UPDATES: U of M Transition to 2018 Regulations
Changes to the Common Rule and other Federal Agency Policies

January 09, 2018

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Introduction:

NOTE:
Relative to the Common Rule changes, this presentation does not address requirements for FDA regulated research or other specific HIPAA requirements
Seminar Topics:

• Important Dates and Unknowns associated with the revised Common Rule
• IRBMED implementation and minimizing the impact on researchers
  o IRBMED Transition Plan – research approved before and after the effective date
  o Consent changes/uploads
  o Changes related to exempt research (*Secondary Use discussion)
  o Continuing Review (CR) and Reporting Requirements
• NIH sIRB Requirement
• FDA Harmonization with the New Common Rule
• Certificates of Confidentiality
• These changes are NOT currently in effect
• Current effective/compliance date is **January 19, 2018**

• On October 7, OHRP submitted a request to OIRA (Office of Information and Regulatory Affairs) to **delay the general implementation date for one year but permit implementation of three “burden-reducing provisions”**.

• OIRA is currently reviewing a final rule titled “Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects” with a receipt date of **January 4, 2018**

> The title of the proposed action has also changed from the previous title, a notice of proposed rulemaking titled “Federal Policy for the Protection of Human Subjects: Proposed 1-Year Delay of the General Implementation Date While Allowing the Use of Three Burden-Reducing Provisions During the Delay Year” **suggesting a more general delay of unknown length**.
**IRBMED Transition Grid for 2018 Regulations**

<table>
<thead>
<tr>
<th>Has Federal Sponsorship</th>
<th>Has No Federal Sponsorship</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Transition to applicable 2018 Regulations at next Amendment (Ame)</strong></td>
<td></td>
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<tr>
<td>- Changes are only required to the extent applicable to ongoing study activity</td>
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<tr>
<td>- Do not create Ame solely for the purpose of transition</td>
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<tr>
<td>- Ame for only non-substantive changes (IRBMED administrative approval) does not trigger transition</td>
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<tr>
<td>- Continuing Review (CR) does not trigger transition</td>
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<tr>
<td><strong>Evaluate Pre-2018 vs. New Regulations</strong></td>
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<tr>
<td>- Could 2018 regulations for no CR be applied?</td>
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<tr>
<td>- If yes, apply the no CR provision</td>
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<tr>
<td>- If no, remain in the old regulations</td>
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<tr>
<td>- After validation of no current Federal sponsorship compliance with 2018 requirements is not required</td>
<td></td>
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<tr>
<td>- Study teams able to transition to the new consent template if desired</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Approved before 2018 effective date</th>
<th>Approved after 2018 effective date</th>
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<tbody>
<tr>
<td><strong>Starts with New Regulations</strong></td>
<td></td>
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<tr>
<td>- Compliance with 2018 regulations is required</td>
<td></td>
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<tr>
<td>- Use all 2018 Common Rule materials including new Standard Consent Template</td>
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<tr>
<td>- Will be required to post informed consents online when additional guidance from federal government is provided.</td>
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<tr>
<td><strong>Generally Starts with New Regulations</strong></td>
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<tr>
<td>- Full compliance with the 2018 regulations is not required; however</td>
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<tr>
<td>- eResearch will embed most 2018 regulations</td>
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<tr>
<td>- After a transition period, the consent template will reflect 2018 regulations</td>
<td></td>
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<tr>
<td>- Study teams will not be required to post informed consents for clinical trials online</td>
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</tbody>
</table>
Federal Sponsorship

• 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.

• Federal department or agency refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

[Training grants, including activities conducted under the CTSA award (e.g. MICHRA Pilot Awards) are considered to have federal sponsorship.]
IRBMED Transition Plan for 2018 Regulations

1. Already approved research will transition to the 2018 regulations when/if triggered by an amendment, and if the research has current federal sponsorship.

2. Already approved research with no current federal sponsorship, the study may not have to comply with 2018 regulations; however the no continuing review provision may be applied.

3. Research with federal sponsorship and approved after the effective date, must comply with the new 2018 regulations.

4. For research, with no federal sponsorship and approved after the effective date, compliance with the 2018 regulations is not required, however, most of the 2018 requirements will be embedded in eResearch and the updated Consent Template.
IRBMED Transition Plan for 2018 Regulations

- Research has Federal Sponsorship; AND
- Approved before 2018 Effective Date

Transition to **applicable 2018 Regulations at next Amendment (Ame)**

- Changes are only required **to the extent applicable** to ongoing study activity
- Do not create Ame solely for the purpose of the transition
- Ame for **only** non-substantial changes (IRBMED administrative approval) does not trigger transition
- Continuing Review (CR) does not trigger transition
- Studies that never amend remain under old rules
IRBMED Transition Plan for 2018 Regulations

- Research has **No** Federal Sponsorship; AND
- Approved **before** 2018 Effective Date

Evaluate Pre-2018 vs. New Regulations

**Could 2018 Regulations for no Continuing Review (CR) be applied?**

- If **yes**, apply the no CR provision
- If **no**, the study remains under the old regulations
  - After validation of **no current** Federal sponsorship compliance with 2018 regulations is not required
  - Study team able to transition to the new consent template if desired
IRBMED Transition Plan for 2018 Regulations

- Research has **Federal Sponsorship; AND**
- Approved **after 2018 Effective Date**

**START with new 2018 Regulations!**

- Compliance with 2018 regulations is required
- Use all 2018 Common Rule materials including updated Standard Consent Template
- Will be required to post informed consents online when additional guidance from federal government is provided
IRBMED Transition Plan for 2018 Regulations

- Research has **No** Federal Sponsorship; **AND**
- Approved **after** 2018 Effective Date

**Generally STARTS with new 2018 Regulations!**

- Full compliance with the 2018 regulations is **not** required; however
  - eResearch will embed most 2018 regulations
  - After a transition period, the consent template will reflect 2018 regulations

- Study teams will not be required to post informed consents for clinical trials online
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)
New Consent Requirements:

Document

“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.”

§ 1.116(5)(ii)
Implementation of New Consent Requirements:
Already Approved Consents

When transition is required:
• Developed cover page to meet new key information requirements
• Minimizes additional work
• Cover page to be added to existing consents when/if study is amended
• No need to re-consent existing subjects
• Studies that never amend remain under old rules
• Any additional study changes may require other updates
Implementation of New Consent Requirements: New Consent Documents

- Cover page meeting new requirements added to an updated Standard Consent Template
- Includes additional Important Information section
- Other minor changes to streamline template and improve readability for subject comprehension
- The updated IRBMED consent template will be forthcoming
- Also awaiting updated NCI template
Updates to Standard Consent Template

• Eliminated study team member names other than PI and Study Coordinator
• Updated Contact Information Section

As Applicable:
• New language regarding HIV Testing and related Michigan Law
• Updated language for research with a Certificate of Confidentiality (CoC)
• Revised section regarding Genomic Data Sharing (GDS)
  ➢ NIH funded genomic research that generates large scale human or non-human genomic data is subject to NIH’s GDS policy
• Enhanced language related to commercialization and sharing of biospecimens
You may be eligible to take part in a research study. Taking part in this study is completely voluntary.

This form contains information that will help you decide whether to take part. All of this information is important, but here are some especially important points to keep in mind:

- It is totally up to you whether to take part in this study.
  - Even if you decide to join the study, you are free to leave at any time if you change your mind.
- This is research; medical scientists do research to learn about diseases and how to treat them.
  - Research is different from regular medical care, which has already been tested in research.
- [Continue this bulleted list with other key points for potential subjects to consider, such as study purpose, risks, benefits, and alternatives to participation.]

- Optional components
  - [If your research includes an optional sub-study, briefly summarize here.]
  - [If your research involves optional broad consent to storage, future use, and/or sharing of specimens and/or data, briefly summarize here.]

Please take time to read this entire form (or have it read to you). After you have finished, you should talk to us about the study and ask us any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study.

If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about.
Broad Consent:

At this time, 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).
Consent for Screening, Recruiting and Determining Eligibility

• “Waiver of Consent” in eResearch will not need to be requested for obtaining information or biospecimens for the purposes of screening, recruiting or determining eligibility, provided certain conditions are met:
  - Information will be obtained by communicating with prospective subject or LAR, OR
  - The information or biospecimens will be obtained by accessing records or stored biospecimens

• This is not a waiver of the consent requirement but rather an exception to the requirement.

• HIPAA Requirements will still apply!
eResearch Update: Q# 10.1

10.1 What type of informed consent will be obtained from adults or minors legally able to consent to treatments or procedures involved in the research?

**With signature:**
- [ ] Comprehensive written
- [ ] Written assent for cognitively or decisionally impaired adults

**Without signature (waiver of documentation):**
- [ ] Comprehensive written
- [ ] Comprehensive oral consent script
- [ ] Assent for cognitively or decisionally impaired adults

**Waivers of informed consent:**
- [ ] Request for waiver of informed consent/parental permission/legally authorized representative consent (Note: no longer required for screening/recruitment)
- [ ] Request for waiver of assent for cognitively or decisionally impaired adults

**Other:**
- [ ] Short form, comprehensive oral script, and witness
- [ ] Request for alteration of informed consent requirements
- [ ] Pre-existing consent(s) covers this activity
- [ ] Re-consent/assent subjects for use of existing data/records/specimens for a new research purpose
**eResearch Update:**

**Q# 10.2**

<table>
<thead>
<tr>
<th>Children</th>
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<tbody>
<tr>
<td>With signature:</td>
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<tr>
<td>- Written document</td>
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<tr>
<td>Without signature (waiver of documentation):</td>
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<tr>
<td>- Written document</td>
</tr>
<tr>
<td>- Oral assent script</td>
</tr>
<tr>
<td>Waiver of assent:</td>
</tr>
<tr>
<td>- Request for waiver of informed assent</td>
</tr>
<tr>
<td>Other:</td>
</tr>
<tr>
<td>- Pre-existing assent covers this activity</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Parents</th>
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<tbody>
<tr>
<td>With signature:</td>
</tr>
<tr>
<td>- Comprehensive written</td>
</tr>
<tr>
<td>Without signature (waiver of documentation):</td>
</tr>
<tr>
<td>- Comprehensive written</td>
</tr>
<tr>
<td>- Comprehensive oral consent/permission script</td>
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<tr>
<td>Waiver of parental consent/permission:</td>
</tr>
<tr>
<td>- Request for waiver of parental consent/permission (Note: no longer required for screening/recruitment)</td>
</tr>
<tr>
<td>Other:</td>
</tr>
<tr>
<td>- Short form permission: comprehensive oral script, and witness</td>
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</tbody>
</table>

- Request to use substitute mechanism for parental permission where research is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects
- Request for IRB to appoint an advocate for children who are wards of the state or any other agency, institution or entity — required for studies related to the children’s status as wards that are approved under 46.406 or 46.407 (see section 33)
- Pre-existing consent/permission covers this activity
Consent:

Posting Consents

• Consent must be posted on a “publicly available Federal Web site”

• Applies only to federally-conducted or supported clinical trials
Consent:

Posting Consents

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

• Posting can take place any time after recruitment closes but no later than 60 days after the last study visit by any subject

• Federal department or agencies may permit/require redactions to the posted information
  • e.g. confidential commercial 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)
Consent:
Posting Consents - Issues

• The Federal web site has not been announced
  • Many think Clinicaltrials.gov is the likely choice

• Which consent should be posted?
  • Should it harmonize with clinical protocol posted on Clinicaltrials.gov?

• Remembering to post the document
IRB-HSBS Review of Certain Exemptions

• IRB-HSBS will now review Exempt Research Categories 2 and 3 that contain PHI

• They will continue to review Exempt Research Categories 1, 2 and 3 that have no PHI

• In the future, they will assume review of some Secondary Use Research
Exemption Four:
Secondary Use of Identifiable Data

Previous/current Exemption Four:

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
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.
Exemption Four: Secondary Use of Identifiable Data

The revised Exemption Four eliminates the requirement that the data exist at the time of the exempt determination; data may be collected prospectively.
New Exemption #4 - Secondary Use Research:

#4 - SECONDARY RESEARCH (IDENTIFIABLE PRIVATE INFORMATION/BIOSPECIMENS)

What's New: The scope of this exemption will be expanded to allow:

- Prospective data review
- Maintenance of identifiers, if all study data is protected health information (PHI)
- Research that is conducted by, or on behalf of, a Federal department/agency or using government-generated or government-collected information obtained for non-research activities

Review Path: An IRB Determination is required; however, if PHI is used then a Privacy Board review (HIPAA) is conducted with the IRB Determination.
Simplifying “Application Type” for Secondary Use

<table>
<thead>
<tr>
<th>Application Type</th>
<th>Description</th>
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<tbody>
<tr>
<td>Human Subjects research involving interaction or intervention (formerly Standard, non-exempt research project - or - Exempt)</td>
<td>Studies that involve either or both of the following:</td>
</tr>
<tr>
<td></td>
<td>• Interaction, including communication or interpersonnel contact between investigator and subject</td>
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<td></td>
<td>• Intervention, including both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or subject’s environment that are performed for research purposes</td>
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<td></td>
<td>Interaction/Intervention studies may also have a “secondary research” component.</td>
</tr>
<tr>
<td>Secondary research uses of private information or biospecimens</td>
<td>“Secondary research” are studies that involve ONLY re-using private information and/or biospecimens that are collected for some other “primary” or “initial” activity, such as earlier research studies, a biospecimen holding specimens obtained with “broad consent,” clinical care, educational records. Do NOT use this application type for:</td>
</tr>
<tr>
<td></td>
<td>• Studies that also have an interaction/intervention component, such as primary collection of information or biospecimens for the purposes of the study. (Choose instead “Human subjects research involving interaction or intervention.”)</td>
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<tr>
<td></td>
<td>• Projects involving secondary use of information/biospecimens for only non-research purposes, such as QA/QI, case studies on one or two individuals, or use in a class to teach research methods. (Choose instead “Activities not regulated as human subjects research.”)</td>
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</tbody>
</table>
Continuing Review:
New Regulations (2018)

Continuing IRB review will **not be** required for:

A. Research eligible for expedited review
B. Research that progressed so that it only involves one or both of the following:
   1. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
   2. Access to follow-up clinical data from standard clinical care procedures
C. Exempt research even if it received limited IRB review

Continuing review **WILL** be required for studies subject to FDA regulations or conducted under ICH-GCP guidelines.
Continuing Review:
New Regulations (2018)

Even when continuing review is not required for a project, the study team must still:

- Submit amendments for project changes
- Report AEs/ORIOs
- Terminate the project once it ends, or when personal identifiers are removed from the data/biospecimens and all codes and keys are destroyed
- U-M will implement an automated annual email in eResearch
- The system email will be sent prior to the anniversary approval date for the study

U-M IRBs may re-evaluate its CR/No CR decision for a project depending on the type of change(s) proposed in an amendment (e.g., protocol change that increases subject risk), or as an outcome of the IRB's review of Adverse Events or ORIOs.
No Continuing Review Requirements:

DISPLAYS ON STUDY WORKSPACE

NO OPTION TO “Create New” CR
Single IRBs (sIRB): Defining

...each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

• This is existing language but takes on new meaning
sIRB Requirements:

Federal

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

• NIH sponsored
  ▪ January 25, 2018

• Common Rule: federally sponsored
  ▪ January 20, 2020
Single IRB:

**Naming Conventions**

Agreements
- IRB Authorization Agreements
- Reliance Agreements
- Cooperative Agreement
- IRB of Record Agreements
- Master Service Agreements
- “Smart IRB” National Agreement

IRBs
- Commercial
- Independent
- External
- Central
Single IRB: How do they 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
Single IRB: Parameters

When relying on a single IRB, only IRB regulatory oversight is ceded to the single IRB – many of the study team 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 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
NIH Single IRB: Requirement

***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:
Challenges for an Institution

• What is known about the Reviewing IRB?
• Consideration of local context
• Apportionment of institutional liability
• Managing ‘shared’ control and accountability
• Developing/agreeing to different standardized procedures
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).
# Waiver of Informed Consent: Current in eResearch

<table>
<thead>
<tr>
<th>10.3.1* This request is for:</th>
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<tbody>
<tr>
<td><strong>Select all that apply:</strong></td>
<td></td>
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<tr>
<td>❑ Waiver of informed consent for <strong>ALL</strong> of the project (Note: Consent cannot be waived if the study is subject to FDA oversight)</td>
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<tr>
<td>❑ Waiver of informed consent for <strong>PART</strong> of the project (Note: Applicable only to the recruitment aspects of the study if the study is subject to FDA oversight)</td>
<td></td>
</tr>
<tr>
<td>❑ An alteration to the required elements of informed consent for <strong>ALL</strong> of the project (Note: The required elements cannot be altered if the study is subject to FDA oversight)</td>
<td></td>
</tr>
<tr>
<td>❑ An alteration to the required elements of informed consent for <strong>PART</strong> of the project (Note: The required elements cannot be altered if the study is subject to FDA oversight)</td>
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</tbody>
</table>
Waiver of Informed Consent: Future State in eResearch

10.3.1* This request is for:

Select all that apply:

- Waiver – General - ALL of the project
- Waiver – General - PART of the project (A waiver is no longer required for screening/recruitment purposes.)
- Alteration to required element(s) – General - ALL of the project
- Alteration to required element(s) - General - PART of the project

Waiver or alteration – Specialized – state/local government research or demonstration project designed to study, evaluate, or otherwise examine:

- Public benefit or service program
- Procedures for obtaining benefits/services under those programs
- Possible changes in or alternatives in those programs or procedures, or
- Possible changes in methods or levels of payment for benefits under those programs

Waiver (OHRP) exception (FDA) – Specialized - Planned Emergency Research Contact the IRB if you think this category may apply. Upload a separate document justifying the requirements for this waiver. OHRP guidance and FDA regulation permit informed consent waiver under a specialized circumstances for a strictly limited class of research, involving research activities that may be carried out in human subjects who are in need of emergency therapy and for whom, because of the subjects' medical condition and the unavailability of legally authorized representatives of the subjects, no legally effective informed consent can be obtained.
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
Revised Common Rule Implementation: Current Status

• U-M is going forward with required changes for compliance

• Efforts are focused towards burden reducing changes

• Awaiting outcome of the new proposed final rule from HHS
Resources:

• Common Rule

• University of Michigan web-site
  • http://research-compliance.umich.edu/human-subjects
Questions?