“This final rule is intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. These revisions are an effort to modernize, simplify, and enhance the current system of oversight.”
Outline of Discussion

1. **New Consent Form Regulations** that Impact Convened IRB Review

2. What’s it mean **and what should members expect?**
Element #1: Broad Consent

1. Is It New?
2. What Does It Mean?
3. What Do I Need To Get It?
Broad Consent: Is this actually new?

- Broad Consent was **previously not discussed in the Common Rule**.
  - Previously, an **industry standard term** for research consent not specific to the primary research project.
  - Non-specific consent that permits institutions to collect/use/store data/specimens for future research use.

- Researchers, IRBs, ethicists, and the government have been **debating for years** Broad vs. Specific Consent.
  - Both practices are currently in place at Penn.
Regulations now define a mechanism for obtaining broad consent from subjects for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens.

This can be accomplished through a separate consent form and process, or as a part of the consent process for another trial.

Future research involving specimens and data where broad consent was obtained would be eligible for exemption and would not require a waiver of consent.
Implications/Challenges of Broad Consent

- Broad Consent allows subjects a mean to **exercise their autonomy** in deciding whether or not to allow secondary research use.

- **No Waiver if Broad Consent Refused**
  - IRB cannot waive consent if individuals were asked, and refused, to provide consent to the storage, maintenance, and use of identifiable private information or identifiable biospecimens.

- The use of Broad Consent will involve a **mechanism for tracking** the affected **information or biospecimens**

- The IRB’s role in certifying whether broad consent is properly documented is unclear
What it Means for Review: This will only sometimes apply, and it will largely be checked upfront.

1. Future use elements will **only be required** if:
   
a) **The study team knows** they will be using the samples or information in the future; or:

   b) **The study team is considering** whether they will use samples

2. The required elements of broad consent are **clearly specified** and will be **checked as part of the administrator’s initial screening process**
Element #2: Changes to ICFs

1. A New One-Page Summary
2. New Elements of Informed Consent
Key Changes in the New Consent Form Regulations

1. **New requirements** were developed for the **information that must be given** to potential research subjects during the consent process.

2. **Informed consent** must begin with a **concise, focused presentation** of key information:
   - Summaries will be protocol-specific
   - Regulations were drafted to allow for flexibility
Part I: The One-Page Summary – What’s It Meant to Do

The consent document must be organized in a way that facilitates comprehension and presents information in a way that does not merely provide lists of isolated facts, but rather facilitates understanding of the reasons why one might or might not want to participate.

How do we accomplish this?

- “One pager consent” template document (for purposes of developing a study specific summary document)
- Guidance for what information to definitely include, consider including or instructions on how to best assess the specific submission and determine what should be included in the summary

What is most important for the potential participant to remember from the consenting process?
According to the Common Rule preamble, the following may encompass a “concise explanation”:
Part I: The One-Page Summary – What it Could Look Like

And there is even more available in guidance documents on our website. For instance...

You are being invited to participate in a research study. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to <INSERT GENERAL OVERVIEW OF THE PURPOSE AND, IF APPLICABLE, WHY POTENTIAL PARTICIPANTS ARE ELIGIBLE>.

If you agree to join the study, you will be asked to complete the following research procedures: <PROVIDE LIST OF STUDY PROCEDURES>.

Your participation will last for <INSERT OVERALL DURATION AND ANY STATEMENT NEEDED ABOUT ONGOING FOLLOW-UP OR ACCESS TO DATA/BIOSPECIMENS>.

<INSERT STATEMENT OF POTENTIAL FOR BENEFIT, IF ANY>. The most common risks of participation are <INSERT LIST OF MOST COMMONLY EXPECTED OR MOST IMPACTFUL RISKS>.

<INSERT INFORMATION ABOUT ALTERNATIVES TO PARTICIPATION AND OTHER IMPACTFUL INFORMATION BASED ON THE RESEARCH BEING PROPOSED. YOU MAY ALSO UTILIZE THIS SUGGESTED LANGUAGE BELOW TO REMIND POTENTIAL PARTICIPANTS THAT THIS IS A SUMMARY ONLY AND THE MAIN ICF HAS A LOT MORE DETAIL NOT DISCUSSED HERE>

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.
Part I: The One-Page Summary – What it Could Look Like

Do:

- State that the study is research/investigational
- Confirm that participation is voluntary
- Provide contact information for study questions and questions about subjects' rights
- See template summary consent for sample paragraph

University of Pennsylvania Research Study Summary for Potential Subjects
ALL INSTRUCTIONAL BLUE TEXT SHOULD BE REMOVED OR REPLACED WITH STUDY SPECIFIC INFORMATION (including headers and footers) PRIOR TO SUBMISSION TO THE IRB.

Protocol Title: Insert Title of Research Study or Acronym
Principal Investigator: Principal Investigator Name and Contact Info
Emergency Contact: Emergency Contact Info (if applicable)

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The research study is being conducted to <INSERT GENERAL OVERVIEW OF THE PURPOSE AND, IF APPLICABLE, WHY POTENTIAL PARTICIPANTS ARE ELIGIBLE>.

If you agree to join the study, you will be asked to complete the following research procedures: <PROVIDE LIST OF STUDY PROCEDURES>.

Paragraph 2 Elements- Study Purpose

Do:

- Provide a brief, non-complex summary regarding the purpose of the study
- Phrase this paragraph in such a way that the subject will understand why they have been chosen
- See template summary consent for sample paragraph

Do not:

- Discuss secondary objectives
- Discuss sub-studies

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.
Part I: The One-Page Summary – What it Could Look Like

<table>
<thead>
<tr>
<th>Do:</th>
<th>Do not:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Provide a list of research specific procedures</td>
<td>• List standard of care procedures</td>
</tr>
<tr>
<td>- List the most significant research procedures that would affect willingness to participate</td>
<td>- List any minimally invasive procedures (i.e. blood draw, vital signs, etc.)</td>
</tr>
<tr>
<td>- For most investigational product trials, the procedures listing can be limited to the use of/implantation of the investigational product (i.e. the element of the research that carries the most risk)</td>
<td></td>
</tr>
<tr>
<td>- When one arm of the study involves placebo, this should be stated specifically</td>
<td></td>
</tr>
<tr>
<td>• See template summary consent for sample paragraph</td>
<td></td>
</tr>
</tbody>
</table>

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And remember, even more guidance documents are available on our website for your perusal!
Part II: Introducing the **New Elements of Consent**

- Additional Basic Elements of Informed Consent
  
  - **One of the following statements** will be required for any research that involves the collection of identifiable private information or identifiable biospecimens:
    
    - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after removal, **could be used for future research studies** or distributed to another investigator for future research studies without additional informed consent; or
    
    - A statement that subject’s information or biospecimens collected as part of the research (even if identifiers are removed) **will not be used** or distributed **for future research studies**
Part II: Introducing the **New Elements** of Consent!

- Additional Elements of Informed Consent
  - A statement that **subject’s biospecimens** (even if identifiers are removed) **may be used for commercial profit** and whether the subject will or will not share in this commercial profit;
  - A statement regarding **whether clinically relevant research results**, including individual research results, **will be disclosed** to subjects, and if so, under what conditions;
  - For research involving biospecimens, **whether the research will** (if known) or might **include whole genome sequencing** (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)
What it Means for Review: Don’t Worry, and Prepare to be Flexible

Most of this will be done before you even get the protocol

• Since these are required elements, they will be incorporated in the completeness checklist
• Protocols that do not have these will be returned or identified to require tabling

The rest will be a matter of flexibility

• While template language is available, these may look a bit different because what's important in each study is different
• Use the template text but read openly when considering what must be communicated
What’s Coming Next & Where to Look for Information

- Per last notification, appears that revisions go into effect **January 19th, 2018**
- **You’ll Start to See in Board Meetings…**
  - New completeness checklists with all the new required elements of consent
  - One-page summaries in informed consent forms, as well as increased use of broad consent
- **And more guidance is always available to you!**
  - Our website has a series of guidance documents at [https://irb.upenn.edu/common-rule-update-2018](https://irb.upenn.edu/common-rule-update-2018), with new ones coming as needed
  - Check out the new completeness checklists & agenda notes
  - Always feel free to reach out to your reg. rep. & the IRB staff with questions!