



Informed Consent and the Revised Common Rule

Health Sciences IRBs

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Goals



- ▶ How the Revised Common Rule affects informed consent requirements
- ▶ What's really new and what hasn't changed (for users of the HS IRBs)
- ▶ How to apply Revised Common Rule requirements
 - ▶ In ARROW applications
 - ▶ In consent forms



Revised Common Rule / 2018 Requirements

- ▶ Applies to studies initially approved on or after 1/21/2019
 - ▶ Studies approved prior to 1/21/2019 remain under “old” Common Rule (pre-2018 requirements)
- 



Waiving or Altering Consent

- ▶ Waiver = not obtaining consent
- ▶ Alteration = obtaining consent, but omitting or altering elements

▶ **Additional requirement:**

If using identifiable* private information or identifiable biospecimens, the study/activity could not practicably be carried out unless these are in an identifiable format

*Code linked to private information is identifiable



Waiving or Altering Consent

- **Is this really new?**

- Not for UW-Madison HS IRBs
- Any time identifiable data or biospecimens were being used, we'd ask you elsewhere to explain why they had to be identifiable

- **What has changed?**

- Justify use of identifiable data or biospecimens as part of a request for waiver or alteration of informed consent

Waiving or Altering Consent

* 2.3 Provide a justification for how the following criteria for a waiver of informed consent will be met: 1) The study involves no more than minimal risk to the subjects; 2) The waiver will not adversely affect the rights and welfare of the subjects; 3) The study could not practicably be carried out without the waiver. **If the study team is requesting a waiver of informed consent to use identifiable information or identifiable biospecimens, also provide justification why the research could not be practicably carried out without using identifiable information or identifiable biospecimens.**

- 1) The activity is minimal risk because....
- 2) The activity does not adversely affect subjects' rights or welfare because....
- 3) We could not practicably perform the study without this waiver because...
- 4) We need the data in an identifiable format because...**



Waiving signed consent: New situation

- ▶ **Subjects are members of a distinct cultural group or community in which signing forms is not the norm**
 - ▶ **Research must be minimal risk**
 - ▶ **Must have an appropriate alternative mechanism for documenting that informed consent was obtained**
- ▶ New option on ARROW page for waiver of signed consent



Screening and recruitment

- ▶ **Consent not required if, for the purpose of screening, recruiting, or determining eligibility,**
 - ▶ **You'll get information through oral or written communication w/potential subject (e.g., phone screening)**
 - ▶ **You'll access records or stored biospecimens to get private information (e.g., pre-screen medical records)**



Screening and Recruitment

- ▶ **We will still ask you...**
 - ▶ How you're recruiting subjects
 - ▶ Who has clinical access to the records/specimens you're accessing
 - ▶ What your procedures are
- ▶ **We will still ask you...**
 - ▶ How you're getting contact info
 - ▶ To create a script for telephone eligibility screening
 - ▶ To give subjects the chance to say no, to tell them whether & how you're keeping responses
- ▶ We **won't** ask you to request or justify a waiver/alteration of consent or waiver of signed consent solely for screening, recruiting, or determining eligibility

Screening and Recruitment

TYPE	REVIEWER	DATE CREATED
<p> IRB Question</p> <p>Under the revised Common Rule of federal regulations governing human subjects research, a waiver of informed consent is no longer required when accessing medical records or clinic schedules to identify potential subjects for a research study.</p> <p>Please uncheck the "Waiver of informed consent" box below.</p>	JACQUELINE LEE	4/12/2019 3:34 PM

Informed Consent: General

* 1.1 What consent process or waivers of consent are you requesting for this study?

- Consent process with signed consent documentation
- Waiver of informed consent
- Waiver of signed consent NOTE: This means that no signature will be obtained from subjects
- Alteration of the required elements of consent

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Screening and Recruitment

- ▶ What about protocol-specified activities?
 - ▶ Fasting
 - ▶ Completing questionnaires or diaries
 - ▶ Withholding medications, changing diet or behavior
 - ▶ Etc.
 - ▶ **Get oral consent**
 - ▶ Describe activity, request consent in screening or recruitment script
 - ▶ Request alteration of consent
 - ▶ Request waiver of signed consent
- 



Take aways

- ▶ Revised Common Rule affects **new** studies
- ▶ **What's really new:**
 - ▶ Can waive signed consent if cultural group/community doesn't sign forms
 - ▶ No waiver needed to pre-screen medical records for eligibility
 - ▶ No alteration/waiver of signed consent for recruitment and screening
- ▶ **What's the same:**
 - ▶ Need to justify using identifiable data under waiver of consent
 - ▶ Need to describe recruitment and screening procedures, provide script
 - ▶ Need consent for activities beyond recruitment and screening



Consent: New basic element

- ▶ **For any research that collects identifiable private information or identifiable biospecimens, must tell subjects:**
 - ▶ **That their information/biospecimens could be stripped of identifiers and used for other research in the future or distributed to other researchers without additional informed consent; OR**
 - ▶ **That their information/biospecimens will NOT be used or distributed for future research.**
- 

Consent: New basic element

- ▶ HS IRBs receive almost constant requests to use data/biospecimens without additional consent:
 - ▶ We want to share banked specimens with a collaborator
 - ▶ We want to use leftover specimens for a new research question
 - ▶ Etc.
- ▶ So HS IRBs consent templates “default” to possible future use:

With appropriate institutional permissions and confidentiality protections, we might use information [and biospecimens] that we collect during this study for other research or share with other researchers without additional consent from you.



Consent: New additional elements

- ▶ “When appropriate,” consent must describe:
 - ▶ Returning clinically relevant results
 - ▶ Commercial profit
 - ▶ Whole genome sequencing

Clinically relevant results

- ▶ Not wholly new to HS IRBs users
- ▶ **What's changed?**
 - ▶ New section in consent form templates
 - ▶ Relevant for studies with any testing
 - ▶ Include whether or not results will be disclosed
 - ▶ Use existing model language
 - ▶ New model language for biospecimen tests

GENERAL		
Assent and Parent/Guardian Permission	Banking of Data and/or Biospecimens for Future Use	Certificate of Confidentiality (COC)
ClinicalTrials.gov	Commercial Products	Conflict of Interest (COI)
Emailing to Communicate with Subjects	Enrolling Students or Employees	Genetic Information Nondiscrimination Act (GINA)
Genetic Research	Genomic Data Sharing (GDS)	Abuse or Neglect Reporting
Illegal Substance Use or Illegal Activities	Reproductive Risks	Sharing of Data, Specimens, Images for Research Purposes
Signature Sections	Video, Audio Recordings, or Photos	
CLINICALLY RELEVANT FINDINGS		
Incidental Findings	Psychological Assessments	Results of Research Tests on Biospecimens
Sexually Transmitted/Communicable Disease Testing		



Clinically relevant results

- Read instructions for new consent form section carefully

Will I receive the results of research tests?

Instructions:

The purpose of this section is to explain whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. See HS IRBs [Clinically Relevant Information and Reporting Guidance](#) for general guidance on this topic.

For the situations listed below, consult the relevant guidance and use the specified model language to describe how research results will be handled. If you plan to disclose other types of clinically relevant research results that are NOT listed here, describe the research results and how they will be disclosed. If receiving results is optional, include yes/no options. If NO clinically relevant research results will be reported to study participants, inform participants of this as well, using the template language below.

- You will release the results of tests performed for research purposes on biospecimens: See this [guidance](#) and specify which test results you will release to subjects and how subjects will receive them (e.g. by mailed letter, through electronic health record). Use model language for **Results of Research Tests on Biospecimens**.

Consent: New additional elements

- ▶ Commercial Profit

- ▶ There may be commercial profit to future uses of data or biospecimens
- ▶ Often relevant when banking biospecimens, or testing a drug or device

- ▶ **Is this new for HS IRBs?**

- ▶ No; we have had template language for some time:

Researchers may develop products from the samples and information you provide for this study. Some of these products may have commercial value. If the research team or others use your sample or information to develop products of commercial value, you will not receive any profits from products created from your samples of information.

Consent: New additional elements

- ▶ Whole genome sequencing
 - ▶ If the research will or might generate the genome or exome sequence of a human germline or somatic specimen, tell subjects
 - ▶ If it could happen in the future (you are banking samples), tell subjects
- ▶ **New? Not for HS IRBs**

Model Language:

Some of the tests we will perform on your [blood/tissue/etc.] will be genetic testing, which is done on your DNA. DNA, or deoxyribonucleic acid, carries the genetic instructions for the cells that make up your body. Genes tell your body how to do things like form your spine, or what color your eyes should be. **Include the following for whole genome testing:** We will do whole genome testing for this study. Your “genome” is the complete DNA instruction book. “Whole genome testing” means making a list of the entire order, or sequence, of the DNA in your genome.



Take aways

- ▶ HS IRBs already required language similar to Revised Common Rule's "new" consent elements
- ▶ What's different?
 - ▶ Revised consent template language about future use of data and specimens
 - ▶ New consent form section to describe handling of clinically relevant results



Consent: Concise & focused key information

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.



Consent: Concise & focused key information

- ▶ If consent form uses an HS IRBs consent template:
 - ▶ 10 pages or less, complies with this requirement
 - ▶ Page count excludes pictures, tables, signature pages
- ▶ Longer than 10 pages, consent must begin with Study Summary
 - ▶ New HS IRBs physical risk consent templates for this situation

Study Summary template

Important things to know about any research study:

- Taking part in research is voluntary. You can choose not to be in this study, or stop at any time.
- If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights.
- **[For potentially therapeutic trials, add:** You don't have to be in this study to get care for your health condition.]

Study Summary

What is this study about?

Provide a brief, **plain language** description of the study's purpose.

Example for phase I trial: We want to find out if **Drug X** is safe to use for **Z condition**, to find a safe dose to use in future studies, and to find out what side effects **Drug X** has in people with **Z**

approved **Drug X** for the treatment of **Z condition**, and **Drug X** can only be given in a research study.

Example for phase III trial: We want to find out if a drug called **Drug X** is a better treatment for **Z condition** than **Drug Y**. **Drug X** is investigational. This means that the US Food and Drug Administration (FDA) has not approved **Drug X** for the treatment of **Z condition**.



Consent: Concise & focused key information

- ▶ **Is this new for HS IRBs?**

- ▶ Based on long practice of requiring “summary information sheets” to summarize lengthy consent forms

- ▶ **Main differences:**

- ▶ Applies to consent forms based on HS IRBs templates
- ▶ Study Summary must now be part of the consent form
- ▶ Study Summary needed only if consent form is longer than 10 pages



Consent: Concise & focused key information

- ▶ What if our study has a coordinating center that uses a different consent template?
 - ▶ If study is **federally funded**, consent must comply with “concise and focused presentation” requirement
 - ▶ Other approaches are acceptable
 - ▶ Don't add Study Summary
- ▶ **Not federally funded**, but consent form uses a non-HS IRBs template?
 - ▶ Likely requires Study Summary if longer than 5 pages
 - ▶ Summary may be separate document



Take aways

- ▶ HS IRBs approach to “concise presentation” requirement should seem familiar
- ▶ Using current HS IRBs consent templates helps ensure compliance with Revised Common Rule
- ▶ When using consent templates from other sites or sponsors:
 - ▶ If federally funded, different compliance approaches acceptable – don’t add Study Summary
 - ▶ If not federally funded, expect that Study Summary will be needed



Broad Consent

- ▶ Revised Common Rule permits “broad consent” for storage, maintenance, and secondary research use of identifiable data and biospecimens
- ▶ Requires researchers/repository responsible for storage to:
 - ▶ Identify types of research that may be conducted
 - ▶ Record and track participant consent/refusal across the entire institution
 - ▶ Track terms of consent to determine if proposed secondary research falls within the scope of research to which someone consented
- ▶ If someone refuses broad consent, the IRB cannot waive consent thereafter



Broad Consent

- Definition and implications unclear
- Tracking requirements burdensome, impracticable
- UW-Madison is not implementing broad consent at this time
 - This includes new exemption categories 7 & 8, which rely on broad consent

Can we still bank specimens and data for future use?

- Yes!
- Request as part of standard, study-specific consent process
- Research with data or specimens may qualify for:
 - waiver of consent
 - Category 4 exemption

Model Language:

What will happen to my [data / biospecimens / data and biospecimens] after my participation ends? We [will OR would like to, if optional] keep your [data / biospecimens / data and biospecimens] for [X period of time OR an indefinite period of time, meaning we have no plans of ever destroying your data / biospecimens]. Keeping data or biospecimens for future research is called “banking.” The banked [data / biospecimens] will be kept in a secure location for use by researchers.

This is what will happen with your banked [data / biospecimens / data and biospecimens]:

- We will use the [data / biospecimens / data and biospecimens] in future research projects about [describe future uses, such as research on a specific disease]. We may also use them for other types of research.
- If you may share the data/biospecimens outside your research team, add: The [data / biospecimens / data and biospecimens] may be shared with other researchers at the University of Wisconsin-Madison [if sharing outside UW, add: and outside the University]. Outside researchers may be at other universities, private companies, or other kinds of organizations.



New requirement: Posting consent forms online

- ▶ Applies to clinical trials supported by a Federal department or agency
- ▶ Requires posting consent form on a publicly-available Federal website
 - ▶ [ClinicalTrials.gov](https://clinicaltrials.gov)? [Regulations.gov](https://www.regulations.gov)?
- ▶ UW Office of Research Compliance, not HS IRBs, will monitor compliance with this requirement



Take aways

- ▶ Use study-specific consent, consent waiver, exemption to store and use identifiable data and biospecimens
 - ▶ No Broad Consent
- ▶ Contact Office of Research Compliance about posting consent forms



Questions?



Contact Information

- Staff Reviewer on call every day: 263-2362
- Email for general questions:
AsktheIRB@medicine.wisc.edu.
- Email for technical assistance with ARROW:
AskARROW@medicine.wisc.edu.
- Request a consultation:
See KB 18204 on our website
- Questions about a study under review
Contact the assigned Staff Reviewer

HS-IRBs Office is located at
800 University Bay Drive, Suite 105

