Children's Hospital LOS ANGELES®

THE SABAN RESEARCH INSTITUTE

Creating Research Consent Forms

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IRB Supervisor

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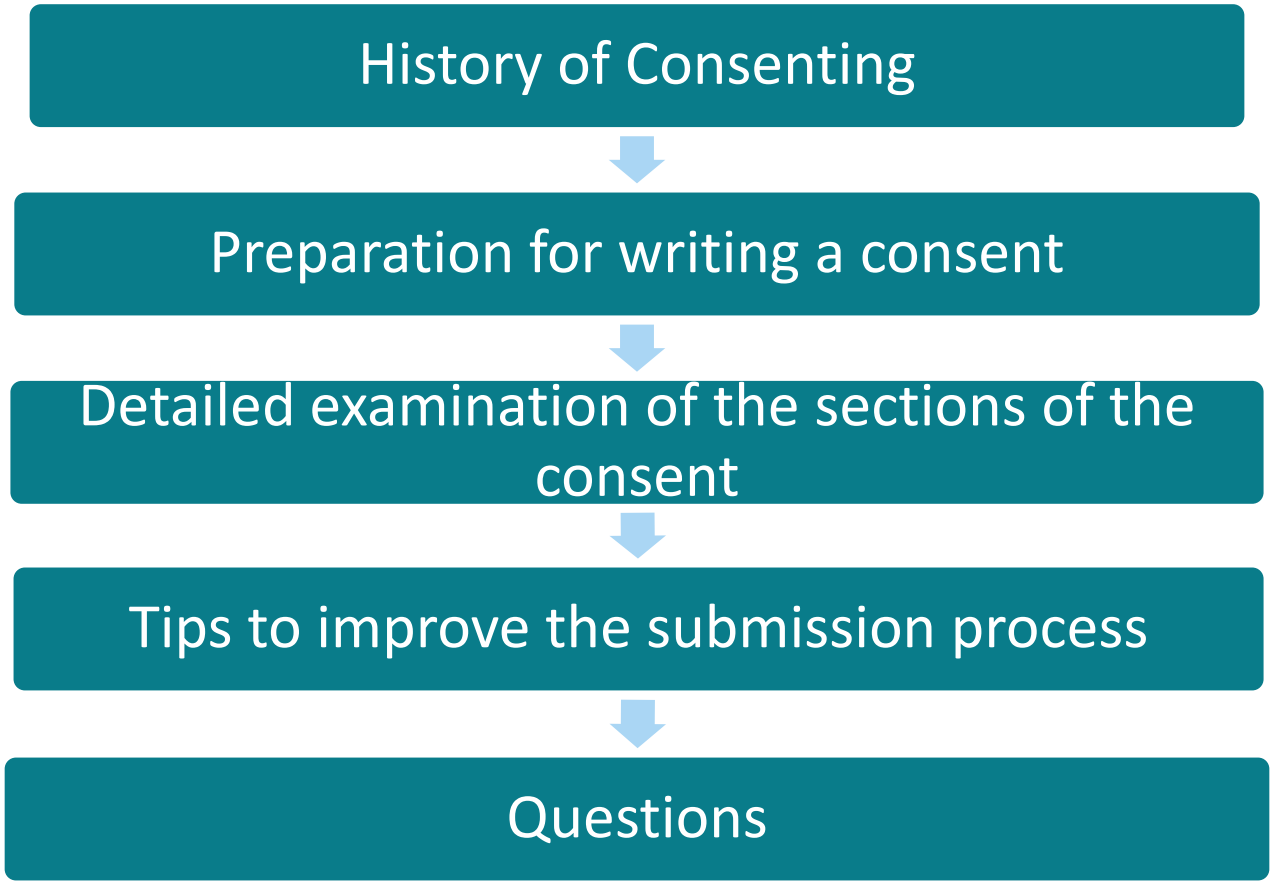

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Consent, A Brief History

Informed consent in research is a relatively recent development.

Research like:

- Nazi research in concentration camps
- Tuskegee Syphilis Study
- Willowbrook Hepatitis Trials
- Stanford Prison Experiment
- Milgram Obedience Experiment
- Project MK Ultra
- Numerous radiation and cancer experiments

All took place without what we would identify as consent

Tuskegee Syphilis Study

Public Health Services enrolled 600 impoverished African American men from Alabama.

- They were never informed that they had syphilis
- We never offered treatment, even once penicillin became available
- Were told the study would last six months, it went on for 40 years

Tuskegee Syphilis Study

28 subjects died directly from syphilis

100 died from complications of syphilis

40 wives infected

19 children born with congenital syphilis

Study ended because of a press leak

What is Consent?

Study Name	**Risks**
PI Name	**Benefits (direct and societal)**
Research Purpose	**Alternatives to participation**
Participation Time	**Confidentiality**
Procedures	**Contact Information**

Consent, A Process, Not a Document

Will we need additional blood draws beyond those for treatment?

Who is paying for the research?

What causes this side effect?

Who do I contact if we experience this side effect?

What do I if my child throws up the study drug?

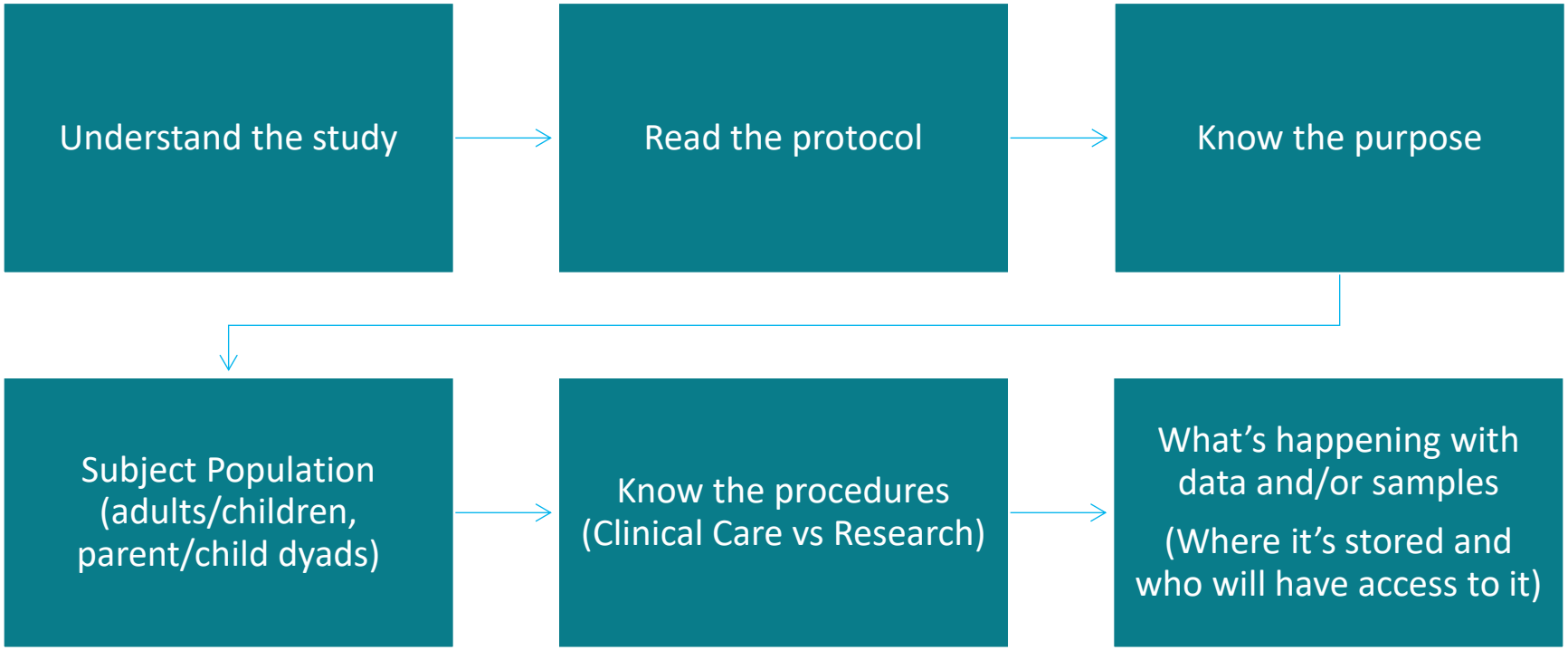
Consent Process Continued

- Capacity Assessment
- Parental Permission
- Simplified Assent
- HIPAA Authorization
- Experimental Subjects Bill of Rights
- Documentation of all the steps taken in the consenting process

How Does Consent Apply to My Study?

- Exempt - Consent is not a regulatory requirement of exempt research. However, it's CHLA's policy that if you are interacting with your subjects, an information sheet is usually required. An information sheet is essentially a simplified version of the consent that usually omits the requirement for a subject signature.
- Expedited - for minimal risk studies, consent IS a regulatory requirement. So again, in almost all cases where you're interacting with the subjects and even some where you otherwise wouldn't be, you're going to need to be prepared to get consent. For certain types of studies like chart reviews, a waiver of consent may be available. However, waivers have relatively strict regulatory requirements which means that their applicability is often narrower than investigators want them to be. So, if you have an exempt or expedited study where you will interact with subjects you should expect to obtain consent using either an information sheet or consent form.
- Full Board - Full Board, greater than minimal risk studies will almost certainly require some combination of consent/parental permission, and assent, so please plan accordingly.

Preparing to Draft a Consent Form



Templates

We only use CHLA templates

(Find them on the HSPP website)

Information Sheet	Consent/Permission/Assent Form	Simplified Assent Form	Addendum Consent for Subjects Turning 18

Just because we won't approve sponsor consents doesn't mean they aren't useful

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CHLA Consent Form Standards and Sample Language

A big time saver that covers many niche situations such as:

- research injury language for industry sponsored studies,
- language to describe genomic testing
- language to describe randomization, and many suggestions for risk language

Document can be found on the CHLA HSPP webpage

Getting Started

Start with a coherent file name. Something like:

Consent Permission Assent 4-16-24

or

Simplified Assent 3-12-24

- The last bit of those is important – A version date in the title and footer of the document help everyone identify which version of the document we're dealing with
- Label study groups – Cohort 1, Control Group, Experimental Group.

Key Information

Simplified version of the consent form that became a regulatory requirement with the updated common rule in 2019.

Required if the consent form is more than 4 pages long excluding the signature section, CHLA requires it.

Follow the format in the template.

Keep it under a single page, simplicity is the point

Introduction

1. Limit study staff listed here to Pi to avoid unnecessary revisions
2. Include study funder if applicable

Purpose

Why this study is happening explained in terms that someone without an MD or PhD can understand.

The purpose of this study is to find out if a new drug works as well or better than the drug we use right now.

The purpose of this study is to find out if this new device can replace the old one.

The purpose of this study is find out what people with this condition might have in common.

Number of Subjects

- This goes back to the understanding the study that we talked about back at the beginning.
- You wouldn't believe the number of contingencies we spend clarifying this issues.
- If you're surveying the parent, they're your subject. If you're collecting information from their child's medical record, they're also your subjects. The consent has to reflect this.

Length of Participation and Procedures

- Active participation vs passive
- Procedures are Possibly the most difficult section to write and the one I spend the most time editing
- We often find it riddled with inaccuracies
- Important details completely omitted
- Repositories

Risks

- State them honestly
- Don’t try to minimize them
- Don’t forget confidentiality risks
- Think about what you would want to know if you were considering joining the study. Tell them that.
- Make sure the description is appropriate for your subject population (reading level).

Benefit to The Subject and Society

If there's no direct benefit, just say so.

You should not expect any benefit from participating in this research.

You may see some improvement in your symptoms.

Compensation is not a benefit

We hope that the information we gather from this study will help us provide better treatment in the future.

Confidentiality

- Directly Identifiable
- Coded
- Anonymous
- De-identified
- Who will have access to the study data?
  - Collaborators
  - NIH
  - FDA
  - Sponsor

Future Use

Is there going to be any? What does the protocol say?

- Repository
- Database
- Registry

Coded/anonymous/de-identified

Can subjects withdraw from the repository? If so, who do they contact?

Injury Language

- Not required for minimal risk studies
- For greater than minimal risks studies, refer to the consent form standards documents

We have standard language, and it is required.

If a sponsor wants to change that language, it requires approval.

Financial Disclosure

If the COIRC conflict management plan requires a disclosure in the consent form, insert the suggested language.

Note: This plan may limit who is allow to consent subjects for participation in the study. Make sure you read this plan.

Signatures

Knowing who needs to sign the document requires that you understand the study population:

- Parent (one parent or two?)
- Child
- Consenter
- Witness

Review of Consent

Have the PI look at it before submission

8th grade or less - Use tool in word to help gauge it

Spelling & Grammar Check in MS Word

Check document formatting (margins, bullets, fonts, and sizes)

Compare documents feature to make edits

Accept all changes before submitting in iStar

Uploading in iStar

- Not Item 5.3
- Section 24
- Document Stacking – use upload revision function

Read Your Approval Letter

- Currently approved version of consent documents
- Assent requirement
- Parental consent/permission requirement (1 parent vs 2)
- Adults lacking capacity to consent

Document Your Consent Process!

- Know what the IRB required by reviewing your approval letter
- Learn the process and requirements for consenting non-English speakers
  - Who can consent (staff vs interpreters)
  - Short form vs. translated consent
- Be aware of the process you described in your iStar application and follow it
- Document the process in the consent notes

Questions?

Feel free to ask now or reach to either your individual IRB administrator for a particular study or the HSPP email inbox for more general questions