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AUGUST 2022 CHANGES TO THE MAIN ICF TEMPLATE

Ben Mooso
Director
Office of IRB Administration

UC San Diego

Outline

- Why is the template changing?
- What are the specific changes?
  - General Updates
  - Contact Information Changes
  - Study Overview Changes
  - Procedures Updates
  - Risks Updates
  - Confidentiality Updates
  - Electronic Consent
  - Optional Procedures

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Why is the template changing?

- Major Reason:
  - To inform subjects in most biomedical studies that their participation will be linked to their medical record.
  - If they don’t have a medical record, one will be created for them.
  - This is to be in compliance with UCSDHP 340.1 which was issued ~3 years ago.
- Additional Reasons:
  - Be more compliant with Revised Common Rule intent
  - Update information to reference HRPP to OIA change
  - Reduce administrative burden on researchers
  - Provide more instruction and template language for researchers

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General Updates

- Contact information for OIA updated from HRPP
  - Correct Phone Number
  - Correct email address
- Updated the format of the document
  - Each section is numbered
    - Easier reference in Action Items
    - Easier reference when speaking with subjects
  - Included examples for SBER & Biomedical studies
    - Same template can be used for all types of studies
- Added Bill of Rights to the end of the template

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General Updates

- Combines adult consent and parent permission into one template

¶
[Include·the·below·note·when·the·study·will·involve·children·or·adults·unable·to·consent·for·themselves.·Otherwise·delete.]¶
Note:·In·this·consent·the·word·"you"·refers·to·the·person·being·considered·for·enrollment·in·the·study·described.·This·may·be·you·as·the·reader·of·this·document,·a·person·for·whom·you·are·serving·as·the·Legally·Authorized·Representative·(LAR)·or·surrogate,·or·your·child.·¶
¶
1.→ Study·Title·and·Number¶
¶
Title:·[Insert·title·of·study]¶
Study·#·[Insert·study·number·from·Kuali]¶

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Contact Information Changes (Sections 3 & 6)

- PI, Research Team, and Emergency Contact moved to first page
  - Easier reference for subjects
  - More compliant with the intent of the Revised Common Rule
- IRB contact information just after section 5 “Study Overview”

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3.→ Principal·Investigator·Phone·Number,·Research·Team·Number,·and·Emergency·Contact·Number¶

¶

[Insert·PI·phone·number,·research·team·phone·number,·and·emergency·contact·number,·if·different]¶

¶

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Study Overview Changes (Section 5)

Added study purpose and subject selection in the beginning

5.→ Study Overview¶

¶

This research study is being conducted to [briefly describe in lay terminology the reason why the study is being conducted].¶

¶

We are inviting you to participate in a research study because [briefly summarize the condition or circumstance that makes an individual eligible for the research. *Do not provide a list of inclusion/exclusion criteria*].¶

¶

This form explains the research so that you may make an informed decision about participating.¶

¶

- Research is voluntary—whether or not you participate is your decision. You can discuss your decision with others (such as family, friends or another physician).¶
- You can say yes, but change your mind later.¶
- If you say no, we will not hold your decision against you.¶
- You can say no even if the person inviting you is part of your healthcare team.¶
- Your decision will not affect your health care or other benefits you may be entitled to.¶
- Please ask the study doctor or study team questions about anything that is not clear, and feel free to ask questions and mention concerns before, during, and after the research.¶
- You may consult with friends, family, a personal doctor, or anyone else before deciding whether or not to be in the study.¶
- You will be given a copy of this consent form and the Participant's Bill of Rights.¶

¶

The purpose of this research study is to [complete with brief statement, no more than 3 sentences. Secondary/exploratory objectives need not be included.].¶

Added benefits templates towards the end

*[Provide a brief summary of what participation involves. Include the **participant's expected time commitment***, e.g., "You will first undergo several procedures to determine if you are eligible for the study. If you are eligible, you will be assigned to receive the study drug or placebo (an inactive substance) over a period of about 6 months. During that time, you will visit our clinic weekly for physical examinations, blood tests and other procedures designed to monitor your safety and measure the effect of the study drug or placebo. Each visit will last up to 2 hours."]¶

¶

The most common risks or discomforts of this study are [finish sentence with 2 or 3 foreseeable risks/discomforts].¶

¶

The most serious risks include [finish sentence with 2-3 serious risks and briefly characterize how rare or common these risks may be].¶

¶

A complete listing of possible risks and discomforts associated with this study can be found in Section 9 of this document.¶

¶

[Insert either option A or B option]¶

¶

[Option A. Use if there is possible direct benefit to participants—please note that compensation or reimbursement is not a benefit of participation. If you need to discuss benefits in additional detail, include an additional section later in the consent document.] We cannot promise any benefit to you or to others from you participating in this research. However, possible benefits include [first describe all potential direct benefits to the participant, then describe any benefits to others or to society as a whole].¶

¶

[Option B. Use if there is no possible direct benefit to the participants] There are no benefits to you from participating in this research. However, possible benefits to others include [describe any benefits to others or to society as a whole].¶

¶

Other options instead of participation in this study are [finish sentence with all the alternatives to participation in the research (e.g., standard therapies, other research studies, observation or supportive care). This is the only section where alternatives will be listed. If the only alternative is to not participate, delete this sentence and state: The alternative to being in this study is not to participate.].¶

¶

More detailed information about this research study is provided below.¶

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Procedures Updates (Section 8)

- Combines sections on procedures and which procedures are experimental vs. standard of care
- Specific instructions of what the IRB is looking for
- Includes template language for:
  - Drugs, devices, and biologics
  - Randomization
  - Blinding and placebo
  - Studies with a washout period
  - Studies involving MRI
  - Studies with Birth Control requirements in gender neutral language
  - Whole genome sequencing (Revised Common Rule requirement)

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Risks Updates (Section 9)

- Specific instructions of what the IRB is looking for
- Includes template language for:
  - Radiation
  - Genetic testing (individuals and family members)
  - MRI (with and without contrast)
  - Loss of confidentiality
  - Reproduction/Pregnancy
  - Sensitive information
  - Interviews/Questionnaires/Quality of Life Assessments with sensitive issues
  - Incidental findings
  - Unknown risks

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Confidentiality Updates (Section 10)

- Removed language for future use to new section (Section 13)
  - Data sharing (internally and externally)
  - Moore clause
  - NIH repositories
- Added template language for photographs of subjects
- Added language about medical record linking

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Confidentiality Updates (Section 10)

[If the study involves pharmacy, laboratory or medical procedures insert either option A (for studies without collection of sensitive information) or option B (for studies with sensitive information). Remove the below language and insert site-specific language when this document is adapted for sites outside UCSD/RCHSD.]

[Option A: This consent form and some details of your study participation will be noted in your UC San Diego Health record. If you do not currently have a UC San Diego Health record, one will be developed for you. People involved with your medical care and insurance at UC San Diego or other organizations may become aware of these details. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your UC San Diego Health record until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.*]*

[Option B if the study involves sensitive information: This consent form and some details of your study participation will be noted in your UC San Diego Health record. If you do not currently have a UC San Diego Health record, one will be developed for you. People involved with your medical care and insurance may become aware of these details. UC San Diego also participates in Health Information Exchange (HIE) with multiple other health systems. Sharing your electronic Health Record (EHR) with other health systems is only allowed when they are involved in your medical care. Study details included in your EHR would also be shared. For more information about HIE, including how you can opt out of sharing, ask the study team.

Federal and state privacy laws give patients the right to access information about their care and treatment contained in their EHR. During this study, you may not be able to access certain information related to this study in your UC San Diego Health record until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.*]

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Electronic Consent (Section 17)

- New Section!

17.→What·are·my·rights·when·providing·electronic·consent?¶

¶

[Include·the·below·language·when·the·consent·documentation·will·be·conducted·electronically·(e.g.·via·DocuSign·or·an·equivalent·system).·If·the·consent·documentation·will·not·be·conducted·electronically,·delete·this·section.·Remove·the·below·language·and·insert·site-specific·language·when·this·document·is·adapted·for·sites·outside·California.]¶

¶

California·law·provides·specific·rights·when·you·are·asked·to·provide·electronic·consent:¶

- → You·have·the·right·to·obtain·a·copy·of·the·consent·document·in·a·non-electronic·format.¶
- → You·have·the·right·to·provide·consent·in·a·non-electronic·format.¶
- → If·you·change·your·mind·about·electronic·consent,·you·have·the·right·to·request·your·electronic·consent·to·be·withdrawn·and·you·can·then·provide·consent·in·a·non-electronic·format;·however,·a·copy·of·your·electronic·consent·will·be·maintained·for·regulatory·purposes.·If·you·wish·to·withdraw·your·electronic·consent·please·tell·the·study·team.¶

This·agreement·for·electronic·consent·applies·only·to·your·consent·to·participate·in·this·research·study.¶

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Optional Procedures (Section 18)

- New Section!

18.→Additional·Choices·to·Consider¶

¶

*[If·any·specific·procedures·are·optional·(i.e.,·participants·can·still·take·part·in·the·research·even·if·they·do·not·agree·to·the·optional·procedure),·add·the·following·to·document·their·choice.·Copy·and·repeat·the·text·below·for·each·separate·optional·procedure·if·subjects·can·choose·to·participate·in·some·optional·procedures·without·participating·in·**all**·optional·procedures.]¶*

¶

In·Section·[X],·we·described·some·extra·procedures·[briefly·summarize·extra·procedures].··These·extra·procedures·are·optional,·meaning·that·you·can·participate·in·the·study·even·if·you·refuse·the·procedures.··Please·indicate·your·choice·by·initialing·the·appropriate·line·below:¶

¶

_____I·AGREE·to·participate·in·these·optional·procedures.¶

¶

_____I·DO·NOT·AGREE·to·participate·in·these·optional·procedures.¶

··¶

[If·you·will·offer·the·option·to·receive·general·results·of·the·research·and/or·any·relevant·individual·results,·please·describe·here·and·provide·participants·with·option·to·document·their·choice.]·¶

·¶

We·would·like·to·offer·the·opportunity·to·receive·general·results·of·the·research·[and·relevant·individual·results].·You·may·also·change·your·mind·about·this·choice.··Please·initial·your·choice·below:¶

¶

_____YES,·send·me·a·summary·of·the·research·results·[and·my·individual·results].¶

¶

_____NO,·do·NOT·send·a·summary·of·the·research·results·[or·my·individual·results].¶

¶

¶

[If·you·would·like·to·use·the·study·population·to·recruit·for·future·studies,·include·the·following·choice:]·¶

¶

The·study·team·would·like·your·permission·to·contact·you·about·participating·in·future·studies.···You·may·still·join·this·study·even·if·you·do·not·permit·future·contact.·You·may·also·change·your·mind·about·this·choice.··Please·initial·your·choice·below:¶

¶

_____YES,·you·may·contact·me¶

¶

_____NO,·you·may·NOT·contact·me¶

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QUESTIONS?