

# IRBIS Changes for the New Common Rule

Laura Cowan, Data and Information Manager, Office of Human Research Ethics



THE UNIVERSITY  
*of* NORTH CAROLINA  
*at* CHAPEL HILL



**On January 21, 2019 OHRE is planning to implement the revised Common Rule changes into IRBIS. There is the possibility that this action will be delayed by the U.S. Department of Health and Human Services, but we wanted to provide some advance notice of the first set of these changes. In the event this action is delayed, an additional update will be sent.**

# Changes to Consent Forms



A Concise Summary section has been added to the beginning of all IRB consent form templates. New language reads:

#### CONCISE SUMMARY

The revised Common Rule requires that consent forms contain a concise presentation of key information. The intention of this section is to provide potential research participants with a better understanding of the project's scope, including major risks and benefits, so they can make a more fully informed decision about whether to participate.

This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form.

Examples of model summary statements are available on the IRB website. [Click here to view examples.](#)

## When “Genetic testing” is selected in A.4.A.7

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A.4.A.7. Does your study involve any of the following? (check all that apply)

- Embryonic stem cells
- Fetal tissue
- Genetic testing (see [GINA](#) and [GWAS](#))
- Other (specify):

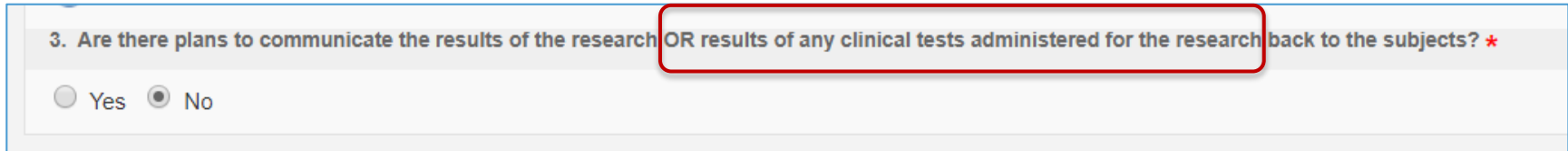
The following language has been added to the IRB Consent templates (in the “What will happen if you take part in the study?” section:

**For Whole Genome Sequencing (WGS):** A statement on 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). (may be omitted if not applicable)

## Changes to A.5.3.

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The wording in A.5.3. has been updated to: “Are there plans to communicate the results of the research OR results of any clinical tests administered for the research back to the subjects?”



3. Are there plans to communicate the results of the research OR results of any clinical tests administered for the research back to the subjects? \*

Yes  No

If “Yes” to A.5.3. the following language has been added to the consent forms **after** the “What if we learn about new findings or information during the study?” section under new heading titled, “Will I receive any clinical results”:

**Will I receive any other clinical results?**

Other clinically relevant results of this research will be communicated with you (describe which test results, when, and under what conditions). (if applicable)

A second paragraph stating, “The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form” has been added to the “Will you receive results from research involving your specimens?” section of the consent form templates:

**Will you receive results from research involving your specimens?**

**[Delete if separate consent for specimens]**

Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.

The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.



## Changes to A.5.3.

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An additional element has been added to section D.3. (Full or partial waiver of consent), which states: “Please explain why it would not be possible to conduct the study with only de-identified data (i.e. without any identifiers listed in A.9).” An explanation is required.

<input type="text"/>	
<b>Please explain why it would not be possible to conduct the study with only de-identified data (i.e. without any identifiers listed in A.9.) *</b>	
<input type="text"/>	
Explain how the requirement to obtain consent would make the research impracticable, e.g., most of the subjects are lost to follow-up or are deceased. *	
<input type="text"/>	

The following sentence has been added to the “How will information about you be protected?” section of the consent form template, “We may use de-identified data and/or specimens from this study in future research without additional consent.”

#### **How will information about you be protected?**

Indicate how privacy and confidentiality will be protected. Briefly but as clearly as possible describe the key procedures for protecting the privacy and confidentiality of the individual’s data, such as:

- How records will be secured.
- Who will have access to individually identifiable data (e.g. research collaborators, sponsors, etc.).
- Whether names or ID numbers will be used (if codes or numbers are assigned, describe how the linkage file will be secured).

Participants will/will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Where applicable, advise participants that they must agree not to reveal anything they learn from interviews, group discussions or other activities.

A copy of this consent form will go in to your medical record. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study.

[Delete if using a separate consent for specimens or if this does not apply to your study and you know data will never be submitted to a data sharing repository (e.g. dbGaP for genome-wide association study (GWAS))]

# New Categories for Exempt Determinations



# Category 1

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Updated to include revised text:

Category 1 ([click here for guidance and examples](#))

The research is to be conducted in established or commonly accepted educational settings. Note: This applies to the location where education research will actually be conducted (e.g., public schools) and NOT to your location at a university.

**And the research specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as:**

Research on regular and special education instructional strategies.

Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**Explain**

## Category 2

Updated to include revised text:

Category 2: [\(click here for guidance and examples\)](#)

Does your study involve minors under the age of 18?

Yes  No

The research involves the use of one or more of the following

- Educational tests (cognitive, diagnostic, aptitude, achievement).
- Survey procedures.
- Interview procedures
- Observation of public behavior.

If at least ONE of the following criteria are true:

- The information obtained is recorded by the investigator in such a manner that participants can readily be ascertained, directly or through identifiers linked to the participants AND there are appropriate provisions in place to protect subject privacy and confidentiality.
- The information obtained is recorded by the investigator in such a manner that any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

Explain

## Category 3

Updated to include revised text:

Category 3 ([click here for guidance and examples](#))

Research with adults involving Benign Behavioral Interventions (BBI) through one of the following:

- Verbal responses
- Written responses (including data entry)
- Audiovisual recording

And at least one of the following are true:

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects
- Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation
- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

If this category is selected, please also explain how the intervention fits the BBI definition: brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and there is no reason to think the subjects will find the interventions offensive or embarrassing.

Explain. If the research involves deceiving the subjects regarding the nature or purposes of the research, please explain how subjects will be prospectively informed that he or she will be unaware of or misled regarding the nature or purposes of the research:

# Category 4

Updated to include revised text:

Category 4 ([click here for guidance and examples](#))

The research involves secondary uses of identifiable private information or identifiable biospecimens.

And one of the following is true:

The identifiable private information or identifiable biospecimens are publicly available.

Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects

The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes."

The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities.

Explain

If Category 4 and the third option “The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated by HIPAA “health care operations” or “research” or “public health activities and purposes.” is selected, a new section of the IRB application is required.

D.4 Full wavier of HIPAA Authorization only applies to studies where the criteria above is met:

✓ Part C. Existing Data, Records, Specimens
⚠ Part D. The Consent Process
⚠ <u>D.4 Full wavier of HIPAA Authorization</u>
✓ Data Security Requirements

1. Use or disclosure involves no more than minimal risk to the privacy of individuals because of the presence of at least the following elements:

a) There is an adequate plan to protect health information identifiers from improper use or disclosure.  
Please provide a complete description of the plan to protect health information identifiers from improper use or disclosure. \*

b) There is an adequate plan to destroy identifiers at the earliest opportunity absent a health or research justification or legal requirement to retain them.  
Please provide a complete description of the plan to destroy identifiers at the earliest opportunity absent a health or research justification or legal requirement to retain them. \*

c) The PHI will not be used or disclosed to a third party except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the Privacy Rule.  
 Please confirm by checking the box that PHI will not be used or disclosed to a third party except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the Privacy Rule.

2. The research could not practically be conducted without the waiver or alteration.  
Please explain how research could not practically be conducted without the waiver or alteration. (See [here](#) for guidance on factors to consider when determining if the requirement to obtain authorization would make the research "impracticable".) \*

3. The research could not practically be conducted without access to and use of PHI.  
Please explain how research could not practically be conducted without access to and use of PHI. I.e. why it could this research not be conducted using non-PHI data? \*



## Category 5

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Updated to include revised text:

Category 5 ([click here for guidance and examples](#))

The project is a research or demonstration project.  
**Required document(s):** Federal Agency Document for Category 5 Exemption

Additionally the following must also be true.

The program under study is designed to study, evaluate, improve, or otherwise examine public benefit or service programs.

The research is conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects).

The Federal department or agency conducting or supporting the research and demonstration projects will establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project will be published on this list prior to commencing the research involving human subjects.

Explain

## Category 6

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No changes have been made to Category 6.

Category 6 ([click here for guidance and examples](#))

The research involves taste and food quality evaluation or is a consumer acceptance study.

Either of the following is true:

Wholesome foods without additives are consumed.

If a food is consumed that contains a food ingredient or an agricultural chemical or environmental contaminant, the food ingredient or agricultural chemical or environmental contaminant is at or below the level and for a use found to be safe by one of the following agencies:

Please check which of following

The Food and Drug Administration.

The Environmental Protection Agency.

The Food Safety and Inspection Service of the U.S. Department of Agriculture.

Explain

# Revised Definitions and Criteria



# Recruitment/screening waivers

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D.2.2. has been added:

2. Are you requesting a waiver of consent solely for recruitment screening? \*

Yes  No

Please select one of the following and in the "Explain" section, describe the recruitment/screening procedures conducted under this waiver. \*

The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Explain: \*

## New Criteria for Waiver of Signed Consent

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Section D.2.1 has been revised to add a third condition box:

- The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Explain

## New / Revised Definitions

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Because of a new definition of Human Subject, updates have been made to Screening Question 2 and 3:

### Screening Question 2

“Will you be obtaining information about a living individual through direct intervention or interaction with that individual? This would include any contact with people using questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them?”

### Screening Question 2, **New Common Rule**

“Will you be obtaining information **or biospecimens** through intervention or interaction with the individual, **and use, study, or analysis of the information or biospecimens**? This would include any communication or interpersonal contact between investigator and subject such as using in-person or online questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them?”

## New / Revised Definitions

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Because of a new definition of Human Subject, updates have been made to Screening Question 2 and 3:

### Screening Question 3

“Will you be obtaining identifiable private information about a living individual collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository).

OR

Will you be using human specimens that are not individually identifiable for FDA-regulated in vitro diagnostic (IVD) device investigations?”

### Screening Question 3, **New Common Rule**

“Will you be obtaining, using, studying, analyzing, or generating identifiable private information **or identifiable biospecimens** collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository).

OR

Will you be using human specimens that are not individually identifiable for FDA-regulated in vitro diagnostic (IVD) device investigations?”

# New / Revised Definitions

Because of a new definition of Human Subject, updates have been made to Screening Question 2 and 3:

The following questions will help you determine if your project will require IRB review and approval.

[The first question is whether this is RESEARCH \(click for details\)](#)

1. Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above. ✖  Yes  No

[The next questions will determine if there are HUMAN SUBJECTS \(click for details\)](#)

2. Will you be obtaining information or biospecimens through intervention or interaction with the individual, and use, study, or analysis of the information or biospecimens? This would include any communication or interpersonal contact between investigator and subject such as using in-person or online questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them? ✖  Yes  No

3. Will you be obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository). OR Will you be using human specimens that are not individually identifiable for [FDA-regulated in vitro diagnostic \(IVD\) device investigations](#)? ✖  Yes  No

The following questions will help build the remainder of your application.

4. Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? (If yes, this application will be reviewed by the CTRC and additional data will be collected.) ✖  Yes  No

5. Does this study directly recruit participants through the UNC Health Care clinical settings for cancer patients or does this study have a focus on cancer or a focus on a risk factor for cancer (e.g. increased physical activity to reduce colon cancer incidence) or does this study receive funding from a cancer agency, foundation, or other cancer related group? (If yes, this application may require additional review by the Oncology Protocol Review Committee.) ✖  Yes  No

6. Are any personnel, organizations, entities, facilities or locations in addition to UNC-Chapel Hill involved in this research (e.g., is this a multi-site study or does it otherwise involve locations outside UNC-CH, including foreign locations)? You should also click "Yes" if you are requesting reliance on an external IRB, or that UNC's IRB cover another site or individual. [See guidance](#). ✖  Yes  No





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