

# Secondary Uses of Biologic Materials and Medical Data by Researchers and Commercial Research Sponsors

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# Agenda

- Overview of the Issues
- Informed Consent to Future Uses
- Commercialization of Data/Materials
  - Subjects' Rights in Data/Materials (Recent Cases)
  - Ability to Obtain a Waiver of Subjects' Rights
- How HIPAA Changes the Analysis
- The Impact on Research Contracts
- Research Involving Genetic Testing
- Future Research Uses of Data/Materials Collected During Standard of Care

# Databases and Tissue Banks

- Many HIPAA-covered entities maintain databases into which patient information is placed, processed, stored
- Databases are often created not for a specific research project but as resources for future research
- Tissue banks containing patient material with identifiable patient data are similarly created and maintained

# Databases and Tissue Banks

- Use of patient information and materials maintained in databases and tissue banks raises patient privacy and property rights concerns
- Specific concern is secondary uses of patient information and materials by:
  - Researchers who collected the data/tissues in primary study
  - Commercial or other research sponsors to which data/tissues have been given during the course of primary research

# What Might Govern?

- Clinical Trial Agreements
- HIPAA
- Common Rule
- FDA Regulations
- Voluntary Accreditation Standards for IRBs
- State Laws and Litigation
- Publication Requirements (ICMJE standards)
- Industry Codes (PhRMA)
- Ethical Obligations

# Differing Laws Govern Researchers and Sponsors Conducting Research



	<b>Common Rule 45 CFR Part 46</b>	<b>FDA regulations in study to be used in FDA application, or studies under IND or IDE</b>	<b>FDA regulations (21 CFR Parts 50 and 56) in study not to be used in FDA application</b>	<b>State laws (e.g., research, genetic testing, medical confidentiality, HIV/AIDS)</b>	<b>HIPAA</b>
<b>Researchers</b>	Yes, if FWA signed	Yes	No, but compliance occurs anyway, due to adherence to FWA and GCP	Likely yes, since most clinical researchers are health care providers	Yes
<b>Commercial Research Sponsors</b>	No	Yes	No	Possibly, depending on what entities are covered by each state law	No

# Issues Facing Institutions, Researchers, IRBs and Sponsors

- Should secondary uses of data and tissues collected during a research study be permitted?
- If allowed, should the practice be reserved for researchers subject to IRB and institutional control?
  - What about commercial research sponsors (falls outside of continuing IRB oversight)?
- What contractual constraints should be imposed on sponsors relating to their secondary uses?
- To what extent may or should subjects in the primary study consent to these secondary uses and authorize the use of their protected health information for this purpose?

# Issues Facing Institutions, Researchers, IRBs and Sponsors

- Specific problems presented by state *genetic testing laws*:
  - State genetic testing laws may apply in addition to other federal and state research and privacy laws
  - Many of these state laws are not specifically geared at research involving genetic testing; however, they often do not contain exceptions broad enough to exempt all research from their applicability
  - Researchers, IRBs and sponsors must consider whether any consent to future uses of biologic materials has been obtained in accordance with all applicable state genetic testing laws if any future genetic testing will be performed

# Informed Consent to Future Uses

- Pre-HIPAA: concern existed over whether it is legal and/or ethical to ask subjects in a primary research study to consent to future research uses of their data or biologic materials collected in the course of the study
- IRB could determine that consent obtained at time of tissue/data collection was sufficiently broad to encompass the proposed future use
- But dilemma facing IRBs is that consents must not be so broadly drafted that they do not give subjects real notice of the study and its limits

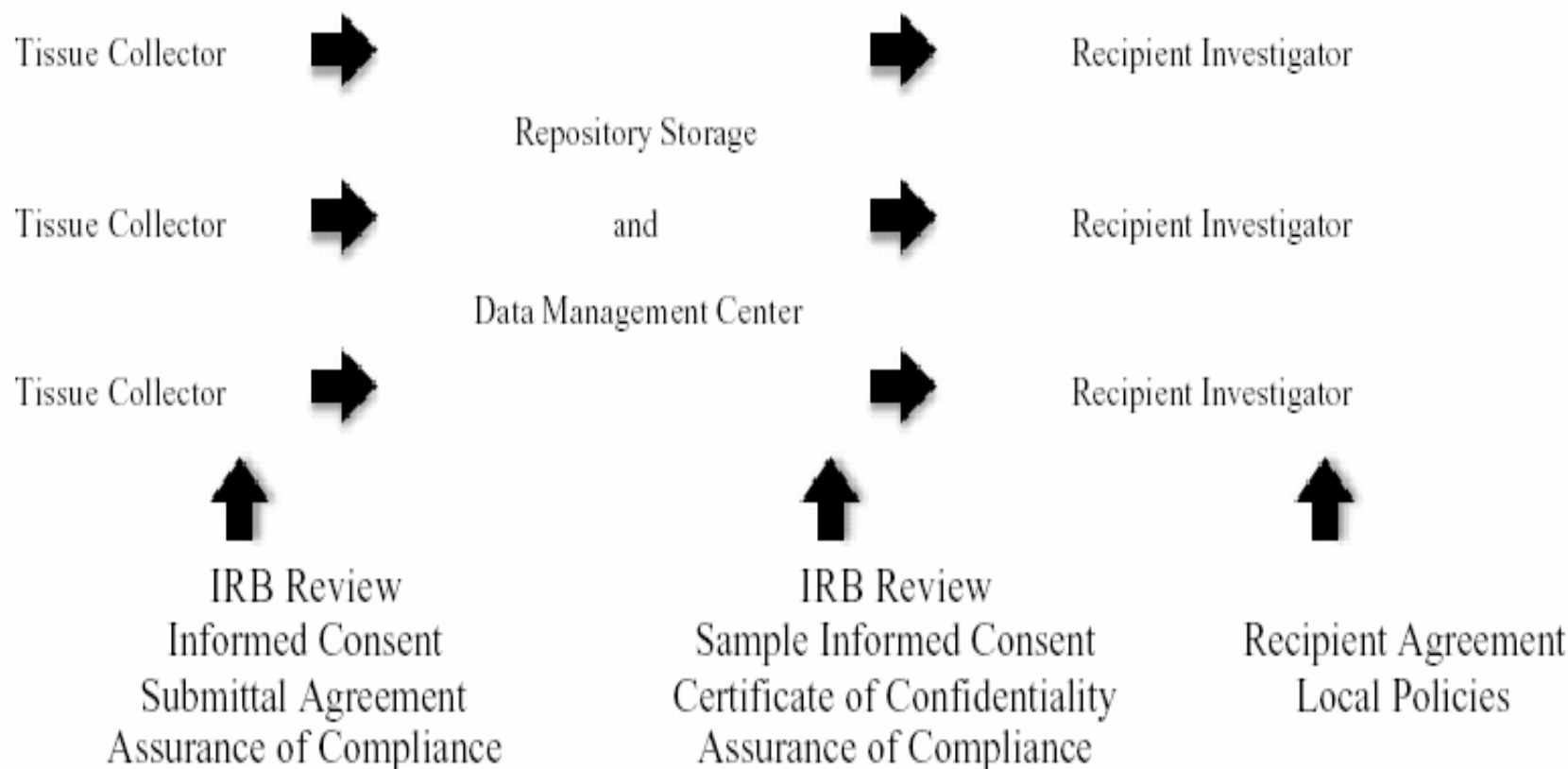
# Informed Consent to Future Uses

- Two Opposed Ethical Arguments:
  - Subjects cannot agree to a future research project about which they have not been, and cannot be, informed
  - Subjects should be permitted to “donate” their own data/materials for future uses

# Informed Consent to Future Uses

- OPRR (OHRP) Guidance for IRB Review of Consent for a Collection Study:
  - Informed consent should include a clear description of:
    - the operation of the repository;
    - the specific types of research to be conducted;
    - the conditions under which data and specimens will be released to recipient-investigators; and
    - procedures for protecting the privacy of subjects and maintaining the confidentiality of data
  - Informed consent information describing the nature and purposes of the research should be as specific as possible.
  - Where human genetic research is anticipated, informed consent information should include information about the consequences of DNA typing (e.g., possible paternity determinations)

# Research Regulations: Informed Consent and IRB Review: OHRP Guidance



Source: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/reposit.htm>

# Informed Consent to Future Uses

- Key Questions for IRB to Consider:
  - Is it appropriate for an IRB to approve a consent form for a study that is vague or broad with respect to possible future uses by a sponsor or researchers?
    - IRB may not have enough information adequately to assess risks to subjects, or that information may not be adequately conveyed in the ICF
    - IRB could approve a collection protocol that contemplates unspecified future uses by institution's investigators (if subject is so informed), but new IRB review (and consent or waiver) would be required before initiating any such future research
  - Can researchers seek on behalf of sponsors a consent broader than the consent that researchers could legally seek for themselves?

# Informed Consent to Future Uses

- Key Questions for IRB to Consider (cont.):
  - Is the proposed use of the data or identified biologic material consistent with the subject's likely understanding of how it would be used under the terms of the consent form?
  - What constitutes a new or different study as opposed to "future" uses that are really part of the primary research study?
  - Who will have access to the information for future research purposes?
  - What identifiers will remain associated with the data/materials? What coding will be done?

# Informed Consent to Future Uses

- Key Questions for IRB to Consider (cont.):
  - How will abuses of the identified information be prevented?
  - What limits (e.g., time or purpose) are being placed on the future uses? (e.g., California law limits on duration of authorization)
  - Do subjects have the ability to revoke their consent to future uses and, if so, will their data/materials be expunged from the databank?
  - How do subjects revoke their consent?

# Informed Consent to Future Uses

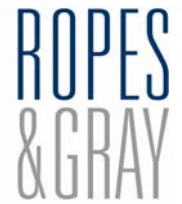
- NCI, together with the National Action Plan on Breast Cancer, developed a model ICF to request consent for future unspecified research use of specimens collected during routine medical care (<http://cancerdiagnosis.nci.nih.gov/specimens/model.html>)
- ICF allows the patient to check “yes” or “no” for each of 3 options:
  - My tissue may be kept for use in research to learn about, prevent, or treat cancer.
  - My tissue may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).
  - Someone from XYZ may contact me in the future to ask me to take part in more research.
- Some oncology groups and others use this form in research interactions in addition to routine care interactions
- However, even if OHRP deferred to or adopted this approach, private research sponsors would not be bound by it, and likely would not agree to it

# Commercialization of Data/Materials: Who Has Ownership and Control?



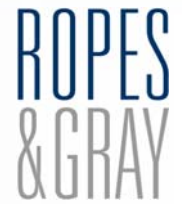
- Related to Consent Issue: is it ethical or legal for researchers, research institutions or commercial research sponsors to use the informed consent form as a vehicle for securing a *waiver of subjects' rights* in the future commercialization of data/materials collected during a research study (e.g., through the patenting of the results of the research, etc.)

# Commercialization of Data/Materials: Who Has Ownership and Control?



- Presently unclear what rights patients or research subjects have in their medical data and biologic materials
- 1987 Study by Office of Technology Assessment
  - Reviewed available legal, ethical and scientific literature
  - Concluded no clear answer to questions of who owns/controls this data/materials
  - Argument that the value of data/materials is derived from the contributions made by researchers (standing alone, very little commercial value)
- FDA, OHRP, and some recent cases have addressed these issues

# Commercialization of Data/Materials: Who Has Ownership and Control?

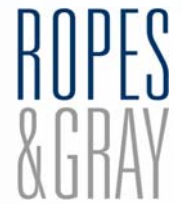


- FDA and HHS regulations prohibit the inclusion in the consent form of exculpatory language through which the subject waives, or appears to waive, any of the subject's legal rights or releases, or appears to release, the investigator, sponsor, or institution from liability for negligence
  - 1996 Guidance (OPRR/OHRP)
  - FDA Information Sheet and Q&A

# Commercialization of Data/Materials: Who Has Ownership and Control?

- 1996 OPRR (OHRP) Guidance
  - Exculpatory Language (unacceptable):
    - By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances.
    - I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
    - By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
  - Acceptable Language
    - Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
    - By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.

# Commercialization of Data/Materials: Who Has Ownership and Control?



- FDA Information Sheet Q&A (1998)
  - Q: Is it acceptable for the consent document to say specimens are “donated”?
  - A: It would be acceptable for the consent to say that specimens are to be used for research purposes. However, the word “donation” implies abandonment of rights to the “property.” 21 C.F.R. 50.20 prohibits requiring subjects to waive or appear to waive any rights as a condition for participation in the study.

# Commercialization of Data/Materials: Who Has Ownership and Control?

- 1989 Letter from OPRR (OHRP) Director, Division of Compliance to University of California in response to question regarding subject waiver of his/her rights to materials collected in study
  - Acknowledges that regulations prohibit inclusion of language in consent form waiving rights
  - BUT “regulations are not intended to prohibit the informed subject from making a legitimate donation of his or her” material
  - “Therefore, an individual human subject of research may waive his or her rights, if any, in the commercial development of biological materials, or any products of biologic derived using them, taken from the subject in the course of a research activity conducted or supported by the Department of Health and Human Services and approved and conducted in accord with 45 CFR 46.”

# Commercialization of Data/Materials: Who Has Ownership and Control?

- Greenberg v. Miami Children's Hospital
  - Plaintiffs are group of individuals who provided genetic material for medical research into Canavan's Disease
  - Researcher and research institution subsequently obtained patent on the results of the genetic research (obtained from using plaintiffs' genetic material) without the knowledge or consent of plaintiffs
  - Southern District of Florida decided May 29, 2003 that plaintiffs may move forward on unjust enrichment claim against researcher and research institution

# Commercialization of Data/Materials: Who Has Ownership and Control?

- Greenberg (cont.)
  - *Unjust Enrichment Claim:*
    - Complaint alleged more than just donor-donee relationship
    - Plaintiffs claimed that they would not have provided their genetic material to help isolate the gene for the disease if they had been informed in advance of defendants' goal of financial gain from research
    - Informed consent form allegedly had failed to discuss financial interest of researcher or research institution

# Commercialization of Data/Materials: Who Has Ownership and Control?



- Parties reached confidential settlement (effective August 6, 2003):
  - Miami Children’s Hospital can continue to license and collect royalty fees for clinical testing for the relevant gene mutation
  - Permits royalty-free research by institutions, doctors and scientists searching for a cure for the disease
  - Plaintiffs agreed not to further challenge Miami Children’s Hospital ownership and licensing of gene patent

# Commercialization of Data/Materials: Who Has Ownership and Control?

- Lessons from Greenberg (notwithstanding settlement):
  - Elaborates principle set forth in Moore v. Regents (CA 1990) that unconsented research uses of human tissue to develop commercial products from which contributors of the tissue will not benefit can give rise to a cause of action against the developer of the commercial products
    - In Moore, cause of action recognized was for breach of fiduciary duty/lack of informed consent
  - Potential ramifications of Greenberg for secondary uses of tissue and data that have been collected in bona fide research study
  - Informed consent form needs to be sufficiently detailed regarding potential future uses/commercialization in order to avoid such a claim
    - Question remains whether that is permissible under federal law

# Commercialization of Data/Materials: Who Has Ownership and Control?

- Washington University v. Catalona
  - Complaint filed by Wash U. (8/4/03) against researcher formerly affiliated with institution
  - Alleged improper assertion of ownership rights in a tissue repository maintained at the institution containing specimens collected from patients and research subjects at Wash U.
  - Institution seeking declaratory judgment that Wash U. is sole owner of tissue samples

# Commercialization of Data/Materials: Who Has Ownership and Control?

- Catalona (cont.)
  - Complaint alleges Dr. Catalona improperly contacted prior research subjects and patients seeking their consent to transport their samples with him to his new position at Northwestern
  - Wash U. seeks declaration that any consents given by prior subjects and patients to Dr. Catalona permitting him to take their samples are invalid
  - Dr. Catalona has argued that patients and subjects retained control over their samples and information even after donating them to the repository and had the right to consent to Dr. Catalona's taking samples with him to Northwestern

# Commercialization of Data/Materials: Who Has Ownership and Control?



- Potential Ramifications of Catalona:
  - Presently, law remains unclear with respect to the rights of patients and research subjects to biological material or information that they give to research institutions for the purposes of conducting a research study
  - Ethical principles (and federal research regulations and state informed consent law) suggest that researchers and institutions have an obligation to seek informed consent to any future uses of this material (HIPAA requires specific authorization for any future use for research purposes by HIPAA covered entities)

# Commercialization of Data/Materials: Who Has Ownership and Control?



- Potential Ramifications of Catalona (cont.):
  - If court holds that consents given to Dr. Catalona by prior patients and subjects are valid, may imply continuing patient/subject ownership interest in the materials that they donate to research institutions in the course of participating in a research study
  - Holding may clarify ability of subjects/patients to waive objection to future uses and/or commercialization of materials collected for research purposes
  - Institutions should clarify tissue/data ownership in their employment agreements, faculty rules/handbooks, and policies and procedures
    - Investigator owns?
    - Institution owns?
    - Joint ownership?

# Commercialization of Data/Materials: Who Has Ownership and Control?

- Tilousi v. Arizona State University
  - Complaint filed by members of Arizona Havasupai Indian Reservation on 2/26/04, alleging misuse of blood samples that were taken during diabetes study
  - Plaintiffs allege that tribe members were told samples would be used only for a study of diabetes, when they were instead used without permission (or proper IRB oversight) in unrelated studies of schizophrenia, inbreeding, and theories regarding the migration of humans to North America
  - This research was allegedly presented in 23 scholarly papers and 15 publications

# Commercialization of Data/Materials: Who Has Ownership and Control?

- Tilousi v. Arizona State University (cont.)
  - Complaint alleges:
    - breach of fiduciary duty and lack of informed consent
    - fraud and misrepresentation/fraudulent concealment
    - intentional and negligent infliction of emotional distress
    - conversion
    - violation of civil rights
    - negligence
  - Lawsuit seeks \$10 million in compensatory damages, \$15 million in punitive damages, and return of data and samples
  - Lawsuit was followed by an additional lawsuit from the tribe itself, for \$50 million

# HIPAA and Secondary Uses

- Confidentiality concerns in research are not new:
  - IRBs generally have been required to find that “there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data”  
45 CFR § 46.111(a)(7)
  - ICFs must state “the extent, if any, to which confidentiality of records identifying the subject will be maintained” 45 CFR § 46.116(a)(5)
- However, HIPAA adds new layers of complexity and has caused research sponsors, sites, IRBs, investigators, and subjects to re-focus on confidentiality and privacy

# HIPAA and Secondary Uses

- Basic Rule: A Covered Entity may not use/disclose any “protected health information” (PHI) for research purposes without an authorization or a waiver of authorization.
- Exceptions:
  - decedents
  - preparatory to research
  - limited data set
  - consents obtained before April 14, 2003
- Research sponsors (and databases and tissue repositories held by research sponsors) are not normally covered by HIPAA, even though databases and tissue repositories held by health care providers typically must be HIPAA-compliant.

# HIPAA and Secondary Uses

- HHS/NIH guidance is clear: the creation and maintenance of a database or repository for future research uses is itself a “research” activity and subject to HIPAA’s rules regarding the use and disclosure of PHI for research purposes
  - Covered entities need authorization (in addition to informed consent) before they can use or disclose subjects’ PHI for the purposes of developing a research database or repository
  - The database itself requires an IRB approved protocol
  - Subsequent authorization (or IRB waiver of the authorization requirement) is necessary before any future research can be performed using the banked data or materials

# HIPAA and Secondary Uses

- Tissue samples can be PHI if labeled with identifying information (e.g., admission date or medical record number).
- Many investigators and IRBs mistakenly regard CRFs as “de-identified” information
- But most CRF templates developed by sponsors will contain PHI because they require:
  - Dates of interaction with the research subjects
    - Note: “Day 2 of Study” is not an identifier, but a specific date is
  - Subject initials
  - Other identifying information, e.g., geographic identifiers

# HIPAA and Secondary Uses

- Research Authorization Forms (RAFs) cannot be “blanket” authorizations
  - HHS said no to “a one-time, blanket authorization from an individual” for marketing because it would not “give individuals sufficient information and notice regarding the type of use or disclosure of their protected health information that they are authorizing.” 67 Fed. Reg. 53,182, 53,186 (Aug. 14, 2002)
  - HHS likewise said no to a blanket authorization for recruitment into future research studies for similar reasons. 67 Fed. Reg. at 53,231
  - NIH guidance on HIPAA and research (rev. 9/25/03) says that RAF therefore may not be for “nonspecific research” or “future, unspecified projects” and must “pertain only to a specific research study”  
<http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp>
  - February 2004 guidance permits seeking subjects’ authorization to include their PHI and contact information into a research recruitment database [http://privacyruleandresearch.nih.gov/clin\\_research.asp](http://privacyruleandresearch.nih.gov/clin_research.asp)

# HIPAA and Secondary Uses

- Compound Authorization Problem
  - RAF can only be combined with informed consent form (or any other form or permission) “for the same research study”
  - Other combinations of RAF and other forms/provisions will invalidate RAF
  - If RAF is written to permit secondary uses, either by researchers or sponsor, is the authorization of those uses limited to “the same research study” described in the ICF? Probably not.

# HIPAA and Secondary Uses

- Compound Authorization Problem (cont.)
  - Recent trend post-HIPAA of research sponsors demanding that the RAF be drafted to permit the sponsor to use the PHI for future purposes outside the context of the primary study.
  - Example: term in CTA requiring hospital to obtain authorization from each subject, the terms of which “will permit the Sponsor’s use of such PHI for the purposes of monitoring the accuracy and completeness of the research data, *performing clinical and scientific research, and medical product development.*” (Emphasis added.)
  - Danger, noted above, is that this type of modification to the RAF invalidates it for the purposes of the primary study.
  - Why?

# HIPAA and Secondary Uses

- According to NIH guidance, no single RAF can cover both:
  - A clinical study on which research-related treatment is conditioned, and
  - Storage of collected tissue in a repository (or database) for future research

[http://privacyruleandresearch.nih.gov/research\\_repositories.asp](http://privacyruleandresearch.nih.gov/research_repositories.asp)
- This is because HIPAA prohibits “compound” authorizations where provision of research-related treatment, payment, or eligibility for benefits is conditioned on only one of the authorizations, and not the other
  - Bottom line: Use a second authorization for the hand-over by primary study investigator to research sponsor

# HIPAA and Secondary Uses

- Technically, primary clinical studies with an intention to bank tissues or data for future uses will need:
  - Informed Consent Form for primary study, including consent for database/repository development
  - Research Authorization for primary study
  - Second Research Authorization for database/repository development
  - Third Research Authorization and a second consent (or IRB waiver of both) for any future research studies performed on the banked data/materials
- What if a single RAF does cover both, but makes clear that (1) the clinical study and database/tissue storage are separate and independent, and (2) the database/tissue storage participation is optional?

# HIPAA and Secondary Uses

- HIPAA's Revocation Right
  - HIPAA requires that the RAF inform the subject of the right to revoke the authorization at any time
    - Exception for situations of “reliance” on the authorization
  - Because maintenance of databases is “research” subject to an authorization, subjects essentially retain the right to recall their PHI from the database or repository at any time
    - Similar to withdrawal of informed consent
    - Reliance exception would not likely permit the covered entity to avoid removing the PHI from the database/repository
  - Obligation to honor subject revocations of authorization do not apply to commercial research sponsors, but IRBs might nevertheless insist
  - Whom should subjects contact to revoke when database or tissue bank is held by a private sponsor?
  - Best alternative: If data/materials are de-identified, then no obligation to remove

# HIPAA and Secondary Uses

- Research institutions should inventory all databases and repositories that contain identifiable data and/or tissue
- Protocols should be drafted, and IRB files opened or re-activated, so that IRB oversight and HIPAA compliance are ensured for each database and repository
- As of April 21, 2005, electronic databases will be required to comply with HIPAA Security Rule as well
  - Institution must be aware of all electronic databases for HIPAA Security Rule assessment

# Synthesizing HIPAA Requirements with Existing Concerns re: Consent to Future Uses



- Reexamine information provided to potential subjects in the consent form
- Determine whether two RAFs are required: (1) for primary study and (2) for “banking” for future uses
- Explain to subjects the limits of subjects’ ability to revoke authorization to banking
- Ensuring consistency between consent form and information in HIPAA authorization
- Comparing the terms of the consent and RAFs with the Clinical Trial Agreement with sponsor

# Terms of Clinical Trial Agreement

- Historically, Clinical Trial Agreements (CTAs) have not placed many restrictions on what commercial sponsors can do with the data and biologic materials they receive in the course of a research study
- Many times, the definition of contractually protected “Confidential Information” is not broad enough to impose a requirements on sponsors to protect the privacy of the identified patient information they may receive

# Terms of Clinical Trial Agreement

- In response to concerns over sponsors' unfettered use of data and materials provided during a research study, some institutions are seeking to limit sponsors' rights according to the terms of the consent and authorization signed by the subjects
- Circular Dilemma: institutions struggling with whether it is permissible to seek subjects' consent and authorization to future uses, and want contractual assurances from sponsors that they will only do what the subject permitted in signing these forms

# Terms of Clinical Trial Agreement

- How can CTA be used to protect sponsors' rights to the identified data and materials without violating ethical and legal principles of informed consent?
  - CTA should, at a minimum, require sponsor to use reasonable efforts to safeguard identified data and not use identified data for direct marketing or contacting subjects or their families
  - Sponsor may also pledge to use identified data of subjects only for purposes of the study, analysis of the test drug or device, research on the medical condition(s) of the study subjects, internal company operations, and interaction with regulatory authorities

# Other Compromises Between Sponsors and Covered Entities

- Disclosing a Limited Data Set
  - Certain direct identifiers not included
  - Sponsor must sign Data Use Agreement limiting the sponsor from further using/disclosing the PHI in a way that would violate HIPAA if done by the covered entity
  - If data/materials stripped of direct identifiers, do subjects need to be informed?
    - The more de-identified the data/materials become, the more tenuous the subjects' rights in controlling future uses

# Other Compromises Between Sponsors and Covered Entities

- Merck Strategy (Public Information)
  - Sponsor receives identified data from research sites and then places identified data in an internal company database from which only limited data sets may be drawn by company researchers
  - Rationale: If HIPAA permits covered entities to use limited data sets for research purposes without subject authorization, the restrictions on non-covered entities (like sponsors) should be no greater

# Other Compromises Between Sponsors and Covered Entities

- Disclosing De-Identified Data
  - Assuming sponsors do not require identifiers in order to complete their research, a covered entity may disclose de-identified data to the sponsor without restriction
  - Again, unclear whether the fact data/materials are de-identified completely undermines subjects' rights to be informed of future uses
    - Again, the less identified, the less risk to subjects and less scrutiny IRB will give informed consents regarding the issue of future uses
  - De-identified data/materials cannot, by definition, be affected by a subject's revocation of participation in the database/repository

# State Laws

- Many states have laws that apply to research in addition to HIPAA, Common Rule, and other federal regulations
- Example -- California: No person shall be subjected to a medical experiment unless informed consent is obtained (Cal. Health & Safety Code § 24175)
  - Applies regardless of funding or purpose of study, but generally is not triggered absent a medical intervention
  - California and some other states also have detailed medical privacy laws that may be more stringent than HIPAA
- Example -- Maryland: All research using human subjects must be done in accordance with the Common Rule (Md. Gen. Code § 13-2002)
  - This applies to research not subject to either the Common Rule or FDA Regulations (e.g., research conducted by manufacturer that will not be submitted to FDA; research by small physician practice not under an Assurance)

# State Laws

State laws on specific areas of medical care and research can apply to BOTH investigators/research sites as well as to private research sponsors in sponsors' secondary research:

- HIV testing and confidentiality
- Mental health records
- Genetic testing and confidentiality

# State Genetic Testing Laws

- State genetic testing laws complicate compliance efforts of researchers and commercial sponsors
- Commercial sponsors (and/or their laboratory contractors) may be subject to these laws depending on how broad the applicability
- Many states require informed consent for genetic testing or disclosure of genetic testing results but contain no “research” exception to one or both of those activities thereby requiring informed consent
- Most exceptions for research activities require a certain level of de-identification of the sample
- Many also place limits on how long DNA samples may be retained before they must be destroyed (absent express consent by the individual to a longer retention period)

# State Genetic Testing Laws

- Issues with Secondary Genetic Research
  - Have state law consent requirements been met?
  - Will results of secondary genetic research be provided to subjects of the primary study?
    - Logistically possible?
    - Required under state law?
    - Liability concerns for disclosing or not disclosing?
  - Will results of secondary genetic research be communicated to subjects' family members?
  - If subjects of primary study are asked to consent to future genetic testing and will learn the results, have relevant risks been communicated in the consent form?
    - Discrimination
    - Anxiety
    - Stigmatization
    - Implications for family members
  - Does the state law give individuals a *property right* to their genetic information?
    - FLORIDA (but limited by the Greenberg decision)
    - NEW JERSEY (legislation pending), Colorado, Georgia

# State Genetic Testing Laws: Examples

- Florida: Fla. Stat. § 760.40(2)(a)
  - *Testing and Disclosure*: “DNA analysis,” including genetic testing and DNA typing, may only be performed with the informed consent of the person tested and the results may not be disclosed without their consent
  - *Notice*: Individual tested must be notified when analysis was performed and information received; notice must state that, upon request of person tested, the results will be made available to his or her physician
  - *Property Right*: Results of DNA analysis, whether held by a public or private entity, are the exclusive property of the person tested

# State Genetic Testing Laws: Examples

- Massachusetts: M.G.L. c. 111, § 70G
  - *Testing and Disclosure*: Requires written informed consent that includes descriptions of each specific disease or condition tested for and the implications of positive and negative test results
  - *Research Exception*: consent requirement does not apply to genetic information that qualifies as “confidential research information”
    - Identity of individual must be “unknown or protected from disclosure by encrypting or encoding” or other means consistent with the Common Rule and FDA regulations

# State Genetic Testing Laws: Examples

- New Jersey: N.J. Stat. § 10:5-43 et seq.
  - *Testing*: Informed consent required before anyone may obtain genetic information from an individual or an individual's DNA sample
    - *Research Exception*: Informed consent requirement does not apply to "anonymous research where the identity of the subject will not be released."
  - *Disclosure*: Prohibits disclosure of the identity of an individual upon whom a genetic test has been performed or disclosure of genetic information that permits identification of the individual (unless the individual authorized the disclosure)
    - Applies to subsequent disclosures
  - *Notice*: Person must be notified that test was performed; person has a right to inspect and request correction of records of genetic information, unless subject directs otherwise in informed consent
  - *Retention*: No person shall retain an individual's genetic information without first obtaining authorization from the individual through informed consent
    - Same research exception as above
  - *Destruction*: DNA sample from an individual who is the subject of a research project shall be destroyed promptly upon completion of the project or withdrawal of the individual from the project or at the individual's specific request, unless the individual directs otherwise through informed consent.

# State Genetic Testing Laws: Examples

- New York: N.Y. Civ. Rights Law § 79-L
  - *Testing*: No person shall perform a genetic test on a biological sample taken from an individual without prior written informed consent
    - Consent must include general description of each specific disease or condition tested for and statement that no tests other than those authorized shall be performed on the sample and the sample shall be destroyed at the end of the testing process or not more than 60 days after sample was taken, unless longer period is expressly authorized in the consent
    - *Research Exception*: Informed consent not required for certain types of research subject to IRB review where (1) the samples have been permanently de-identified or (2) a coding system is in place to protect the identity of the individuals who provided the samples and the coding system was approved by the IRB

# State Genetic Testing Laws: Examples

- New York (cont.)
  - *Disclosure*: Records, findings and results of any genetic test performed on any person may not be disclosed without written informed consent of the person to whom such genetic test relates
    - NO RESEARCH EXCEPTION for this prong of the statute
    - Therefore, must obtain informed consent of individual to the genetic testing in order to disclose the results to a commercial research sponsor
  - *Retention*: Any retention of a DNA sample past 10 years requires explicit consent for a longer or indefinite period of retention

# State Genetic Testing Laws: Examples

- Missouri law (Mo. Stat. § 375.1309):  
“Any person who in the ordinary course of business, practice of a profession or rendering a service, creates, stores or receives genetic information .... Shall hold such information as confidential medical records and shall not disclose such genetic information except pursuant to written authorization of the person to whom such information pertains.”

# State Genetic Testing Laws: Examples

- Missouri law contains research exception for:  
“health research conducted in accordance with the provision of the federal common rule ... or ... health research using medical archives or databases in which the identity of individuals is protected from disclosure by coding or encryption, or by removing all identities.”

# Data/Materials Collected During Standard of Care

- Related issues arise when covered entities develop research databases or repositories with data or biologic materials collected from patients who are receiving standard of care treatment (as opposed to research subjects enrolled in a primary research study)

# Data/Materials Collected During Standard of Care

- Patients receiving standard of care will not be asked to sign research informed consent and RAF in the normal course; however, still need these documents signed for the database/repository “study”
- Still need IRB approval and oversight of the database or repository

# Data/Materials Collected During Standard of Care

- Possible to incorporate an altered version of the research informed consent and authorization requirements into an institution's standard treatment/procedure informed consent form
  - Requires IRB approval of the alteration
  - “Minimum risk” requirement likely met
  - “Impracticability” requirement less clear – arguably impracticable (and harmful to patients) to present them with three long and confusing documents when the relevant information can be communicated with a carefully drafted paragraph
- Best practices = “opt-in” check-box for patient to initial

# Questions?



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