## Integrating 2018 Common Rule Requirements into currently approved consent forms

This document is intended to be a tool to assist study teams with currently approved consent forms integrate the new consent form requirements as outlined in the 2018 Common Rule. Some of the changes may not be applicable to certain studies (i.e. information about bio specimens or future use).

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| **Pre-2018 Common Rule Template Language:** | **2018 Common Rule Template Language:** |
| **New Required Basic Elements of Informed Consent (Note: This only outlines the newly added elements of informed consent. It does not outline all required elements of informed consent).** | |
| What is the purpose of this research study? The purpose of this research study is to XXXX.  Example: The purpose of the research is to see if XXXX improves the health of children with sickle cell disease.  Describe the purpose of the research in lay language.  Provide the information that a reasonable and responsible parent would want to know before allowing their child to enroll in the study (i.e. focus on the major concepts rather than including detailed explanations of the science behind the research).  Don’t include every single detail about the study.  The consent form should include an explanation that is sufficient for most and offer the opportunity for the parent/subject to discuss any aspect of the study in more detail with the investigator.  If the study involves an experimental intervention, agent, device or diagnostic, provide a concise description that includes whether or not it is approved by the FDA. If it is approved, discuss whether it is approved for use for children. | Study Overview Include a concise statement explaining the research. If the consent form is brief and straightforward, the concise statement can be omitted. An example is provided below; use/modify it as appropriate. The entire concise statement should fit on the first page.  This example is relevant for studies that involve investigational drug. Additional examples for concise statements can be found below in the appendix and on the IRB’s website at: <https://irb.research.chop.edu/consent-templates>  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.”*  The purpose of this study is to find out if drug XYZ works better than drug ABC.  If the study involves an experimental intervention, agent, device or diagnostic, provide a concise description that includes whether or not the intervention is approved by the FDA. If it is approved, discuss whether it is approved for its proposed use – i.e., for children.  If you agree to take part, your participation will last for XXXX and will involve XXXX study visits. You will need to take the study drug ABC or XYZ (or placebo) for XXX weeks. A placebo is an inactive substance. There are differences between this study and your usual care. If you take part the main differences are you will (*this listing of procedures should be limited to the most burdensome and/or main procedures that a reasonable person would want to know*):  Receive a study drug or a placebo; you will not know which.  Have X extra research clinic visits;  Have a research MRI;  Have research blood tests, etc.  The main risks of this study are from the study drug ABC or XYZ. These include: death, stroke, hemorrhage, infection, etc.  You may benefit if drug ABC or XYZ proves to be more effective. OR – You will not benefit directly from participating in this study.  Participation in this study is voluntary. 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).  If you are interested in learning more about the study, please continue to read below.  In the sections that follow, the word “we” means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word “you” refers to your child. |
| What is involved in the study? If the procedures or study design are complicated (e.g. randomization, crossover design, etc.) a brief description of these procedures can be included. If the procedures are simple, the “What is involved” section can be deleted. | See concise statement language above.  Note: There are no changes to this section.  If this section duplicates information in the newly added concise statement, the section can be deleted entirely.  If this section is still relevant to studies with a complex design (i.e. randomization, multiple arms/phases, etc.), it should remain in the consent form. |
| **N/A**  The following language should be included before the main study signature blocks with the other optional signature blocks (as applicable). | If identifiable data or specimens will be retained for future secondary research, then subjects must consent to its use.  **One of the following statements must be included:**  **What will be done with my data and specimens (if applicable) when this study is over?**  (Use one of the following three options regarding the use of data and/or specimens for future research.):  NO secondary (future) research **with or without identifiers**:  Your data and/or samples (include as applicable) will not be used for any future research after this study is complete.  Secondary (future) research **without identifiers**:  We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.  Secondary (future) research **with identifiers:**  If there is ANY chance of using the data and/or specimens for future research and they are linked to identifiers or identifiable information; either   * include an “Optional Future Use of Data and/or Specimens” section (see the next section of the template). Or * if future use of individually identifiable specimens/data is mandatory for study enrollment, then this must be explicitly stated below (the header and option to document consent to the future use should be deleted).  Please note that this section does NOT constitute broad consent. |
| **Additional elements of informed consent (as appropriate to the research)** | |
| **Study Procedures:**  Genetic Testing: Thousands of genes are found in every cell in your body. Each of these genes contains a set of instructions that are read by the cell. This allows your body to make proteins. Genes are passed on from both parents to their child. Sometimes, the instructions aren’t written properly and can result in disease. These differences are called variants. Everyone has variants in their genes. The meaning of most variants is not yet known. By looking at your genes we hope to learn about the causes of your disease | **Study Procedures:**  Genetic Testing:  Thousands of genes are found in every cell in your body. Each of these genes contains a set of instructions that are read by the cell. This allows your body to make proteins. Genes are passed on from both parents to their child. Sometimes, the instructions aren’t written properly and can result in disease. These differences are called variants. Everyone has variants in their genes. The meaning of most variants is not yet known. By looking at your genes we hope to learn about the causes of your disease.  (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). If genetic testing may only be performed in the future, this statement can be included in the “what will be done with my specimens” section instead of here. |
| **What will be done with my data and specimens during this study?**  During the study, we will collect blood [urine, tissue etc., include as applicable] samples from you. By agreeing to participate in the study, you  [if stored at CHOP] agree to give these samples to CHOP for research purposes. | **What will be done with my data and specimens during this study?**  During the study, we will collect blood [urine, tissue etc., include as applicable] samples from you. By agreeing to participate in the study, you  [if stored at CHOP] agree to give these samples to CHOP for research purposes.  **Will I receive any results from the tests done as part of this study?** (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. (<https://irb.research.chop.edu/incidental-findings>) Results that could be important for your clinical care will be shared with you. We will not share other results with you. |
| **Who might receive your data and specimens (or data, or specimens as applicable) as part of this study?**  We may share your specimens and data with third parties (other researchers/institutions or for profit companies). If there are patents or products that result from the research, the third parties may make money from the research. You will not receive any financial benefit from research done on your specimens or data. | **NOTE:** There is no net change to the CHOP IRB’s current template language. This is included because of the changes to the regulatory requirements.**Who might receive your data and specimens (or data, or specimens as applicable) as part of this study?**  **(only include if sharing with a commercial company is possible)**  (7) A statement is required to inform subjects that their 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; (Example statement below)  We may share your specimens and data with third parties (other researchers/institutions or for profit companies). If there are patents or products that result from the research, the third parties may make money from the research. You will not receive any financial benefit from research done on your specimens or data. |

## Appendix 1

**Concise Summary Templates:**

**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 study drug works better than current drug. 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 one year. A placebo is an inactive substance. There are differences between this study and your usual care. If you take part the main differences are 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 study drug proves to be more effective and you receive the active drug. You will not benefit if you receive the placebo.

Participation in this study is voluntary. 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.

If you are interested in learning more about the study, please continue to read below.

In the sections that follow, the word “we” means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word “you” refers to your child.

**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 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).

Participation in this study is voluntary. If you do not choose to take part in this study, you can discuss other options with your doctor. You may also be eligible for a different research study (only if applicable).

If you are interested in learning more about the study, please continue to read below.

In the sections that follow, the word “we” means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word “you” refers to your child.

**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, but 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. The researchers who use your samples 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.

Participation in this study is voluntary and choosing not to participate will not impact your usual clinical care.

If you are interested in learning more about the study, please continue to read below. In the sections that follow, the word “we” means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word “you” refers to your child.