Welcome & Introduction

IRBMED Seminar Series: Eleventh Hour Common Rule Preparedness

December 18, 2018

Judy Birk, JD
Yes, we have been here before

2011 ANPRM
Sought comments to potential changes to common rule

2015 NPRM
Sought comments on proposals to review the Common Rule

2017 Final Rule Issued Jan 19
2nd the last day of Obama administration; January 2018 implementation date

2018 Delay until July, 2018

2018 Delay until...

January 21, 2019
Overview of Changes

• Definition of human subjects now includes identifiable biospecimens
• Informed consent
  • Concise and focused presentation of key information
  • New elements of informed consent were added
  • Posting of clinical trial informed consent to website
• Modified definition of what is not research
• Existing exemption categories are added to and modified
• Continuing review eliminated in some cases
• Single IRB for multi-site research January, 2020
• Waiting for:
  • Exempt decision tool
  • Privacy and security guidance
  • Informed consent guidance
  • General guidance
Impact on Current and Future Research

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December 18, 2018

Ray-Nitra Reynolds, MLIS, CIP
NOTE:
Relative to the Common Rule changes, this presentation does not address requirements for FDA regulated research or other specific HIPAA requirements.
Impact on Current and Future Research

- Application of the updated regulations depends on
  - Federal Sponsorship
  - Approval before or under the updated regulations
  - 4 Quadrant Transition Grid

- Updates to eResearch

- Impact on Study Teams
## Transition to 2018 Regulations Grid

<table>
<thead>
<tr>
<th>Has Federal Sponsorship</th>
<th>Has No Federal Sponsorship</th>
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<tr>
<td><strong>Transition to applicable 2018 Regulations at next Amendment (Amr)</strong></td>
<td><strong>Pre-2018 Regulations; need for CR will be assessed</strong></td>
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<tr>
<td>- Study's next usual Amr should include transition to 2018 compliance</td>
<td>- Validation of no current Federal sponsorship - Not required to comply with additional 2018 requirements</td>
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<tr>
<td>- Changes are only required to the extent applicable to ongoing study activity</td>
<td>- Study teams able to transition to the new consent template if desired</td>
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<td>- Do not Amend solely for the purpose of transition</td>
<td>- Continuing Review (CR) will be ended per institutional practice for many minimal risk studies</td>
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<td>* eResearch will embed most 2018 regulations</td>
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<td>- Will be required to post informed consents online when additional guidance from federal government is provided.</td>
<td>* Consent template will reflect 2018 regulations</td>
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<td>- Study teams will not be required to post informed consents for clinical trials online</td>
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Federal Sponsorship under the Common Rule

• Rule applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research.

  NEW 45 CFR 46.101(a)
  OLD 45 CFR 46.101(a)

• Federal Training grants are considered federally sponsored under these regulations.
Has Federal Sponsorship Approved before Updated Regulations

Transition to *applicable* Updated Regulations at next Amendment

• Study's next usual Amendment should include transition to requirements
• Changes only required to the extent applicable to the ongoing study activity
• Do not Amend solely for the purpose of transition
• Non-substantive changes (IRBMED administrative approval only) may defer transition
• Continuing Review (CR) does not trigger transition
Has **No Federal Sponsorship Approved** before Updated Regulations

Pre-Updated Regulations; need for CR will be assessed

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- Validation of **no current** Federal sponsorship
- Then, not required to comply with additional updated requirements
- Study teams able to transition to the new consent template if desired
- Continuing Review (CR) will be ended per institutional practice for many minimal risk studies
Has Federal Sponsorship
Approved under Updated Regulations

Starts with New Regulations

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• Compliance with updated regulations is required
• Use all updated Common Rule materials including new Standard Consent Template
• Will be required to post informed consents online
Has No Federal Sponsorship
Approved under Updated Regulations

• Starts with New Regulations

• Full compliance with the 2018 regulations is not required; however
  • eResearch will embed most 2018 regulations
  • Consent template will reflect 2018 regulations
  • Study teams will not be required to post informed consents for clinical trials online
Recent eResearch Updates

June of 2018 U-M piloted some of the 2018 Common Rule enhancements prior to the implementation of the federal regulations.

These changes apply only to non-federally funded human subjects research

- New Application Type page
- Exemption changes
- Informed Consent changes (Section 10)
- No Continuing Review Requirement (Expedited Research)
- Terminations
- Updated External Sponsor Information (Section 2)
The Exempt Human Subject Research application type was retired.
Exemption questions and exemption review path options are embedded within the
application type associated with the exemption category.

The Standard application type was renamed “Human subjects research
involving interaction/intervention.”
This application type is used for non-exempt research or for exempt research qualifying for
exemptions 1, 2, 3, 5, and 6.

The Secondary Use application type was renamed “Secondary research uses
of private information or biospecimens.”
This application now routes all secondary use studies through the correct IRB
review/determination path (i.e., Not Regulated, Exempt 4, or Full IRB Regulated Secondary
Use), eliminating the need for study teams to self-identify the required level of review.
Exemption Changes in eResearch

• New “exemption screener” in the interaction/intervention Application Type

• Selecting “Yes” routes the application for full (comprehensive) IRB review or expedited review.

• Selecting “No” displays the list of Exemption Category options

• Existing “standard” studies will display the “exemption screener” question at the next amendment; a response will be required
Exemption Four:
Secondary Use of Identifiable Data

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable specimens, if at least one of the following criteria is met:

1. The identifiable private information or identifiable biospecimens are publicly available; or

2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained directly, or through identifiers linked to subjects, the investigator does not contact subjects, and the investigator will not re-identify subjects; or
Exemption Four: Secondary Use of Identifiable Data

3. The research involves only information collection and analysis involving the investigator’s use of identifiable health information, when that use is regulated under 45 CFR parts 160 and 164 [HIPAA]; or,

4. The research is conducted by, or on behalf of, a Federal department or agency or using government-generated or government-collected information obtained for nonresearch activities.
Informed Consent Changes in eResearch

• Section 10, Informed Consent, was reorganized to help investigators select the correct informed consent category: With signature, without signature (waiver of documentation), Waivers of informed consent, or Other.

• This reorganization applies to the sections for adults and for children.

• In most cases, selections prior to June 10, 2018 will display and do not need re-answering. In some cases, questions 10.1 and/or 10.2 must be fully re-answered, as these cases have answers that could not be directly converted.
No Continuing Review Required - eResearch

- Qualifying minimal risk research will be given a No Continuing Review determination, and these studies will no longer have an option to create a new Continuing Review.

1. Research eligible for expedited review

2. Research that progressed so that it only involves one or both of the following:
   - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
   - Access to follow-up clinical data from standard clinical care procedures

3. Exempt research even if it received limited IRB review

Note: FDA has not aligned with the revised Common Rule and FDA-regulated minimal risk studies or studies or conducted under ICH-GCP guidelines will still require continuing review
No Continuing Review Required - eResearch

- If Continuing Review is not required, then a study workspace message will display on the application’s main tab: **No Continuing Review Required**. Amendments and AE/ORIOs are required when applicable.

A “No Continuing Review” determination must be an IRB determination in eResearch.
Terminations in eResearch

• A new Termination process in the Study workspace will allow the Principal Investigator (PI) or Faculty Advisor to close approved or exempt studies upon completion of the research.

• “Creating a Termination Report step-by-step procedure” available in eResearch

• Previously, study termination was initiated through the SCR process.

• “Creating a Scheduled Continuing Review step-by-step procedure” has been updated in eResearch
External Sponsor Information in eResearch

• External Sponsor questions were removed from Section 2, and are now indicated by linking a related Proposal Approval Form (PAF) or Unfunded Agreement (UFA) from eResearch Proposal Management (eRPM).

• “Adding a PAF or Internal Sponsor step-by-step procedure” available in eResearch

• Certain PAF and UFA data will be imported and displayed in eRRM. This data will display in both the application and in the Related Projects tab.

• A new required question was added: 2.4: Is there any other financial or non-financial sponsorship or support not covered in the sections above?
Exempt Self-Determination

• Only applicable for Exempt categories 1, 2, and 3 when there is no PHI or recording of sensitive information

• Self-determination means that the Principal Investigator is permitted to issue a system-generated exemption determination letter based on responses to key questions within qualifying human subjects exemption categories.

• Once the activity is completed, the application will be in the state of Exempt Self Determination.

• Investigators may choose not to apply self-determination but, instead, choose to submit a study for an IRB determination of exemption.
Summary - Impact of Common Rule Changes on Study Teams

For New Research:
- Be aware of application type options
- Continuing review may not be required
- Be familiar with new consent template
- May need to post consent online
- Be aware of possible Federal sponsorship

For Existing Research:
- Continuing review may not be required
- An updated consent may be required at next amendment
- May need to post consent online
- Be aware of possible changes in Federal sponsorship
Additional Federal and Institutional Updates

IRBMED Seminar Series: Eleventh Hour Common Rule Preparedness

December 18, 2018

Corey Zolondek, PhD, CIP
FDA Harmonization

• 21st Century Cures Act

• FDA Guidance – Waiver of Informed Consent

• FDA Guidance – Impact of the Common Rule
FDA – New Guidance on Waivers of Consent

- Guidance issued July 2017
- Towards Common Rule Harmonization
- Guidance currently in effect

FDA does not intend to object to the initiation or conduct of certain minimal risk clinical investigations for which an IRB waives or alters the informed consent requirements in 21 CFR 50.25
FDA Waiver of Informed Consent Criteria:

1. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects

3. The clinical investigation could not practicably be carried out without the waiver or alteration

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation
FDA WAIVER OF INFORMED CONSENT

Example:

Secondary use of identifiable biospecimens in order to test an *in vitro* Diagnostic Device (a IVD device study).
Guidance – Impact of the Revised Common Rule on FDA-Regulated Clinical Investigations

Key Takeaways...

- Common Rule consent revisions are not inconsistent with existing FDA requirements
- Expedited review should follow existing FDA requirements
- The FDA has not removed its continuing review requirement
NIH Certificates of Confidentiality:

• Effective October 1, 2017, all human subjects research funded by NIH will be automatically be issued Certificates of Confidentiality as part of the terms and conditions of the award

• Applicable to research commenced or ongoing after December 13, 2016

• Part of the 21st Century Cures Act

• NIH will not provide a document, the award itself is confirmation

• The regular application process for Certificates of Confidentiality will be available for research that is not NIH funded

• The CDC and FDA are now also automatically issuing Certificates of Confidentiality via notice of an award.
Single IRB (sIRB) Mandates:

Use of a single IRB in multi-site research is now a requirement for NIH funded research

• NIH sponsored
  ▪ January 25, 2018

• Common Rule: federally sponsored
  ▪ January 20, 2020

Note: This Common Rule element is not on hold/delayed
Single IRB Requirement: Common Rule

• Implementation date of January 20, 2020
  - Applies to all federally supported multi-site studies
  - This is not limited to clinical research

• Final rule seems to allow agencies or departments to exclude certain broad types of research from the requirement
  - No other information available
Single IRB Requirement:

**NIH**

*Implementation date of January 25, 2018*

- Applies to all NIH sponsored multi-site studies
- This is *not limited to clinical research*
- Applies only to domestic research sites conducting the same protocol

Not subject to the requirement:

- Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a *compelling justification for the exception*.
- The NIH will determine whether to grant an exception following an assessment of the need.
Single IRB (sIRB):

Naming Conventions

**Agreements**
- IRB Authorization Agreements
- Reliance Agreements
- Cooperative Agreement
- IRB of Record Agreements
- Master Service Agreements
- “Smart IRB” National Agreement (not an “IRB”)

**IRBs**
- sIRB
- Commercial
- Independent
- External
- Central (an IRB specifically created for the study)
Use of Single IRB:

How does it work?

• Collaborating institutions complete the agreement document
  ▪ These are not signed by the PI or the IRB

• Roles and responsibilities are apportioned between IRBs and the institution

• Assure all internal institutional documents are in alignment with the arrangements
  ▪ Such as Standard Operating Procedures

• Does not require OHRP or FDA signature or approval
When relying on a single IRB, only IRB regulatory oversight is ceded to the single IRB – many institutional obligations remain in-house such as:

- All ancillary committee reviews
  - Research Pharmacy, Radiation Safety, etc.
- Conflict of Interest review and management plans
- Monitoring
- Maintaining compliance with educational requirements
Single IRB:  
**Intended Benefits**

- Reduces duplicative review across sites
- Reduces variability of the study design across sites
- Decreases cumulative review time
- Decreases burdens on local IRBs
- Costs are reduced locally and for the study as a whole
Single IRB:
Challenges for an Institution

- Familiarity with the Reviewing IRB
- Consideration of local context
- Apportionment of institutional liability
- Managing ‘shared’ control and accountability
- Developing/agreeing to different standardized procedures
U-M and Single IRBs – Ceding Oversight

Generally

- U-M may consider ceding of oversight to an external IRB for:
  - Industry-sponsored research,
  - Clinical trials (including some early phase trials) where the sIRB will provide the project oversight and U-M will be added on as a performance site or,
  - NIH multi-site research (requires sIRB)
  - NCI-CIRB clinical trials (required for all phases)
How to Request use of an External Single IRB

• Study team creates a Clinical Trial Routing Form (CTRF) and indicates which sIRB will be used.

• In eResearch Proposal Management (eRPM), study teams must indicate on the PAF Application which sIRB will be used.

• In eResearch Regulatory Management (eRRM), complete the “Requesting Review by a Non-UM IRB” (aka Ceding) application.

• The ceding application will be reviewed by the ancillary committees, and reviewed and acknowledged by the U-M IRB.

If interested in initiating an Institutional IRB request, please call 734-763-4768, and ask to speak with the Ceding Applications Coordinator.

*This workflow is subject to change due to an increasing volume of requests and ongoing efforts to improve efficiencies.
Local context reviews conducted by U-M includes the following:

a. Local ancillary committee reviews as applicable (e.g., pharmacy, radiation safety, clinical billing, conflict of interest or PRC).

b. Ensure that the U-M study teams are appropriately qualified, and have completed educational requirements, i.e. PEERRS.

c. Local analysis of any specific requirements of state or local laws, regulations, policies, standards (social or cultural) or other factors applicable to the study.

d. Identify if the project has changed status and would no longer be appropriate for ceding IRB oversight.
Audits and Inspections

• Study conduct and regulatory recordkeeping requirements remain unchanged.

• Study teams should continue to keep regulatory binders.

• Study teams should contact the External IRB and the U-M IRB if notified of an impending audit or inspection.
Reporting Requirements (to IRB MED)

- Serious Adverse Events that are related to the research per IRB MED guidance
- Unanticipated Problems
- Protocol deviations that may represent a systematic problem requiring local evaluation by IRB MED to determine that sufficient local resources are available for safe conduct of the study
- Reports of Continuing and/or Serious Non-Compliance
- Study holds or suspensions that are not built into the study design (e.g., interim analysis or enrollment complete need not be reported)
Requesting IRBMED as Single IRB in Multi-site Research

- *Must be approved in advance by IRBMED Leadership*

- If associated with NIH grant submission
  - Complete an intake form for IRBMED consideration
  - Provide details about the roles of each site and personnel
  - If approved by Leadership, IRBMED will prepare a comprehensive sIRB plan for inclusion in the grant application
  - The other sites must indicate their reliance on IRBMED

- If declined by IRBMED, consider use of a commercial IRB or another participating site
Updated Informed Consent Requirements

IRBMED Seminar Series: Eleventh Hour Common Rule Preparedness

December 18, 2018

Joseph Austin, JD LL.M
Informed Consent Changes

Under the revised 2018 Common Rule, the requirements for informed consent change, with the addition of:

- "Key information" to be presented at the beginning of the consent form
- New consent elements
- Changes to waiver criteria and documentation (plus other process changes)
- A "broad consent" option for unspecified future use of identifiable data/biospecimens
As a general matter, a brief description of these **five factors** would encompass the key information most likely to assist a reasonable person (or legally authorized representative) in understanding the reasons why one might or might not want to participate in research, as required by § II.116(a)(5)(i) and § II.116(a)(4).
In general, we would expect that to satisfy §ll.116(a)(5)(i), the beginning of an informed consent would include a concise explanation of the following:

1) the fact that consent is being sought for research and that participation is voluntary;
2) the purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research;
3) the reasonably foreseeable risks or discomforts to the prospective subject;
4) the benefits to the prospective subject or to others that may reasonably be expected from the research; and
5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.
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.

§ __.116(5)(i)
General Requirements for Informed Consent

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.

§__.116(a)(5)(ii)
# New Consent Elements

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<tr>
<th>When your project will involve...</th>
<th>Include in the informed consent...</th>
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| The collection of identifiable private information or identifiable biospecimens | A statement indicating whether:  
  • identifiers may be removed, and  
  • de-identified information or biospecimens may or may not be used or shared for future research |
| Use of biospecimens | A statement indicating whether:  
  • biospecimens may be used for commercial profit, and  
  • the subject will share in that profit |
| Clinically relevant results | A statement indicating whether the clinical results, including individual research results, will be returned to the subject, and if so, under what conditions |
| 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) | A statement indicating that the research will or might include whole genome sequencing |
Changes to Waiver Criteria and Documentation

• A waiver of informed consent for the secondary use of identifiable private information/biospecimens (not covered by Broad Consent) must justify why the use of identifiers is necessary to carry out the research.

• Use of identifiable information/biospecimens to identify potential subjects (i.e., screening for recruitment purposes) is allowed without informed consent under certain circumstances. A waiver of consent will no longer be needed for these screening activities.
  • **Note**: HIPAA requirements still apply - including asking for a HIPAA waiver.

• For federally-sponsored clinical trials, a copy of the consent form must be posted to a "publicly available, federal website" post-recruitment and no later than 60 days after the last study visit by any subject.
Broad Consent

The U-M HRPP and IRBs will not mandate nor implement the institutional use of Broad Consent, as the tracking requirements may be burdensome.

- Exemption categories 7 and 8, which rely on Broad Consent, will not be available

- U-M will continue to support study teams seeking subject permission for the collection and storage of identifiable private information/biospecimens for future secondary use research through the following processes:
  - Study-specific consent and comprehensive IRB review
  - IRB waiver of consent (as eligible) and comprehensive IRB review
  - Exemption #4
  - De-identification to remove the research activity from Common Rule purview and not require IRB review or consent

Note: For studies designed to collect identifiable data and/or biospecimens solely for the purpose of maintaining a repository, the study team may find it useful to employ a specialty informed consent template (e.g., biorepository template).
Updated Standard Informed Consent Template

- Updated template was made available in advance of the general compliance date
- Meets requirements of the existing Common Rule and revised Common Rule
- As of December 3, 2018, the updated template is required for new studies
- The pre-transition informed consent template is no longer in use
- Consent documents approved on or after January 21, 2019 must comply with the new consent requirements

- OHRP may still issue guidance clarifying the requirements
- Any updates will be communicated as early as possible.
Updates to Standard Template

For all new consents:

(Section 1)

• Study teams are instructed to list only a study’s principal investigator and study coordinator in the consent document.

• Key information about study participation has been reformatted

As Applicable:

(Section 4)

• The Genomic Data Sharing language has been updated

• Box C is now divided into Boxes C and D to distinguish “sub-studies” and “unspecified future use”

• Enhanced language related to commercialization and sharing of biospecimens
New Study Descriptors for Key Information Section

- These descriptors describe the phase or nature of the study and the role of the participant in the research.
- Add detail as indicated and any special circumstances (e.g. randomization).
- Create a new study descriptor as needed.
Risk Information in Key Information Section

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include [INDICATE REASONABLY FORESEEABLE RISKS; SEE EXAMPLES BELOW.] More detailed information will be provided later in this document.

- serious health complications of your current [DISEASE/CONDITION] such as [BRIEFLY DESCRIBE]
- no improvement of your current [DISEASE/CONDITION]
- new symptoms from use of the [drug/device] such as [BRIEFLY DESCRIBE]
Benefit Information in Key Information Section

This study may offer some benefit to you now or others in the future by [BRIEFLY SUMMARIZE POTENTIAL BENEFITS].

This study may not offer any benefit to you now but may benefit others in the future by [BRIEFLY SUMMARIZE POTENTIAL BENEFITS].

More information will be provided later in this document.
We expect the amount of time you will participate in the study will be [INDICATE HOW LONG SUBJECTS WILL BE IN THE STUDY].

You can decide not to be in this study. Alternatives to joining this study include [BRIEFLY ADDRESS ALTERNATIVES SUCH AS STANDARD OF CARE ALTERNATIVES OR OTHER CLINICAL TRIALS].

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.
Section 4: Information about Study Participation

The following statements are now required:

As part of this study, your samples and collected information may be shared with [SPONSOR NAME, OR DELETE THIS SENTENCE IF THERE IS NO SPONSOR].

With appropriate permissions, your samples and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.
Updates to Standard Template

As Applicable:

(Section 9)
• Certificate of Confidentiality language has been updated to be in accordance with new NIH policy
• ClinicalTrials.gov language has been updated

(Section 11)
• Addition of State of Michigan HIV testing language has been included (this will eliminate the need to use the separate State of Michigan pamphlet)

(Section 12)
• Signature boxes have had minor updates
Certificate of Confidentiality language has been updated to be in accordance with new NIH policy.

If your study is NIH-funded or you have or plan to obtain a Certificate of Confidentiality, insert the following:

This research [is/will be] covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.
Section 9: CONFIDENTIALITY OF SUBJECT RECORDS

ClinicalTrials.gov language has been updated.

ClinicalTrials.gov

Required Registration and Reporting for ACTs
Applicable Clinical Trials (ACTs) are required by federal law to be registered and to report results in www.ClinicalTrials.gov. The federal checklist for evaluating whether a clinical study is an ACT under 42 CFR 11.22(b) should be consulted with careful attention to the pages associated with the initial checklist. ACTs must use the unaltered consent template language provided below in the template.

NIH and other Sponsor Requirements for Registration and Reporting
Many sponsors require registration and some (such as NIH) also require results reporting. NIH funded clinical trials that began on or after 1/18/2017 must refer to ClinicalTrials.gov in their informed consent document (unless they are conducted under a grant submitted prior to that date, with no competing renewals on or after 1/18/2017). If the trial is an NIH funded ACT, it must use the unaltered template language for ACTs. If the trial is NIH funded but is not an ACT, use the language listed in the next paragraph for Non-ACTS.

Registration for Non-ACTS (including for purposes of publication)
All clinical trials should be registered to preserve the right to publish as per ICMJE requirements. Note that this indication of registration constitutes a “promise” to participants that the trial will be registered, so it must meet that obligation. Thus, if you plan to register a trial that is not an ACT, whether because a sponsor requires it or to preserve the right to publish, replace the template statement below with the following:

“This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.”

Registries and observational studies
Check to see if the funding agency requires it, but if the study is NOT a clinical trial (e.g., an observational study) and you do not plan to register it, you do not need to include any statement about www.ClinicalTrials.gov and should delete the consent template language below.

Questions? Contact the Medical School’s Office of Regulatory Affairs by emailing UMMS-RegAffairs@med.umich.edu or calling 734-647-1576.
Section 11: Record of Information Provided

Addition of State of Michigan HIV testing language has been included (this will eliminate the need to use the separate State of Michigan pamphlet).

Additional information about HIV testing — Part 1 of 3

The State of Michigan requires providers give information to patients prior to administering an HIV test. If your study procedures include HIV testing, copy all of the text from the 3 boxes and paste it into the body of the consent document. You will not need to provide a separate pamphlet to subjects when including this information.

11.2 Additional required information

Because this study requires you to receive an HIV test in order to be a part of the study, the State of Michigan requires information about HIV to be provided to you.

HIV testing information
New Studies

New studies submitted for IRB review after January 21, 2019 must utilize an updated informed consent template to ensure compliance with the revised Common Rule.

IRB applications submitted shortly before January 21, 2019 may not be reviewed in time to qualify under the current human subjects protection regulations.

Applications undergoing the review process at the time of transition may be returned to the study team to update the informed consent elements.
Posting Consent Forms Online

• Clinical trials with federal sponsorship will be required to post an IRB-approved consent form on a publicly available Federal Web site after recruitment is closed, per 45 CFR 46.116 (h).

• Two publicly available federal websites that will satisfy this requirement, as required by the revised Common Rule, have been identified by OHRP as of August 28, 2018:

1. ClinicalTrials.gov
2. a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).
Posting Consent Forms Online

• The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

• Only one IRB-approved version used to enroll subjects is required
  • Even if multiple exist, multisite study, or different subject groups

• Federal department or agencies may permit/require redactions to the posted information
  • Could determine that the very existence of a particular clinical trial should not be publicly disclosed, in which case no posting would be required (rare)

• The IRB will not be involved in the process for posting consents online.
Questions