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Clinical Trials and Human Research Compliance: New FDA Guidance and Revised Common Rule

Complying With Agency Regulations for Informed Consent, Expedited Review and IRB Continuing Review

THURSDAY, MARCH 14, 2019

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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FDA's Response to HHS' Revised Common Rule:

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Background

- FDA's regulations on human subject protection (21 CFR part 50) and Institutional Review Boards (IRBs; 21 CFR part 56) exist to ensure that the rights, safety, and welfare of human subjects participating in FDA-regulated clinical investigations are protected.
- HHS, through its application of the Common Rule, regulates human subject research that is conducted or supported by HHS.
- On January 19, 2017, HHS published a final rule, which revised the Common Rule. The revisions to the Common Rule ("2018 Requirements") have created certain differences between FDA's human subject regulations and HHS' human subject regulations.

Background

- Some FDA-regulated clinical investigations are conducted or supported by HHS, and are, therefore, subject to both sets of regulations, which would require sponsors, investigators, and IRBs to be familiar and comply with both HHS' and FDA's regulations.
- In October 2018, FDA published guidance, *Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations*, in an attempt to curb potential confusion.

FDA Guidance: Informed Consent

- FDA's position:
  - The provisions of the 2018 Requirements related to the content, organization, and presentation of information included in the consent form and process as well as the basic and additional elements of informed consent are not inconsistent with FDA's current policies and guidances. This may avoid the need for sponsors or investigators to develop, and IRBs to review, two separate informed consent forms.

FDA Guidance: Expedited Review Procedures and List

- FDA regulations set forth expedited IRB review procedures for research involving no more than minimal risk as established through a Federal Register Notice. See 21 C.F.R. § 56.110(a).
- FDA established and published a list of categories of such research in the Federal Register. 63 Fed. Reg. 60353 (November 9, 1998).
- Under Section 56.110(b), IRB reviewers must find that the research on the list involves no more than minimal risk for the IRB to use the expedited review procedure.
- Despite the revised Common Rule providing for limited IRB review proceeding via the expedited review mechanism, FDA stated that IRBs must continue to use the list in the Federal Register when reviewing research subject to HHS and FDA human subject regulations.

FDA Guidance: IRB Continuing Review

- FDA's recent guidance clarifies that, where the regulations differ, the regulations that offer the greater protection to human subjects should be followed, as has been the historical position of FDA.
- For example, the revised Common Rule eliminated the requirement that research involving no more than minimal risk undergo an annual, continuing review.
- However, FDA maintains its requirement under 21 C.F,R . § 56.109(f) regarding studies required to undergo an annual, continuing review.

FDA Guidance: Future Rulemaking

- FDA intends to issue three more guidances aimed at harmonizing the agency's regulations with HHS' Common Rule.
- On October 17, 2018, the White House's 2018 fall regulatory agenda indicated that the FDA will engage in the formal rulemaking process, including accepting and considering public comments, in advance of issuing the guidances: Part 50 Protection of Human Subjects and Part 56 Institutional Review Boards, which would add definitions, conform wording, and other changes to FDA regulations to harmonize with the revised Common Rule; Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations, which would permit an IRB to waive or alter the informed consent requirements under certain conditions for minimal risk clinical investigations; and Institutional Review Boards; Cooperative Research, which would replace current FDA requirements for cooperative research so that any U.S. institution participating in multisite cooperative research could rely on approval by a single IRB for the portion of the research that is conducted in the U.S., with some exceptions.

PERKINSCOIE

COUNSEL TO GREAT COMPANIES

Revised Common Rule:
What Changed and Why

March 14, 2019

Disclaimer and Acknowledgements

- Any opinions put forth in this presentation are not to be construed as the legal or regulatory advice.
- Attribution to David Vulcano for contributions to this presentation

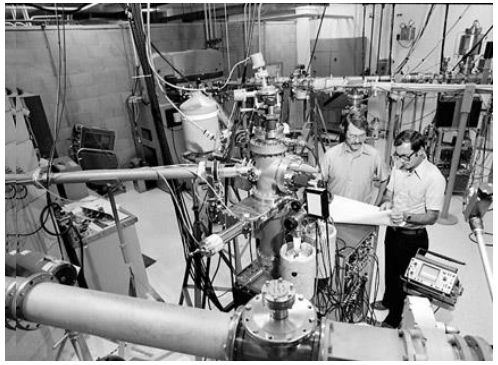
Agenda

- Status of the Effective Date of Revised Common Rule
  - Grandfathering
  - Transitioning
- Summary of the Revised Common Rule
  - Definition of Human Subjects
  - Exemption Classifications
  - IRB Continuing Review and Approval Criteria
  - Cooperative Research
  - Informed Consent Forms
  - Waiver of Consent

THEN AND NOW

Belmont Report -1979

Sandia National Laboratory



Common Rule 1991

Institute of Medical Science
Toronto

Revised Common Rule

2019

Joslin Diabetic Research Center

THEN AND NOW, cont'd.

Rational for Modernizing the Common Rule (Preamble)

- Preserve Belmont Report Principles – respect for persons, beneficence, and justice
- Recognize and adapt to changing nature of research
  - Evolving technologies – imaging, mobile, computing power
  - Developing technics to Integrate different types of data
  - Deploying sophisticated software programs to study social and behavioral science
  - Leveraging the Human Genome Project in biomedical science for precision medicine
  - Clinical research networks with connected electronic health records
  - Shift of research from academic centers to clinical settings
  - Growth of secondary analysis of biospecimens and data

Status of Effective Date (45 CFR 46.101(l))

- Revised Common Rule
  - Applies to 20 Federal Agencies, including HHS
  - Published in January 19, 2017
  - Original Effective Date in January 20, 2018
  - Amended to delayed Effective and Compliance Date to July 19, 2018
  - Second amendment to delayed Compliance Date to January 21, 2019, but allows for implementation of three burden-reducing provisions
    - Revised definition of “research”
    - Eliminate annual continuing reviews for certain research
    - Eliminate IRB review of grant applications

Status of Effective Date, cont'd

- Status depends on the date of the initial review/exemption determination
- Grandfathering of All Research
  - Approved/waived/exempted **before** January 20, 2019 follows Pre-2018 Rule – Life of the Research
    - Optional transition to New Rule if the research complies and the IRB documents transition.
    - Case-by-case

Status of Effective Date, cont'd

- Transitioning of All Research
  - Approved/waived/exempted **on or after** January 20, 2019 but **prior to** January 20, 2020 follows New Rule
    - Except mandated use of single IRB for Cooperative Research (multicenter studies) under §___. 114(b).
  - Approved/waived/exempted **on or after** January 20, 2020 follows New Rule

Summary Of The New Common Rule (45 CFR 46)

Change to Definition - “Human Subject” (§___.102(e)(1)

- *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research ~~obtains~~:
  - (i) Obtains ~~data~~ information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - (ii) Obtains uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Changes to Categories of Research Exempt from Common Rule (§_.104(d)

- Regulation moved from §__.101(b) to §___.104(d)
- Nearly all existing exemptions have been revised in format or substance or both
- Changes in the use of Data __.104(d)(4)
  - the Data does not have to "exist" at the start of the Research
  - Identifiable data allowed if recorded in accordance with HIPAA
- 2 new exemptions for Secondary Research __.104(d)(7) & (8)
  - Broad consent is required
  - Limited IRB review
  - Waiver of consent or documentation of consent

Changes to IRB Continuing Review (§_.109(f)

- IRB may not longer require annual Continuing Review, if…
  - Research eligible For Expedited Review (i.e. Initial or Subsequent Review of Remaining Activity)
  - Research reviewed by Limited IRB Review
  - Research progress to the point of …
    - (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    - (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Change to IRB Approval Criteria (§_.111(8))

- IRB no longer has to review grant applications
- New review criteria for “Limited IRB Review” (§_.111(a)(8))
  - (i) Broad Consent for storage, maintenance, and secondary research use obtained;
  - (ii) Broad Consent is appropriately documented (or waiver of documentation is appropriate)
  - (iii) Adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data for changes in storage and/or maintenance of information/biospecimens.
- New review criteria to ensure protections in study for vulnerable populations ((§_.111(b))

Changes to Cooperative Research (multicenter studies) ((§_.114)

- New provision mandates Single IRB (“sIRB”) Review for research conducted in the US (§_.114(b)(1))
  - Federal funding agency selects or proves the IRB
- Exceptions to Single IRB Review
  - More than sIRB required by law
  - Federal department documents sIRB is not appropriate for the study
- Effective Date 1/20/2020

Changes to Structure Of Consent Forms (§_.116)

- New requirements of Informed Consent form under (§_.116(a)(5)(i))
  - Must "begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension."

Changes to Content Of Consent Forms (§_.116)

- Informed Consent now require “one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimensunder.” (§_.116(b)(9))
  - (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
  - (ii) A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Changes To Content Of Consent Forms (§_.116(c)(7), (8) & (9))

- Additional elements to include where appropriate:
  - "A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit";
  - "A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions"; and
  - "For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)."

Addition of "Broad Consent" Alternative For Future Unspecified Research (§_.116(d)

- Allowed only for storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes).
- Requires the "non-study specific" requirements of consent plus…
  - A general description of the types of research that may be conducted;
  - A description of the identifiable private information/biospecimens that might be used or shared and the types of institutions or researchers that might conduct the research;
  - The period of time (which period of time could be indefinite) that the identifiable private information or identifiable biospecimens may be stored/maintained and used for research purposes;
  - Unless otherwise, they will not be informed of the details of any specific research studies that might be conducted; and
  - Unless otherwise, a statement that clinically relevant results may not be disclosed to the subject.

Changes to Waivers or Alterations of Consent (§_.116(f))

- Limitation of waiver for secondary research use of identifiable private information or biospecimen:under (§_.116(f)(1))
  - If a Broad Consent was sought and subject refused, IRB cannot "overturn" refusal of Broad Consent by granting a waiver

  (Requires tracking of those offered Broad Consent and their response)
- New Added Criteria For General Waivers/Alterations (§_.116(f)(3)(iii)):
  - "If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format."
- New "Screening Consent Waiver" Criteria (§_.116(g)) for subject screening…
  - Investigator will obtain information through oral or written communication with the prospective subject; or
  - Investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens

Changes to Waivers of Documentation of Consent (§_.117)

- New Optional Criteria to waive documentation (§_.117(c)(1)(iii))
  - "If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained."

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THANK YOU

QUESTIONS?

PERKINSCOIE

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IMPACT OF THE REVISED COMMON RULE ON THE REGULATORY LANDSCAPE
&
TIPS FOR COMPLIANCE

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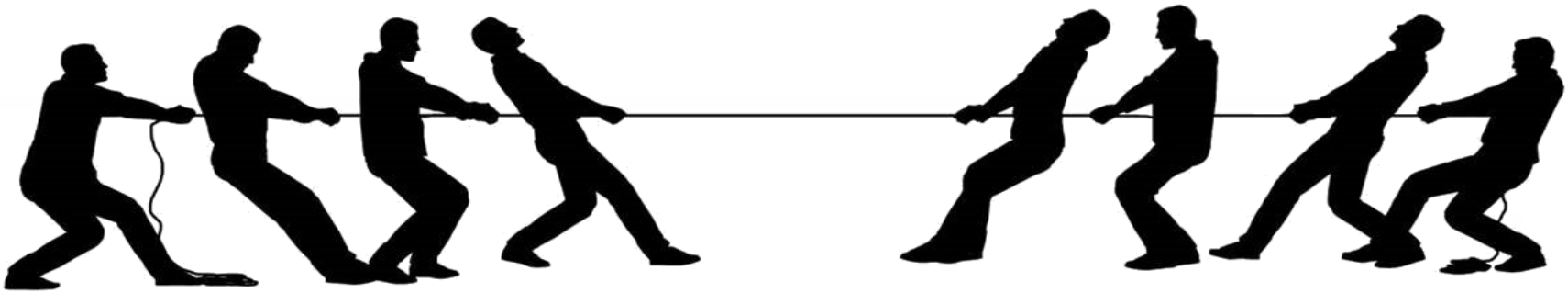
Specific focus on how the Revised Common Rule impacts the use of data and biospecimens (in both identifiable and non-identifiable form) for secondary research purposes

Revisions to the Common Rule reflect a common theme…

PURSUIT OF RESEARCH



DIGNITARY INTEREST OF HUMAN SUBJECTS

IDENTIFIABILITY

PURSUIT OF RESEARCH

DIGNITARY INTEREST OF HUMAN SUBJECTS

- Notice of Proposed Rule Making (NPRM) originally proposed to redefine human subject to include all biospecimens, regardless of identifiability
- Proposal was generally not supported by the research community
  - Concerns included:
    - Reduced number of biospecimens available for research
    - Increased costs and complications for tracking consent
    - Question of how much patients value autonomy over potential for innovative diagnostics, treatments, or preventative interventions
- Proposal was not adopted in the final version of the Revised Common Rule
  - Definition of human subject continues to apply to identifiable private information or identifiable biospecimens

Compromise for not expanding the definition of human subject to include all biospecimens, regardless of identifiability:

A. Expanded transparency requirements for informed consent

B. New obligations and considerations for secondary research use of identifiable private information and identifiable biospecimens

BASIC INFORMED CONSENT

- New requirement that informed consent forms must account for potential future uses of *non-identifiable* private information and/or biospecimens
- Informed consent must contain either:
  i. Statement that identifiers might be removed from identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject; or

  ii. Statement that the subject's information or biospecimes collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies *46.116(b)(9)(i)*
- "This new requirement is intended to give the potential subject a right to know that identifiers might be removed from information or biospecimens and be used for future research without additional consent, when such a possibility exists, so he or she can make a fully informed decision about whether to participate in the research." 82 Fed. Reg. 7149, 7215 (Jan. 19, 2017)

BASIC INFORMED CONSENT

- Other important examples of informed consent elements that relate to identifiability:
  - Statement that subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will share in those commercial profits *46.116(c)(7)*
  - Statement of whether research may include whole genome sequencing (WGS) *46.116(c)(9)*
    - The NPRM contained (as an alternative to expanding the definition of human subject to include all biospecimens regardless of identifiability), a proposal to expand the definition of human subject to include WGS
    - Inclusion of informed consent requirement regarding WGS speaks to OHRP's concern that certain technologies increase the likelihood of identifiability and, accordingly, increase risk to the subject

BROAD INFORMED CONSENT

- Revised Common Rule includes the new concept of broad consent for the storage and maintenance of identifiable private information and biospecimens for future research purposes *46.116(d)*
  - Broad consent: seeking prospective consent for future unspecified research
  - If investigator obtains broad consent, he/she can use the identifiable private information and biospecimens for future, unspecified research without obtaining additional consent
  - Before implementation of Revised Common Rule, if investigator had not obtained consent for specific research use in the initial consent, he/she had only two options for using the identifiable private information or biospecimens for future research purposes: (1) obtain an IRB waiver of consent or; (2) remove all identifiable information

BROAD INFORMED CONSENT

"Although we recognize public commenters' concern that broad consent might not be as meaningful or informative as study-specific consent, it is also important to note that when an investigator chooses to use this new option, doing so will generally provide increased protection to the autonomy of research subjects. It will give them a choice to say no to such research, in contrast to most of the other routes by which an investigator might generally choose to conduct this type of research, such as with a waiver of informed consent, which allows research to take place regardless of the wishes of the person whose information or biospecimens are being studied, and without their knowledge."

82 Fed. Reg. 7220

BROAD INFORMED CONSENT

Elements of Broad Consent *46.116(d)*

1. General description of types of research that may be conducted with identifiable private information or identifiable biospecimens (must include sufficient information that a reasonable person would expect that the broad consent would permit the types of research conducted)
2. Description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens
3. Description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which may be indefinite) and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes

BROAD INFORMED CONSENT

Elements of Broad Consent (continued)

4. Unless subject or LAR will be provided details about specific research studies, statement that they will not be informed of the details of any specific research studies that might be conducted using subject's identifiable private information or identifiable biospecimens, including purposes of the research, and that they might have chosen not to consent to some of those specific research studies
5. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject
6. Explanation of whom to contact for answers to questions about subject's rights and about storage and use of subject's identifiable private information or identifiable biospecimens, and whom to contact in event of research related harm

WAIVER OF INFORMED CONSENT

- Remember that under the Revised Common Rule, the option still exists of asking an IRB to waive informed consent requirements for the use of identifiable private information and identifiable biospecimens
- BUT, Revised Common Rule imposes new restrictions on IRB waivers of consent:
  - If individual refused broad consent, IRB cannot waive consent for the use of identifiable private information or identifiable biospecimens *46.116(f)(1)*
  - If asking for a waiver of informed consent for research that uses identifiable private information or identifiable biospecimens, IRB has to find that the research could not practicably be carried out without using the information or biospecimens in an identifiable format *46.116(f)(3)(iii)*

IRB EXEMPTION DETERMINATIONS

- Revised/expanded IRB exemption categories also reflect OHRP's enhanced focus on identifiability
- IRB Exemption Category 4 – Secondary research for which consent is not required *46.104(d)(4)*
  - Can obtain an exemption from IRB review for secondary research that uses identifiable private information or identifiable biospecimens if the information is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly or though identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects
  - Can also obtain exemption from IRB review for secondary research that uses identifiable private information or identifiable biospecimens when the research involves only information collection and analysis involving investigator's use of identifiable health information regulated under HIPAA Privacy Rule for purposes of "health care operation," "research," or "public health activities and purposes"
    - In preamble to Revised Common Rule, OHRP states that HIPAA Privacy Rule adequately protects identifiable information, such that overlapping regulatory requirements under the Common Rule would be overly burdensome *82 Fed. Reg. 7194*

IRB EXEMPTION DETERMINATIONS

- IRB Exemption Category 7 and IRB Exemption Category 8 remove most IRB review responsibilities if broad consent was used to collect the identifiable private information or identifiable biospecimens, but IRBs must focus on measures used to protect the privacy of subjects' information
  - Exemption 7 – storage and maintenance of identifiable private information or identifiable biospecimens for potential secondary research use may be exempt if the IRB conducts a limited IRB review to determine broad consent was obtained and there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of data *46.104(d)(7); 46.111(a)(8)*
  - Exemption 8 – secondary analysis of existing identifiable data and identifiable biospecimens may be exempt if IRB determines broad consent was obtained and appropriate documentation was secured or waived and IRB must conduct a limited review to determine there are adequate provisions to protect privacy of subjects, maintain the confidentiality of data, and that the use of the identifiable information and identifiable biospecimens is within the scope of the broad consent *46.104(d)(7); 46.111(a)(7)*

WHEN ARE DATA AND BIOSPECIMENS ***IDENTIFIABLE***?

IDENTIFIABILITY

- "Identifiability" is an open question – and a moving target
  - Hinges on the concept of whether a subject's identity is readily ascertainable
- Under both pre-2018 and Revised Common Rule, "identifiable private information" is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information
- Revised Common Rule includes new definition for "identifiable biospecimen"
  - "Biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen." *46.102(e)(6)*

IDENTIFIABILITY

When is identity readily ascertainable?

- OHRP isn't clear on this, but recognizes it is an evolving concept that is impacted by technological advancements
- Revised Common Rule establishes a process for ongoing updates to the term "identifiable information" *46.102(e)(7)*
  - Every four years Common Rule departments and agencies are required to reexamine the meaning of the terms "identifiable private information" and "identifiable biospecimens"
  - Common Rule agencies will be permitted to alter the interpretation of identifiable private information or identifiable biospecimens, including through the issuance of guidance

IDENTIFIABILITY

- In addition to updates to the definition of identifiable private information and identifiable biospecimens, there will be a creation of a list of technologies that, if applied to information or biospecimens that are not identified, lead to the generation of identifiable private information or identifiable biospecimens
  - Expectation is that WGS will be one of the first technologies to be evaluated to determine whether it should be placed on this list
  - Notice and opportunity for public comment would take place before technology or techniques are placed on this list
- "The ultimate goal is to implement the Common Rule in a way that is aligned with the evolving understanding of the concept of identifiability while protecting subjects and encouraging and facilitating valuable research" *82 Fed. Reg. 7169*

TIPS FOR COMPLIANCE WITH THE REVISED COMMON RULE

TIPS FOR COMPLIANCE

- DON'T FORGET TO CONSIDER OTHER RELEVANT STATE LAWS
- State laws often add another layer of complexity, particularly to the informed consent process
  - **Common example is in the context of genetic privacy laws**
    - Some states have additional requirements for informed consent when genetic testing will be conducted on biospecimens (e.g. NY, MA, AK, MN, OR, etc.)
    - Some states place additional requirements on the maintenance and storage of biospecimens in the context of genetic testing (e.g. time limitations on storage, absent explicit informed consent)
    - Different concepts of "identifiability"
      - Various states, including Alaska, New Hampshire, and Oregon, impose informed consent requirements regardless of identifiability
      - Some states, such as Minnesota, take the view that all genetic information is, by its very nature, identifiable
      - New York distinguishes between "anonymized" information, which cannot be linked to an identifiable individual under any circumstances, and "de-identified" information, which can be linked to an identifiable individual through the use of a code
    - Some states require that an IRB review genetic research involving anonymous or coded information and biospecimens
      - Example: Under Oregon's genetic privacy laws, investigators proposing to conduct anonymous research, coded research, or genetic research that is otherwise thought to be exempt from review must obtain an IRB determination that the proposed research is exempt from review and must disclose to the IRB the proposed used of DNA samples, genetic testing or genetic information
    - Some (but not all) states make exceptions to informed consent requirements for anonymous research

TIPS FOR COMPLIANCE

- For entities that only interact with secondary data/biospecimens (i.e. entities that do not perform initial sample collection), consider requiring the entities/collaborators that supply your biospecimens to represent and warrant that samples have been collected in accordance with federal and state laws
- Examples:
  - Compliance with state specific informed consent requirements
  - Compliance with state specific IRB review and approval requirements
  - Appropriate anonymization or de-identification methods for samples, depending on state requirements

TIPS FOR COMPLIANCE

- Don't disregard your pre-2018 research policies and procedures yet!
  - Studies initiated prior to January 21, 2019 will continue to be subject to the pre-2018 Common Rule requirements, unless the institution choose to transition the study to the Revised Common Rule during the transition period (between July 19, 2018 and January 21, 2019)
  - This means there may be a period of time when institutions and IRBs are simultaneously operating under pre-2018 policies and procedures and policies and procedures governed by the Revised Common Rule
  - Be sure all investigators know which policies and procedures apply to a given study
- Be careful when it comes to continuing review!
  - Under the Revised Common Rule, most studies that qualify for the expedited review process are exempt from continuing review, as are studies that have completed subject intervention/interaction and in which activity is limited to final analysis of identifiable data or identifiable biospecimens or involve only observational follow up in conjunction with standard clinical care
  - However, IRBs still have discretion to mandate more frequent review
  - FDA regulated research is still required to undergo continuing review *21 CFR 56.109(f)*
  - Investigators remain responsible for updating the IRB about adverse events, unanticipated problems, and other changes to research (e.g. protocol revisions)

TIPS FOR COMPLIANCE

- Update all institutional material to comply with Revised Common Rule
  - Examples:
    - IRB or institutional policies and procedures
    - Informed consent forms/templates
    - IRB review forms
    - Training material
- Watch for further updates
  - Examples:
    - OHRP has stated that it intends to eventually update the other subparts of the Common Rule
    - OHRP has indicated that there may be guidance on what does and does not constitute "minimal risk"
    - As previously mentioned, there will be updates regarding the interpretation of the terms identifiable private information and identifiable biospecimens