NEW COMMON RULE IMPLEMENTATION @ EMORY

PART 1 OF 2

BEFORE WE START…

Big disclaimer: we have made a plan based on available information from OHRP and FDA. It is likely that new information from those agencies may alter our plan. If that is the case, we will inform the community promptly.

TOPICS WE WILL COVER TODAY

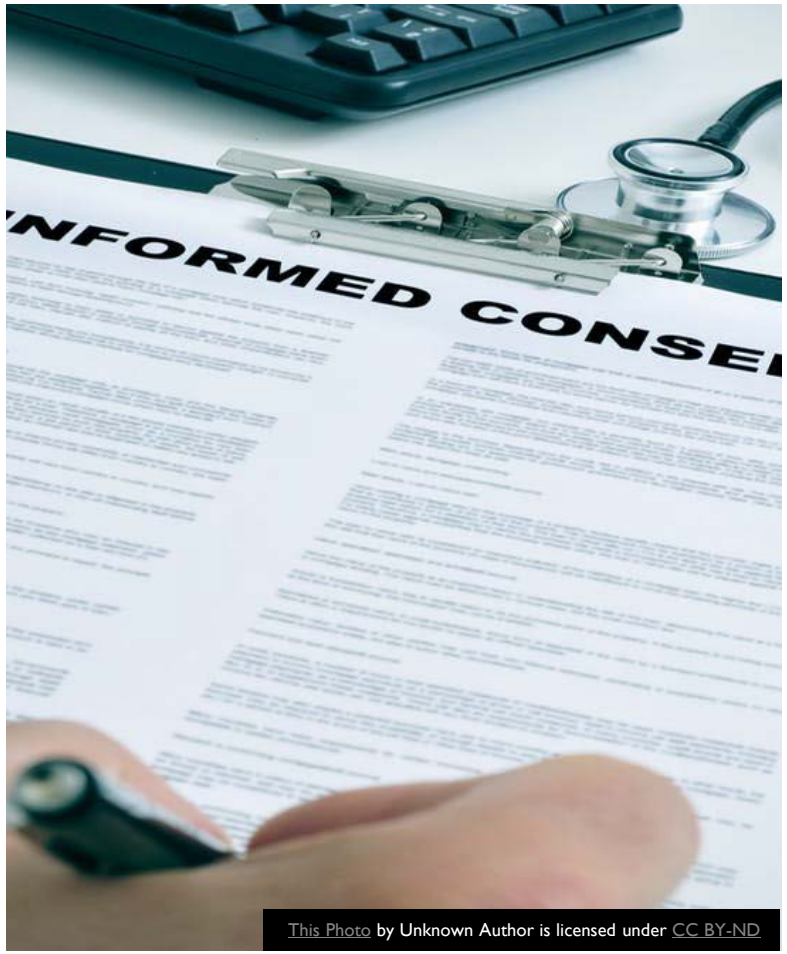
- Background information
- Informed Consent Changes
- Minimal risk studies and Continuing Review
- Questions?

BACKGROUND INFORMATION

- The 2018 Common Rule (effective on January 21, 2019) will impact the regulatory requirements for human subjects' research
- Some of the changes will not impact investigators
  - E.g., pregnant women are no longer considered a "vulnerable population." This will not affect how you submit a study, but may change the way we review
- What does affect investigators:
  1. The information required to be in the informed consent,
  2. Continuing review of studies considered "minimal risk," and
  3. Expansion and changes of expedited and exempt categories.
- In this webinar, we will cover (1) and (2)
- NOTE: FDA has not aligned with these changes at this time

INFORMED CONSENT CHANGES

- Under the revised 2018 Common Rule, the **requirements for informed consent** will 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
- The intent of these changes is to facilitate the subjects' understanding of the proposed research and also ensure that they understand how their data and biospecimens may be used.

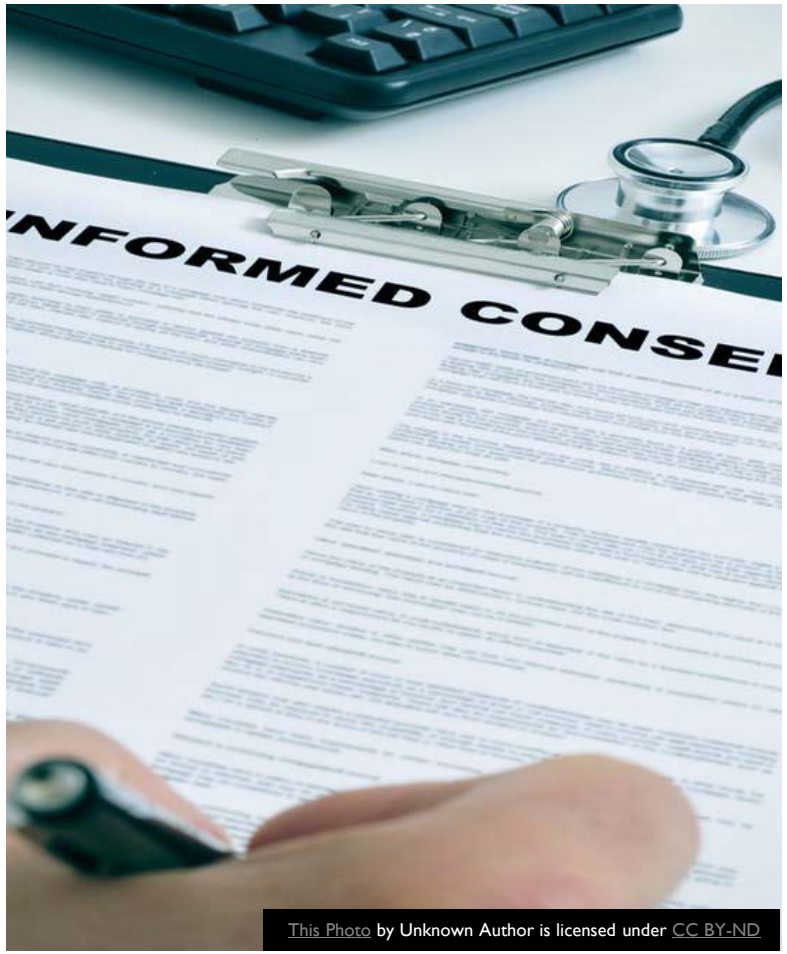


INFORMED CONSENT CHANGES, CONTINUED

- New **overall content** requirement:
  - The subject/LAR "must be provided with the information that a **reasonable person** would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
  - "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."
- Emory IRB's interpretation: Explain why the research is done, important things to know before making a decision, risks involved…
- Emory IRB's plan: We will provide additional guidance on these areas in our template. *Awaiting more OHRP guidance…*

INFORMED CONSENT CHANGES , CONTINUED

- **Broad consent**: subjects consent (or not) for a storage, maintenance, and secondary research on data and/or specimens
  - Requires very specific elements in ICF
  - Two new exemption categories for storage and use of data/specimens under broad consent
  - Many peers are **not planning** to implement due to IT and other challenges
  - Consents can continue to ask permission for unspecified future research + sharing of data/specimens, just couldn't use new exemptions
- Emory IRB's Plan: Continue to review "non-regulatory 'broad consent'" as before. We will consider "regulatory" broad consent only with major IT consultation. EHC-wide broad consent is not contemplated (yet).
- *Note*: this is different from the "front-door authorization" already in place at EHC: only opt-in for *contact* about future studies

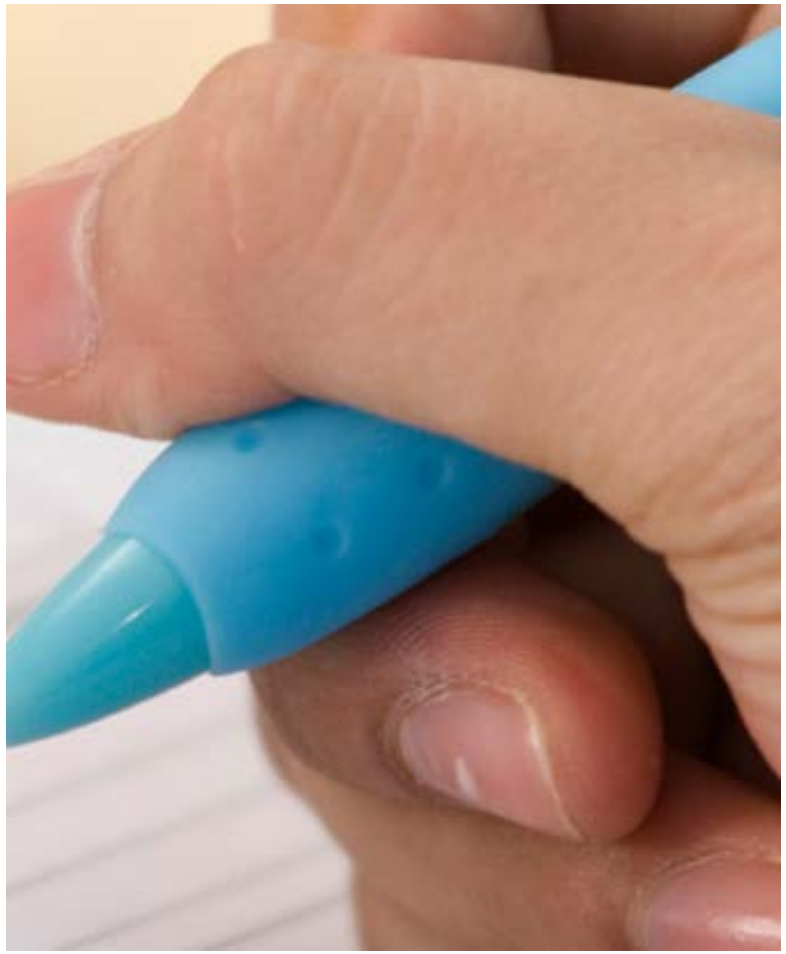


INFORMED CONSENT CHANGES, CONTINUED

- New cover page(s)…
  - "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."
- Emory IRB's plan: Our current cover page will be replaced with a key-points template, to be completed by study team with study-specific information.
- Challenge: There is no guidance to state that the same information does not need to be repeated in the "main" consent area – leading to redundancy… *Awaiting more OHRP guidance*

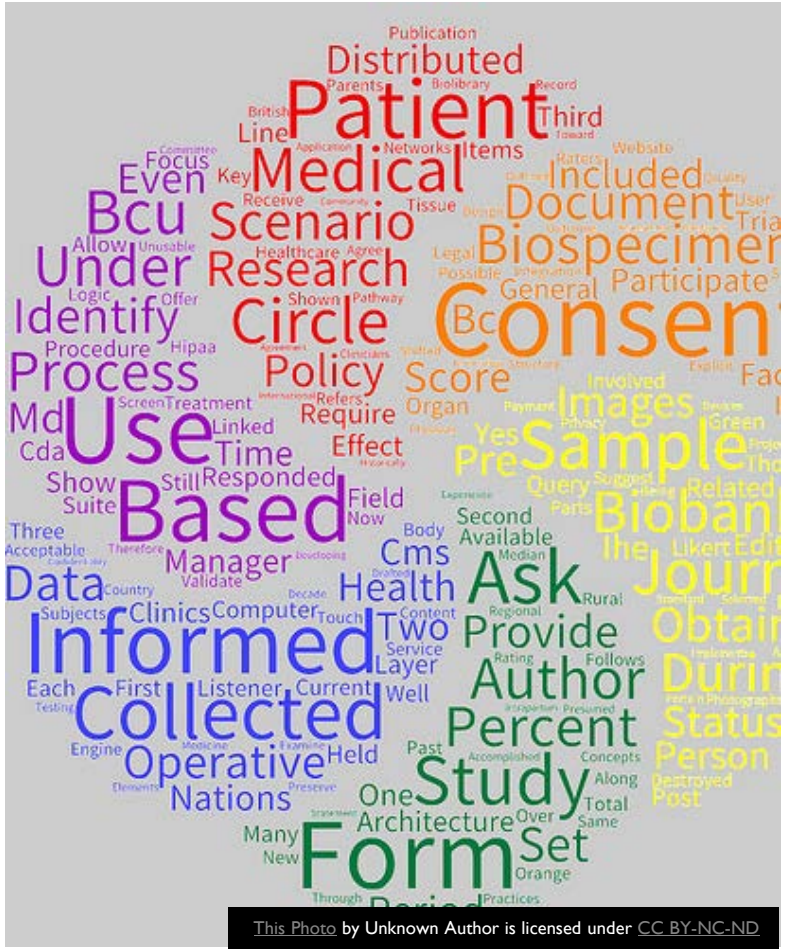
INFORMED CONSENT CHANGES , CONTINUED

- New "Basic" element of Informed Consent - for research involving collection of *identifiable private information or specimens:* Either…
  - (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens **could be used** for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
  - (ii) A statement that the 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."
- Emory IRB's plan: Revised consent template
- Many consents already included this information



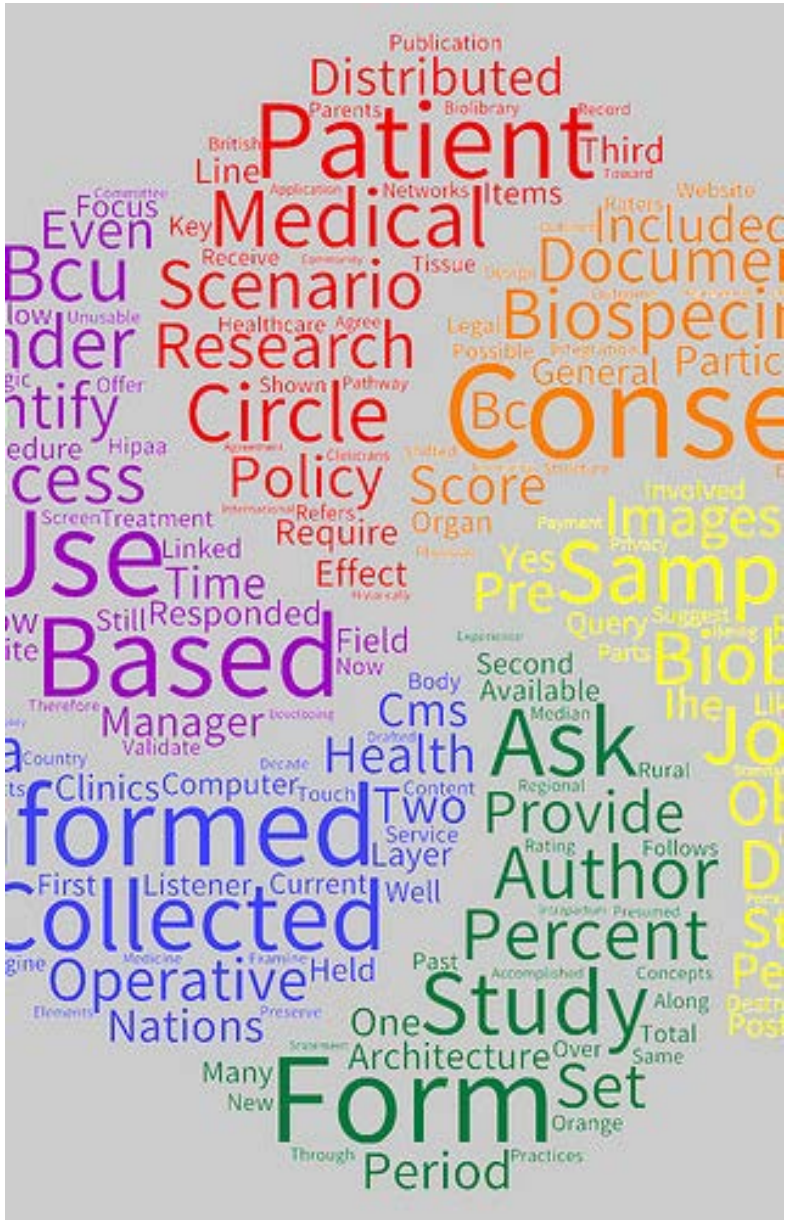
INFORMED CONSENT CHANGES , CONTINUED

- New "Additional" elements of consent when working with **biospecimens** or data that may yield information:
  - (7) A statement that the 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;
  - (8) A statement regarding whether **clinically relevant research results**, including individual research results, will be **disclosed** to subjects, and if so, under what conditions; and
  - (9) 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).
- Emory IRB's plan: Revised consent template and/or "modular language" document

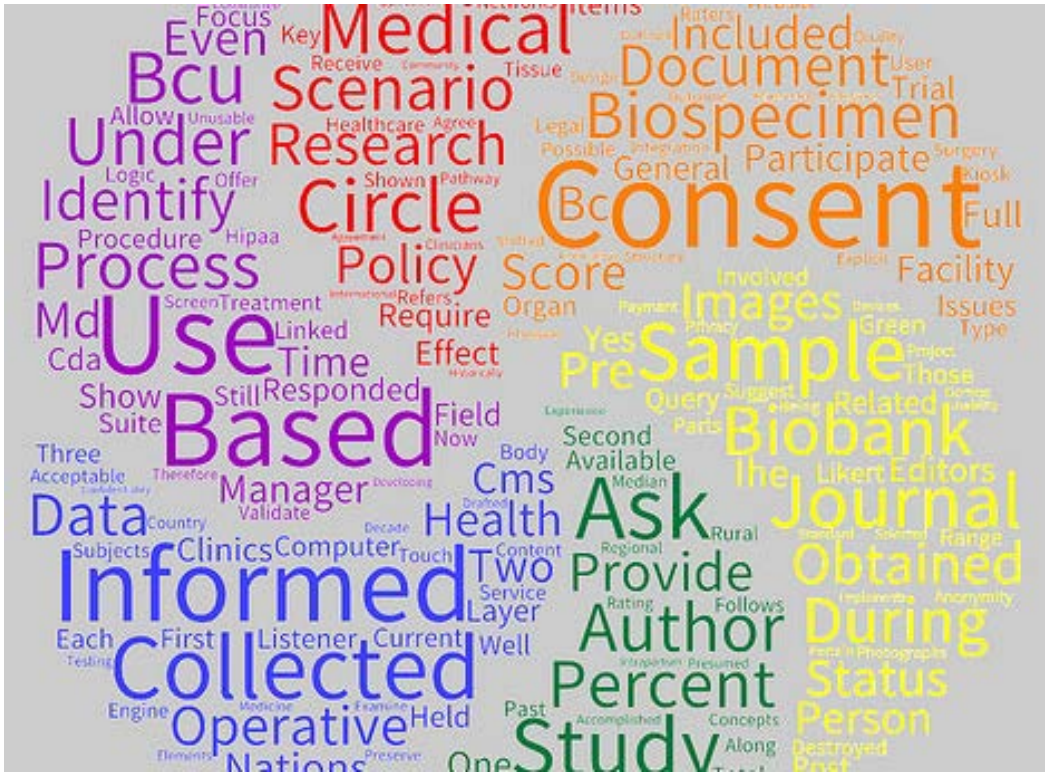


INFORMED CONSENT CHANGES, CONT …

- Ability to screen prior to consent
  - "An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:
    - (1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
    - (2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens."
- Currently, we require a consent (or consent waiver) for the above-described activities
- Emory IRB's plan: consider carefully what data will be obtained, and ensure it is not stored or used for research without consent or waiver



INFORMED CONSENT CHANGES, CONTINUED



- Posting of clinical trial consent form: the new common rule requires posting the consent form used in a clinical trial supported with federal money in clinical trials.gov.
- "The informed consent form must be posted on the Federal website 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."

CONTINUING REVIEW OF STUDIES CONSIDERED "MINIMAL RISK"

- Current Common Rule and FDA requirement: Non-exempt minimal risk studies undergo an expedited review at least once per year
- Minimal risk definition: "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."
- Revised Common Rule (**but not FDA regs yet!**) eliminates the requirement for continuing review
- E.g. chart reviews, focus groups, survey studies and studies in long-term follow up or data analysis only

CONTINUING REVIEW OF STUDIES CONSIDERED "MINIMAL RISK"

- **Still working on an action plan**
- For *non-FDA-regulated* studies approved before 1/20/19, the IRB is considering:
  - Chart reviews, DAO and LTF studies will be transitioned to revised Common Rule via administrative amendment, removing expiration
  - Other minimal risk studies may have option to move to the new Common Rule via amendment
    - May require revised consent(s)
  - Transitioning may be more work than benefit if study not continuing for much longer

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QUESTIONS?