Making a List, Checking It Twice... The Revised Common Rule Is Coming to Town!

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September 27, 2018
altogether better
Integrated research compliance solutions to streamline your study
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- Founding member, NCCN IRB Directors Forum
- Previously served as Senior Director, Dana Farber Cancer Institute, Office for Human Research Studies
- Lawyer by training
About Today’s Presenters

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- Co-Lead, NIH Health Systems Research Collaboratory, Regulatory/Ethics Core
- Previously served as Assistant Dean for Human Research Protection and Director of the HRPP, Johns Hopkins University School of Medicine
- Lawyer by training
What Would Cat Stephens Say?

It's now time to make a change,
Just sit down, take it slowly...
Objectives

- Review many but not all of the Common Rule changes and the impact on policies, processes and templates
- Describe the regulatory agency guidance documents that are now available and those we hope are forthcoming
- Identify the action items necessary to implement changes

We assume that most of the audience is familiar with the Common Rule changes, so we won’t be reviewing the changes in detail.

The purpose of this webinar is to remind people more generally about the most significant changes and considerations in implementing the changes.
1. Compliance dates:
   - **January 21, 2019**, for the revised Common Rule, except for the requirement for mandated single IRB review, which remains January 20, 2020

2. Changes you could implement between now (September 27, 2018) and January 21, 2019

3. Guidance that is needed to fully implement the changes

4. Changes necessary to implement the revised Common Rule
Why Revise the Common Rule?

- Reduce administrative burdens
- Better protect research subjects
  - Changes are intended to make informed consent more meaningful so that research subjects will have the necessary information to make informed decisions
Overview of Webinar

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Transition: Easiest, Clearest Route

- Before January 21, 2019, all activities must comply with the pre-2018 rule
  - These studies are grandfathered in provided you do not apply any of the revisions to these studies

- After January 21, 2019, all studies must comply with the 2018 revised Common Rule
  - This is the final date after 2 delays

- Requirement for single IRB (sIRB) review in multi-institutional studies goes into effect January 20, 2020
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Burden-Reducing Provisions *(Effective July 19, 2018)*

**Changes that can be implemented during the transition:**
1. Redefining “research,” to reduce the number of activities falling under this definition;
2. Eliminating the requirement for annual continuing review of certain categories of research; and
3. Eliminating requirement that IRBs review grant applications or other funding proposals related to the research

**Action items:**
- Determine whether burden-reducing provisions will be implemented at your institution prior to the 1/21/19 compliance date (Note: all 3 need to be implemented)
- Review and revise IRB policies/SOPs/review forms/IT system prior to implementing
- Track any research to which a burden-reducing provision was applied
  - It must be re-reviewed on January 21, 2019, to ensure that all other required revisions have been applied to that research
Definition of Research

What’s changed? 4 activities deemed not to be research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected

2. Public health surveillance activities, including collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority
   • Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products)
   • Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters)

3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes

4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions

Action items:

> Revise IRB policies/SOPs/checklists/review forms to change the definition of research
Continuing Review

What’s changed?

- Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:
  - Research eligible for expedited review in accordance with the expedited review categories; and
  - Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
    - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

Action items:

- Review and revise IRB policies/SOPs/review forms/IT system prior to implementing
NIH Grant Review

What’s changed: 45 CFR 46.103(d)

- IRBs no longer required to review the grant application or contract proposal when reviewing the study protocol and other related IRB materials
- Instead, certification is required when the research is supported by a federal department or agency and not otherwise waived under 45 CFR 46.101(i) or exempted under 45 CFR 46.104
- For such research, institutions shall certify that each proposed research study covered by the assurance has been reviewed and approved by the IRB

Action items:

- Review and revise IRB policies/SOPs/review forms/IT system prior to implementing
NIH Requirement for IRB Review of the Grant

Purpose

The purpose of this notice is to provide guidance to the extramural research community regarding the implementation of the three burden-reducing provisions in the Final Rule on the Federal Policy for the Protection of Human Subjects (Common Rule). The HHS Office of Human Research Protections (OHRP) issued a Final Rule delaying implementation of the Common Rule until January 21, 2019. While general compliance is delayed, the Rule provides recipients with the option to implement three burden-reducing provisions during the delay period (July 19, 2018 through January 21, 2019).

- These burden-reducing provisions include (1) the 2018 Requirements’ definition of “research,” which deems certain activities not to be research, (2) removal of the requirement for annual reviews for certain categories of research, and (3) removal of the requirement for Institutional Review Boards (IRBs) to review grant applications related to the research.

- Studies that choose to implement the burden-reducing provisions during the delay period must, beginning January 21, 2019, comply with all of the 2018 Common Rule requirements for the remainder of the study.
  - An institution’s decision about whether to transition a study to the 2018 Requirements to take advantage of the three burden-reducing provisions might vary depending on the nature and progress of the study, including any elements of the study to be conducted on or after January 21, 2019.
  - Additional details, including requirements and processes for adopting the new provisions, can be found in the Final Rule (83 FR 28497).

- For recipients that implement the burden reduction provisions, IRB review of grant applications or other funding proposals and annual reviews for certain categories of research will no longer be required.
  - However, certification of IRB review will still be required for all NIH-supported non-exempt human subjects research studies, and recipients must still provide certification to NIH that the research protocol has been reviewed and approved by the IRB.
Revisions That Are Not Inconsistent

Changes in the revised Common Rule that are not inconsistent with the current regulations may be implemented immediately.

<table>
<thead>
<tr>
<th>What Cannot Be Implemented*</th>
<th>What Can Be Implemented Immediately*</th>
</tr>
</thead>
<tbody>
<tr>
<td>• New exemptions</td>
<td>• Additional elements of consent</td>
</tr>
<tr>
<td>• Limited IRB review</td>
<td>• Three burden reducing provisions</td>
</tr>
<tr>
<td>• Broad consent</td>
<td>• New element for waiver of consent</td>
</tr>
<tr>
<td></td>
<td>• Apply the additional consent</td>
</tr>
<tr>
<td></td>
<td>requirements to FDA regulated research</td>
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* The above chart lists examples of changes within each category and is not a comprehensive list.
Transition Exception

Before January 21, 2019, you may implement the following:

- Revised Common Rule provisions that do not conflict with the pre-2018 rule
- The 3 burden reducing provisions
  - Revised definition of research (scholarly and journalistic activities)
  - Elimination of continuing review for expedited review
  - Elimination of IRB review of research applications and proposals

If you do, all of those studies that took advantage of some part of the revised Common Rule must, on January 21, 2019, **comply with all parts of the revised rule for subjects enrolled after that date**
Example of consequences of studies that take advantage of one of the burden reducing provisions or provisions that are not inconsistent, subject to the doctrine of prospective application:

- **Expedited review study with consent**
  - 50 enrolled prior to January 21, 2019
  - 50 more to be enrolled after January 21, 2019
  - Burden reducing provision of no continuing review applied to this study
    » The subjects enrolled after January 21, 2019, must be consented with a consent that is compliant with the revised 2018 rule
Transitioned Studies (cont’d)

- Expedited review study with waiver of consent
  - 50 records reviewed
  - 50 more records to be reviewed after January 21, 2019
    » Burden reducing provision of no continuing review applied to this study
  - For the records reviewed after January 21, 2019, must:
    » Re-review with reference to the new waiver criteria OR
    » Might be able to find the study is exempt under 104(iii) as secondary research that is subject to HIPAA
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What Guidance Is Available Now?

- Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements

- When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements

What Guidance Is Available Now?

Posting consent forms

- At this time, 2 publicly available federal websites that will satisfy the consent form posting requirement, as required by the revised Common Rule, have been identified: ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021)
- HHS and other Common Rule departments and agencies are developing instructions and other materials that provide the regulated community more information about this posting requirement
What Guidance Is Available Now?

- OHRP Education and Outreach
  - Educational videos
  - Draft guidance documents
SACHRP Recommendations: Only Recommendations

- Broad consent
- Broad consent template
- Benign behavioral interventions
- Exceptions to mandated single IRB review
- Proposed expedited review list

These are SACHRP Recommendations, not OHRP Guidance Documents
Additional Guidance Needed on Common Rule Revisions

- Consent revisions
- Broad consent
  - What does it mean to decline broad consent?
- New expedited review list
- Posting Consent forms in Multi-site Research
  - After last subject study visit
- Guidance on limited IRB review
- Guidance on new element for waiver provision
- Guidance on exemptions
  - E.g., what does it mean to determine that an education practice will not adversely impact a student’s opportunity to learn
Harmonization

FDA regulations vs revised Common Rule

• Consent requirements
• Continuing review for expedited studies

Sponsor perspective on research informed consent vs institutional perspective and different views of applicable regulatory obligations

• IRB staff should be prepared to discuss the reasons for the revised consent template (with new key information and elements) with sponsors
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Revisions That Require Changes to Policies, Procedures, Forms & IT Systems

- Revised definitions
- Exempt categories
- Limited review
- Expedited categories
- Continuing review
- Consent form requirements
- Broad consent

- Screening and recruitment
- Grant review
- Single IRB
- Secondary research – data and repositories
- Ongoing research – transition plan
Revised Definitions

What’s changed?

➢ Definition of research
  • The 4 new exclusions as discussed

➢ Definition of human subject
  • To include (i) obtaining information or biospecimens through intervention or interaction with a subject and using, studying, or analyzing the information or biospecimens, or (ii) using, studying, analyzing or generating identifiable private information or identifiable biospecimens

Action items:

➢ Review and revise IRB policies/SOPs/review forms/IT system prior to implementing

➢ Expect further guidance from OHRP on these definitions
Exempt Categories

What’s changed?

- 6 existing exemptions expanded to 8 exemptions
- Exemptions 3, 7 & 8 are new
- Exemption 1 – an additional restriction was added
- Exemptions 2, 4 & 5 – expanded
- Exemption 6 – unchanged

Action items:

- Review and revise IRB policies/SOPs/review forms/IT system
- Develop limited IRB review process for exemptions 2, 3, 7 & 8
- If exempt reviews are currently conducted by non-IRB members, modify practice to require limited IRB review by an IRB member
Exempt Categories

What’s changed?

- **Exemption 1:** Revised – Normal educational practices, added restriction “not likely to adversely impact student’s opportunity to learn required educational content, or assessment of educators who provide instruction”
  - Note: Some research that now qualifies for Exemption 1 may not under the revised rule
- **Exemption 2:** Revised – Research that only includes interactions involving educational tests, surveys, interviews and observations of public behavior, when the data is recorded so that the subjects cannot readily be identified, or disclosure of the data will not be harmful, or subject can be identified but limited IRB review is conducted
  - Note: Limited to data collection only (including audio and video recording, does not include interventions)
- **Exemption 3:** New – Benign behavioral interventions – intervention (e.g., interview, survey, audio/video recording) combined with data collection from adult subjects with prospective agreement, when the data is recorded so that the subjects cannot readily be identified, or disclosure of the data will not be harmful, or subject can be identified but limited IRB review is conducted.
  - Note: deception only permitted if authorized, does not include physiological data (e.g., wearable devices)
  - “Benign intervention” – brief in duration, harmless, not physically invasive, painless, not embarrassing or offensive, and not likely to have a lasting adverse impact
Exempt Categories

What’s changed?

- **Exemption 4: Revised** – Secondary research with identifiable private information or biospecimens, expanded to include prospective data review (eliminating requirement for review of existing data only), maintenance of identifiers if all study data is protected health information and research conducted by, or on behalf of, a federal department/agency or using government-generated or government-collected information obtained for non-research activities
  - Note: This is a significant change as it allows for secondary research to be done on data (not biospecimens) otherwise subject to HIPAA

- **Exemption 5: Revised** – Public benefit service program research/federal demonstration projects, expanded scope slightly and added new eligibility requirement that the project must be published on a federal website

- **Exemption 6: Unchanged** – Taste and food quality evaluation and consumer acceptance

- **Exemption 7: New** – Storage or maintenance for secondary research for which broad consent is required, allows for storage and maintenance of identifiable data and identifiable biospecimens when an IRB conducts limited IRB review

- **Exemption 8: New** – Use of identifiable data and identifiable biospecimens obtained with broad consent for secondary research use when an IRB conducts a limited IRB review
Exempt Categories – Applying Subparts B, C & D

What’s changed?

- **Subpart B:** *Pregnant women, fetuses, neonates* – Exemptions may be applied to research subject to Part B
- **Subpart C:** *Prisoners* – Exemptions apply to research intended to involve a broader population and only incidentally includes prisoners
- **Subpart D:** *Children* – Exemption 2 involving surveys, interviews or observation of public behavior, applies only when investigators do not participate in the activities being observed, and may not be applied when identifiers are recorded
  - Exemption 3 (benign behavioral interventions) does not apply to children
Limited IRB Review

What’s changed? Limited IRB review is required for certain exemptions and does not require an IRB to consider all of the IRB approval criteria at §46.111

There are 4 exemptions that may require it:

- **Exemption 2**: Educational tests/surveys/interviews/observations of public behavior – if identifiable information is recorded, limited IRB review is required to protect privacy and confidentiality
- **Exemption 3**: Benign behavioral research – same as Exemption 2
- **Exemption 7**: Storage and maintenance of identifiable private information or biospecimens for secondary research use obtained with broad consent – limited IRB review is required to determine that the elements of broad consent are met, that it is appropriately documented or documentation has been waived; and that there are adequate provisions to protect privacy and confidentiality
- **Exemption 8**: Secondary research involving identifiable private information or identifiable biospecimens obtained with broad consent – adequate provisions to protect privacy and confidentiality and that the research is within the scope of the broad consent

Action items:

- Develop IRB policies, SOPs, review forms/IT systems for limited IRB review (to be conducted by IRB Chair or expedited reviewer)
Expedited Review

What’s changed? *No changes in Expedited Review List*

- **Issues:**
  - New exemptions rely upon research being removed from the current expedited review list
  - New exemptions may otherwise impact the expedited review list (e.g., some benign behavioral research may not meet the definition for exemption and will need to be reviewed under an appropriate expedited review category)
  - Need a revised list from the government – the list will need to go out for public comment, so this is your opportunity to look at the SACHRP proposal and see what additional changes/suggestions you would like made

**Action items:**

- Review and revise IRB Policies/SOPs/review forms/IT system to reflect new expedited review list (when available)
- Revise IRB policies/SOPs/review forms/IT system to require documentation of rationale if reviewer determines research on the expedited review list is more than minimal risk
Continuing Review

What’s changed?

- Continuing review is not required for:
  - Research that is eligible for expedited review
  - Research that had limited IRB review
  - Research that has completed all interventions and now is limited to analyzing data (even if the information or biospecimens are identifiable)
  - Research that has completed all interventions and now is limited to accessing follow-up clinical data from clinical care

- If the IRB determines continuing review should be conducted when it is not required, the rationale must be documented

Action items:

- Note: Continuing review will still be required for FDA-regulated studies unless FDA harmonizes with the revised Common Rule
- Develop process for documenting if the IRB will conduct continuing review when not otherwise required
- Determine whether there will be a transition process for pre-2018 studies that meet the requirements for elimination of continuing review
- Revise IRB approval notice to indicate when continuing review is not required (with reminder that amendments, AEs and study termination report are still required)
- Generally, review and revise IRB policies/SOPs/review forms/IT system to reflect these changes to continuing review policy
What’s changed?

- Key information about the study must be added at the beginning of the ICF
- 1 basic consent element and 3 additional elements (to be included when appropriate) should be added to the ICF template
- ICFs for clinical trials must be posted to a public federal website
- In jurisdictions where there is no applicable law for allowing a legally authorized representative (LAR) to provide consent on behalf of a subject for research, an individual who is recognized by institutional policy as acceptable for providing consent in the non-research context will be considered an LAR for purposes of consent to the research

Action items:

- Revise ICF template
- Create policy and disseminate information to investigators on posting ICFs to the identified public federal websites for clinical trials supported or conducted by a Common Rule department or agency
- Revise policy on LAR if applicable to your jurisdiction
- Generally, review and revise IRB policies/SOPs/review forms/IT system to reflect these changes to continuing review policy
“Informed consent 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.”

45 CFR 46.116
What Is Key Information?

The preamble (FR v. 82, no. 12, Jan 19 2017, page 7214) provides the following list of topics that the Common Rule departments and agencies indicated generally would encompass the key information required to satisfy 116(a)(5)(i):

- The fact that consent is being sought for research and that participation is voluntary
- The purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research
- The reasonably foreseeable risks or discomforts to the prospective subject
- The benefits to the prospective subject or to others that may reasonably be expected from the research
- Appropriate alternative procedures or courses of treatments, if any, that might be advantageous to the prospective subject

The preamble language is not legally binding on the Common Rule agencies’ future interpretation
Key Information: Can There Be Standard Questions?

- What are the main reasons a subject will want to join this study?
- What are the main reasons a subject will not want to join this study?
- What is the research question the study is trying to answer? Why is it relevant to the subject?
- What aspects of research participation or this particular study are likely to be unfamiliar to a prospective subject, diverge from a subject’s expectations, or require special attention?
- What information about the subject is being collected as part of this research?
- What are the types of activities that subjects will do in the research?
- What impact will participating in this research have on the subject outside of the research? For example, will it reduce options for standard treatments?
- How will the subjects’ experience in this study differ from treatment outside of the study?
- In what ways is this research novel?

• Note: Content derived from a working document out of the July SACHRP public meeting
Who Is the Reasonable Person and What Do You Need to Tell Them?

“...information that a reasonable person would want to have in order to make an informed decision about whether to participate and an opportunity to discuss that information.”

Later qualified by the words:

“...in understanding the reasons why one might or might not want to participate in the research.”

45 CFR 46.116
“Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate.”

45 CFR 46.116
Summary of new basic element:

- Notice about whether information and biospecimens collected as part of the current research might be stripped of identifiers and used for future research

Consent form needs to state:

- That the deidentified information or biospecimens could be used for future research without additional consent (*notice of traditional secondary research uses*); or
- That the subjects’ information or biospecimens will not be used for future research (*use with caution*)
3 New Additional Elements

When appropriate:

7. 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;

8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

9. 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
New Broad Consent

What’s changed?

➢ Broad consent is a new process geared toward repositories and focused on secondary research use, recognizing the type of future research use may not be known at the time the broad consent is obtained.

➢ It is permitted as an alternative to the standard informed consent requirements.

➢ Some of the traditional consent elements are not required for broad consent, but some additional elements are required, such as:
  • General description of types of research that may be conducted with the identifiable private information or identifiable biospecimens, with sufficient information so that a reasonable person would expect the broad consent permits the types of research conducted.
  • Description of the identifiable private information/biospecimens that might be used in research, whether sharing of identifiable private information/biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information/biospecimens.

➢ Much of the discussion around broad consent concerns tracking and determining what future research has actually been refused.

➢ The issue – if an individual refused to provide broad consent, the IRB can’t waive informed consent for the subject’s identifiable private information/biospecimens in the secondary study.
Action items:

- Determine whether your institution will use broad consent
- If so, create a broad consent template for institutional use
- If so, develop an active method for tracking broad consent agreement and refusal
- Update investigator guidelines for informed consent to reflect changes and explain context for specific vs broad consent
- Create broad consent review form for IRB reviewers
- Review and revise IRB policies/SOPs/review forms/IT system to reflect the addition of broad consent
Waiver of Consent

What’s changed?

➤ For broad consent, the IRB can’t waive consent if a subject has refused a broad consent

➤ For waiver or alteration of consent when using specific consent: there is a new waiver criterion which applies to research with identifiable private information or identifiable biospecimens
  • The IRB must determine that the research could not practicably be carried out without using the information or biospecimens in an identifiable form

Action items:

➤ Review and revise IRB policies/SOPs/review forms/IT system to reflect these waiver requirements
Screening & Recruitment

What’s changed?

- IRB review not required for screening, recruitment and determining eligibility for a research study
- This means the IRB is not required to waive consent for investigators to record identifiable private information for screening, recruiting and determining eligibility
  - This is an exception to the consent requirement, not a waiver
- The information must be obtained (i) through oral or written communication with the subject or the LAR, or (ii) through accessing records or stored biospecimens

Action items:

- Review and revise IRB policies/SOPs/review forms/IT system to reflect new exception for screening and recruitment
What’s changed?

- Eliminating the requirement that institutional review boards review grant applications or other funding proposals related to the research (as discussed)
- Instead, certification is required when the research is supported by a Federal department or agency and not otherwise waived under §46.101(i) or exempted under §46.104
  - For such research, institutions shall certify that each proposed research study covered by the assurance has been reviewed and approved by the IRB

Action items:

- Review and revise IRB policies/SOPs/review forms
- Confirm the grant/research administration office is aware of these changes
Single IRB (sIRB)

What’s changed?
- Starting 1/25/18, all multi-center NIH-funded studies were required to use an sIRB
- Starting 1/20/20, most federally funded multi-center research projects located in the US will be required to use an sIRB

Action items:
- Ensure all current reliance arrangements are documented and the responsibilities of both entities are set forth in the agreement or otherwise in an institutional policy
- Determine whether your institution will serve as the sIRB for multi-site studies, and, if so, develop policies, SOPs and IT systems to provide for this service
- Develop a policy/procedure for requesting an exception from the use of an sIRB
- Set up communication plan between grant/research administration offices and the IRB
Secondary Research

What’s changed?

➢ 4 options currently for conducting secondary research
  • Non-identified information or biospecimens – not human subjects research
  • IRB waiver of consent
  • IRB review, standard consent
  • Meeting an exemption – exemption 4 (when identifiers are not recorded)

➢ New
  • Obtaining broad consent – new exemptions 7 and 8
  • Expanded exemption 4 (allowing secondary research with identifiable information otherwise covered by HIPAA)

Action items:
➢ Identify existing databases and repositories in which information and materials are stored for possible secondary research purposes.
➢ Determine whether existing repositories will remain governed by pre-2018 rule or will voluntarily shift to compliance with 2018 rule.
Relax it will all be fine

Can someone bring me a drink?
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