

# The Bare Essentials

01.24.2018

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1. Obtain prior IRB review and approval for all human subjects research — including research that fits one or more of the exemption categories.
2. Download all forms and templates fresh from the IRB website. Stop recycling earlier versions.
3. Note the expiration dates indicated in your approval letters. Create a reminder system to ensure timely submission of continuing reviews and study closures.
4. Obtain prior IRB review and approval for all proposed changes to research.
5. Submit a closure to the IRB when your research is completed, even if it's deemed exempt.

If in doubt, consult the 1- to 2-page summary documents that are arranged by topic on the IRB website, attend a help session, or contact the IRB for assistance.

# New Human Subjects Regulations

## Who, What, When, Where, Why, and How

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### WHO

All users are affected by changes the UMMS IRB is making to forms and processes to ensure compliance with the new human subjects regulations.

### WHAT

The changes that will be most noticeable to users include:

- A new consent template – **originally posted 12.20.2017**
- Additional exemption categories that do not require Continuing Review (but do require Modification & Study Closure)
- Three-year approval periods for some new expedited research
- Annual reminders from eIRB of investigator obligations

Research that is FDA-regulated or funded/supported by Department of Justice will use the new consent template, but is not eligible for new exemption categories or extended approval periods.

### WHEN

The effective date of the New Rule is January 21, 2019.

- We refer to “Pre-2018” and “2018 Regulations” because the original effective date of the New Rule or Revised Common Rule was January 19, 2018.
- New studies approved on or after January 19, 2018, must use the new consent template (originally posted December 20, 2017).
- Studies approved before January 19, 2018, are not required to transition to the new consent template.
- The IRB is already asking for some consent form changes during the review process.

## WHERE

Users will encounter changes in:

- Forms and templates – Check <https://www.umassmed.edu/ccts/irb/> regularly for updates
- Approval letters - Look for expiration dates and set a reminder for yourself; once the New Rule is in effect, the approval letter will indicate if the research is under the Old Rule or the New Rule
- eIRB Notifications - All research will trigger an annual reminder of investigator obligations until the PI closes the research

## WHY

*Why does expedited research at UMMS have a three-year approval period? Don't the new regulations do away with continuing review for minimal risk research?*

- The new regulations continue to hold UMMS responsible for all research that the institution conducts.
- A three-year approval period reduces burden on investigators, while allowing UMMS to maintain oversight of non-exempt research and the capability to generate reporting metrics required by accrediting bodies and funding agencies.
- In the future, UMMS may consider extending the approval period or removing expiration dates entirely for minimal risk research.

## HOW

Research that is FDA-regulated or funded/supported by Department of Justice will use the new consent template, but remains subject to the existing regulations.

All other research approved on or after the effective date is subject to the New Rule.

For all other research approved before the effective date, the UMMS IRB will determine on a case-by-case basis whether the research stays under the existing regulations or transitions to the New Rule.

- Research that involves intervention or interactions with human subjects will continue under the existing regulations. It will have a one-year approval period.
- The current goal is to transition eligible research only when it does not require Modification to the approved informed consents or study plans.
- In most cases, the IRB may transition research that obtained informed consent, is not FDA-regulated or federally funded, and only has data analysis or long-term follow-up left to complete.

# Informed Consent

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**A template that meets the new requirements is available here:**

[https://www.umassmed.edu/ccts/irb/forms\\_templates/](https://www.umassmed.edu/ccts/irb/forms_templates/)

**The new template combines the consent and HIPAA authorization into one document (with a 6-year data retention requirement).**

## **NEW REQUIREMENTS**

- Provide the information a reasonable person would want to know, creating the opportunity to discuss that information
- Begin with a concise and focused presentation of key information most likely to aid in understanding why someone might or might not want to participate (e.g., research, voluntary, purpose, duration, procedures, risks, benefits, alternatives)
- Indicate whether clinically relevant research results - including at the individual level - will be disclosed, and if so, under what conditions
- If research involves collection of identifiable private information or identifiable biospecimens:
  - Include a statement that identifiers might be removed and material shared or used in future research without additional consent
  - or that no sharing or use in future research will occur even if identifiers are removed
- If collecting biospecimens:
  - And if a possibility: include a statement that specimens (even if identifiers are removed) may be used for commercial profit & whether subjects will share in the profits
  - indicate whether 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)

## CONSENT FORM SIGNATURE

- Documentation of consent in writing is expected for research that involves sharing of identifiable information or identifiable biospecimens.
- IRBs can now waive written documentation of consent if research participants are members of a distinct cultural group or community in which signing forms is not the norm, the research is minimal risk, and there is an alternative mechanism for documenting that informed consent was obtained.

## ELECTRONIC CONSENT

- Electronic consent satisfies a requirement to document consent in writing.
- FDA has two guidance documents for those considering electronic consent:
  - Use of Electronic Information Consent Questions and Answers, December 2016 (<https://www.fda.gov/downloads/drugs/guidances/ucm436811.pdf>)
  - Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 - Questions and Answers, June 2017 (<https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm563785.pdf>)

## SHORT FORM CHANGES

- Short forms – which may apply when obtaining consent from individuals with limited English proficiency – must state that key information was presented first before other information.
- Revised UMMS short forms are pending.
- Use the existing short forms for now
  - If research is not federally funded
  - If research is federally funded and approved before the effective date.
- Submit new short forms with your research if the research is federally funded and approved on or after the January 21, 2019, effective date.

## USE AN ADDENDUM TO RECONSENT

- If you need to reconstent research participants, use a consent addendum that includes just the new information.
- A consent addendum is easier for research participants to understand, and it fits easily with the old and new regulations.

See also  
**ADDITIONAL REQUIREMENTS  
FOR FEDERALLY-FUNDED RESEARCH**  
Consent Language for Certificates of Confidentiality  
Consent Form Posting Requirements

# New Human Subjects Regulations

## Requirements for Federally-Funded Research

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### **AUTOMATIC CERTIFICATE OF CONFIDENTIALITY (CoC)**

- All NIH research that was commenced or ongoing on or after December 13, 2016, and will collect identifiable sensitive information as defined here (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>) now has a Certificate of Confidentiality.
- It is especially important to read the definition of identifiable sensitive information at the link above if you collect biospecimens or generate individual level, human genomic data from biospecimens.
- You will need to ensure that the overall consent and the use cases for which you seek permission are consistent with the Certificate of Confidentiality.
- See the consent form template for suggested wording for studies with a CoC.

### **CLINICAL TRIALS MUST POST CONSENT FORM**

- Each clinical trial that is conducted or supported by a Federal department or agency is required to post one consent form used to enroll subjects to a public Federal Web site.
- The public Federal Web site is TBD.
- Posting is required 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.
- *Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

## **sIRB (SINGLE IRB MANDATE)**

- NIH policy mandates single IRB review for non-exempt multi-site studies for submissions with due dates on or after January 25, 2018.  
(<https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm>)
- Effective January 20, 2020, the 2018 regulations require federally-funded cooperative research to use a single IRB for the portion conducted in the US, unless otherwise precluded (e.g., by tribal law) or deemed by the sponsoring agency as not required.
- Contact the UMMS IRB if you are seeking to use an external IRB or to use the UMMS IRB as the single IRB.



# Exemptions & Waivers

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## MANDATORY IRB REVIEW

- At UMMS human subjects research that fits one or more exemption categories has always required – and will continue to require – prior IRB review and approval.
- This is already in compliance with the new requirement that only an IRB issue exemptions that require “limited review.” (See **KEY DEFINITIONS**)

## APPROVAL PERIOD

- Exempt research at UMMS already has no expiration date.
- Research that has been deemed exempt will receive an annual reminder notification of the investigator’s obligations until the PI submits a study closure to the IRB.
- The PI must submit a Modification to close exempt research.
- The PI must obtain prior IRB review and approval when changes involve HIPAA, risks, the exemption category, or the scope of the research.

## NEW EXEMPTION CATEGORIES AFTER NEW RULE TAKES EFFECT JANUARY 21, 2019

- Additional types of research will qualify for exemption, most notably:
  - Uses of secondary data and biospecimens that are already subject to HIPAA (**at UMMS use is contingent on additional Federal guidance**)
  - Research involving benign behavioral interventions with adults
  - Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior, even if identifiers are recorded and disclosure may pose a confidentiality risk to research participants
- Investigators will still be expected to obtain informed consent for prospective data collection.



## **BENIGN BEHAVIORAL INTERVENTION WITH ADULTS**

- This is a new exemption category.
- The exemption is only permitted with adults.
- A benign behavioral intervention is brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
- Medical tests, procedures, and devices (e.g., EEG recording) are excluded.
- Research participants must be prospectively informed if they will be unaware of or misled regarding the nature or purposes of the research.

## **CHANGES TO CRITERIA FOR WAIVER OF INFORMED CONSENT**

- If the waiver of consent involves identifiable private information or identifiable biospecimens, investigators must justify why the research could not practicably be carried out without using the information or biospecimens in an identifiable format.
- FDA now permits a waiver of informed consent for clinical investigations involving no more than minimal risk that previously were ineligible. This is independent of the New Rule.
- All waivers of informed consent require prior IRB review and approval.
- Waiver requests must be requested through the Consent Process section of the Investigator Study Plan either as a part of a new study or as a Modification to an existing study.

# New Human Subjects Regulations

# Expedited Review

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- Once the New Rule takes effect January 21, 2019, some research that previously qualified for expedited review will now qualify for exemption including:
    - Research involving benign behavioral interventions with adults
    - Research listed below provided the IRB conducts a “limited review” to ensure there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data:
      - Uses of secondary data and biospecimens that are subject to HIPAA (**at UMMS use is contingent on additional Federal guidance**)
      - Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior, even if identifiers are recorded and disclosure may pose a confidentiality risk to research participants
  - Designated reviewers must document their rationale if they determine that research appearing on the expedited review list is greater than minimal risk (and thus requires Committee review).
  - US Department of Health of Human Services is now required to review the list of expedited categories every 8 years and to amend the list if needed following consultation with agencies and an opportunity for public comment.
  - At UMMS new expedited research approved under the new regulations is eligible for a three-year approval period, unless it is FDA-regulated or funded or supported by the Department of Justice.
    - The new regulations continue to hold UMMS responsible for all research that the institution conducts.
    - A three-year approval period reduces burden on investigators, while allowing UMMS to maintain oversight of non-exempt research and the capability to generate reporting metrics required by accrediting bodies and funding agencies.
    - In the future, UMMS may consider extending the approval period or removing expiration dates entirely for minimal risk research.

# Key Definitions

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## HUMAN SUBJECT (REVISED)

- The definition is revised to explicitly mention biospecimens and the possibility of generating identifiable private information or identifiable biospecimens.
- The US Department of Health and Human Services is now required to provide guidance within the first year and then at least every four years regarding how identifiable private information or identifiable biospecimens might be generated.
- A research activity that does not involve human subjects today may in the future involve human subjects.
- HIPAA regulations can still apply to research involving deceased individuals.
- **Once the New Rule takes effect on January 21, 2019:** A Human Subject is defined as “a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”
- **Current Regulations:** A Human Subject is defined as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information.”

## CLINICAL TRIAL (NEW)

- *Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
- This definition is relevant to the requirement that each clinical trial that is conducted or supported by a Federal department or agency post one consent form used to enroll subjects to a public Federal Web Site.
- See also **REQUIREMENTS FOR FEDERALLY-FUNDED RESEARCH** and the obligation for such clinical trials to post one consent form to a public Federal Web site.

## LIMITED REVIEW (NEW)

- Several categories of exempt research require the IRB to conduct a “limited review” to ensure there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.
- This is not new for UMMS. The exemption criteria already include such considerations, and all human subjects research - including exemptions - requires prior IRB review and approval.
- Under the new regulations, the Federal Government is required to provide guidance as to what provisions are considered adequate.

# New Human Subjects Regulations

## What Is Yet to Come

### From the Federal Government

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- The effective date of the New Rule is January 21, 2019.
- We refer to “Pre-2018” and “2018 Regulations” because the original effective date of the New Rule or Revised Common Rule was January 19, 2018.

Once the New Rule becomes effective:

- Within the first year and then at least every four years, the Department of Health and Human Services (DHHS) will consult with experts to:
  - Re-examine the meaning of identifiable private information and identifiable biospecimens
  - Assess whether there are analytic technologies or techniques that generate identifiable private information or identifiable biospecimens
- DHHS is required to review the list of expedited review categories every 8 years and to amend the list if needed following consultation with agencies and an opportunity for public comment.
- DHHS is required to provide guidance regarding what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of the data (provisions required under “limited review”).

# Transition Requirements

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- New studies approved on or after January 19, 2018, must use the new consent format (originally posted 12.20.2017).
- Existing approved consents are not required to convert to the new template. However, the IRB may require the addition of new elements during the review process.
  - See **INFORMED CONSENT** for a summary of consent form changes.
- Use new templates for new submissions as soon as the templates are released.
- Always download all forms and templates fresh from the IRB website. Stop recycling earlier versions.
- The UMMS IRB will determine on a case-by-case basis whether research approved before January 21, 2019, stays under the existing regulations or transitions to the new rules.
- The effective date of the New Rule is January 21, 2019. We refer to “Pre-2018” and “2018 Regulations” because the original effective date was January 19, 2018.
- The current goal is to transition eligible research only when it does not require Modification to the approved informed consents or study plans. In most cases, this is research that obtained informed consent, is not FDA regulated or federally funded, and has only data analysis or long-term follow-up left to complete.
- Turn the page for a summary table of when the IRB may transition existing approved research to the New Rule.

The UMMS IRB will determine on a case-by-case basis whether research approved before the effective date of the New Rule stays under the existing regulations or transitions to the new rules.

The current goal is to transition eligible research only when it does not require Modification to the approved informed consents or study plans. In most cases, this is research that obtained informed consent, is not FDA regulated or federally funded, and has only data analysis or long-term follow-up left to complete.

The effective date is January 21, 2019.

	Review Category	Potential Transition Point	The IRB may transition research to the new regulations if the research:	What is the advantage of transitioning?
Approved before the effective date of the New Rule	Exempt	Modification – Any change involving HIPAA, risks, exemption category, or scope of research requires prior IRB review and approval	Fits entirely within new exemptions	There is none
	Expedited	Continuing Review (with or without Modification)	Has no additional research-related interventions or interactions	Permits three-year approval period
	Committee		Does not involve a waiver of informed consent Is not FDA-regulated Is not federally funded or supported	



# Annual Reminder of Investigator Obligations

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- **HRP-800 INVESTIGATOR GUIDANCE: Investigator Obligations** outlines all investigator obligations. (<https://www.umassmed.edu/ccts/irb/investigator-guidance/>)
- The following table outlines the requirements for Approval, Modification, Continuing Review, and Closure according to whether research is Exempt, Expedited, or reviewed by the Full Committee.

		Requires prior IRB review and approval?	Requires prior IRB review and approval of Modifications?*	Requires Continuing Review?	Requires Closure?
Category of Review	<b>Exempt</b>	Yes	Yes – if the changes involve HIPAA, risks, exemption category, or scope of research	No	Yes – submit Modification
	<b>Expedited</b>	Yes	Yes – all changes	Yes – has one-year or three-year approval period	Yes – submit final Continuing Review
	<b>Committee</b>	Yes	Yes – all changes	Yes – has maximum one-year approval period	Yes – submit final Continuing Review

\*Changes to eliminate immediate apparent hazards to research participants are permitted and must then be reported promptly to the IRB.

- All approved research – including exempt research – will receive an annual notification of investigator obligations until the PI submits a study closure.
- For Expedited and Full Committee studies, the annual notification is in addition to the first and second continuing review reminders, which are issued as a courtesy in the months prior to expiration.
- Exempt and Full Committee approval periods are unchanged: Exempt approvals never expire; Full Committee approvals do not exceed one-year.
- New Expedited research approved under the new regulations is eligible for a three-year approval period, unless it is FDA-regulated or funded or supported by the Department of Justice.

### **Annual Reminder for Exempt Research**

*This is an annual reminder that you are required to conduct the research in accordance with the Investigator's Manual. Your obligations include, but are not limited to:*

- *Obtaining prior IRB review and approval for all Modifications that involve HIPAA or that potentially change the risks, exemption category, or scope of the research;*
- *Maintaining a current list of CITI-trained Active Study Staff in eIRB;*
- *Adhering to Prompt Reporting Requirements;*
- *Updating conflict of interest declarations; and*
- *Closing the study via Modification.*

*<https://www.umassmed.edu/ccts/irb/investigator-manual/>*

### **Annual Reminder for Expedited and Full Committee Research**

*This is an annual reminder that you are required to conduct the research in accordance with the Investigator's Manual. Your obligations include, but are not limited to:*

- *Obtaining prior IRB review and approval for all Modifications;*
- *Maintaining a current list of CITI-trained Active Study Staff in eIRB;*
- *Adhering to Prompt Reporting Requirements;*
- *Updating conflict of interest declarations; and*
- *Closing the study via Continuing Review.*

*If your research expires this year, you may receive additional reminder notifications related to the Continuing Review.*

*<https://www.umassmed.edu/ccts/irb/investigator-manual/>*

New Human Subjects Regulations

# Designated Reviewer and Committee Review Changes

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- Designated reviewers must document their rationale for determining that research appearing on the expedited review list is greater than minimal risk and thus requires Committee review.
- IRBs must document the rationale for conducting continuing review of research that otherwise would not require continuing review.
- By institutional standard operating procedure, non-exempt minimal risk human subjects research at UMMS may be approved for no longer than three years.

# What is *Broad Consent* and is UMMS using it?

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- Two new exemption categories in the New Rule pertain to broad consent.
    - The term *broad consent* applies to identifiable private information or identifiable biospecimens that already exist for non-research purposes (e.g., clinical data, leftover pathology specimens).
    - Individuals are asked to consent to the storage, maintenance, or use of this identifiable private information or identifiable biospecimens for research purposes.
  - UMMS does not have a process to seek broad consent from all patients.
  - Broad consent requires an infrastructure to track patient responses and any changes over time. There are no plans at this time to build this infrastructure at UMMS.
  - IRBs are prohibited from granting waivers of informed consent that override a patient's decision to refuse broad consent.
  - The IRB is still able to review and approve research involving existing data or biospecimens.

Version History for 2018 Summaries

<b>Document</b>	<b>Date</b>	<b>Status</b>
01_BareEssentials	12/20/17	Initial post
	01/24/18	Changed 2018 reference to New
02_WhoWhatWhenWhereWhyHow	12/20/17	Initial post
	01/02/18	WHEN: Fixed date consent template posted
	01/24/18	Changed 2018 references to New, and NIJ references to DOJ; WHEN: updated for delays
	09/03/18	WHEN: updated effective date; added explanation of Pre-2018/2018
03_InformedConsent	12/20/17	Initial post
	01/24/18	Changed 2018 references to New; added reminder re: 6-year data retention; adjusted references to effective date
	09/03/18	Updated effective date; fixed broken link
04_ForFederallyFunded	12/20/17	Initial post
	01/24/18	Changed 2018 reference to New
05_ExemptionsAndWaivers	12/20/17	Initial post
	01/24/18	Changed 2018 reference to New; added references to effective dates; clarified that FDA waiver of informed consent is in effect now

	09/03/18	Updated effective date; added caveat that use of new HIPAA exemption is contingent on additional Federal guidance
06_ ExpeditedReview	12/20/17	Initial post
	01/24/18	Changed 2018 reference to New, and NIJ reference to DOJ; added references to effective dates
	09/03/18	Updated effective date; added caveat that use of new HIPAA exemption is contingent on additional Federal guidance
07_KeyDefinitions	12/20/17	Initial post
	01/24/18	Changed 2018 reference to New; added references to effective dates
	09/03/18	Updated effective date; revised to refer to “within the <i>first year</i> ”
08_WhatIsYetToComeFromTheFederalGovt	12/20/17	Initial post
	01/24/18	Changed 2018 reference to New; added references to effective dates
	09/03/18	Updated effective date; added explanation of Pre-2018/2018
09_TransitionTable	12/20/17	Initial post
	01/24/18	Changed 2018 reference to New; added references to effective dates
	09/03/18	Updated effective date; added explanation of Pre-2018/2018

10_AnnualReminderInvestigatorObligations	12/20/17	Initial post
	01/24/18	Changed 2018 reference to New, and NIJ reference to DOJ; added references to effective dates
	09/03/18	Fixed broken link
11_DesignatedReviewAndCommitteeReview	12/20/17	Initial post
	01/24/18	Changed 2018 reference to New
12_BroadConsent	12/20/17	Initial post
	01/24/18	Changed 2018 reference to New