

December 31, 2019

Monika Lau  
[via Email]

Re: **CIRB Approval of the Annual Signatory Institution Worksheet About Local Context**

Signatory Institution: **Yale University**

Dear Monika Lau,

On December 23, 2019, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for Yale University received on November 18, 2019. The information contained in this Worksheet contributes toward establishing the Institution's local context considerations for the CIRB. The review conducted by NCI Pediatric CIRB applies to all boards.

The CIRB reviewed and approved the consent form boilerplate language and institutional requirements. The CIRB understands that no consent form text is being deleted from the CIRB-approved consent form(s) without CIRB approval.

**No changes to either the boilerplate language or institutional requirements may be implemented without prior CIRB approval.** Any changes must be reported promptly to the CIRB for review and approval prior to implementation.

**The CIRB-approved boilerplate language to be inserted into the CIRB-approved consent form(s) by the Investigator is as follows:**

### Yale's Boilerplate Language

**1. Header of the consent form**

The following header should be added to the consent forms:

Principal Investigator:		IRES IRB#:	
Funding Source:		Sponsor Protocol Number:	
Sponsor ICF Template Version:		Sponsor ICF Template Date:	

**2. Footer of the consent form**

The following footer should be included in the consent forms:

Page x of x  
YCC v# (dd-mmm-yyyy)

**3. Heading**

The following name of the institution should be added to the consent form:

YALE UNIVERSITY  
YALE-NEW HAVEN HEALTH  
SMILOW CANCER HOSPITAL CARE CENTERS

**4. Section Titled 'Where can I get more information?'**

The following text should be added:

If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Research Protection Program at (203) 785-4688.

**5. Section titled 'My signature agreeing to take part in the study':**

5.1. The following two lines should be added for primary and secondary consent personnel:

\_\_\_\_\_

Primary person  
obtaining consent (print  
name)

Signature

Date

Secondary consenting  
personnel, if applicable  
(print name)

Signature

Date

- 5.2. For pediatric studies only, printed Name Line should be added in addition to the participant's signature:

Participant (print name)

Date

6. Addition to section titled 'What risks can I expect from taking part in this study?'  
used as a separate sheet.

The following language must be provided to subjects enrolled at Saint Francis Hospital and Medical Center, which is part of the Trinity Health of New England, a faith based network:

#### IMPORTANT INFORMATION ABOUT REPRODUCTIVE RISKS

##### MEN

<insert here> drugs such as the ones offered as part of this clinical trial can affect an unborn child. If you are a man able to have children, it is important that you do not father a child while you are taking part in this study, and perhaps even for some time after you stop taking the study drugs. Your doctor will discuss this in detail with you.

Trinity Health Of New England sites are dedicated to your health and well-being. While abstinence is the most effective way of preventing a pregnancy, we understand that you may consider other methods of pregnancy prevention. Sites within Trinity Health Of New England will not provide contraception products as part of this study, nor does it endorse, approve, or intend contraception, other than abstinence, by complying with the requirements of this study.

<insert here> drugs such as the ones offered as part of this clinical trial may affect your ability to father a child in the future. Your doctor will discuss this in detail with you.

The "Reproductive Risks" section of this Informed Consent Form discusses what forms of pregnancy prevention are adequate for use in this study and which forms are not. The "Risks

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Section” may also discuss options to preserve your ability to father a child in the future. You are encouraged to ask your study doctor or research nurse for more information about reproductive risks and pregnancy prevention.

As a Catholic Healthcare system, Trinity Health Of New England abides by the Ethical and Religious Directives for Catholic Health Care Services, as determined by the United States Conference of Catholic Bishops. As such, Trinity Health Of New England neither endorses nor provides medical practices and/or procedures that contradict the moral teachings of the Roman Catholic Church.

Patient Initials \_\_\_\_\_

## **IMPORTANT INFORMATION ABOUT REPRODUCTIVE RISKS**

### **WOMEN**

<insert here> drugs such as the ones offered as part of this clinical trial can affect an unborn child. If you are a woman able to have children, it is important that you do not become pregnant while you are taking part in this study, and perhaps even for some time after you stop taking the study drugs. Your doctor will discuss this in detail with you. Women who are breast feeding should stop breast feeding while taking part in this study.

Trinity Health Of New England sites are dedicated to your health and well-being. While abstinence is the most effective way of preventing a pregnancy, we understand that women may also decide to use other methods of pregnancy prevention. Sites within Trinity Health Of New England will not provide contraception products as part of this study, nor does it endorse, approve, or intend contraception, other than abstinence, by complying with the requirements of this study.

The “Reproductive Risks” section of this Informed Consent Form discusses what forms of pregnancy prevention are adequate for use in this study and which forms are not. You are encouraged to ask your study doctor or research nurse for more information about reproductive risks and pregnancy prevention.

As a Catholic Healthcare system, Trinity Health Of New England abides by the Ethical and Religious Directives for Catholic Health Care Services, as determined by the United States Conference of Catholic Bishops. As such, Trinity Health Of New England neither endorses nor provides medical practices and/or procedures that contradict the moral teachings of the Roman Catholic Church.

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Patient Initials \_\_\_\_\_

**The translation of the CIRB-approved boilerplate language to be inserted into the CIRB-approved consent form(s) by the Investigator is as follows:**

- None.

**The CIRB agrees that Investigators conducting CIRB-approved studies must comply with the institutional requirements as follows:**

COG Youth Information Sheets will be used to document assent, if provided. The following information and signature block will be added to the Youth Information Sheet:

Writing your name on this page means that that you agree to be in the study, and know what will happen to you. If you decide to quit the study all you have to do is tell the person in charge.

[Signature Lines to be added:]

_____ Signature of Child	_____ Date	
_____ Person obtaining consent (print name)	_____ Signature	_____ Date
_____ Interpreter/ Witness (print name) - only if applicable, otherwise blank	_____ Signature	_____ Date

If a Youth Information Sheet is not available for the study, the following Assent Form template will be used.

1. Header of the Assent Form

Study Doctor:		HIC #:	
Sponsor Protocol Number:		Protocol Version and Date:	

2. Footer of the Assent Form

Page x of x  
YCC vX.0 (dd-mmm-yyyy)

3. Heading

Child's Assent for Being in a Research Study  
Yale University School of Medicine - Yale-New Haven Hospital

Study Title: [Insert simplified version of the study title]  
Study Doctor: [Insert name of the PI]  
Study Doctor's Phone Number: [Insert phone number]  
Study Doctor's Mailing Address: [Insert address of the PI]

4. Assent Form

Why am I here?

We are asking you to take part in a research study because we are trying to learn more about [briefly outline the purpose of the study in language that is both appropriate to the child's maturity and age]. We are inviting you to be in the study because [state why the child is being asked to participate].

**Why are they doing this study?**

[Outline what the study is about in language that is both appropriate to the child's maturity and age]

**What will happen to me?**

[Describe what will take place from the child's point of view in language that is both appropriate to the child's maturity and age]

[If the study will involve pregnancy testing, include:

If you are a girl who has started her period, we will do a test to see if you are pregnant. If you are pregnant, we have to tell the Connecticut Department of Children and Families (a state agency that is concerned with the overall well-being of children)]

**Will the study hurt?**

[Describe any risks to the child that may result from participation in the research]

**Will the study help me?**

[Describe any benefits to the child from participation in the research]

**What if I have any questions?**

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me [insert study doctor's telephone number] or ask me next time. [If applicable add: You may call me at any time to ask questions about your disease or treatment.]

**Do my parents know about this?**

This study was explained to your parents and they said that you could be in it. You can talk this over with them before you decide.

**Do I have to be in the study?**

You do not have to be in the study. No one will be upset if you don't want to do this. If you don't want to be in this study, you just have to tell them. You can say yes now and change your mind later. It's up to you.

**5. Signature Page**

Writing your name on this page means that that you agree to be in the study, and know what will happen to you. If you decide to quit the study all you have to do is tell the person in charge.

[Signature Lines to be added:]

\_\_\_\_\_



\_\_\_\_\_  
Signature of Child

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person obtaining consent (print  
name)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Interpreter/ Witness (print name)  
– only if applicable, otherwise blank

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

- Short Forms (Version 2014\_1) in the following languages:

- English
- Creole
- Albanian
- Arabic
- Georgian
- Korean
- Mandarin
- Polish
- Portuguese
- Punjabi
- Russian
- Spanish
- Thai
- Turkish
- Ukrainian
- Urdu
- Cantonese
- French
- Greek
- Italian
- Hindi
- Hebrew
- Yiddish

- Recruitment Flyer

The Signatory Institution Principal Investigator has the responsibility for ensuring that CIRB-approved boilerplate language is appropriately inserted into the CIRB-approved consent form(s) and institutional requirements are met.

The following institutions are included in this approval and future CIRB approvals will pertain to these institutions also, until the CIRB is notified of a change:

**Component Institutions:** Component Institutions are defined by the CIRB as meeting all of the following criteria:

- the Component Institution operates under a different name than the Signatory Institution, but the Signatory Institution has legal authority for the Component Institution;
- the FWA number for the Component Institution is the same as the Signatory Institution;
- the local context considerations of the Component Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Signatory Institution Worksheet About Local Context;
- the boilerplate language and institutional requirements of the Component Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Signatory Institution Worksheet About Local Context; and
- the conduct of research at the Component Institution and the Signatory Institution is monitored by the same office.

Component Institutions list:

**Affiliate Institutions:** Affiliate Institutions are defined by the CIRB as meeting all of the following criteria:

- the local context considerations of the Affiliate Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Signatory Institution Worksheet About Local Context;
- the boilerplate language and institutional requirements of the Affiliate Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Signatory Institution Worksheet About Local Context; and
- the conduct of research at the Affiliate Institution and the Signatory Institution is monitored by the same office.

Affiliate Institutions list:

1	Greenwich Hospital (CT031)
2	Lawrence and Memorial Cancer Center (CT126)
3	Smilow Cancer Center/Yale-New Haven Hospital (CT037)
4	Smilow Cancer Hospital Care Center at Saint Francis (CT008)
5	Smilow Cancer Hospital Care Center-Fairfield (CT127)
6	Smilow Cancer Hospital Care Center-Trumbull (CT053)
7	Smilow Cancer Hospital-Derby Care Center (CT114)
8	Smilow Cancer Hospital-Hamden Care Center (CT077)
9	Smilow Cancer Hospital-Orange Care Center (CT113)
10	Smilow Cancer Hospital-Sharon Care Center (CT124)
11	Smilow Cancer Hospital-Torrington Care Center (CT043)
12	Smilow Cancer Hospital-Waterbury Care Center (CT079)
13	Yale-New Haven Hospital North Haven Medical Center (CT125)
14	Yale-New Haven Hospital Saint Raphael Campus (CT023)
15	Yale-New Haven Shoreline Medical Center (CT078)

The CIRB reminds you that any additions or deletions of Component or Affiliate Institutions that change the approved local context considerations included in this letter must be reported to the CIRB in a timely manner.

If you have any questions regarding this review, contact the CIRB at [ncicirbcontact@emmes.com](mailto:ncicirbcontact@emmes.com).

Sincerely,

NCI Pediatric CIRB

cc: Signatory Institution Primary Contact(s)  
Signatory Institution Principal Investigator(s)  
NCI CIRB Operations Office