sensing to health research applications has been consistently demonstrated over the last number of years by the increased number of institutional resources available for conducting health-related remote sensing research, as well as the increased number of articles and workshops dealing with these issues. See, e.g., Beck et al., *supra* note 4, at 217 (describing the increased number of investiga-

connection between remote sensing and health research that this article seeks to explore in light of the newly enacted Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule,⁷ the first comprehensive federal statute dealing with health information privacy concerns.

Prior to April 14, 2003, this remote sensing researcher in the hypothetical above would most likely have been able to contact these health care providers and work out an arrangement to obtain the necessary health information,⁸ all the while pledging to maintain, to the greatest extent possible, the confidentiality of the health records of the affected individuals.⁹ Today,

tors in the health community using remote sensing techniques to explore disease-vector habitats and human transmission risks, and describing two such studies involving Lyme disease and cholera); Joanne Irene Gabrynowicz, Paper Presentation, *Data, Information, Confidentiality, and the Legal Landscape*, NASA Confidentiality & Geospatial Data Workshop (Washington D.C. July 16, 2003) (examining the application of remote sensing law to human health research issues at a workshop sponsored by NASA's Public Health Application Program in conjunction with the National Academy of Sciences) (materials on file with author); see also Beck et al., *supra* note 4, at 220-21 ("NASA has participated in sessions on remote sensing and health at professional meetings sponsored by national and international health organizations."). Indeed, NASA's Ames Research Center in California has been involved in public health work since 1985. CHAART was established by NASA in 1995 to continue this work in the area of remote sensing and health and it continues to develop technologies for disease risk modeling (also called "landscape epidemiology"), with a special emphasis on vector-borne diseases. See SGE Research web site, at <http://www.arc.nasa.gov/sge/research.html> (last visited Aug. 8, 2004). CHAART seeks to make its remote sensing expertise available to researchers throughout the health community. *Id.*

⁷ Health Insurance Portability and Accountability Act, PUB. L. NO. 104-191, § 264, codified at 42 U.S.C. § 1320d-2 note (Aug. 21, 1996) [hereinafter HIPAA]. HIPAA was enacted as an amendment to the Employee Retirement Insurance and Security Act of 1973 (ERISA), 29 U.S.C. §§ 1001-1461 (1999). The applicable HIPAA provisions can be found at 29 U.S.C. §§ 1181-1183.

⁸ *But see infra* Part III.B (discussing the need for an institutional review board's approval for certain federally conducted or supported human subjects research, even prior to the enactment of the HIPAA Privacy Rule).

⁹ The remote sensing researcher would also likely have previously been constrained from disclosing sensitive health information under state statutory medical privacy laws and principles of state tort law (including the torts of invasion of privacy and breach of confidentiality). See DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule 1* (Apr. 14, 2003), available at http://privacyruleandresearch.nih.gov/pr_02.asp (last modified Sept. 25, 2003) [hereinafter *Understanding HIPAA*]. Some of these state laws may still apply after HIPAA to the extent that state law is more stringent than HIPAA. In such cases, HIPAA would not preempt such state laws. See *In re: PPA Litigation*, 2003 WL 22203734, at *12 (N.J. Super. L., Sept. 23, 2003) (discussing HIPAA preemption provisions at 45 C.F.R. § 160.203(a) (2003)).

however, the enactment of HIPAA, and the subsequent promulgation of the HIPAA Privacy Rule,¹⁰ have altered the applicable legal rules for any remote sensing researcher contemplating the use of health information as part of his or her research.¹¹ Indeed, it is the central thesis of this article that the new HIPAA Privacy Rule is a fly (or, better put, a mosquito) in the ointment; a more inconvenient than necessary procedural scheme that could potentially, and inadvertently, derail new advances in medical research made possible for the first time by innovative remote sensing technologies.

Interestingly enough, this change in legal orientation for remote sensing researchers engaged in health-related research does not derive from the fact that a remote sensing researcher is a "covered entity"¹² under the HIPAA Privacy Rule; in almost all cases, they are not.¹³ Nevertheless, hospitals, doctors, and other health care providers from whom health information must be obtained are normally considered covered entities.¹⁴ As a result, under HIPAA authorization standards,¹⁵ the health care provider must normally obtain a signed HIPAA-compliant authorization form¹⁶ from each individual from whom the researcher seeks protected health information (PHI).¹⁷ Since there may be thousands, if not hundreds of thousands of individuals being studied for a particular research study, it might be very difficult to obtain an authorization from every individual; and/or at the very least, it would be prohibitively expensive.

Nonetheless, recognizing that researchers still need access to health information to conduct medical research, the HIPAA Privacy Rule contains an express exception from the authoriza-

¹⁰ HIPAA, *supra* note 7.

¹¹ See *PPA Litigation*, 2003 WL at *8 (noting that enactment of HIPAA Privacy Rule marks dramatic departure from the current state of medical and legal practice).

¹² For a definition of this term, see *infra* notes 29-32 and accompanying text.

¹³ See DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Privacy Boards and the HIPAA Privacy Rule 1* (Sept. 25, 2003), available at http://privacyruleandresearch.nih.gov/privacy_boards_hipaa_privacy_rule.asp (last modified Aug. 4, 2004) ("Researchers are not themselves covered entities, unless they also provide health care and engage in any of the covered electronic transactions.") [hereinafter *Privacy Board Fact Sheet*].

¹⁴ See *infra* notes 29-32 and accompanying text.

¹⁵ See *infra* Part II.B.

¹⁶ See *id.*

¹⁷ See *infra* note 33.

tion requirement for researchers.¹⁸ Under the research exception, the researcher normally must obtain a waiver of, or alteration to, the authorization requirement through either the use of an institutional review board (IRB) or HIPAA privacy board (HPB).¹⁹ Unfortunately, the waiver standards promulgated for utilization by these review boards are vague and ambiguous and could potentially cause disparate and inequitable results in whether, and how, such health information is disclosed to researchers.²⁰ For this reason, this article proposes that the HIPAA Privacy Rule's research waiver standards be modified to substitute more readily understandable, and precedentially-based, legal terminology. This proposed legal salve substitutes the application of a Fourth Amendment-like "reasonableness/special needs" approach for the current "necessary and adequate" approach for future research waiver cases.²¹

As discussed in more detail below, the benefits of substituting this new standard are many. As currently written, the research waiver standards under the HIPAA Privacy Rule may lead to many unanticipated, and undesirable, results, including: (1) a dramatic increase in the cost associated with the collection of health data; (2) an increase in time expended before such data can be obtained; and, in the end, (3) a reduction in the use of sophisticated remote sensing techniques altogether in medical research. In short, compliance with the HIPAA Privacy Rule's research exemption might generate difficulties with a West Nile Virus-type research study as a consequence of remote sensing researchers not being able to know for certain whether they will ever receive the necessary health-related information

¹⁸ See *infra* Part III. "The Rule balances an individuals' interest in keeping his or her health information confidential with other social benefits, including health care research." See *Understanding HIPAA*, *supra* note 9, at i.

¹⁹ See *infra* Parts III.B and III.C.

²⁰ See *infra* Part IV.A; see also Pietrina Scaraglino, *Complying with HIPAA: A Guide for the University and its Counsel*, 29 J.C. & U.L. 525, 565 (2003) ("The requirements of the Privacy Regulations concerning access to PHI pursuant to an IRB or Privacy Board waiver are more complex and have created some anxiety in the research community.")

²¹ U.S. CONST. amend. IV. The Fourth Amendment of the United States Constitution applies only to government and state actors and most remote sensing researchers do not fall into this category. *Id.* For reasons discussed below the reasonableness standard is borrowed from the public sector for purposes of this analysis. See *infra* Part IV.B.

to complete their studies. On the other hand, the proposal advanced in this article has the advantage of being part of a well-developed area of law to which researchers and covered entities alike may turn for guidance when deciding whether to grant a waiver to the HIPAA authorization requirement and release PHI to remote sensing researchers for research purposes.

In Part II of this Article, I offer a brief introduction to the HIPAA Privacy Rule, including its legislative and regulatory history, as well as pertinent substantive provisions surrounding the authorization requirement. In Part III, I focus on the research exception to the normal PHI authorization requirement, with special emphasis on the nature and characteristics of IRBs and HPBs. Finally, with the applicable HIPAA provisions concerning health-related remote sensing research front and center, Part IV concludes by proposing an important modification to the existing research waiver standards through application of a "reasonableness/special needs" balancing analysis, first developed in the Fourth Amendment privacy context.

II. A HIPAA PRIMER

A. *Legislative and Regulatory History*

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)²² was enacted by Congress to address concerns relating to non-discrimination in the provision of health insurance, the portability of health insurance coverage, pre-existing conditions exclusions, electronic data interchanges, and concerns surrounding the confidentiality of health information.²³ Specifically with regard to privacy concerns, Congress included a section entitled, "Recommendations With Respect to Privacy of Certain Health Information,"²⁴ which mandated the Secretary of

²² HIPAA, *supra* note 7.

²³ See generally ABA SECTION OF LABOR AND EMPLOYMENT LAW, EMPLOYEE BENEFITS LAW 46-47 (2nd ed. 2000).

²⁴ This mandate was a response to growing concerns over the potential abuse of confidential health information by health care entities and others without an individual's consent or authorization. See DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Institutional Review Boards and the HIPAA Privacy Rule - NIH Fact Sheet 1* (Aug. 15,

Health and Human Services (HHS) to provide to Congress "detailed recommendations on standards with respect to the privacy of individually identifiable health information."²⁵ Congress directed HHS to issue such a recommendation by August 21, 1997.²⁶

Eventually, HHS' final health privacy regulations (the HIPAA Privacy Rule)²⁷ went into effect for most "covered entities" on April 14, 2003.²⁸ As defined by the HIPAA Privacy Rule, "covered entities" include health care providers,²⁹ health care clearinghouses,³⁰ and other health plan entities³¹ that transmit any health information in electronic form in connection with a transaction covered by HIPAA.³² These covered entities are

2003), available at <http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp> (last modified Aug. 4, 2004) [hereinafter *IRB Fact Sheet*].

²⁵ HIPAA, *supra* note 7, at § 264(a). HHS was directed to consider: "(1) The rights that an individual who is a subject of individually identifiable health information should have[;] (2) The procedures that should be established for the exercise of such rights[; and] (3) The uses and disclosures of such information that should be authorized or required." *Id.* § 264(b).

²⁶ *See id.* § 264(c).

²⁷ *See* General Administrative Requirements, General Provisions, 45 C.F.R. §§ 160.101 - 160.104 (2003); Security and Privacy, Privacy of Individually Identifiable Health Information, 45 C.F.R. §§ 164.501 - 164.534 (2003).

²⁸ After HHS submitted a report to Congress urging the enactment of extensive privacy legislation, and Congress failed to act by August 21, 1999, HHS was required by HIPAA to finalize its regulations on privacy. *See* ABA SECTION OF LABOR AND EMPLOYMENT LAW, EMPLOYEE BENEFITS LAW - 2002 CUMULATIVE SUPPLEMENT 218-219 (Stanley ed. 2002). After submitting proposed regulations in November 1999 and receiving many comments from numerous parties, the final HIPAA Privacy Rule was issued in December 2000. *Id.* at 219. After further postponement by the new presidential administration, final modifications to the Privacy Rule were adopted on August 14, 2002, with a new compliance date for most plans of April 14, 2003. *Id.* In reality, all covered entities are now required to be in compliance with the Privacy Rule, as even smaller covered entities had only until April 14, 2004 to comply. *See* HIPAA, *supra* note 7, at § 264(c)(1); *see also* 42 U.S.C. § 1320d-4(b).

²⁹ Health care providers include doctors, hospitals, and pharmacies. 45 C.F.R. § 160.103.

³⁰ Health care clearinghouse "means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and 'value-added' networks and switches," that either processes health information in one of two designated manners. *Id.*

³¹ Other health plan entities include health insurance issuers, health maintenance organizations (HMOs), issuers of long-term care policies, other employee welfare benefit policies that provide health benefits, and other government-related programs. *Id.*

³² Interestingly, this definition suggests that as long as a health care provider or other covered entity does not "transmit health information in electronic form," the health care provider is not covered under HIPAA. *Id.* Unfortunately for most covered

regulated by the terms of the HIPAA Privacy Rule in how they both use and disclose PHI.³³

As a result, unless a remote sensing researcher is employed by a covered entity, it is unlikely that the HIPAA Privacy Rule would apply directly to the activities of the researcher.³⁴ Nevertheless, because remote sensing researchers, like other researchers, utilize medical research, and by extension PHI, as part of their research activities,³⁵ it is likely that many remote sensing researchers will have to adhere to several HIPAA standards in order to obtain PHI from covered entities with whom they interact.³⁶

B. Pertinent Substantive Provisions³⁷

Because researchers are not directly covered entities as discussed above, the issue regarding use of PHI for remote sensing research purposes boils down to essentially one issue: Under what circumstances may a covered entity disclose PHI to a researcher wishing to combine geospatial data with medical research data?

entities, this exception does not provide much solace as almost all potentially covered entities, with the possible exception of some doctors or pharmacies, engage in some manner of electronic transmission of health information.

³³ PHI is defined in the HIPAA Privacy Rule as individually identifiable health information that is transmitted or maintained in any form of media. Notable exceptions to this broad rule are provided for employment records and education records. *Id.* The HIPAA Privacy Rule is enforced by HHS' Office of Civil Rights. See *Understanding HIPAA*, *supra* note 9, at i.

³⁴ See *supra* note 13.

³⁵ This scenario is demonstrated by the West Nile Virus example in the introductory section of this article. See *supra* Part I.

³⁶ See *Understanding HIPAA*, *supra* note 9, at 1.

³⁷ This article is limited to discussing the HIPAA Privacy Rule's authorization requirement, and waivers or modifications of that requirement, as discussed below. Thus, other important aspects of the HIPAA Privacy Rule, including consent requirements, non-research exceptions to the authorization requirement, notice of privacy practice provisions, internal safeguard provisions, certification provisions, and business associate provisions, are beyond the scope of this article and will not be discussed. For an in depth discussion of these topics, see generally Julie Bruce, *Bioterrorism Meets Privacy: An Analysis of the Model State Emergency Health Powers Act and the HIPAA Privacy Rule*, 12 ANNALS HEALTH L. 75 (2003); Diane Kutzko et al., *HIPAA in Real Time: Practical Implications of the Federal Privacy Rule*, 51 DRAKE L. REV. 403 (2003); Peter A. Winn, *Confidentiality in Cyberspace: The HIPAA Privacy Rules and the Common Law*, 33 RUTGERS L. J. 617 (2002).

As far as the circumstances under which PHI may be used or disclosed under the HIPAA Privacy Rule, the Rule seeks to limit significantly the number of permissible uses and disclosures.³⁸ In particular, there are six permitted uses and disclosures of PHI under the HIPAA Privacy Rule.³⁹ However, only two of these provisions are pertinent to remote sensing researchers seeking the disclosure of PHI: the authorization provisions and the provisions providing exceptions to the authorization provisions.⁴⁰

Generally, under the authorization provisions, "a covered entity may not use or disclose protected health information without an authorization that is valid under [the HIPAA Privacy Rule]."⁴¹ For the authorization to be "valid," it must contain six "core elements"⁴² and three "required statements."⁴³ Once an authorization is received by a covered entity, all subsequent uses of PHI under the authorization must be consistent with the terms of the authorization.⁴⁴

³⁸ See 45 C.F.R. § 164.502(a).

³⁹ *Id.* § 164.502(a)(1).

⁴⁰ *Id.* § 164.502(a)(1)(iv), (vi). The other four provisions which are not pertinent concern permitted disclosures of PHI: (1) to the individual; (2) for treatment, payment, or health care operations; (3) consistent with the "minimum necessary" standard, where applicable; and (4) to other specified situations where the individual does not object to the use or disclosure. See *id.* § 164.502(a)(1)(i), (ii), (iii) and (v). The "minimum necessary" standard does not apply to disclosures pursuant to a signed authorization. *Id.* § 164.502(b)(2)(iii).

⁴¹ *Id.* § 164.508(a)(1). An authorization can generally be revoked at the discretion of the individual who initially signed the authorization, unless the covered entity has taken action in reliance on the authorization. *Id.* § 164.508(b)(5)(i).

⁴² These core elements include: (1) a specific and meaningful description of the information to be used or disclosed; (2) the name of people authorized to make the requested use or disclosure; (3) the name of people to whom the covered entity may make the requested use or disclosure; (4) a description of each purpose of the requested use or disclosure; (5) an expiration date or expiration event; and (6) signature of the individual or personal representative and the date. *Id.* § 164.508(c)(1)(i)-(vi). It is the last core element, the individual signature, which makes the authorization provisions so incompatible with the needs of most medical researchers dealing with massive data sets.

⁴³ The required statements are designed to place the individual on notice concerning his or her rights under the HIPAA Privacy Rule. They include: (1) a statement that the individual may revoke the waiver in writing; (2) a statement that treatment, payment, enrollment or eligibility is a condition or not a condition on such a waiver; and (3) a statement concerning the potential for PHI disclosure pursuant to the authorization to be redisclosed by the recipient and no longer be protected by the HIPAA Privacy Rule. *Id.* § 164.508(c)(2)(i)-(iii).

⁴⁴ *Id.* § 164.508(a)(1).

Not all uses and disclosures of protected health information, however, require an authorization from the affected individual. In addition to certain permitted uses and disclosures,⁴⁵ required disclosures,⁴⁶ and uses and disclosures requiring an opportunity for the individual to agree or to object,⁴⁷ the HIPAA Privacy Rule also establishes twelve categories of uses and disclosures for which an authorization or opportunity to agree or object is not required.⁴⁸ In other words, in these twelve categories, a covered entity is permitted to use or disclose PHI without an authorization; the authorization requirement in these cases is altered or modified.⁴⁹ The one exception to the authorization requirement which is of primary importance to this article is the so-called "research exception."⁵⁰ The next section explores the research exception to the authorization requirement and the manner in which IRBs and HPBs may be utilized to obtain a research waiver of the authorization requirement.

III. THE RESEARCH EXCEPTION, IRBS, AND HPBS

A. *The Research Exception*

"Research" is defined by the HIPAA Privacy Rule as a "systematic investigation, including research development, testing,

⁴⁵ *Id.* § 164.502(a)(1).

⁴⁶ *Id.* § 164.502(a)(2).

⁴⁷ *Id.* § 164.510.

⁴⁸ *Id.* § 164.512. For instance, exceptions exist for uses and disclosures required by law, concerning victims of abuse, neglect, or domestic violence, for judicial and administrative proceedings, and for law enforcement purposes. *Id.* § 164.512(a),(c), (e), and (f).

⁴⁹ *Id.* § 164.512.

⁵⁰ *Id.* § 164.512(i); see also *infra* Part III.A. Although some of the other categories may appear on their face to assist remote sensing researchers engaging in medical research (see, e.g., "public health activities" (*Id.* § 164.502(b)), "health oversight activities" (*Id.* § 164.512(d)), and "serious threat to health or safety" (*Id.* § 164.512(j))), these exceptions generally would not apply to remote sensing researchers engaging in medical research. For instance, the "public health activities" exception only applies to public health authorities authorized by law to collect or receive such information or other similar entities, see *id.* § 164.512(b)(1)(i)-(v), and the "health oversight activities" exception only applies to an health oversight agency engaged in oversight activities authorized by law. See *id.* § 164.512(d)(1)(i)-(iv). Most independent remote sensing researchers would not appear to come under these exceptions (with the notable exception of such individuals working for the Food and Drug Administration (FDA) or similar government health agency).

and evaluation, designed to develop or contribute to generalizable knowledge."⁵¹ A covered entity may use or disclose PHI for research, regardless of the source of funding, in three different circumstances: (1) if an IRB or HPB approves a waiver of the authorization requirement; (2) if the scenario involves reviews merely preparatory to research; and (3) if the research concerns a decedent's health information.⁵²

Proceeding in reverse order in examining these three types of research exceptions, a remote sensing researcher may only obtain PHI from a decedent for research purposes without obtaining an authorization if three additional conditions are met. First, the researcher must represent that the PHI is solely for research on the PHI of decedents.⁵³ Second, the researcher must provide documentation that the decedents in question are, in fact, dead.⁵⁴ Third, the researcher must explain why the decedents' PHI is "necessary" for research purposes.⁵⁵

This third condition regarding the necessity of the decedent PHI for research purposes may prove to be the most difficult requirement to meet, depending on the predisposition of the covered entity to cooperate with the researcher. One can easily imagine where a health care provider, especially one who is gun-shy of HIPAA's well-publicized labyrinthine procedures, may say that no research is "necessary" under any circum-

⁵¹ *Id.* § 164.501. Such a broad definition would seem to clearly apply to all forms of remote sensing research.

⁵² *Id.* § 164.512(i)(1)(i)-(iii). Another possible way to avoid the impact of the HIPAA Privacy Rule as a researcher is to "de-identify" the health information to be disclosed, thus making the information no longer "individually identifiable health information," and not subject to HIPAA generally. See 45 C.F.R. § 164.502(d); § 164.514(a), (b) (implementation specifications for de-identification). Although de-identification serves as a possible method by which remote sensing researchers may obtain relevant health information, in most cases the researchers will need demographic information concerning the individual (including their addresses) which will make it unlikely that the de-identified health information would be of much use to the researcher.

⁵³ *Id.* § 164.512(i)(1)(iii)(A). This requirement is needlessly confusing. Does it mean that one can only use decedent PHI for research purposes if the researcher represents that his or her research only concerns decedents or instead that the researcher must represent that the decedent PHI will not be used for non-research purposes? Either interpretation is certainly plausible, but the latter one seems more reasonable.

⁵⁴ *Id.* § 164.512(i)(1)(iii)(B). Morbid humor aside, one assumes that a death certificate will suffice in this regard.

⁵⁵ *Id.* § 164.512(i)(1)(iii)(C).

stance. In such instances, it is unclear in what manner an aggrieved researcher needing decedent PHI could challenge this determination. Nevertheless, to the extent a remote sensing researcher needs only decedent PHI to complete his or her research, it would appear, in most cases, that the HIPAA Privacy Rule would not pose insurmountable difficulties.⁵⁶

With regard to reviews preparatory to research, the second type of research exception, the usefulness of this provision to remote sensing researchers is substantially limited. Under these provisions, use or disclosure is restricted to preliminary utilization of PHI to develop a research protocol or "for similar purposes preparatory to research."⁵⁷ This condition appears to leave little room for the more thorough research manipulation for which most remote sensing researchers would require PHI. This prong of the research exception is also hindered by the same "necessary" query surrounding decedent PHI.⁵⁸ As a result, this prong of the research exception provides little relief for the remote sensing researcher hoping to obtain PHI for medical research purposes.

Because the decedent and the preparatory language provisions are limited in their overall usefulness to remote sensing researchers seeking to obtain and use PHI for medical research, researchers most likely will have to attempt to comply with the remaining research exception, which requires either an IRB or HPB to sign off on a waiver of the HIPAA authorization requirement. Under the waiver prong, the burden appears to be on the *covered entity*, rather than the researcher,⁵⁹ in acquiring

⁵⁶ Of course, this prong of the exception does not assist a remote sensing researcher needing to combine geospatial data with PHI concerning the living.

⁵⁷ *Id.* § 164.512(i)(1)(ii)(A).

⁵⁸ *Id.* § 164.512(i)(1)(ii)(C). A third condition is that no PHI may be removed by the researcher from the premises of the covered entity in the course of review. *Id.* § 164.512(i)(1)(iii)(B). Needless to say, it would be hard to perform effective research under this additional burdensome condition.

⁵⁹ In this regard, the statutory language states: "A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that: (i) *Board approval of a waiver of authorization.* The covered entity obtains documentation that an alteration or waiver ... of the individual authorization [requirement] ... has been approved by either: (A) An Institutional Review Board (IRB) . . . , or (B) A privacy board . . ." *Id.* § 164.512(i)(1)(i)(A)-(B) (emphasis added). Compare this language to the decedent and preparatory language of the research excep-

documentation that an alteration to, or waiver of, the authorization requirement is necessary.⁶⁰

B. Institutional Review Boards (IRBs)

IRBs, unlike their HPB counterparts, are not new entities created by the HIPAA Privacy Rule. Indeed, IRBs have been around for quite a while and were created to protect research participants from risks surrounding human subjects research.⁶¹ Not surprisingly, then, the HIPAA Privacy Rule not only requires IRBs to meet new privacy criteria established by the Rule, but also requires the IRB to conduct its waiver review in line with criteria already established under the so-called "Common Rule," also called the "Federal Policy for Protection of Human Subjects."⁶²

Briefly,⁶³ an institutional review board "is a board, committee, or other group formally designated by an institution to re-

tion in which the researcher must carry the burden of establishing that the requested PHI is "necessary" for the research purposes. *Id.* § 164.512(i)(1)(ii)(C), (iii)(C).

⁶⁰ *Id.* § 164.512(i)(1)(i)(A)-(B).

⁶¹ See *IRB Fact Sheet*, *supra* note 24, at 1 (citing 45 C.F.R. Part 46 (Department of Health and Human Services Regulations for the Protection of Human Subjects) and 21 C.F.R. Parts 50 and 56 (Food and Drug Administration Regulations on Protection of Human Subjects)); see generally Office for Human Research Protections website, at <http://www.hhs.gov/ohrp/> (last visited Oct. 15, 2004) or the FDA Human Research website, at <http://www.fda.gov/oc/gcp> (last visited Oct. 14, 2004). Other federal and state laws may provide additional privacy limitations, which may not be waived by either an IRB or HPB. *IRB Fact Sheet*, *supra* note 24, at 1; see also *supra* note 9 (concerning HIPAA preemption).

⁶² 45 C.F.R. § 164.512(i)(1)(A). Indeed, the HIPAA Privacy Rule does not change the composition or a number of procedural requirements that IRBs normally follow under the Common Rule when considering whether to approve proposed human subjects research. *IRB Fact Sheet*, *supra* note 24, at 3-4.

⁶³ A comprehensive recitation of all the regulations that typically apply to IRBs in human subjects research under the Common Rule is well beyond the scope of this article. For further information on this topic, see generally Judith F. Daar, Symposium, *Genetic Testing and Human Subjects Research*, 24 WHITTIER L. REV. 429 (2002); Bernard Lo, M.D. & Michelle Groman, Symposium, *NBAC Recommendations on Oversight of Human Subjects Research*, 32 SETON HALL L. REV. 493 (2002); Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Eugenics Past, Present, and Future?*, 36 CONN. L. REV. 125 (2003); Nancy M. Pliske, *The Impact of the Privacy Rule on Research Activities*, 676 PLI/Pat 105 (2001) (published prior to August 2002 HHS modification of research waiver provisions); Daniel J. Powell, Symposium, *Using the False Claims Act as a Basis for Institutional Review Board Liability*, 69 U. CHI. L. REV. 1399 (2002).

view researching humans as subjects,"⁶⁴ and generally consists of at least five members with varying backgrounds to ensure complete and adequate review of the proposed research activities.⁶⁵ These IRBs are given broad authority to approve, disapprove, or modify, all research activities concerning the use of human research subjects, which are conducted or supported by federal departments or agencies.⁶⁶ Under the Common Rule, IRBs apply specified criteria to the proposed research to determine if the research in question should be approved.⁶⁷ Not only must an IRB initially approve human subjects research according to a defined set of criteria, it must periodically review the progress of the research.⁶⁸

Even before the HIPAA Privacy Rule was contemplated, one of the criteria that IRBs applied to determine whether to approve human subjects research concerned the privacy of the human subject. The regulation in question provides that the research protocol must include, "adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."⁶⁹ Although it can be assumed that past IRBs sought to comply with this privacy standard in good faith; nevertheless, there did not exist either the comprehensive individual authorization requirements concerning PHI, nor provisions concerning

⁶⁴ *IRB Fact Sheet, supra* note 24, at 2. The National Institute of Health's Fact Sheet underscores the importance of IRBs in stating that, "Every institution engaged in human subjects research conducted or supported by a Federal department or agency that has adopted the Common Rule (Federal Policy for Protection of Human Subjects) is required to designate one or more IRBs under an assurance of compliance." *Id.* Institutions covered by these regulations include hospitals, academic medical centers, and government units engaged in federally supported or conducted human subjects research. *Id.*

⁶⁵ *Id.* at 3. Not only is appointment to the IRB based on considerations of expertise, diversity, and experience, but at least one member must not be affiliated with the institution, one member must be from a scientific area, one member must be from a non-scientific area, and no member may have a conflict of interest. *Id.* at 3-4.

⁶⁶ *Id.* at 2.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ See 45 C.F.R. § 46.111(a)(7) (HHS provision); 21 C.F.R. § 56.111(a)(7) (FDA provision). The ambiguity inherent in legal standards relying upon "adequate provisions" language will be discussed in detail below. See *infra* Part IV.A.

the waiver of such requirements, prior to the effective date of the HIPAA Privacy Rule.⁷⁰

Now, IRBs have been given the additional task to determine whether a covered HIPAA entity may release PHI without an individual's authorization for research purposes.⁷¹ Although existing IRBs are most likely only to act on waiver of authorization requests in connection with research activities they already oversee,⁷² IRB members will need to quickly familiarize themselves with the relevant substantive provisions of the HIPAA Privacy Rule. These provisions will require IRBs to produce documentation that establishes five specific conditions, in addition to any other existing requirements that may apply under the federal Common Rule.

First, the IRB waiver document must include a statement identifying the IRB and the date on which the waiver of the authorization requirement was approved.⁷³ Second, the waiver document must include "adequate assurances" that the IRB has determined that the release of the PHI to the researcher meets three express criterion: (1) the use of the PHI causes no more than a "minimal risk" to the privacy of individuals, based on the presence of an "adequate plan" (a) to protect identifiers from improper use,⁷⁴ (b) to destroy the identifiers at the earliest possible opportunity consistent with the conduct of the research,⁷⁵ and (c) to protect the PHI from improper reuse or disclosure to any other person or entity,⁷⁶ (2) the research could not be practi-

⁷⁰ The NIH Fact Sheet explains that the HIPAA Privacy Rule supplements previous HHS and FDA privacy provisions to ensure greater security of private health information. *IRB Fact Sheet*, *supra* note 24, at 2.

⁷¹ All that being said, IRBs will not be responsible for ensuring compliance with other provisions of the HIPAA Privacy Rule. For example, IRBs will not be responsible for reviewing and approving individual authorizations to release PHI, only whether a waiver of the authorization requirement is appropriate under the circumstances. *Id.*

⁷² *Id.*

⁷³ 45 C.F.R. § 164.512(i)(2)(i).

⁷⁴ *Id.* § 164.512(i)(2)(ii)(A)(1).

⁷⁵ *Id.* § 164.512(i)(2)(ii)(A)(2). Destruction of the identifiers within the released PHI need not occur to the extent that there is a health or research justification for retaining the identifiers or that such retention is required by law. *Id.*

⁷⁶ Again, there are exceptions to this general proscription against improper reuse or disclosure, including situations where such uses or disclosures are required by law, for authorized oversight of the research, or for other research for which the use of the PHI would be permitted by the HIPAA Privacy Rule. *Id.* § 164.512(i)(2)(ii)(A)(3).

cally done without a waiver;⁷⁷ and (3) the research could not practically be conducted without access to the PHI.⁷⁸

Third, the IRB waiver documentation must include a brief description of the PHI for which access has been determined to be necessary.⁷⁹ Fourth, the documentation must contain assurances that the waiver has been approved under either normal⁸⁰ or expedited⁸¹ review procedures already established by the Common Rule.⁸² Fifth, and finally, the documentation supporting the waiver of the HIPAA individual authorization requirement must be signed by the chairman of the IRB, or a designee selected by the chairman of the IRB.⁸³ If all these conditions are met, the disclosure of the PHI to the researcher will be approved by the IRB, and the covered entity will be free to release the necessary PHI to the researcher without the researcher being required to obtain a HIPAA-compliant authorization from affected individuals.

C. HIPAA Privacy Boards (HPBs)

So why does the HIPAA Privacy Rule also provide for HPBs in addition to already existing IRBs when a waiver of the HIPAA authorization requirement is at stake? Most simply, HPBs "do not exercise any other powers or authorities granted to IRBs under Federal laws relating to federally conducted or supported human subjects research and research involving products regulated by the Food and Drug Administration (FDA)."⁸⁴ Consequently, it is easier to establish an HPB if a researcher is not otherwise covered by federal human subjects research law. Thus, in situations in which a remote sensing

⁷⁷ *Id.* § 164.512(i)(2)(ii)(B).

⁷⁸ *Id.* § 164.512(i)(2)(ii)(C).

⁷⁹ *Id.* § 164.512(i)(2)(iii). HHS has observed the researcher requesting the waiver of authorization may be in the best position to write the brief description of the PHI required by this section. HHS contemplates that the researcher could submit this information as part of the request for waiver approval. *Privacy Board Fact Sheet*, *supra* note 13, at 5.

⁸⁰ See generally 21 C.F.R. § 56.108; 45 C.F.R. § 108.

⁸¹ See generally 21 C.F.R. § 56.110; 45 C.F.R. § 110.

⁸² 45 C.F.R. § 164.512(i)(2)(iv).

⁸³ *Id.* § 164.512(i)(2)(v).

⁸⁴ *Privacy Board Fact Sheet*, *supra* note 13, at 2.

researcher is just obtaining health information records concerning past or current medical conditions, the HIPAA Privacy Rule allows an HPB to grant the necessary waiver of authorization without the researcher having to worry about complying with additional federal laws and regulations that apply to human subjects research.

In addition to not being subject to burdensome federal laws revolving around federal human subjects research, there are a number of other potential advantages to forming an HPB versus forming, or relying upon, an existing IRB.⁸⁵ For one thing, an HPB need only consist of at least two members, as opposed to the five member panels of an IRB.⁸⁶ Furthermore, the HIPAA Privacy Rule, in addition to a normal review procedure,⁸⁷ sets out a less burdensome expedited review procedure for cases in which there is only a "minimal risk" to the privacy of individuals involved.⁸⁸ In expedited instances, the Chair alone, or his or her designee, may grant the necessary waiver without convening the full HPB.⁸⁹

Nevertheless, these additional advantages provided by the HPB provisions are still circumscribed by many of the same rules that apply to IRBs. For instance, as far as HPB membership is concerned, the HPB must produce the same documentation that establishes the five specific conditions discussed above in relation to an IRB.⁹⁰ These conditions also include the same three adequate assurances under which the HPB must deter-

⁸⁵ An existing IRB set up at a given institution for one purpose does not preclude that same institution from establishing an HPB for another research purpose. IRBs and HPBs can coexist at the same institution. *See id.* at 3.

⁸⁶ *Id.* at 2; *see also* 45 C.F.R. § 164.512(i)(2)(iv)(B).

⁸⁷ The normal HPB review procedure requires that a majority of the HPB members be present, including one of whom satisfies the nonaffiliated criteria, and the waiver must be approved by the majority of the privacy board members present at the meeting, unless the HPB elects to utilize an expedited review. *See* 45 C.F.R. § 164.512(i)(2)(iv)(B).

⁸⁸ 45 C.F.R. § 164.512(i)(2)(iv)(C). The expedited procedures available for IRBs appear to be much more onerous for researchers to use than those expedited procedures established for HPBs under the HIPAA Privacy Rule. *See id.* § 164.512(i)(2)(iv)(A). For instance, to qualify for an expedited review by an IRB, one must fall within a list of categories of research established by the FDA. *See* 21 C.F.R. § 56.110(a),(b).

⁸⁹ 45 C.F.R. § 164.512(i)(2)(iv)(C). Nevertheless, that member must meet the unaffiliated criteria set forth in 45 C.F.R. § 164.512(i)(2)(iv)(B).

⁹⁰ *See supra* notes 70-80 and accompanying text.

mine that the release of the PHI in question is permissible.⁹¹ Additionally, members of an HPB must have varying backgrounds and the requisite experience and knowledge,⁹² including one of whom is not affiliated in any manner with the institution involved.⁹³ Similarly, no one may serve on the HPB if that person has a conflict of interest.⁹⁴

All in all, however, the HPB appears to provide an easier procedural device for a remote sensing researcher to obtain the necessary waiver of authorization when individual authorizations for the release of PHI are impractical to acquire. Nonetheless, and as with the IRB provisions, there are many HPB provisions which may be subject to abuse and detrimentally impact the ability of a remote sensing researcher to obtain PHI to complete his or her geospatial research. The next Section explores some of these potential pitfalls and recommends a "special needs" approach consistent with Fourth Amendment privacy law.

IV. SWATTING THE MOSQUITO: A CONSTITUTIONAL-BASED OINTMENT

A. *The Mosquito: The Enigmatic Nature of the Research Waiver Approval Process Under the HIPAA Privacy Rule*

Not surprisingly, when the research waiver provisions were modified in August 2002 in response to growing criticism, they were still censured for being "confusing, redundant, and internally inconsistent."⁹⁵ Although HHS has since issued a number of guidance documents,⁹⁶ little comfort has been provided for IRB or HPB members who must implement the provisions. For instance, how does one know whether they are eligible for the

⁹¹ See *supra* notes 71-73 and accompanying text.

⁹² 45 C.F.R. § 164.512(i)(1)(B)(1).

⁹³ *Id.* § 164.512(i)(1)(B)(2).

⁹⁴ *Id.* § 164.512(i)(1)(B)(3).

⁹⁵ See Scaraglino, *supra* note 20, at 566 (quoting Standards for Privacy of Individually Identifiable Health Information, 67 FED. REG. 53, 229).

⁹⁶ See generally *Understanding HIPAA*, *supra* note 9; *Privacy Board Fact Sheet*, *supra* note 13; *IRB Fact Sheet*, *supra* note 24.

quick, less expensive, expedited review procedure? This expedited review would appear to permit one, unaffiliated privacy board member to sign off on a disclosure of PHI for research purposes.⁹⁷ All that is known is that expedited review is permitted in cases in which “the research involves no more than *minimal risk* to the privacy of the individuals who are the subject of the protected health information.”⁹⁸ Of course, the question is begged: What in the world is a “minimal risk”?

Although there is no definition provided in the expedited review section of the HIPAA regulations or in the guidance documents for this important terminology,⁹⁹ the same “minimal risk” language is used in discussing the waiver criteria for approving a waiver of authorization by either an IRB or HPB under normal review procedures. In this context, we are told that:

The use or disclosure of protected health information [must] involve[] no more than a *minimal risk* to the privacy of individuals, based on, at least, the presence of the following elements; (1) An adequate plan to protect the identifiers . . . ; (2) An adequate plan to destroy the identifiers at the earliest opportunity . . . ; and (3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity . . .¹⁰⁰

At first sight, this language would suggest that these three waiver criteria create the floor for a HPB finding that the disclosure of certain research does not present more than a minimal risk to the privacy of the individual. But there are at least two problems with this reasoning. First, it makes the normal and expedited review procedures practically indistinguishable with regard to the minimal risk standard.¹⁰¹ This result makes little sense since the normal review provisions specifically differentiates its procedures from the expedited review proce-

⁹⁷ See *supra* note 9 and accompanying text.

⁹⁸ 45 C.F.R. § 164.512(i)(2)(iv)(C) (emphasis added).

⁹⁹ See 45 C.F.R. § 160.103; 45 C.F.R. § 164.501.

¹⁰⁰ *Id.* § 164.512(i)(2)(ii)(A)(1)-(3) (emphasis added).

¹⁰¹ Of course, the normal review procedure would also require a statement that the research could not practically be conducted without the waiver and without access to and use of the protected health information. *Id.* § 164.512(i)(2)(ii)(B), (C).

dures.¹⁰² Second, even if we were to make the three waiver criterion the *sine qua non* of meeting the minimal risk standard for expedited waiver purposes, these three criteria still require us to define the meaning of such imponderables as “adequate plan” or “adequate written assurances.”

Again, a question is begged: “adequate” to whom? The notion that this determination may be based on little more than what an IRB or HPB member ate for breakfast¹⁰³ is more than a little disconcerting for those of us particular about such things as consistency and uniformity in the law. In short, we are left with highly-indeterminate legal standards, with no statutory definitions or precedent available for guidance, and whether PHI is permitted to be disclosed, and in how quickly a fashion this disclosure may proceed, may depend on nothing more than on how decisionmakers individually define “minimal risk,” “adequate plan,” or “adequate written assurances.” Hardly the stuff to make remote sensing researchers rush to their nearest HIPAA covered entity, ask for the creation of an HPB, and then cross their fingers that their research meets the minimal risk/adequate plan/adequate assurances criteria of the HPB expedited review procedures.

*B. Proposed Constitutional-Based Ointment:
A Fourth Amendment “Special Needs” Approach*

In deciding what would be a more appropriate approach to disclosure of PHI for research purposes than the current one, it is worthwhile to consider at least the following questions: How much value should we place on keeping our health records and information private? Is health information privacy so sacrosanct that we are willing to proscribe medical research that might assist in the eradication of diseases from which we and our loved ones now, or one day will, suffer? Are there not times when there is a substantial need for medical research to help

¹⁰² *Id.* § 164.512(i)(2)(ii)(B).

¹⁰³ See Frank B. Cross, *Decisionmaking in the U.S. Circuit Courts of Appeals*, 91 CAL. L. REV. 1457, 1464-65 (2003) (observing the common legal realist critique of judicial decision making).

fight a disease, but the inevitable price is the loss of some individual medical privacy?

My approach to these thorny questions is based on giving sufficient consideration to each of the competing interests and then attempting to balance these interests based on the specific circumstances of each PHI disclosure case. This balancing approach in the individual health privacy context is certainly not novel; it draws upon the Supreme Court's treatment of "reasonableness/special needs" cases¹⁰⁴ under the Fourth Amendment to the United States Constitution.¹⁰⁵ Even though the Fourth Amendment applies only to the federal government (and to the states through the Fourteenth Amendment),¹⁰⁶ and thus may not apply to a large number of remote sensing researchers seeking PHI for research purposes,¹⁰⁷ such a well-developed and well-established area of law nevertheless helps to fill in some of the more glaring gaps in the current version of the HIPAA Privacy Rule's research waiver provisions.

In "special needs" cases, the warrant and probable cause requirements of the Fourth Amendment are relaxed to permit the satisfaction of special government needs in carrying out governmentally-sanctioned searches of individuals and their effects.¹⁰⁸ In these cases, rather than require the government to

¹⁰⁴ See *Griffin v. Wisconsin*, 483 U.S. 868, 875 (1987) (supervision of probationers constitutes "special need" requiring more relaxed rule for searches); *O'Connor v. Ortega*, 480 U.S. 709, 722 (1987) (the need of an employer to enter an employee's office, desk, or files comprises "special need" and no warrant is required); *New Jersey v. T.L.O.*, 469 U.S. 325, 340-41 (1985) (finding warrant requirement unsuited to school context because it unduly interferes with the maintenance of swift and informal disciplinary procedures).

¹⁰⁵ U.S. CONST. amend. IV ("The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.")

¹⁰⁶ See *Maryland v. Pringle*, 124 S. Ct. 795, 799 (2003) (citing *Mapp v. Ohio*, 367 U.S. 643 (1961)).

¹⁰⁷ The Fourth Amendment would presumably apply to remote sensing researchers employed by federal agencies, such as NASA, or state agencies, such as the Mississippi Bureau of Narcotics. It would not, however, apply to the purely private acts of remote sensing researchers. For an insightful discussion of the state action doctrine under the United States Constitution, see generally Erwin Chemerinsky, *Narrowing the State Action Doctrine*, 35 TRIAL 101 (1999).

¹⁰⁸ See Seth M. Haines, Comment, *Rounding Up The Usual Suspects: The Rights of Arab Detainees in a Post-September 11 World*, 57 ARK. L. REV. 105, 121 (2004) ("In spe-

obtain a warrant supported by probable cause before permitting such a search, the Supreme Court has permitted "reasonableness" to be the touchstone upon which the analysis revolves.¹⁰⁹ In turn, "whether a particular search meets the reasonableness standard 'is judged by balancing its intrusion on the individual's Fourth Amendment interests against its promotion of legitimate governmental interests.'"¹¹⁰

These "special needs" cases are, in fact, similar in orientation to the inquiry for research waivers under the HIPAA Privacy Rule. In each situation, a sensitive balancing of individual privacy interests in certain information must be weighed against some external (governmental or otherwise) need for that same information.¹¹¹ More specifically, in the HIPAA context, the question introduced may be "the single most important [one]

cial needs cases, intrusions upon Fourth Amendment were allowed because they 'serve[d] special governmental needs, beyond the normal need for law enforcement . . .') (quoting *Nat'l Treasury Employees Union v. Von Raab*, 489 U.S. 656, 665-66 (1989)) (alteration in original). The *Von Raab* Court stated, "our cases establish that where a Fourth Amendment intrusion serves special governmental needs . . . it is necessary to balance the individual's privacy expectations against the Government's interests to determine whether it is impractical to require a warrant or some level of individualized suspicion . . ." *Von Raab*, 489 U.S. at 665-66.

¹⁰⁹ See *Vernonia Sch. Dist. 47J v. Acton*, 515 U.S. 646, 652 (1995) ("As the text of the Fourth Amendment indicates, the ultimate measure of the constitutionality of a governmental search is 'reasonableness.'").

¹¹⁰ *Id.* at 652-653 (quoting in part *Skinner v. Ry. Labor Executive Assn.*, 489 U.S. 602, 617 (1989)); see also *T.L.O.*, 469 U.S. at 337 (reasonableness depends on "balancing the need of the search against the invasion the search entails.") (quoting *Camara v. Mun. Ct.*, 387 U.S. 523, 536-37 (1967)). Specifically, the Court makes its reasonableness determination by weighing the nature and character of the individual's privacy interest against both the character of the intrusion by the government and the nature and immediacy of the government's concern. See generally *Vernonia*, 515 U.S. at 654-664; *Bd. of Educ. of Independent Sch. Dist. No. 92 v. Earls*, 536 U.S. 822, 829-838 (2002). In *Vernonia*, for instance, this balance was struck in favor of allowing the school district to implement a student athlete drug policy in a high school environment. See *Vernonia*, 515 U.S. at 663. In *Earls*, the Court extended *Vernonia* to permit drug testing to all students engaged in competitive extracurricular activities. See *Earls*, 536 U.S. at 830.

¹¹¹ Let me stress that this analogy to the Fourth Amendment only goes so far. Clearly, the HIPAA Privacy Rule does not normally concern criminal behavior, nor the potential of incarceration. Nevertheless, the schemata established by the "special needs" line of Fourth Amendment cases brings much needed clarity and simplification to the legal analysis surrounding research waivers under the HIPAA Privacy Rule.

raised in the 21st century by Americans, namely balancing... privacy concerns versus technological advancements."¹¹²

Under the special needs HIPAA balance, the nature of the individual's privacy interest in his or her medical records will always be strong, as individuals have significant and legitimate expectations of privacy in their PHI.¹¹³ Nevertheless, as strong as that privacy interest is, in analogous contexts courts have recognized that others may have sufficient reason to justify intrusion into the private health records of an individual.¹¹⁴ In the HIPAA research waiver context, if the character of the intrusion is minimally invasive (in that disclosure of the PHI is limited to a small number of researchers), and the nature and the immediacy of the concern is compelling (in that an epidemic of some sort is at hand), this might lead an IRB or HPB to permit the disclosure of PHI for research purposes.

More concretely, and starting where we began, the West Nile Virus example helps to illustrate how the "special needs" approach would apply in deciding whether to release medical information to a remote sensing researcher hoping to combine medical data with his or her geospatial research. To begin with, the individual privacy interest in their health records would be high.¹¹⁵ Thus, an individual who has, or had, West Nile Virus, may be unwilling to sign an authorization to release their medical records for research purposes. Nevertheless, under a special

¹¹² See *PPA Litigation*, 2003 WL 22203734, at *8. "The more accessible that personal information becomes, the more critical it is to create intelligible guidelines to provide an equitable balance between the individual's interest in his or her privacy and the national interest, in this instance, [sic] HIPAA compliance." *Id.*

¹¹³ As an example of the importance of the privacy of medical records, prior appellate decisions have held that the United States Constitution provides a qualified protection for medical records sought by search warrant or subpoena. See *In re Search Warrant (Sealed)*, 810 F.2d 67, 71-72 (3d Cir. 1987); *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 577 (3d Cir. 1980). Of course, the HIPAA Privacy Rule itself is a strong indication of the strong federal policy in favor of protecting the privacy of individual health records. See *United States v. Sutherland*, 143 F. Supp. 2d 609, 612 (W.D. Va. 2001) (noting that the recent Health Insurance Portability and Accountability Act demonstrated "strong federal policy" of protecting medical records).

¹¹⁴ See, e.g., *United States v. Mazzola*, 217 F.R.D. 84, 88-89 (D. Mass. 2003) ("[I]ndividual's privacy interest in medical records must be balanced against the legitimate need of others in obtaining disclosure.") (quoting *United States v. Polan*, 970 F.2d 1280, 1285 (3d Cir. 1992)).

¹¹⁵ See *supra* note 113.

needs balancing test, the argument can be made that the character of the disclosure of the West Nile Virus PHI to the remote sensing researcher is minimally invasive, as the researcher may be able to limit his or her informational needs to the physical address of the individual, and may not need other demographic, sensitive information.

Moreover, the nature and immediacy of the researchers and the public's concern are substantial in light of the barrage of press coverage West Nile Virus has received in the last five years and the impact this disease had had, both physically and psychologically, on society in general.¹¹⁶ Performing the special needs balancing in this manner, it appears that it would be reasonable for a HPB or IRB to grant a waiver to the normal authorization requirement and allow limited, specified disclosures of individual health information concerning an individual's contraction of the West Nile Virus. Although by no means empirically proven, my sense is that most people would be willing to agree to such a minimal intrusion into their health records if they believed that they, or their loved ones, could benefit from the eradication of a disease such as West Nile Virus.

The advantage of the "special needs" approach over the current "necessary and adequate" approach is obvious: there is a well-established and significant line of case law to which to analogize the situations that covered entities and remote sensing researchers are likely to find themselves in relation to the disclosure of PHI. On the other hand, as currently written, the HIPAA Privacy Rule provisions that shape IRB or HPB determinations are too ambiguous to properly place the competing interests to be balanced directly in front of the decisionmakers. There are simply no helpful definitions provided for these standards. The danger is that current waiver determinations will not be based on properly structured discretion, but rather on

¹¹⁶ A search of "West Nile Virus" on Westlaw's ALLNEWS database returned over 10,000 results on May 26, 2004. Some recent, representative press clippings include, Dan D'Ambrosio, *West Nile: Disease No One Can Figure Out How To Fight*, CAPITAL TIMES & WISCONSIN STATE JOURNAL, May 24, 2004, at A1; Edie Lau, *West Nile's Virulence in U.S. probed as new season nears*, CINCINNATI POST, May 20, 2004, at A22; Christopher Windham, *West Nile Vaccine Prompts Antibodies in Tests*, WALL ST. JOURNAL, May 25, 2004, at D3.

Board members' "gut" feelings; dissimilar results for similar factual scenarios being the unfortunate consequence.

Additionally, the current approach may lead remote sensing researchers to shy away from undertaking this important medical research if the procedural hurdles prove too difficult or unrewarding. For instance, having to proceed through the IRB or HPB process might both dramatically increase the time and expense associated with the collection of PHI. The unintentional consequence may be that remote sensing techniques that are essential to the eradication of a disease such as West Nile Virus might not be sufficiently utilized. In the end, of course, we will all be worse off if diseases like West Nile linger and continue to claim victims.

To avoid this unappealing scenario, this article proposes that the waiver approval process of the research exception to the HIPAA authorization requirement be modified to require both HPBs and IRBs to undertake a Fourth Amendment-type special needs analysis, with the concept of reasonableness at its foundation, in order to determine whether to disclose specific PHI to remote sensing researchers. Such a revamped, simplified procedure will have the advantage of being more time and cost-effective as time-tested legal analyses are applied in place of burdensome, technical provisions. This approach will also have the advantage of spurring additional remote sensing research in health-related areas.

V. CONCLUSION

The challenge for those that administer the HIPAA Privacy Rule in the future will be to recognize that protecting patient health information is not an all or nothing proposition, but instead requires a nuanced and subtle approach which accommodates the competing interests at stake. By providing for the research exception and the related IRB and HPB waiver provisions in the HIPAA Privacy Rule, HHS seems to have already grasped this essential notion. Indeed, this article does not contest the basic approach that HHS has adopted in leaving waiver determinations to the individual IRBs and HPBs to decide under what conditions sensitive health information can be re-

leased for research purposes. Nevertheless, adoption of the proposed "special needs" analysis in place of the current "necessary and adequate" approach will substantially eliminate uncertainty for remote sensing researchers who will be increasingly utilizing medical records and information in conjunction with their remote sensing and geospatial research.

In the end, if IRBs and HPBs are successfully able to manage the balancing process through use of these clearer and simplified waiver standards, then society will surely reap the benefits of important new medical discoveries. This is because as more and more remote sensing researchers are able to access necessary medical research in a more timely and less expensive manner, diseases like West Nile Virus will more quickly become a distant memory of a less technologically-sophisticated past.