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Key Information Section

A 2018 Common Rule Requirement for the Informed Consent Form

Office of Research Integrity
Human Research Compliance

http://research.weill.cornell.edu/...RB

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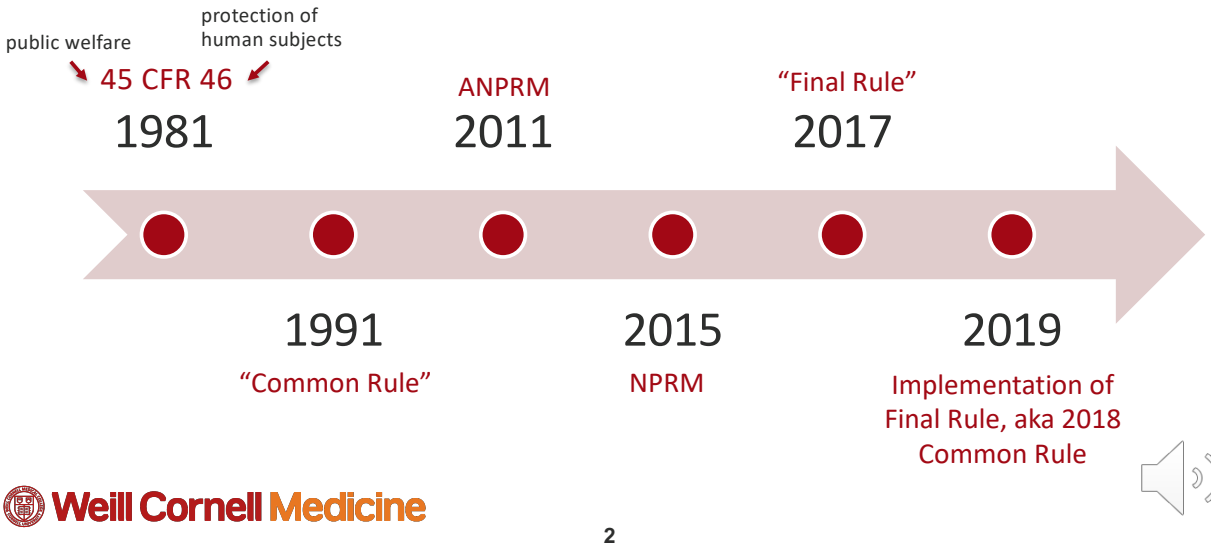
2018 Common Rule (45 CFR 46)



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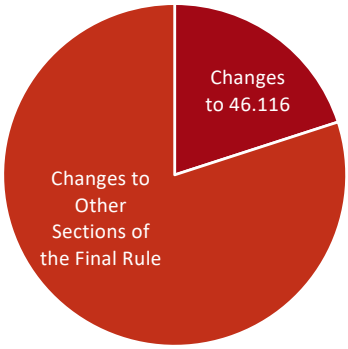
Changes to Informed Consent



Almost 20% of the Final Rule's preamble is dedicated to explaining changes to this one section of the regulation

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from www.citiprogram.org

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Preamble to the 2008 Revised Common Rule

1. **Project is research/participation is voluntary**
2. **Summary of research**
3. **Risks or discomforts**
4. **Expected benefits**
5. **Alternate procedures, if any**

"This part of the informed consent must be organized and presented in a way that facilitates comprehension."

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What is the Key Information Section?

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What the Key Information Section Is

- The first thing your participant sees during the IC process
- Should include the most crucial information needed to decide on participation
- It is NOT a summary
- It does NOT have all elements of the IC
- It does NOT include exclusion criteria*
- It does NOT have to look identical to our template

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Key Information Elements

**This part of the informed consent must be organized and presented in a way that facilitates comprehension.*

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What is considered "key"?

- Varies with context of the study
- Investigator's experience with study population
- Empirical research
- Systematic participant feedback
- Potential participants input
- (Patient) Associations or Support Groups

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What Goes Into the Key Information Section?

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Study Description

Key Information About This Research Study

We are asking you to choose whether to volunteer for a research study about [*insert general description of study*]. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

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Study Purpose

What is the study about and how long will it last?

By doing this study, we hope to learn _____. Your participation in this research will last about [*state in hours, days, months, years*].

[If testing Food and Drug Administration (FDA)-regulated products for safety or effectiveness, include the following]: **The purpose of this research is to gather information on the safety and effectiveness of** _____ *[state name of drug, device, etc. Indicate if the drug, device, or biologic is FDA-approved and whether it is being used in the study for an alternate use or consistent with labeling indications].*

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Study Benefits

Key reasons you might choose to volunteer

State the most important reason(s) {i.e., potential benefit(s)} of volunteering to participate in this study.

For studies with no direct benefit, we suggest: [The study will not include a direct benefit to you. However, some participants appreciate knowing they have contributed to research that may benefit others in the future.] **For a complete description of benefits, refer to the Consent Document below.**

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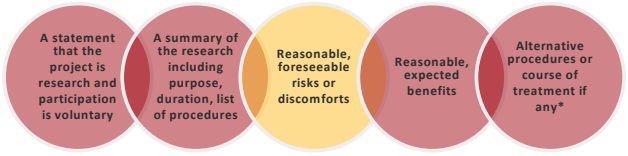
Study Risks



Key reasons you might choose NOT to volunteer

[State the most important reason(s)/risk(s) why a participant may NOT want to volunteer for this study considering the participant's perspective.
For a complete description of risks, refer to the Consent Document below.

[If alternative treatments/procedures are key to the participant's choice, discuss those that might be advantageous to the subject or indicate if no known alternative exists.] **For a complete description of alternate treatment/procedures, refer to the Consent Document below.**

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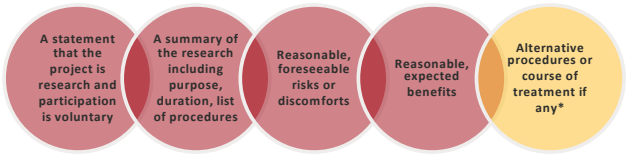
Study Participation



Do you have to take part in the study?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care *[delete 'or access to care' if not applicable]* **you would normally have if you choose not to volunteer.**

[Add the following for student volunteers:] **As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or class grade(s).**

[Add the following for employees of WCM/NYP] **As an employee of WCM/NYP, if you decide not to take part in this study, your choice will have no effect on your employability or performance review.**

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Study Contact

What if you have questions, suggestions, or concerns?

The person in charge of the study is *[Principal Investigator]*, [PI]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: *[PI contact information]*.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Weill Cornell Medicine Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 646-962-8200 or send an e-mail to irb@med.cornell.edu.

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Key Information Note to Include

This overview does not include all the information you need to know before deciding whether to take part in the study. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

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Changes to the Informed Consent Form

- Identifiable private information or identifiable biospecimens
  - Will the identifiers be removed?
  - Will they be used for future research by you or others?
- When applicable:
  - Biospecimens may be used for commercial profit
  - Whether results will be disclosed to participants
  - Will the research include whole genome sequencing?

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When Do I Use the Key Information Section

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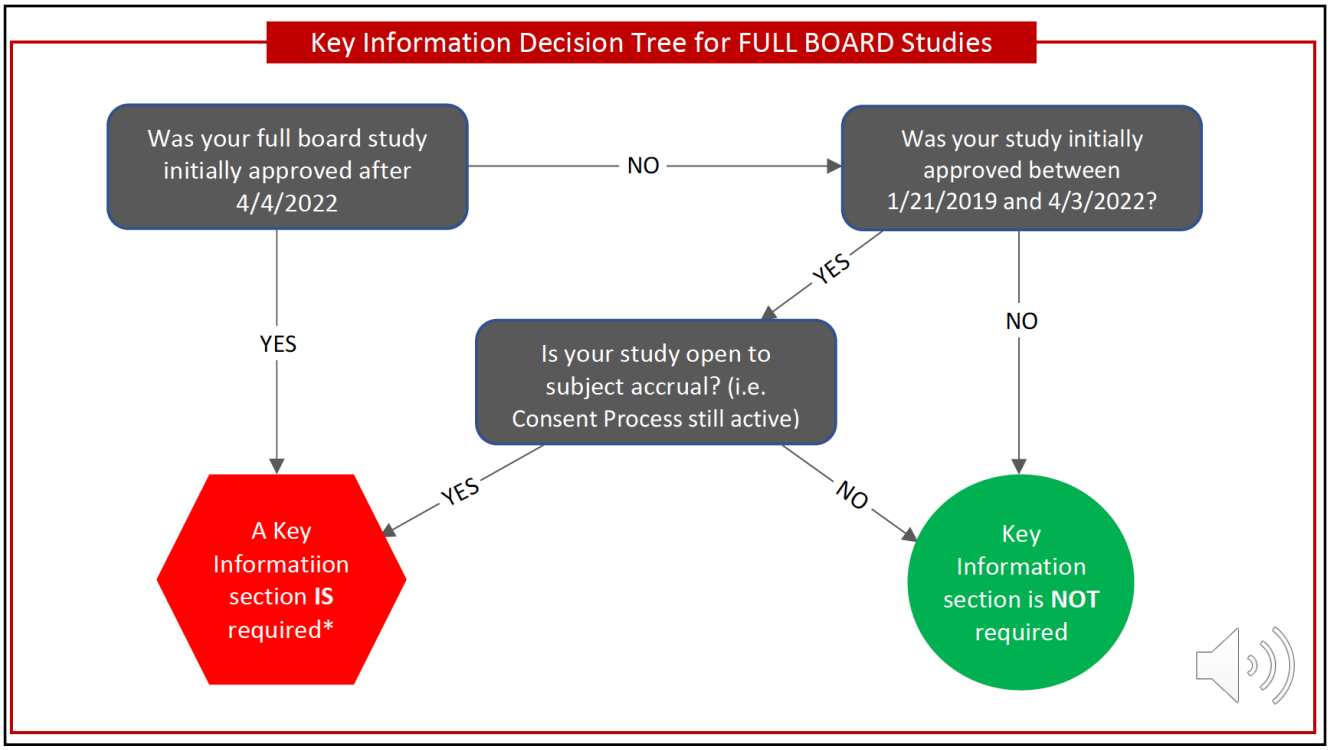
Key Information Decision Tree for FULL BOARD Studies
Was your full board study initially approved after 4/4/2022
NO
Was your study initially approved between 1/21/2019 and 4/3/2022?
YES
NO
YES
Is your study open to subject accrual? (i.e. Consent Process still active)
YES
NO
A Key Informatiion section IS required*
Key Information section is NOT required

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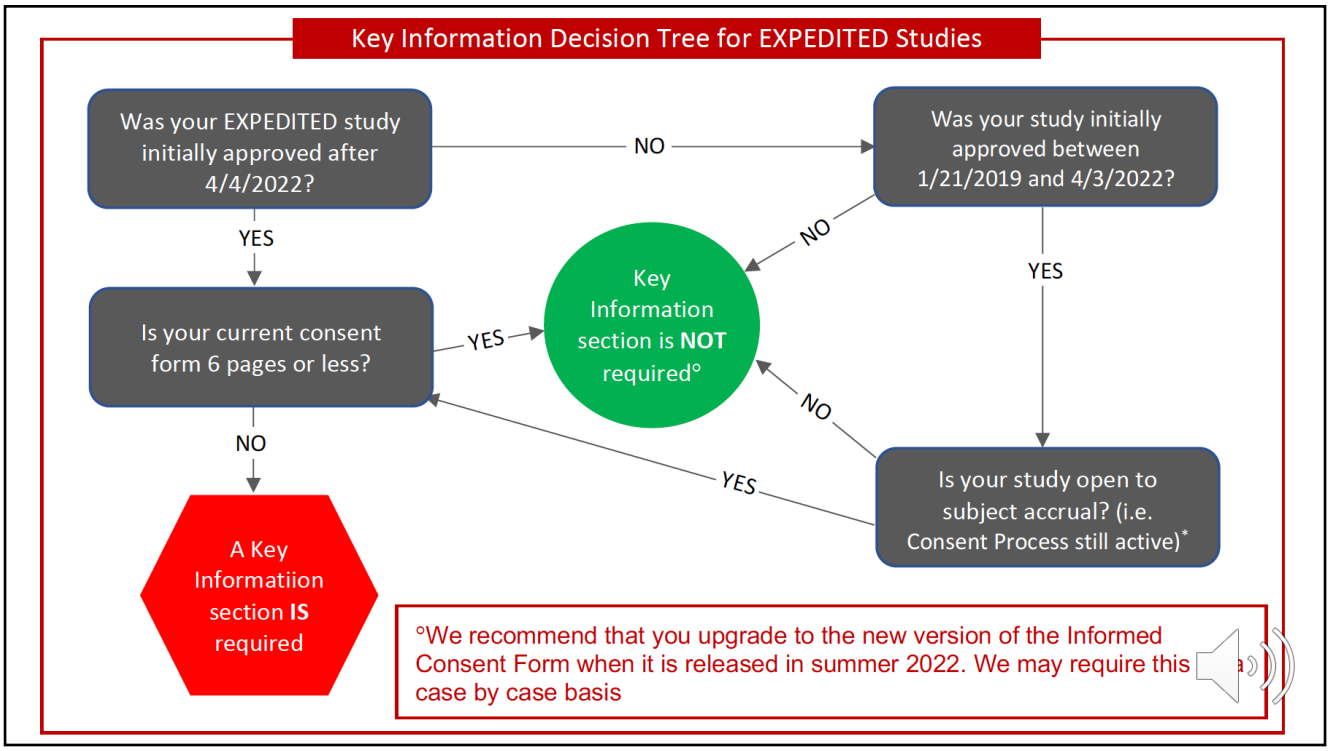
Key Information Decision Tree for EXPEDITED Studies
Was your EXPEDITED study initially approved after 4/4/2022?
NO
Was your study initially approved between 1/21/2019 and 4/3/2022?
YES
NO
YES
Key Information section is NOT required°
Is your current consent form 6 pages or less?
YES
NO
NO
YES
Is your study open to subject accrual? (i.e. Consent Process still active)*
A Key Informatiion section IS required
°We recommend that you upgrade to the new version of the Informed Consent Form when it is released in summer 2022. We may require this
case by case basis

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Do I need to revise my existing IRB-approved consent documents?

Studies approved prior to 1/21/2019

NO

Studies approved on 1/21/2019 and later

YES

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Is Reconsent Required?

- **Change limited to KI section = NO**
  - ***Example:*** ***The*** **only difference between the old ICF and this new one is the addition of the KI section; EVERYTHING ELSE remains the same**
- **Change to KI section AND another element of the ICF = YES**
  - ***Example:*** **Methodology changed such that risk level has increased since prior approval (initial; CR)**

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When should we expect updated ICFs?

- **We are NOT asking analysts to search all previous submissions to check for the KI section**
- **Check for the KI section at next submission (amendment, Continuing Review, PAM)**
  - **If no, request KI section before renewal is granted**
- **PIs may submit alone as an amendment**

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Expedited vs. Full Board Review

Guide for study teams on how to confirm

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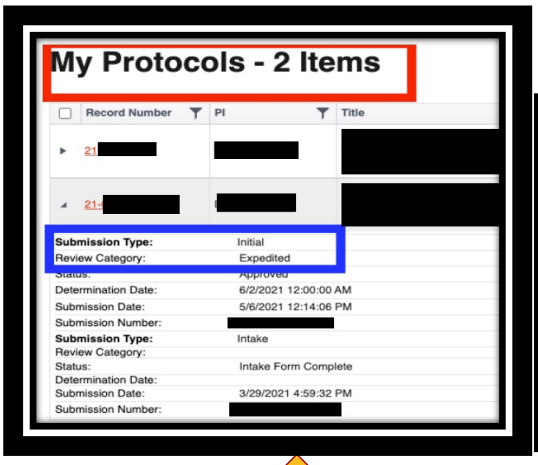
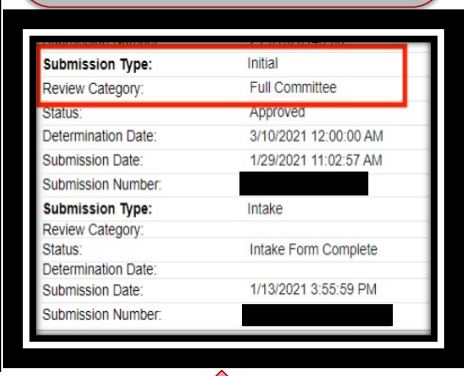
How to Confirm Review Category: 'My Protocols'

Steps

1. Log into WRG
2. Click on the 'Human Subjects' Landing Page
3. Find the protocol you would like to find the status on under 'My Protocols'
4. Click the 'Expand' arrow to show details under the My Protocols Widget
5. Find the specific submission you are looking for an update on
6. Find the 'Review Category' row





Expedited Study

Full Board Study

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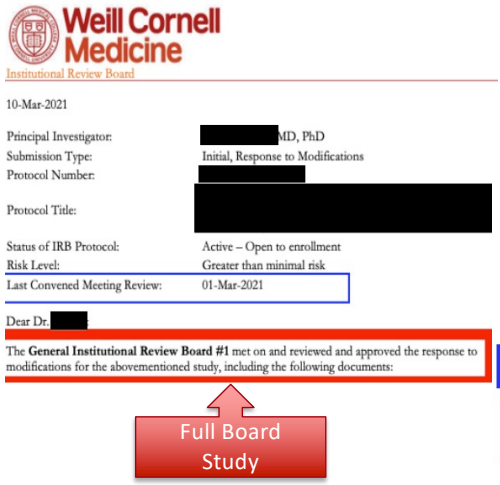
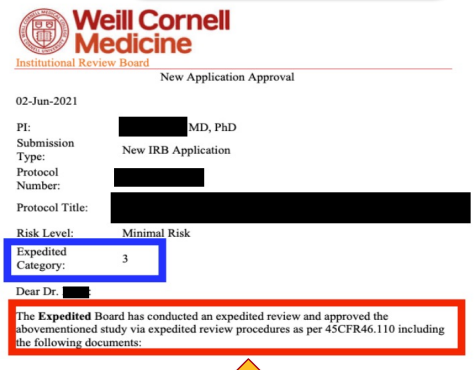
How to Confirm Review Category: Initial Approval Letter

Steps

1. Log into WRG
2. Enter the Protocol number in the 'Quick Find' search box
3. Hover-over the Protocol Number
4. Find the 'Initial' submission and go into the Submission Package
5. Find the 'Communications' the in the lower-left corner of the page
6. Here you will find the 'approval letter' for the Initial submission.





Full Board Study

Expedited Study

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Is There a Template?

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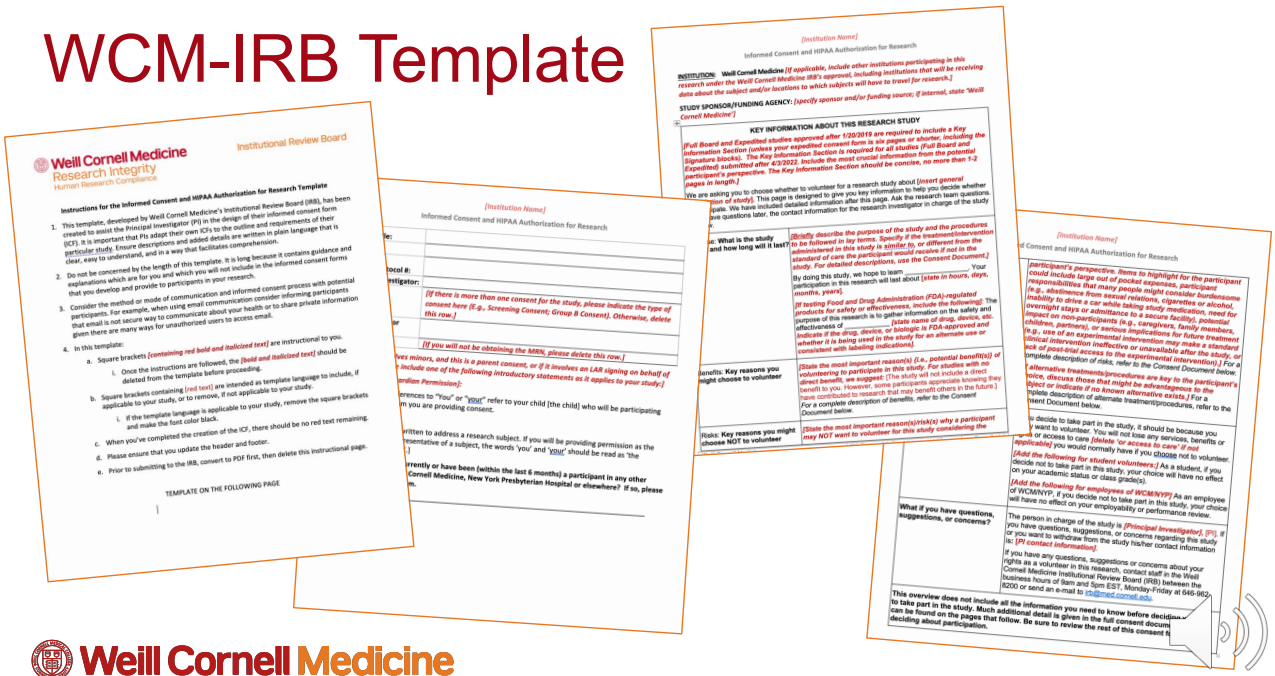
WCM-IRB Template



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FAQs

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Q: **Do I have to begin my consent document with the Key Information Section?**
A: Full Board and Expedited studies approved after 1/20/2019 are required to include AND begin with a concise and focused presentation of the key information relevant to the study.
Q: **Is this required for all consent documents?**
A: If your study is MINIMAL RISK (expedited) and your consent form is 6 pages or shorter (including the Signature blocks), the new Key Information section is not required A: If your study is under one of the six Exempt Categories, the new Key Information section is not required.
Q: **When does the new requirement go into effect?**
A: The Key Information section will be required for all submissions that have not yet received initial approval by 4/3/2022. All submissions scheduled to receive initial approval on or after 4/4/2022 will need the updated ICF (with the Key Information section included)

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Q: Do I need to revise my existing IRB approved consent documents?

A: Beginning 4/4/2022, all studies approved by Full Board review after 0/2019 nd before 4/4/2022 **AND** open to subject accrual (meaning an active consenting process) will be required to submit [updated] consent documents at their next continuing review (CR) but may choose to submit an amendment prior to CR submission.

For Expedited studies still open to subject accrual (meaning an active consenting process), a KI section will **not** need to be retrospectively added to approved consent documents when you submit an amendment (as PAM-ARs do not allow for document changes), but we **strongly recommend** you upgrade to the new version of the ICF (which includes the KI section) when it is released in Summer 2022

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Examples

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Biorepository

You or your child are being asked to take part in this research study because you have XXX.

The purpose of this study is to collect and store data and samples, such as blood and saliva, for future research (about XXX). The future research will include genetic testing. You will not receive results from any of the tests that are performed as part of future research studies.

If you agree to take part, you will need to give a blood or saliva samples once. We will also review your medical records. The information from your medical record will be collected once a year (Or other frequency).

Your data and samples will be shared with other researchers at CHOP as well as researchers at other institutions or for profit companies. Before sharing your data or samples, all information that can identify you will be removed. These researchers, who use your samples for future research, will not know who you are.

The main risks from this study are related to bleeding or infection from the blood draw and risks related to a possibility of a breach of confidentiality of your samples and data. Every precaution will be taken to secure your personal information to ensure confidentiality.

You will not benefit directly from taking part in this study.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time. If you do not choose to take part in this study, you can discuss treatment options with your doctor. You may also be eligible for a different research study (only if applicable).

Please see below for additional details about the study.

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Minimal Risk

You or your child are being asked to take part in this research study because you have XXXX. *Briefly include the major reasons why the subject is being approached to participate. For example, "…you have been diagnosed with sickle cell disease and are scheduled to have an MRI."*

This is a research study to learn more about how XXXX effects/relates to/changes XXXX.

You will be asked to come to CHOP for X study visit(s) that will (each) last about XX hours. If you take part, you will be asked to (*this listing of procedures should be limited to the most burdensome and/or main procedures that a reasonable person would want to know*):

- Complete cognitive function tests and questionnaires;
- Have a research blood draw;
- Perform computer tasks.

The main risks of this study are from the cognitive assessments. These include fatigue and embarrassment.

You will/not benefit directly from participating in this study (if there are direct benefits, describe them).

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time. If you do not choose to take part in this study, you can discuss treatment options with your doctor. You may also be eligible for a different research study (only if applicable).

Please see below for additional details about the study.

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Greater than Minimal Risk

You or your child are being asked to take part in this research study because you have [DISEASE/CONDITION].

The purpose of this study is to find out if the study drug works better than current drug. The study drug is not approved by the FDA.

If you agree to take part, your participation will last for XXX and will involve XX study visits. You will need to take the study drug or placebo for XXX weeks. A placebo is an inactive substance. There are differences between this study and your usual care. As a participant in this research you will:

- Receive a study drug or a placebo; you will not know which
- Stop your regular medication
- Have X extra research clinic visits;
- Complete a double-blind food challenge;
- Have research blood tests, skin prick allergy tests, and other procedures.

The main risks of this study are from the study drug. These include: allergic reaction and skin irritation.

You may benefit if drug ABC or XYZ proves to be more effective. OR – You will not benefit directly from participating in this study.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time. If you do not choose to take part in this study, you can discuss treatment options with your doctor. You may also be eligible for a different research study (only if applicable).

Please see below for additional details about the study.

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Any Questions?

- **About the key information section or consent form:**

  Contact the IRB at irb@med.cornell.edu

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