By promoting ways to accelerate the collection and application of biological materials in research—biobanking—we can significantly advance the search for new diagnostic and therapeutic tools that are vastly lacking for scores of patients with limited or no treatment options...

In March 2009, TIME magazine listed biobanks as one of the “Ten Ideas That Are Changing the World Right Now.” ... TIME’s claims are a bit premature. Biobanks are changing how institutions conduct research, but they are not yet changing the world. Technical, institutional, ethical, and regulatory challenges remain, for example: 1) the quality of materials; 2) privacy concerns; 3) regulatory confusion; and 4) ownership, trust, and stewardship issues.

Indeed, the regulatory challenges in biobanking are increasing:

- On July 26, 2011, The HHS Office for Human Research Protections (OHRP) issued an Advance Notice of Proposed Rulemaking (ANPRM)—a request for public comment before a proposed rule is issued—to revamp the HHS Common Rule, and how it will apply to research with human biospecimens. And while it is not a rule yet, the ANPRM foretells significant developments in biobanking and research regulation. (See 76 Fed. Reg. 44512 (July 26, 2011), available at http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/pdf/2011-18792.pdf.)

- State courts are limiting the use of blood samples obtained through newborn screening programs.

- The HHS Office for Civil Rights (OCR), the agency that enforces the Health Insurance Portability and Accountability Act (HIPAA), issued proposed amendments to the HIPAA Privacy Rule that, if finalized, will have significant impact on biobanking and research.
I. The HHS OHRP Advance Notice of Proposed Rulemaking

In July 2011, OHRP issued an ANPRM as a request for public comment on the OHRP’s proposal to completely revamp the Common Rule. As summarized so well by Rachel Nosowsky on behalf of the AHLA AMC/TH Practice Group:

Many of the proposed changes will be embraced by research institutions for reducing administrative burden that does not translate to enhanced human research protections. Other changes likely will, if adopted, increase the burden on research and possibly undermine the viability of some kinds of projects entirely. And while some patient advocates likely will embrace expanded information security protections and informed consent requirements, others may balk at some of the burden-reducing proposals contemplated in ANPRM, or may not feel that the proposals for enhanced protections go far enough.

The revisions seek to address these concerns:

1. Failure of the current regulations to adequately calibrate the research review process to the risks inherent in specific proposals. ANPRM identifies three principal categories of risk: physical, psychological, and informational. It proposes evaluating informational risks based primarily on standards developed under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, as amended, minimizing those risks via standardized data protection rules, and then excluding from the scope of institutional review board (IRB) consideration of those risks. ANPRM also proposes to update, simplify, and streamline “expedited” (single reviewer) approval requirements, and to eliminate continuing review for minimal risk studies that, at inception or as they have progressed, are subject only to the expedited review process. In addition, it proposes to substantially expand the categories of research that may qualify for exemption to include, among others, retrospective and prospective “secondary use” activities, which would be subject only to new—and in some cases significant—consent, data security, and registration and oversight mandates. (Given these new mandates, HHS now refers to the studies as excused from IRB oversight rather than exempt.)

2. Inefficiencies in multi-site research. Recognizing inefficiencies inherent in, and additional risks potentially created by, duplicative IRB oversight, ANPRM proposes mandating use of a single IRB in multi-site research subject to the Common Rule. But, not U.S. Food and Drug Administration (FDA) regulations, because the Food, Drug & Cosmetic Act precludes such a change.

3. Deficient informed consent requirements and practices. ANPRM contemplates potentially significant changes to informed consent (and
waiver) rules, including prescription of appropriate content (and its presentation); limitations on length of specified sections of forms; and reduction of institutional “boilerplate” that the [OHRP] has concluded is often intended to protect institutions from suit but not to genuinely inform subjects. OHRP does not address how these requirements might be made to work (absent express preemption) with state-mandated language.

4. Addressing informational risks. As noted above, ANPRM proposes adopting HIPAA standards for describing de-identified data sets, limited data sets, and identifiable data. However, the administration is considering treating all biospecimen research as if it involves identifiable data (HIPAA does not treat specimens as data). ANPRM also proposes imposition of security standards comparable to (or stronger than) those adopted under HIPAA, including requirements for data encryption and breach notification, on any human subjects research involving “identifiable” information. However, the administration also may soften current requirements by permitting researchers to perform de-identification without losing exempt (Excused) or expedited status, with the goal in part to obviate the need for complex honest broker arrangements. Finally, the administration plans on requiring written “general” consent for research use of biospecimens, even in Excused studies and even where the researcher does not possess the information needed to identify the person whose biospecimen is being studied; and for secondary use of research data, again regardless of the researcher's access to identifiers. Waiver of informed consent may be permitted under specified conditions not defined in ANPRM.

5. Oversight effectiveness. ANPRM describes proposals to streamline adverse event and unanticipated problem reporting by harmonizing vocabularies and reporting mandates across federal agencies with respect to existing reporting requirements and utilizing existing web-based systems to handle mandatory reports. The intent is not, according to ANPRM, to expand existing reporting requirements. Separately, numerous comments in ANPRM suggest that the administration is contemplating replacement of IRB oversight in some areas with alternative (but as-yet undefined) processes.

6. Unequal protection. Absent legislation applying the Common Rule to all research regardless of funding source, the administration is contemplating extending Common Rule protections to all studies performed at institutions that receive some federal funding for human subjects research from any Common Rule agency. This approach previously has been adopted by the National Institutes of Health Office of Biotechnology Activities in connection with its published Guidelines for Research Involving Recombinant DNA Molecules.
7. Harmonization. Throughout ANPRM, proposals are made and comments sought on clarification and harmonization of the various regulations, guidance, and interpretations that now govern the performance of human subjects research. The document does recognize, however, that variation may be necessary or otherwise appropriate as a result of the differing and sometimes inconsistent enabling legislation on which the relevant agencies' respective rules are based, as well as their differing roles as regulatory bodies, funding sources, and/or research organizations in their own right.

In connection with the above proposals, ANPRM specifically seeks stakeholder input on a very broad range of questions (seventy-four specific questions in all), including:

- Secondary use of biospecimens and data;
- Criteria for evaluating psychological and other non-physical/ non-information risks;
- Identification of survey instruments or questions that pose greater than minimal risk;
- Regulation of research results reporting to research participants;
- Clarification of the application (or not) of the Common Rule to quality improvement, program evaluation studies, and public health activities; and appropriate treatment of certain fields of study—such as history and journalism—under the Common Rule;
- Additional ideas for expanding or modifying expedited and Excused categories;
- Considerations that promote duplicative IRB review today; pros and cons of mandating (rather than simply encouraging) single-IRB review of research projects; and mechanisms to choose the single responsible IRB if one must be designated;
- Factors that contribute to excessive length and complexity in consent forms; requirements for oral consent where permitted; potential changes to current standards for waiver of consent, or documentation of consent, and the need for those changes in view of the proposed expansion of Excused research categories;
- Harmonization of HIPAA and Common Rule standards and requirements; adequacy of existing or contemplated de-identification and
other data protection standards; relaxation of HIPAA requirements (e.g., data use agreements) in those cases where recipient researchers are subject to Common Rule protections equivalent to those imposed by HIPAA;

- Identification of organizations that should develop and disseminate standardized protocols and consent forms to further facilitate and simplify research administration;

- Appeal mechanisms for investigators unsatisfied with IRB determinations; and

- Retrospective application of new rules.

ANPRM further extends an open-ended invitation for comment on other changes that could reduce regulatory burden without decreasing subject protections; or meaningfully add to subject protections without regard to regulatory burden. It does not propose specific changes to the "subparts" of 45 C.F.R. part 46 that provide for special protections in connection with research involving specified vulnerable populations (women, fetuses, and neonates in subpart B; prisoners in subpart C; and children in subpart D), but notes that these provisions and other laws and regulations likely will require harmonization with some proposals for revision of the Common Rule.


The comment period on the ANPRM closed on October 26, 2011. (See http://www.gpo.gov/fdsys/pkg/FR-2011-09-01/html/2011-22341.htm.) For comments filed in response to the ANPRM, see http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html. This paper focuses only on the ANPRM proposal to require consent for biospecimen research, as a number of other presentations at the conference will cover other aspects of the ANPRM.

The ANPRM proposes a significant change in biospecimen research: all biospecimen research, even that involving de-identified biospecimens, would require individual consent. As summarized in the ANPRM itself, the ANPRM proposes:

[generally requiring written consent for research use of any biospecimens collected for clinical purposes after the effective date of the new rules (such as research with excess pathological specimens). Such consent could be obtained by use of a brief standard consent form}
agreeing to generally permit future research. This brief consent could be 
broad enough to cover all biospecimens to be collected related to a 
particular set of encounters with an institution (e.g. hospitalization) or 
even to any biospecimens to be collected at any time by that institution. 
These studies using biospecimens collected for clinical purposes would 
also fall under the expanded and revised exempt categories ... and thus 
would not require IRB review or any routine administrative review but 
would be subject to the data security and information protection 
standards discussed above. This change would conform the rules for 
research use of clinically-collected biospecimens with the rules for 
biospecimens collected for research purposes. The general rule would be 
that a person needs to give consent, in writing, for research use of their 
biospecimens, though that consent need not be study-specific, and could 
cover open-ended future research. (76 Fed. Reg. 44515.)

There is good news and bad news in the ANPRM related to biospecimen research. 
The good news:

(1) The consent may be a “general” consent obtained as part of a consent process for 
clinical care, such as a hospital Conditions of Admission (COA) form. The 
ANPRM does not contain suggested prescriptive language for such consent, 
which, if adopted, will give hospitals and other providers substantial flexibility 
in how to structure such consent.

(2) OHRP proposes that the consent requirement will apply prospectively only, to 
specimens collected after the effective date of the eventual final rule. This will 
give hospitals and other providers a substantial amount of time to amend their 
COAs and other treatment consent forms.

(3) No IRB review will be required to use biospecimens, even if those biospecimens 
are identifiable, because they will have been obtained with consent.

Unfortunately, requiring affirmative consent for the use of biospecimens (even de-
identified) poses some substantial problems, as well:

(1) Requiring consent to use biospecimens for research means that there is a 
potential for introducing consent bias into the collection procedures. (See 76 Fed. 
Reg. 45424 (“investigators are concerned that the need for informed consent for 
every use of a biospecimen will greatly inhibit research. (Citations omitted.) ... 
They ... worry that research will be skewed by individuals who refuse 
consent, undermining the scientific validity of the research.”)

(2) Requiring consent will introduce the need to determine the biospecimen 
“provenance” to ensure that it was collected with the individual’s consent. As 
noted in Moore v. The Regents of the University of California, 793 P2d 479 (Cal. SCt. 
1990) that will pose a substantial risk for downstream researchers that receive
biospecimens for their research. As stated in Moore, the plaintiff “is asking us to . . . impose a tort duty on scientists to investigate the consensual pedigree of each human cell sample used in research. To impose such a duty, which would affect medical research of importance to all of society, implicates policy concerns far removed from the traditional two-party ownership disputes in which the law of conversion arose.” (793 P.2d at 487.) (See also 76 Fed. Reg. at 44524 (noting that researchers “worry that obtaining individual consent for each separate research study will create unmanageable logistical demands, making valuable research impossible.”).

(3) We can anticipate challenges that a “general” consent in a COA or other condition to treat form is not “informed” for purposes of conducting research.

In short, the APNRM suggests a radical change to the biospecimen research status quo, which deserves careful monitoring.

II. State Developments

In the past year, there have been developments at the state level, particularly with regard to expansive interpretations of state genetic information privacy laws. For example, in Bearder v. State of Minnesota (Minn. S. Ct. Nov. 16, 2011), the Minnesota Supreme Court held that the Minnesota Genetic Privacy Act, Minn. Stat. § 13.386 (2010), restricts the collection, use, storage and dissemination of blood samples collected under the newborn screening statutes. The Court held that such samples may be used only for testing, recording and reporting the test results, maintaining a registry for follow-up services needed, and storing the test results as required by federal law.

In Bearder, nine families sued the State of Minnesota and others over the Minnesota Department of Health’s practice of using blood samples for purposes other than initial screening of newborns, including for research. The Department had a contract with Mayo Medical Laboratories to perform screening tests, and the contract permitted Mayo to use the specimens if the specimens had been de-identified or if Mayo obtained the consent of the parents. The families claimed that the Minnesota Genetic Privacy Act requires parental consent before the Department of Health may use blood specimens for research, and the Supreme Court agreed.

The Minnesota Genetic Privacy Act, in relevant part, provides:

Unless otherwise expressly provided by law, genetic information about an individual:
(1) may be collected by a government entity . . . or any other person only with the written informed consent of the individual;
(2) may be used only for purposes to which the individual has given written informed consent;
(3) may be stored only for a period of time to which the individual has given written informed consent; and
(4) may be disseminated only: (i) with the individual’s written informed consent; or (ii) if necessary in order to accomplish purposes described by clause (2). A consent to disseminate genetic information under item (i) must be signed and dated. Unless otherwise provided by law, such a consent is valid for one year or for a lesser period specified in the consent. Minn. Stat. § 13.386, subd. 3.

The primary issue discussed by the Court was whether blood samples were “genetic information” protected by this statute. The Court concluded yes: “It is the DNA within the blood samples that is the information that brings the blood sample within the protection of the Genetic Privacy Act. Thus, the blood samples fit within the common understanding of ‘medical or biological information collected from an individual.”’ (Bearder, page 11). The Court concluded that the Department thus could only collect, use, store and disseminate newborn blood screening samples as expressly authorized by the newborn screening statute to conduct tests for heritable and congenital disorders and conduct follow-up services. (Id. at 13-14.)

III. HIPAA Developments1

On July 14, 2010, the HHS Office for Civil Rights (OCR) published a Notice of Proposed Rulemaking (NPRM) to implement the Health Information Technology for Economic and Clinical Health Act (the HITECH Act). (See 75 Fed. Reg. 40868.) The NPRM proposes to amend the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, at 45 C.F.R. Part 160 and Part 164, Subparts A and E. These proposed rules, if finalized, could substantially affect the conduct of research in the United States, in both a positive and negative manner. As of the submission of this paper, the final HIPAA regulations have not yet been published, and are expected during the first quarter of 2012.

A. Prohibition on the “Sale” of PHI

Section 13405(d) of the HITECH Act (codified at 42 U.S.C. § 17935(d)) provides that “a covered entity or business associate shall not directly or indirectly receive remuneration in exchange for any [PHI] of an individual” unless the covered entity obtains the individual’s authorization. To implement this requirement, the OCR proposes to require a covered entity to obtain an authorization “for any disclosure of [PHI] for which the disclosure is in exchange for direct or indirect remuneration from or on behalf of the recipient of the [PHI].” See proposed 45 C.F.R. § 164.508(4).

In the proposed rule, the OCR also implements various statutory exceptions where remuneration is permitted. Id. Four proposed regulatory exceptions are particularly relevant to the research community:

1 This section of the paper is based on comments submitted to the Office for Civil Rights by the author on behalf of the National Cancer Institute, cancer Biomedical Informatics Grid (caBIG®) and various organizations and individuals that conduct research. For a copy of those comments, please contact the author at krosati@csblaw.com.
• The prohibition against remuneration will not apply to disclosures of PHI for research under § 164.512(i) (the general rule on research disclosures) or § 164.514(e) (disclosures of a Limited Data Set for research), “where the only remuneration received by the covered entity is a reasonable cost-based fee to cover the cost to prepare and transmit the [PHI] for such purposes.” The OCR requests public comment on the types of costs that should be permitted under this provision. See 75 Fed. Reg. at 40891.

• The prohibition against remuneration will not apply to disclosures of PHI for public health purposes under § 164.512(b) (the general rule on disclosures to public health authorities and for other public health purposes) or § 164.514(e) (disclosures of a Limited Data Set for public health activities). The HITECH Act requires HHS to evaluate whether payment under this exception should be capped at the cost to prepare and transmit PHI (as in the research exception); the OCR seeks public comment on this issue. See 75 Fed. Reg. at 40891.

• The prohibition against remuneration will not apply to disclosures “[t]o or by a business associate for activities that the business associate undertakes on behalf of a covered entity pursuant to §§ 164.502(e) and 164.504(e), and the only remuneration provided is by the covered entity to the business associate for the performance of such activities.”

• The prohibition will not apply to disclosures permitted by the HIPAA Privacy Rule where the only remuneration received is a reasonable cost-based fee to cover the cost to prepare and transmit the PHI, or is a fee otherwise expressly permitted by other law. This is referenced as the “general exception” in our discussion below.

(1) The costs included in a “reasonable cost-based fee”

The research exception and the “general exception” both permit remuneration2 “where the only remuneration received by the covered entity is a reasonable cost-based fee to cover the cost to prepare and transmit the [PHI] for such purposes.” Comments to the NRPM urged the OCR to adopt an expansive definition of a “reasonable cost-based fee” to allow organizations to recoup their investment and other indirect costs in the fees they charge for PHI used for research. Many organizations have invested a substantial amount of money in the creation and maintenance of their clinical data repositories, research databases, and biospecimen banks (most of which maintain associated clinical data), in order to be able to capture, store, manage and adequately protect PHI used for research. None of these costs are expressly contemplated by the proposed rule. In permitting others

2 “Remuneration” is not defined in the rule, although the common definition is payment or compensation. See http://www.merriam-webster.com/dictionary/remuneration. “Financial remuneration” is defined in the definition of “marketing” as “direct or indirect payment from or on behalf of a third party whose product or service is being described. Direct or indirect payment does not include any payment for treatment of an individual.” See proposed 45 C.F.R. § 164.501.
to utilize that PHI, organizations should be permitted to recoup this investment and all costs of managing those resources rather than be required to absorb these costs and operate potentially at a loss. Further, as noted below, the failure to permit recoupment of these costs for research-related infrastructure may be an unconstitutional confiscation of property.

More specifically, commenters urged the OCR to allow the inclusion of costs related to the following items:

- Equipment, such as server and storage hardware;
- Software licensing fees related to hardware and for applications related to the curation, maintenance and protection of the data;
- Staffing and internal and external consulting costs for individuals involved in the collection, curation, management and protection of data. This would include, for example, services related to management/supervision, data entry, programming, system administration, bioinformatics, de-identification of PHI or the creation of Limited Data Sets, quality control and quality assurance, legal, compliance, IRB review, diagnostic analysis (for biospecimens) and other research support functions;
- Overhead (including but not limited to power costs, special cooling requirements, rent/lease costs); and
- Other indirect costs associated with the creation and management of the data.

Permitting recoupment of a wide range of costs is essential to the continued use of electronic health infrastructures to facilitate the widespread sharing of research data. If organizations that deploy electronic health infrastructure are not permitted to recoup the costs of building and managing that infrastructure, those organizations will no longer make those resources available beyond their own institutions. Sharing of research data is essential to substantial progress in various collaborative, transformational research areas. As only one recent example, see Sharing of Data Leads to Progress on Alzheimer’s, New York Times (Aug. 12, 2010).

Both the private sector and the federal government support a wide range of research collaborations involving data sharing. A few examples include:

- The National Biomedical Imaging Archive (NBIA), a searchable, national repository hosted by the NCI that integrates in vivo cancer images with clinical and genomic data. NBIA provides the cancer research community, industry, and academia with public access to DICOM images, image markup, annotations, and rich metadata. This tool enables the development of imaging resources that lead to improved clinical decision support, accelerated decision-making and quantitative imaging assessment of drug response. NBIA provides Web-based access to de-identified DICOM images, markups, and annotations using role-based security. See https://cabig.nci.nih.gov/tools/NCIA. In addition to the NCI-hosted instance of NBIA, institutions can adapt NBIA for data storage by standing up an instance of NBIA at their institutions with assistance from caBIG® licensed service providers.
The NCI’s Cancer Genetics Network contains a “core dataset ... on each participant and contains information on sociodemographic characteristics, history of cancer and/ or premalignant conditions, cancer-relevant surgeries, four-generation cancer family pedigree, history of tobacco use, and expressed interest in genetic counseling. Data also are available on some participants who enrolled in special studies, such as on cancer-related outcomes, screening, counseling, and attitudes. Limited biospecimens include DNA samples from participants with early onset cancer, multiple cancers, and prostate cancer; and longitudinal blood samples on participants in ovarian and breast cancer studies.” See http://epi.grants.cancer.gov/CGN/. The Cancer Genetics Network is a national network of fourteen academic research centers that enroll individuals and families in the network, and provide a wide variety of research services and specialized expertise to assist investigators with approved studies. Id.

The NCI’s Clinical Trials Cooperative Group Program is designed to promote and support clinical trials “of new cancer treatments, explore methods of cancer prevention and early detection, and study quality-of-life issues and rehabilitation during and after treatment. Cooperative groups include researchers, cancer centers, and community physicians throughout the United States, Canada, and Europe. They work with NCI to identify important questions in cancer research and to design clinical trials to answer these questions. The Cooperative Group Program involves more than 3,100 institutions that contribute patients to group-conducted clinical trials.” See http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-trials-cooperative-group. The Cooperative Groups maintain patient registries and biospecimen repositories with participation by numerous partners, including health care providers and researchers from the pharmaceutical industry.

The Cancer Genome Atlas Project (TCGA), jointly sponsored by the NCI and the National Human Genome Research Institute (NHGRI), is a comprehensive and coordinated effort to accelerate the understanding of the molecular basis of cancer through the application of genome analysis technologies, including large-scale genome sequencing. The TCGA project is aggressively pursuing more than 20 types of cancer to yield a comprehensive, rigorous and publicly accessible data set that will improve the ability to diagnose, treat and prevent cancer. In order to systematically characterize the genomic changes that occur in cancer, translational genomic information with clinical data obtained for each subject enrolled in the study. Tissue Source Sites (TSS) supply the TCGA biospecimen core repositories with tumor specimens, matching normal tissue/ blood, and clinical data via Case Quality Control Forms, Case Report Forms (CRFs) and de-identified-coded pathology reports to the project. Limited Data Sets are a critical part of the clinical data that is collected in the CRFs.

The Quantitative Imaging Network (QIN) is a multi-site initiative “to improve the role of quantitative imaging for clinical decision making in oncology by the
development and validation of data acquisition, analysis methods, and tools to tailor treatment to individual patients and to predict or monitor the response to drug or radiation therapy.” The goals require multidisciplinary efforts, from oncologists, clinical and basic imaging scientists, and industrial partners, in the development and adaptation/implementation of quantitative imaging methods to aid cancer therapies. [https://wiki.nci.nih.gov/display/CIP/QIN](https://wiki.nci.nih.gov/display/CIP/QIN). Participating sites will collect phenotypic and diagnostic information from patients, “scrub” the data and load de-identified information and Limited Data Sets onto the network (including images).

It is good public policy to encourage research collaborations, as they frequently yield powerful and more efficient research results. Individual organizations and researchers frequently want to share data but need some benefit or incentive to contribute their data and research resources to engage in research collaborations. Collaboration is an important vehicle for conducting research today; the HIPAA regulations should not create an unnecessary barrier to data sharing that facilitates such collaboration.

Moreover, failing to permit these costs may be an unconstitutional taking of property. As discussed in detail in a paper authored by Barbara J. Evans at the University of Houston Health Law & Policy Institute, permitting organizations to recoup only their variable operating costs would be treated as “confiscatory” under traditional infrastructure rate law. Pulling from over a century of rate litigation involving other areas in which regulated industries are permitted to recoup reasonable cost-based fees, Professor Evans argues that the federal courts will require the OCR to recognize a variety of fees, including recovery of capital invested, fixed operating costs, and a fair rate of return on capital used to provide the services. As Professor Evans notes:

A variable-cost-only fee would be analogous to letting a railroad charge its passengers only for diesel fuel and wages paid to the engineer and conductors while the passenger actually was riding the train, but ignoring the capital costs of the train itself and the tracks on which it runs. In an 1890 railroad rate case, the Supreme Court noted that a “reasonable” charge involves an “element of reasonableness both as regards the company and as regards the public”:

> “If the company is deprived of the power of charging reasonable rates for the use of its property... it is deprived of the lawful use of its property and thus, in substance and effect, of the property itself, without due process of law and in violation of the Constitution of the United States; and in so far as it is thus deprived, while other persons are permitted to receive

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4 Id. at 18-19, citing CHARLES F. PHILLIPS, JR., THE REGULATION OF PUBLIC UTILITIES.
reasonable profits upon their invested capital, the company is deprived of the equal protection of the laws.”5

To conform to United States Supreme Court decisions related to regulation of a reasonable cost-based fee, Professor Evans persuasively argues that organizations should be permitted to recoup a wide range of costs:

A reasonable, cost-based fee for data provisioning can and indeed must include an allowance for recovery of the capital invested to create the underlying health information infrastructure, plus a reasonable rate of return on that invested capital. A data holder is in a position to respond to a request for data only because it previously invested to create the information systems from which the data are being drawn. If the data holder were limited to a price that shares the benefits of that capital investment with customers (in this case, the researchers) for free, that could amount to a taking of the data holder’s capital. Also, singling out health database operators for earnings restrictions that do not apply to investors in other types of databases (such as retail sales databases) could deny equal protection.6

As Professor Evans also notes, the task of allocating those costs among various research requests will be a daunting task for the OCR:

In addition to capital costs, database operators also have fixed operating costs that are not directly traceable to any specific data request but which nevertheless must be incurred to keep the system ready to respond. An example would be wages for the IT personnel who routinely keep the system operating and secure, even if they are not personally involved in responding to data requests. In many infrastructure industries, operating costs are the largest item that must be recovered in rates and these costs may include significant fixed-cost components that are not traceable to particular services the system provides. A reasonable cost-based fee for infrastructure services must include an allowance for recovery of fixed costs, but there is an obvious challenge in deciding how much of the shared costs each user should pay: “[W]here as here several classes of services have a common use of the same property, difficulties


6 Id. at 19.
of separation are obvious. Allocation of costs is not a matter for the slide-rule. It involves judgment on a myriad of facts. It has no claim to an exact science.”

In addition to expressly permitting the recoupment of the categories of costs noted above, commenters urged the OCR to establish a stakeholder consensus mechanism to gather input on what specific costs elements will be permitted, how those will be demonstrated or documented by the data holders, and how those costs will be allocated across research requests.

(2) Disclosure of research results

HIPAA covered entities frequently receive payment through contracts with or grants from the sponsors of research to participate in or to conduct a variety of research, including clinical trials, health services research, public health research and epidemiological studies, and comparative effectiveness research. Through these contracts or grants, organizations receive payment for the conduct of their services provided in the research project, and are required to communicate research results to the sponsor of the research (which results may contain PHI if permitted by the HIPAA Privacy Rule). Commenters expressed concern that the prohibition against the sale of PHI may be triggered upon disclosure of the research results unless they are expressly exempted.

For example, in clinical trials, sponsors pay health care providers for clinical trial activity (such as the administration of the investigational drug or device to the patient and associated monitoring), and this payment occurs upon submission of completed case report forms (CRFs), which capture the data related to patients participating in the trial. While the payment represents the fair market value for the services (not the data) provided by the health care provider in the clinical trial, the provider generally does not receive payment until it submits the data to the sponsor related to the patient’s progress in the clinical trial.

This issue will also arise in the context of research activities conducted under grants or contracts awarded by the federal government or private research funders. In fact, the failure to exempt the communication of research results threatens to compromise Congressional goals in the Patient Protection and Affordable Care Act of 2010 (PPACA), which demonstrates Congress’ commitment to increasing the use of HIT and the sharing of health information for comparative effectiveness and other research. Just a few examples of the research required or encouraged by the PPACA include:

- PPACA section 3501 provides funds for the Agency for Healthcare Research and Quality (AHRQ) Center for Quality Improvement and Patient Safety to support research related to innovative quality improvement practices. Section 4301 requires the Centers for Disease Control (CDC) to provide funding for research on evidence-based practices for prevention and strategies for public health services. Much of this

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7 Id. at 19-20, citing Colorado Interstate Gas Co. v. Federal Power Comm’n, 324 U.S. 581, 589 (1945).
research will center on the evaluation of patient populations across providers and plans, and the results likely will contain PHI (or Limited Data Sets).

- **PPACA section 6301** creates a nonprofit organization called the “Patient-Centered Outcomes Research Institute.” The Institute will provide funding to conduct comparative effectiveness research, develop clinical registries and health outcomes data networks, and to create an interoperable network to link data from multiple sources, including EHRs.

Because the fees received by providers in conducting research represent remuneration for the services provided (not the data provided), commenters urged the OCR to use its regulatory authority to exempt the disclosure of research results. The OCR has the regulatory authority to make this exception. Section 13405(d)(2)(G) of the HITECH Act provides authority to the OCR to make additional exceptions for disclosures of PHI that the OCR judges to be “similarly necessary and appropriate” as the other enumerated statutory exemptions to the sale of PHI.

(3) Effect on quality assurance/quality improvement activities

The proposed regulations do not currently contain an express exception for quality assurance or quality improvement (QA/QI) activities. Because many QA/QI activities will be collaborations among different organizations, and thus involve the exchange of health information, commenters urged the OCR to add such an exception under its authority under section 13405(d)(2)(G) of the HITECH Act to make additional exceptions for disclosures of PHI that the OCR judges to be “similarly necessary and appropriate” as the other enumerated statutory exceptions.

QA/QI activities will have an increasingly important role in the federal government’s efforts to improve the quality and efficiency of health care in this country. PPACA demonstrates Congress’ commitment to using health information for QA/QI purposes, which goals could be compromised by prohibiting direct or indirect remuneration in exchange for PHI in these projects. A few examples from PPACA include:

- **PPACA section 3011** requires HHS to create a strategy to utilize health care data to improve the quality, efficiency and transparency of patient outcomes. HIT and the study of electronic health information is expected to perform a central role in this strategy.

- **PPACA section 3002** extends the PQRI program, which provides financial incentives to physicians who report quality data to the Medicare program. By January 2012, HHS is required to develop a plan to integrate these quality reporting requirements into the regulations regarding payment incentives for “meaningful use” of EHRs. Receiving payments in exchange for reporting quality data likely would be considered financial remuneration if not exempted.
PPACA section 3022 creates Accountable Care Organizations, which will promote evidence-based medicine, report on quality and cost measures, and coordinate care across different legal entities. Many of these efforts will depend on the use of HIT and the exchange of electronic health information to coordinate activities among various parties. Any exchange of payment or indirect benefit between these parties could trigger the prohibition against the “sale” of PHI if these activities are not exempted.

Moreover, to the extent that QA/QI activities are permitted by the “general exception,” which exempts disclosures permitted by the HIPAA Privacy Rule where the only remuneration received is a reasonable cost-based fee to cover the cost to prepare and transmit the PHI, or is a fee otherwise expressly permitted by other law, commenters urged the OCR to treat it similarly to research. In the Preamble to the proposed rule, the OCR explains that this particular exception would be limited to the “actual cost incurred to prepare, produce, or transmit” the PHI, unless a state or other law sets forth a specific fee for the type of disclosure. See 75 Fed. Reg. at 40892. As with the research exception, organizations should be permitted to recoup investment and other indirect costs.

(4) Receipt of “indirect remuneration”

The OCR proposes to require a covered entity to obtain an authorization “for any disclosure of [PHI] for which the disclosure is in exchange for direct or indirect remuneration from or on behalf of the recipient of the [PHI].” See proposed 45 C.F.R. § 164.508(4). While the regulations do not define “remuneration” or “indirect remuneration,” under the Stark Law8 indirect remuneration includes any benefit received, even if it is a nonfinancial benefit.9

The OCR’s interpretation that the HITECH Act prohibits “indirect remuneration” could pose a substantial problem for collaborative research and QA/QI activities. For example, many hospitals and academic medical centers participate in research (or QA/QI) collaborations, in which they contribute their PHI to a centralized, secure database to create aggregated data sets that do not display any individually identifiable information. Even if the organization is not paid for its data contributed to the research database, contributing data may provide the organization a number of nonfinancial benefits, including:

- The ability to utilize the aggregated information for research;
- Access to a valuable research or QA/QI tool;
- Being listed as an author on publications resulting from the use of the research data;
- Reimbursement of travel expenses for meetings related to the data collaboration; or
- Other nonfinancial benefits.

Prohibiting the receipt of these non-financial benefits for contributing data to collaborative research and QA/QI activities would undermine many other HHS efforts to encourage data

9 42 C.F.R. § 411.354(a)(2).
sharing and research collaborations. (See sections above on exemptions for disclosure of research results and for QA/QI activities, for an example of these data sharing and research collaborations.)

Thankfully, the HITECH Act does not require this prohibition against indirect remuneration. The statute provides that a covered entity or business associates shall not “directly or indirectly receive remuneration in exchange” for PHI; in the statute, “direct or indirect” modifies the receipt of remuneration. In contrast, the proposed regulation prohibits “direct or indirect remuneration,” where “direct or indirect” modifies remuneration, and which thus could be interpreted as prohibiting the receipt of non-financial benefits.

The OCR could interpret the remuneration prohibited by the statute as limited to financial remuneration. The intent of the statute clearly is to prohibit payment, as the title of the statute reflects the prohibition against the “sale” of PHI and all of the legislative history indicates a similar concern. The legislative history does not reflect any concern with the receipt of non-financial benefit. Moreover, the statutory exception for research demonstrates that only financial remuneration is contemplated, as it permits a reasonable cost-based fee to cover the cost to prepare and transmit the PHI, and that concept is not applicable to the receipt of non-financial benefit. The OCR intended to follow the statutory language and intent, and incorrectly cited the statute as prohibiting direct or indirect remuneration, rather than direct or indirect receipt of remuneration. See 75 Fed. Reg. at 40891.

Even if the OCR does not exempt indirect remuneration from the rule as a whole, commenters urged the OCR at least to limit the fee cap in both the research and general exceptions (which limit the remuneration to a reasonable cost-based fee to cover the cost to prepare and transmit the PHI) to any financial remuneration received, and to expressly exempt indirect remuneration in these exceptions. The OCR has the regulatory authority to make this exception. Section 13405(d)(2)(G) of the HITECH Act provides authority to the OCR to make additional exceptions for disclosures of PHI that the OCR judges to be “similarly necessary and appropriate” as the other enumerated statutory regulations.

(5) Limited Data Sets and the prohibition on remuneration

The OCR proposes that the exception for research and public health activities should apply to disclosures of Limited Data Sets (LDS) under 45 C.F.R. § 164.514(e). See 75 Fed. Reg. at 40891. The inclusion of LDS was not required by the statute, and the OCR explained that it added LDS to these exceptions “to ensure that a covered entity or business

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10 See ARRA Conference Report, House Report No. 111-16 (Feb. 12, 2009) (explaining that section 13405 of the conference agreement was to require regulations to govern the “sale” of PHI); House Report No. 11-7(1) (Jan. 26, 2009) (explaining that the parallel section in the original House bill was to clarify that the “sale” of PHI would not be permitted); Senate Report 111-3 (Jan. 27, 2009) (same).

11 A Limited Data Set is mostly de-identified data, but which may include dates related to an individual and geographic designations above street level. 45 C.F.R. § 164.514(e).
associate that discloses [PHI] ....in limited data set form is also excepted from the authorization requirement. We believe it is consistent with the statutory language to also except the disclosure of a limited data set where Congress has already excepted the disclosure of fully identifiable [PHI] for the same purpose from the remuneration prohibition.” See 75 Fed. Reg. at 40891.

Commenters urged the OCR to exempt LDS from the prohibition on receipt of remuneration entirely. The HIPAA Privacy Rule already limits the purposes for which LDS may be disclosed for research, public health and health care operations. See 45 C.F.R. § 164.514(e). More importantly, the Privacy Rule requires the recipient of an LDS to sign a Data Use Agreement, under which the recipient must agree to use the LDS only for the purpose permitted by the Data Use Agreement, to report to the covered entity any other use or disclosure of the LDS, not to use the LDS to identify individuals, and to require its agents to follow the same restrictions. Id. These provisions provide substantial protection against inappropriate use of LDS, and the OCR should exclude LDS from the prohibition against receipt of remuneration. Section 13405(d)(2)(G) of the HITECH Act provides authority to the OCR to make additional exceptions for disclosures of PHI that the OCR judges to be “similarly necessary and appropriate” as the other enumerated statutory exceptions.

(6) Disclosure of PHI to business associates

The OCR proposes an exception permitting disclosure of PHI “[t]o or by a business associate for activities that the business associate undertakes on behalf of a covered entity pursuant to §§ 164.502(e) and 164.504(e), and the only remuneration provided is by the covered entity to the business associate for the performance of such activities.” See proposed 45 C.F.R. § 164.508(4). The intent of this provision apparently is to prevent a third party from paying a business associate for activities performed for a covered entity, in essence creating an indirect payment to the covered entity. In its explanation in the Preamble, the OCR states: “This proposed exception would exempt from the authorization requirement... a disclosure of [PHI] by a covered entity to a business associate or by a business associate to a third party on behalf of the covered entity, as long as any remuneration received by the business associate was for payment for the activities performed by the business associate pursuant to a business associate contract.” See 75 Fed. Reg. at 40891 (emphasis added). Commenters urged the OCR to clarify that the regulation prohibits a business associate from receiving remuneration from a third party for activities on behalf of a covered entity, but does not prohibit a covered entity from receiving remuneration from the business associate (particularly if “remuneration” includes non-financial benefit, as discussed above). Commenters also urged the OCR to clarify that disclosures of PHI (and payment) by a business associate to its subcontractors to perform services on behalf of the business associate for the covered entity.

(7) Grandfathering existing research

The proposed rule does not include a transition provision for existing research studies. In the original HIPAA Privacy Rule, the OCR included the following transition provision at 45 C.F.R. § 164.532:
Notwithstanding any provisions in §§164.508 and 164.512(i), a covered entity may, to the extent allowed by one of the following permissions, use or disclose, for research, protected health information that it created or received either before or after the applicable compliance date of this subpart, provided that there is no agreed-to restriction in accordance with §164.522(a), and the covered entity has obtained, prior to the applicable compliance date, either:

(1) An authorization or other express legal permission from an individual to use or disclose protected health information for the research;
(2) The informed consent of the individual to participate in the research; or
(3) A waiver, by an IRB, of informed consent for the research, in accordance with 7 CFR 1c.116(d), 10 CFR 745.116(d), 14 CFR 1230.116(d), 15 CFR 27.116(d), 16 CFR 1028.116(d), 21 CFR 50.24, 22 CFR 225.116(d), 24 CFR 60.116(d), 28 CFR 46.116(d), 32 CFR 219.116(d), 34 CFR 97.116(d), 38 CFR 16.116(d), 40 CFR 26.116(d), 45 CFR 46.116(d), 45 CFR 690.116(d), or 49 CFR 11.116(d), provided that a covered entity must obtain authorization in accordance with §164.508 if, after the compliance date, informed consent is sought from an individual participating in the research.

Commenters urged the OCR to adopt the same transition provision apply to the new regulation prohibiting the sale of PHI.

B. Authorizations for Research

The HIPAA Privacy Rule currently poses two problems for research that involves storage of PHI (such as in biospecimen or data repositories): the prohibition against compound authorizations and the prohibition against seeking authorization for use of PHI for future unspecified research. OCR proposes to fix these problems.

(1) Compound authorizations

Currently, if a research participant is participating in a clinical trial and a research repository, the HIPAA authorizations for those activities must be separate. This is because

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12 See HHS, Research Repositories, Databases, and the HIPAA Privacy Rule (NIH July 2004), available at http://privacyruleandresearch.nih.gov/pdf/research_repositories_final.pdf, at 6 (“May a single Authorization permit a covered entity to use or disclose PHI for multiple activities of a specific research study, including the collection and storage of tissues for only that study? Does the option for using a single Authorization differ if a research study also collects and stores PHI as part of a central repository for future research? A: A single Authorization may cover uses and disclosures of PHI for multiple
the HIPAA Privacy Rule permits a HIPAA covered entity to require an individual to sign a HIPAA authorization as a condition of receiving treatment in a clinical trial; however, the OCR has concluded that a covered entity may not condition treatment received in a clinical trial on signing a HIPAA authorization to include PHI in a research repository if that PHI will be used for purposes other than the specific clinical trial. The HIPAA problem is created because the current Privacy Rule prohibits combining authorizations for separate research activities into a “compound authorization,” where the individual is required to sign one authorization but not the other. Having to separate these HIPAA authorizations often causes research participant (and researcher) confusion.

In the NPRM, the OCR acknowledges that the research community has expressed concern about this lack of integration and proposes to fix this prohibition against compound authorizations in research by amending § 164.508(b)(3) as follows:

An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same or another research study. This exception includes combining an

activities of a specific research study, including the collection and storage of tissues for that study. In addition, where two different research studies are involved, such as where a research study collects information for the study itself, and collects and stores PHI in a central repository for future research, the Privacy Rule generally would permit them to be combined into a single, compound Authorization form. However, a compound Authorization is not allowed where the provision of research-related treatment, payment, or eligibility for benefits is conditioned on only one of the Authorizations, and not the other. See section 164.508(b)(3)(iii) of the Privacy Rule. For example, a covered entity that conducts an interventional clinical trial that also involves collecting tissues and associated PHI for storage in a central repository for future research would not be permitted to obtain a compound Authorization for both research purposes if research-related treatment is conditioned upon signing the Authorization for the clinical trial. Any compound Authorization must clearly specify the different research studies covered by the Authorization so the individual is adequately informed.

13 See 45 C.F.R. § 164.508(b)(4) (permitting a covered entity to condition participation in a clinical trial on signing an authorization to use or disclose the individual’s PHI for the clinical trial).
14 See HHS, Research Repositories, at 6.
15 See 45 C.F.R. § 164.508(b)(3) (“An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows: (i) An authorization for use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of protected health information for such research or a consent to participate in such research.”) (emphasis added). See also 67 Fed. Reg. 53231, Aug. 14, 2002 (“Under the Common Rule, [OHRP] has interpreted the definition of “research” to include the development of a repository or database for future research purposes. See also http://ohrp.osorhp.HHS.gov/humansubjects/guidance/reposit.htm (“[HHS] interprets the definition of “research” in the Privacy Rule to be consistent with what is considered research under the Common Rule. Thus, the development of research repositories and databases for future research are considered research for the purposes of the Privacy Rule.”).
authorization for the use or disclosure of protected health information for a research study with another authorization for the same research study, with an authorization for the creation or maintenance of a research database or repository, or with a consent to participate in research. Where a covered health care provider has conditioned the provision of research-related treatment on the provision of one of the authorizations, as permitted under paragraph (b)(4)(i) of this section, any compound authorization created under this paragraph must clearly differentiate between the conditioned and unconditioned components and provide the individual with an opportunity to opt in to the research activities described in the unconditioned authorization. See 75 Fed. Reg. at 40892-93.

This new requirement could be implemented through a variety of ways, including describing the “unconditioned research” (i.e. the repository) on a separate page of the authorization, by using a separate check-box for the unconditioned research, or distinct signature lines. Id. The OCR requested comments on “additional methods that would clearly differentiate to the individual the conditioned and unconditioned research activities on the compound authorization.” Id.

Commenters supported permitting compound authorizations for participation in clinical trials and research repositories, and urged the OCR to allow organizations to decide whether an “opt-in” or “opt-out” process should be required for a particular study, as long as the research participant clearly understands that he or she is not required to participate in the unconditioned research. This recommendation was based on experience with implementing an opt-in process in collecting biospecimens for a research repository: one of the commenting organizations sent specimen collection kits to participants’ homes, who were instructed to check a box if they agreed to participate in the study. Many participants sent back specimens and signed informed consents, but did not check the boxes, requiring the organization to recontact the individuals to gain permission to utilize the specimens collected. On the other hand, organizations that have implemented an opt-out provision find that individuals concerned with the use of their health information or specimens are keen to understand how to opt-out of that use. Whether an opt-in or opt-out is more appropriate for a particular study and a particular population should be left to a reviewing Institutional Review Board, which will apply knowledge of the local population to protect individuals in its community.

(2) Authorizations to seek permission for use of PHI for future research

The second HIPAA authorization problem for research repositories is that the OCR has interpreted the HIPAA Privacy Rule as requiring an authorization to be study specific, because the rule states that an authorization must describe each purpose of the requested use or disclosure.16 In the research repository context, an authorization thus may not seek

permission to use or disclose PHI for future unspecified research, but may only seek permission to store PHI in the repository.\textsuperscript{17} This interpretation conflicts with the Common Rule, which permits an informed consent document to seek consent to use a subject’s information in future research as long as the future research is described in enough detail to allow informed consent.\textsuperscript{18} This has caused a disconnect between the content of the informed consent document and HIPAA authorization form, again causing much confusion in the research setting.

The research community recognizes that this limitation should be changed. In its recent report regarding the HIPAA Privacy Rule and its impact on research, the Institute of Medicine recommended that HHS change its interpretation of this rule. See http://www.nap.edu/previewwidget.php?record_id=12458&wid=682312011320090608182255.

The OCR recognizes this problem, as well, but has not yet proposed new language (or a new interpretation of the existing language). Instead, the OCR solicited public comment on whether to modify its interpretation and is considering a number of options, including: (1) permitting an authorization to seek permission for future research, if adequately described; (2) permitting authorization for future research, with certain required elements or statements (and what those should be); or (3) permitting an authorization for future research, with limits on sensitive research areas, such as genetic or mental health research. See 75 Fed. Reg. at 40893-94.

Commenters supported the OCR’s effort to ensure consistency between the HIPAA Privacy Rule and the Common Rule, to avoid the current disconnect between the content of informed consent documents under the Common Rule and HIPAA authorization in research. Inconsistencies between these documents create difficulty in designing consent forms that participants can understand, increase recruiting cost and time, cause delays in IRB approval, and cause selection bias in participants.

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\textsuperscript{17} See HHS, “Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule” (at http://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf). In this document at page 11, HHS states: “A valid Privacy Rule Authorization is an individual’s signed permission that allows a covered entity to use or disclose the individual’s PHI for the purposes, and to the recipient or recipients, as stated in the Authorization. When an Authorization is obtained for research purposes, the Privacy Rule requires that it pertain only to a specific research study, not to nonspecific research or to future, unspecified projects. The Privacy Rule considers the creation and maintenance of a research repository or database as a specific research activity, but the subsequent use or disclosure by a covered entity of information from the database for a specific research study will require separate Authorization, unless the PHI use or disclosure is permitted without Authorization (discussed later in this section). If an Authorization for research is obtained, the actual uses and disclosures made must be consistent with what is stated in the Authorization. The signed Authorization must be retained by the covered entity for 6 years from the date of creation or the date it was last in effect, whichever is later.” (Emphasis added)

Commenters also suggested that option (1) above is most beneficial to encourage research in the US; that is, permitting an informed consent/authorization to seek permission for use of PHI for future research, as long as the informed consent/authorization is clear to individuals about what research they are agreeing to participate. Many research repositories (whether they are patient registries collecting information about particular diseases or biorepositories collecting biospecimens for research) are intended to support a wide array of research over a long period of time, and it will be problematic to attempt to describe the particular types of research that will be conducted with that information. As long as the informed consent/authorization is clear and an individual understands the scope of the permission granted, the OCR need not further regulate the scope of that permission.

Commenters also cautioned the OCR against requiring specific required elements or statements in the authorization, as that approach tends to generate template language that is not tailored to particular research and which may not match the reading level required in informed consent documents. Most commenters did not support the third approach above, to permit an authorization for future research but with limits on sensitive research areas, such as genetic or mental health research. Most research now involves some genetic analysis, and so restrictions on the authorization for this type of research will necessarily impact most research conducted.

In summary, it is clearly within the province of an IRB to protect research participants and to ensure that an informed consent document/HIPAA authorization is specific enough so that consent to participate in research is “informed.” Hopefully, the OCR will defer to the substantial body of expertise regarding the ethical conduct of research, which charges IRBs with making precisely these types of determinations to protect research participants.

C. Business Associate Agreements in Research

In its guidance on how the HIPAA Privacy Rule applies to research, HHS has explained that a business associate agreement between a covered entity and a third party in research is required where the third party performs de-identification services for the covered entity or creates a Limited Data Set on behalf of the covered entity to use for research, because de-identification and the creation of a Limited Data Set are health care operations under HIPAA. However, because research is itself not a function or activity

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19 See HHS, Clinical Research and the HIPAA Privacy Rule, at http://privacyruleandresearch.nih.gov/pdf/clin_research.pdf ("Q: Does a covered entity need an individual’s Authorization before de-identifying the PHI or creating a limited data set? A: No. The Privacy Rule does not require a covered entity to obtain an individual’s Authorization before using or disclosing the PHI for creating de-identified health information or a limited data set. The Privacy Rule considers such activity to be a health care operation, as defined at section 164.501, of the covered entity. As such, a covered entity could contract with a business associate, including a researcher, to create de-identified data or a limited data set."); ("Q: I am a researcher, and my research data source
that is regulated under HIPAA (which is limited to the conduct of treatment, payment and health care operations functions),20 the disclosure of PHI for research, including research support services, does not require a business associate agreement.21 Many covered entities is asking me to sign a business associate agreement. Is this necessary? A: Business associates are persons who perform certain services for, or functions or activities on behalf of, the covered entity that require access to PHI, but who are not part of the workforce of the covered entity. If the data source is not a covered entity, no business associate contract is required because the Privacy Rule only applies to covered entities. If the data source is a covered entity, whether a business associate contract is required depends on the services, functions, or activities that the researcher is providing to, or performing for, the covered entity. Researchers are not business associates solely by virtue of their own research activities (although they may become business associates in some other capacity, e.g., if de-identifying PHI on behalf of a covered entity). A business associate agreement will typically be a legally enforceable contract, so a researcher may wish to consult legal counsel before signing one.”

See also HHS, Research Repositories, Databases, and the HIPAA Privacy Rule (NIH July 2004), available at http://privacyruleandresearch.nih.gov/pdf/research_repositories_final.pdf (“Q: Does the Privacy Rule permit a covered entity to de-identify health information or create a limited data set without obtaining Authorization, waiver of the Authorization requirement from an IRB or Privacy Board, or representations for reviews preparatory to research? A: Yes. In the Privacy Rule, creating de-identified health information or a limited data set is a health care operation of the covered entity, and thus, does not require the covered entity to obtain an individual’s Authorization, a waiver of the Authorization requirement, or representations for reviews preparatory to research. If a business associate is hired by a covered entity to de-identify health information or create a limited data set, such activity must be conducted in accordance with the business associate requirements at sections 164.502(e) and 164.504(e).”); (“Q: I am a researcher, and my research data source is asking me to sign a business associate agreement. Is this necessary? A: Business associates are persons who perform certain services for, or functions or activities on behalf of, the covered entity that require access to PHI, but who are not part of the workforce of the covered entity. If the data source is not a covered entity, no business associate contract is required because the Privacy Rule only applies to covered entities. If the data source is a covered entity, whether a business associate contract is required depends on the services, functions, or activities that the researcher is providing to or performing for the covered entity. Researchers are not business associates solely by virtue of their own research activities (although they may become business associates in some other capacity, e.g., if de-identifying PHI on behalf of a covered entity). A business associate agreement will typically be a legally enforceable contract, so a researcher may wish to consult legal counsel before signing one.”).

20 67 Fed. Reg at 53252 (August 14, 2002) (explaining that, because research is not a “covered function or activity” “disclosures from a covered entity to a researcher for research purposes as permitted by the Rule do not require a business associate contract”).

21 See 45 C.F.R. § 160.103 (defining business associate as: “(1) Except as provided in paragraph (2) of this definition, business associate means, with respect to a covered entity, a person who: (i) On behalf of such covered entity or of an organized health care arrangement (as defined in §164.501 of this sub-chapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of: (A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or (B) Any other function or activity regulated by this sub-chapter; or (ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in §164.501 of this sub-chapter), management, administrative, accreditation, or financial services to or for such covered
are not aware of this distinction, and thus seek business associate agreements in the research arena. Because the HIPAA rules will apply to organizations and individuals that sign business associate agreements (which will be enforceable by the OCR as of the enforcement date of the final regulations), the implications for organizations providing research support services is substantial. Commenters to the proposed rule suggested that the OCR take this opportunity to reflect this limitation in the definition of business associate.

OCR was also urged to clarify that its incorporation of “data transmission services” as triggering a business associate agreement does not apply to research. Section 13408 of the HITECH Act (codified at 42 U.S.C. § 17938) provides that certain entities are business associates if they transmit PHI to a covered entity and require access to PHI on a routine basis, including Health Information Exchange Organizations, Regional Health Information Organizations, e-prescribing gateways, or vendors that contract with a covered entity to allow that covered entity to offer a personal health record to patients as part of its EHR. The OCR implements this requirement by providing that a Health Information Organization (“HIO”), e-prescribing gateway or other person that provides “data transmission services” to covered entities are business associates if they transmit PHI to a covered entity and require access to that PHI on a routine basis. To the extent that an organization transmits PHI to a covered entity (say, to a shared research repository housed by a covered entity), the language may be broad enough to include the exchange of PHI for research as “data transmission services.” Because the regulations are not intended to regulate research as a covered function (see above), a clarification that this definition does not apply in the research context would be helpful.