Revised Informed Consent/Parental Permission Form for Research: Regulatory and Other Changes to Children’s Template

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Overview

• Background
  – Revised federal regulations for human subject protections
• New regulatory changes to informed consent requirements (Final Rule) and revisions to consent/parental permission template
• Additional changes to informed consent
  – Revised NIH policy on Certificates of Confidentiality, etc.
• Q and A: OPHS@childrensnational.org
Background
The “Final Rule” was intended to go into effect on January 19, 2018, but DHHS has delayed full implementation for 12 months.

The new effective date is **January 21, 2019**
Implementation of Final Rule Changes

• Studies that are approved by the IRB prior to January 21, 2019 will remain subject to the pre-2018 regulations

• Studies approved by the IRB on or after January 21, 2019 must comply with the revised Common Rule
Summary of Key Changes to the Common Rule

1. Definitions

2. Informed consent
   • General revisions
   • New elements
   • Waiver and alteration of informed consent
   • Posting of clinical trials consent forms

3. Exempt research categories

4. Streamlining of expedited review, including the elimination of certain continuing IRB reviews

5. Single IRB review

Updated 1/18/2018
What This Means for Investigators

• Children’s informed consent/parental permission template has been updated to ensure compliance with the new regulations
  o Today’s presentation focuses on changes to informed consent
  o The revised template will be required for new submissions to the IRB beginning 1/22/2018
• The IRBear electronic application form is being updated
• Future OPHS presentations will describe changes to the categories of research exempt from IRB review and single IRB review
Final Rule Changes to Informed Consent
Rationale for Final Rule Changes: Promoting Autonomy

• Regulatory changes are intended to make informed consent more meaningful so that research subjects will have the necessary information to make informed decisions

• New standard: Provide the information that a reasonable person would want to make an informed decision about participation.
Final Rule Changes to Informed Consent

• Requires a concise and focused presentation of key information in the first section of the form

• 1 New basic element – Statement whether or not subjects’ information or biospecimens could be used for future research without additional consent

• 3 New additional elements:
  o Statement regarding whether research includes whole genome sequencing (for research involving biospecimens)
  o Statement regarding whether clinically relevant research results will be given to subjects
  o Statement regarding possible commercial profit (for research involving biospecimens)
Revised Consent Form Template Available on the IRBear Home Page

The new informed consent/parental permission form template is available here.

http://www.IRBear.org
Key Information Section of Consent Form
New Requirement: Summary of Key Information

• Consent forms will now require a concise summary prior to the body of the consent document. Includes:
  o Statement that participation is voluntary;
  o Study purpose, procedures, and duration;
  o Reasonable expected risks or discomforts;
  o Reasonable expedited benefits;
  o Alternatives to participation.

• Information must be presented in sufficient detail and organized to facilitate potential subjects’ understanding.
  o Not merely lists of isolated facts
SUMMARY AND KEY INFORMATION (Template page 2)

INSTRUCTIONS

THE SUMMARY AND KEY INFORMATION SECTION MUST INCLUDE 5 KEY PIECES OF INFORMATION: (1) STATEMENT THAT PARTICIPATION IS VOLUNTARY; (2) SUMMARY OF RESEARCH TO INCLUDE PURPOSE, DURATION, AND PROCEDURES; (3) REASONABLE EXPECTED RISKS OR DISCOMFORTS AND (4) REASONABLE EXPECTED BENEFITS; (5) ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT TO RESEARCH PARTICIPATION. TEXT FOR PART 1 OF THE KEY INFORMATION IS PROVIDED FOR YOU BELOW.
KEY SUMMARY SECTION: PART 1

SUMMARY AND KEY INFORMATION

INSTRUCTIONS

The Summary and Key Information section must include 5 key pieces of information: (1) Statement that participation is voluntary; (2) Summary of research to include purpose, duration, and procedures; (3) Reasonable expected risks or discomforts and (4) Reasonable expected benefits; (5) Alternative procedures or courses of treatment to research participation. Text for Part 1 of the key information is provided for you below.

We are inviting you to be part of a research study at Children’s National Medical Center (Children’s National). Taking part in this study is your choice. You can choose to take part or you can choose not to take part in this study. You also can change your mind about participating at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

To help you decide if you would like to participate, we want you to know why we are doing the study, what you will be expected to do and the possible risks and benefits of being in the study. This form has information to help you make your choice about whether or not to take part in the study.
Key Summary Section: Part 2

**KEY INFORMATION PART 2 INSTRUCTIONS**

- BRIEFLY SUMMARIZE THE: (1) PURPOSE OF THE RESEARCH; (2) KEY PROCEDURES; (3) DURATION OF PARTICIPATION. TELL THE PARTICIPANT WHAT TO EXPECT USING LAY LANGUAGE AND SIMPLE TERMS.

**Sample text: purpose of study (1-2 sentences)**

“This is a research study to find out if a drug called 123 is safe and to determine the safest, dose of the drug”

or

“The purpose of this research study is to determine the effectiveness of physical therapy in the treatment of patients with ABC.”

(Template page 2)

(Template page 3)
**Sample text: purpose, procedures, duration (4-8 sentences)**

“Depending on when you enroll in this study, you will receive higher doses of ABC-123 until the safest and best tolerated dose is reached. ABC-123 is given via i.v. infusion in the clinic at Children’s. You will have tests, exams and procedures that are part of your standard care and for study purposes. Each clinic visit will last 4-5 hours. Infusions of study drug will be given during week 1 of each 3-week cycle.”

Or

“Participants will undergo a 2-day screening that includes a blood draw, exercise testing, and completion of quality-of-life surveys. Once screening is complete, participants will complete a physical therapy program that will require visits to Children’s three times each week for 16 weeks, for a total of 48 visits. Each visit will take about 2 hours. Participants will also be asked to complete a pain diary and have blood draws every 4 weeks throughout the study. Follow-up phone calls from the study team will occur at 4 weeks and 8 weeks after completion of the physical therapy program. Total study duration is about 6 and one-half months.”
There are risks to this study drug that are described in this document. Some risks include: nausea, diarrhea, low white and red blood cell count, being tired and weak, fever, muscle pain and radiation risks from CT scans. There is no benefit to you directly from taking part in this study. What we learn from this study will help doctors decide about whether this drug may continue to be tested for use in treating ABC. There is some evidence (*select and modify as appropriate: in animals, in living human cells, in living animal cells, in people with another cancer*) that this treatment can (*shrink or stabilize*) cancer (*insert targeted mutation as appropriate, e.g., with a change in the EGFR gene*), but we do not know if this will happen in people. It is unlikely that this (*insert intervention*) will help you live longer. This study may help the study doctors learn things that may help other people in the future.”

The greatest risks of this study include the possibility of injury during the physical therapy program and loss of confidentiality of your study information. Risks of taking the blood sample are discomfort and/or bruising; infection, excess bleeding, clotting, or fainting are also possible. It is possible that the physical therapy will help you with the treatment of ABC.”
Sample text
“The usual approach for patients who are not in a study is treatment with (*insert usual treatment modality, e.g., more chemotherapy; indicate if FDA-approved*). (*Insert if appropriate: There are no treatments that are proven to help patients with your health condition live longer*).”

or

“The usual approach for patients who are not in a study is treatment with surgery, radiation, or drugs (*indicate if FDA-approved*). Sometimes, combinations of these treatments are used. Your doctor can explain which treatment may be best for you.”

or

The usual approach for patients who are not in a study is to get advice from their doctor. This advice might include ways to exercise and how to do their daily activities so they are less tired.”

If you are interested in learning more about this study, please continue reading below.
New Elements of Informed Consent
Currently Required Elements of Informed Consent

- Purpose, duration, and procedures of the research
- Risks or discomforts
- Benefits
- Alternative procedures or treatments (when applicable)
- Extent of confidentiality of the data
- Availability of compensation and or medical treatment if injury occurs
- Contact information regarding the research, subjects’ rights, and research-related injury
- Participation is voluntary
New Required Element of Informed Consent

Notice about possible future research use of deidentified (stripped of HIPAA or other identifiers) information or samples:

• Notifying prospective subject that their deidentified information or biospecimens could be used for future research without additional consent; or

• Notifying prospective subject that their deidentified information or biospecimens will not be used for future research.
Future Research Use of Information or Biospecimens

What kinds of information will the study collect? Will any information be shared with me? (Template page 19)

**INSTRUCTIONS**

- **IF THIS STUDY INVOLVES COLLECTION OF IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS, YOU MUST INCLUDE A STATEMENT INFORMING PARTICIPANTS WHETHER THEIR DE-IDENTIFIED INFORMATION OR BIOSPECIMENS COULD BE USED FOR FUTURE RESEARCH.**

- **IF THIS STUDY INVOLVES COLLECTION OF IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS, CHOOSE ONLY ONE STATEMENT BELOW (1 OR 2) AND DELETE THE OPTION THAT DOES NOT APPLY.**

- **IF THIS STUDY DOES NOT INVOLVE COLLECTION OF IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS, DELETE BOTH STATEMENTS 1 AND 2 BELOW,**

1. If identifiers like your name, address, date of birth and phone number are removed from the data and samples that are collected during this research, that information or those samples could be used for future research studies or given to another investigator for future research studies without your additional informed consent.

2. Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers, name, address, date of birth and phone number are removed.

Updated 1/18/2018
3 New Additional Elements of Informed Consent

1. Notice about whether research might include whole genome sequencing (for research involving biospecimens)

2. Notice about whether clinically relevant research results, including individual research results, will be given to subjects, and if so, under what conditions

3. Notice about possible commercial profit, and whether subject will share in this profit (for research involving biospecimens)
Whole Genome Sequencing (GWAS)
Research Involving Biospecimens

What kinds of information will the study collect? Will any information be shared with me? (Template page 15)

**Instructions**
- **Briefly Describe the kinds of data and specimens to be collected in the study and the kind of tests/analyses to be done on the data and samples.**
- **For research with biospecimens, specify whether the study might include Whole Genome Sequencing (GWAS) (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that individual or specimen) and whether GWAS data will be put into federal or other databases (e.g., DBGap).**
- **Describe whether individual clinically relevant research results will be shared with participants and, if so, under what conditions.**
  - **For results of genetic or other tests that to be shared, the testing must be done at a CLIA lab prior to sharing with a participant. Describe whether the study will do or pay for such testing or whether the subject will need to pay for such testing.**
Sample GWAS Text

Sample text for GWAS studies:
“Genome-wide association studies (GWAS) look at the genetic differences between people that may be found in the human genome (the complete set of all human genes or DNA) to find out if there is a relationship between certain traits (such as blood pressure, or weight) and having or not having a disease or condition.”

“As part of this study, we will be collecting genetic data about you and will send this data to the National Institutes of Health (NIH) GWAS repository (a repository is a place where data are stored for use in future research). The data will not be labeled with any information that can be used to identify you. This data may be shared with other researchers around the world. Researchers will have to get approval from an ethics board to use this information for research prior to getting access to this data.”

“Even without your name or other identifiers, your genetic information is unique to you. There is a potential risk that someone will identify you from your genetic information or learn something about you by looking at your genetic information. This risk may increase in the future as technologies advance and as more researchers study your genetic information. These risks may also affect members of your family. You should discuss your participation in this study with your family and ask the study doctor about any questions or concerns you may have.

Your samples and genetic information may be used for research for many years in the future.”
### Sharing of Clinically Relevant Research Results with Subjects

What kinds of information will the study collect? Will any information be shared with me? (Template page 15)

##### Instructions

- **Briefly Describe the kinds of data and specimens to be collected in the study and the kind of tests/analyses to be done on the data and samples.**

- **For research with biospecimens, specify whether the study might include whole genome sequencing (GWAS) (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that individual or specimen) and whether GWAS data will be put into federal or other databases (e.g. dbGap).**

- **Describe whether individual clinically relevant research results will be shared with participants and, if so, under what conditions.**
  
  - For results of genetic or other tests that to be shared, the testing must be done at a CLIA lab prior to sharing with a participant. Describe whether the study will do or pay for such testing or whether the subject will need to pay for such testing.
-sharing of research findings with subjects

INCLUDE ONE OF THE FOLLOWING STATEMENTS:

1. Most tests done on samples in research studies are only for research and have no clear meaning for health care. If we find that certain data or results from tests done as part of the research have meaning for your health care [if applicable, include specific data or tests], we will contact you to let you know what we have found and what this could mean for your health care.

OR

2. Most tests done on samples in research studies are only for research and have no clear meaning for health care. It may be possible that some study data and test results have meaning for your health care. We are not planning to share data or test results from this research study with you.
Potential for Future Commercial Profit Research Involving Biospecimens

Will I be paid for taking part in this study? (Template page 25)

**INSTRUCTIONS**

- FOR RESEARCH INVOLVING BIOSPECIMENS, DESCRIBE POTENTIAL FOR FUTURE COMMERCIAL PROFIT AND WHETHER SUBJECT WILL SHARE IN THIS. USE LANGUAGE BELOW AND SPECIFY WHETHER PARTICIPANTS CAN EXPECT TO SHARE IN ANY PROFITS.

Your information and samples (both identifiable and de-identified) may be used to help researchers create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you or to pay you or your family.

OR

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, we plan to tell you and to pay you or your family.
Additional Template Changes
Additional Revisions to Informed Consent/Parental Permission Template

• Return of individual research results to subjects
  o Results must be come from or be verified by a Clinical Laboratory Improvement Amendments (CLIA) certified lab before sharing with study subjects

• Certificates of Confidentiality – NIH policy

• ClinCard method of payment to subjects
What kinds of information will the study collect? Will any information be shared with me? (Template page 15)

**INSTRUCTIONS**

- Briefly describe the kinds of data and specimens to be collected in the study and the kind of tests/analyses to be done on the data and samples.

- For research with biospecimens, specify whether the study might include whole genome sequencing (GWAS) (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that individual or specimen) and whether GWAS data will be put into federal or other databases (e.g. dbGap).

- Describe whether individual clinically relevant research results will be shared with participants and, if so, under what conditions.

- For results of genetic or other tests that are to be shared, the testing must be done at a CLIA lab prior to sharing with a participant. Describe whether the study will do or pay for such testing or whether the subject will need to pay for such testing.
Sample text for sharing of research testing by CLIA and non-CLIA labs:

“If we think that there are genetic or other research test results that might have meaning for you, these tests should be re-done by a certified clinical laboratory. The study has funding to get such testing re-done and to offer you any needed appropriate genetic or other counselling.”

“If we think that there are genetic or other research test results that might have meaning for you, these tests should be re-done by a certified clinical laboratory. The study does not have money to do this testing. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic or other counseling. You or your insurance company may have to pay for those additional services.”
Certificates of Confidentiality (CoC): Change to NIH Policy

• As of October 1, 2017, CoCs automatically issued for all NIH-funded research ongoing as of December 13, 2016 which collects or uses identifiable, sensitive information (no physical CoC issued)

• Investigators and institutions responsible for determining whether a research project is eligible for a CoC.
  • Screening questions now embedded in IRB <bear>

• CoC information must be disclosed in the informed consent/parental permission forms or in an information sheet (for exempt or other studies that do not require documentation of informed consent.)
Certificates of Confidentiality: Broader Applicability

How will you protect my privacy if I take part in this study? (Template page 20)

**INSTRUCTIONS**
- Include the section below if your study has a Certificate of Confidentiality (CoC). Use the text as it is written: Do not edit this text.
- All NIH funded studies active as of December 13, 2016, that collect or use sensitive identifiable information must include the CoC language below.
- Delete the section on the Certificate of Confidentiality if it is not applicable to your study.

Certificate of Confidentiality
Sometimes people tell us some very personal information about themselves when they participate in a study and it becomes part of their research record. To help us protect your privacy, the investigators have obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS).

- It is important that you know that a Certificate of Confidentiality does not stop you or a member of your family from voluntarily giving information to others about yourself or your taking part in this research. You should also know that if an insurer or employer learns about your participation and you give them permission to receive research information about you, we cannot use the Certificate of Confidentiality to keep your information private from them. This means that you must also actively protect your own privacy.

- Finally, it is important that you know that we are not prevented from taking steps to prevent serious harm to you or to others. If we learn that you or someone else is harming you or others around you, we may be required by law to report this to the police or a social services agency to get emergency help if it is needed.

Updated 1/18/2018
Will I be paid for taking part in this study? (Template pages 24-25)

**INSTRUCTIONS**

- INCLUDE THE FOLLOWING TWO PARAGRAPHS AS WRITTEN IF MONETARY PAYMENT IS GIVEN TO PARTICIPANTS USING CLINCARD. PARTICIPANTS SHOULD ALSO RECEIVE THE CLINCARD BROCHURE AND FAQ SHEET.

- DELETE THESE TWO PARAGRAPHS IF NO MONETARY PAYMENT IS GIVEN TO PARTICIPANTS.

You will receive your study payments through a “ClinCard” debit card. ClinCard follows laws, like HIPAA, which protect your identifiable information. After each completed study visit for which you will be paid, the payment amount will automatically load onto your card within 3 business days. You can use your ClinCard at an ATM or bank to get cash, or at any store to make a purchase. There is a $4.50 monthly service charge that will automatically be debited from your ClinCard and there is a fee for using the card at an ATM machine.

The study team will give you a ClinCard and forms with more information about how to use it and about ClinCard user fees.
Additional Regulatory Changes Related to Informed Consent

Updated 1/18/2018
Criteria for IRB Waiver of Informed Consent

1. No more than minimal risk to subjects;
2. Rights and welfare of subjects will not be adversely affected;
3. The research could not practicably be carried out without the waiver;
4. The research could not *practically* be carried out without accessing or using identifiers;  
   *New criterion*

For research with identifiable information or biospecimens

5. When appropriate, subjects will be provided with additional pertinent information after participation

Updated 1/18/2018
Requirement for Posting of Consent Forms for Clinical Trials

For clinical trials supported by federal funding, one IRB-approved consent document must be posted on a publicly available federal website No later than 60 days after the last study visit is concluded

• Federal department or agency may permit or require redactions
• HHS will announce website after 1/19/18
Questions? Please contact OPHS!

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301-565-8447

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**In Person**
Satellite Office, SZ Campus
Main Building
Floor 3.5, Room 232
Tel: 202-476-3472
Office hours *Tuesdays and Fridays, 9:00 a.m. – 4:00 p.m.*
Questions and Answers

More guidance to come!

Watch for announcements for additional webinars on Final Rule requirements.
Thank you for joining us for today's presentation.