National Cancer Institute
Central IRB Initiative

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May 16, 2017

Monika Lau
[via Email]

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

Signatory Institution: **Yale University**

Dear Monika Lau,

On May 12, 2017, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for Yale University received on May 11, 2017. 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 recognizes that HIPAA language has been provided as part of the boilerplate language. The CIRB accepts this inclusion as part of the boilerplate language, but the CIRB does not function as a Privacy Board. Therefore, the CIRB is not reviewing this language for compliance with HIPAA regulations.

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

1. Header of the consent form

Principal Investigator:		**HIC #:**	
Funding Source:		**Sponsor Protocol Number:**	
Sponsor ICF Template Version:		**Protocol Version:**	
Sponsor ICF Template Date:		**Protocol Date:**	

2. Footer of the consent form

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YCC v# (mm-dd-yyyy)

3. Heading

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL/SMILOW CANCER HOSPITAL CARE CENTERS/SAINT FRANCIS HOSPITAL

Study Title: *[Insert title of the study.]*
Principal Investigator: *[Insert name and mailing address.]*
Principal Investigator's Phone Number: *[Insert phone number]*
24-Hour Phone Number: *[Insert 24-hour phone number]*
Principal Investigator's Mailing Address: *[Insert address of the PI]*

4. Risks Associated with Radiation

This research study involves exposure to radiation from *[Describe: e.g., research required extra head CT scan]*. Please note that this radiation exposure is **not** necessary for your medical care and is for research purposes only. Although each organ will receive a different dose, the amount of radiation exposure will receive from this study is equal to a uniform whole-body exposure of [*XX]* rem. This calculated value is known as the "effective dose" and is used to relate the dose received by each organ to a single value.

This amount of radiation is well below the dose guidelines established by the federal government and adhered to by the Yale-New Haven Hospital Radiation Safety Committee for research subjects. To give you an idea about how much radiation you will get, we will make a comparison with an every-day situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. This research gives your body the equivalent of about YY extra years' worth of this natural radiation.

(*Note: average natural exposure is 300mrem or 0.3rem, so compare XX to 0.3rem*)

5. If the study involves HIV/Hepatitis testing:

Positive results of HIV and Hepatitis will be reported to CT Department of Public Health.

6. Confidentiality

Information about your study participation will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, these results are accessible to all of your providers who participate in the EMR system. Information within your EMR may also be shared with others who are appropriate to have access to your EMR (e.g. health insurance company, disability provider.)

7. If pregnancy testing of the child is required, add the following:

Your daughter will be asked to have a pregnancy test before starting this study. Only your daughter will be told the results. If she is pregnant, we will also advise her to get care for her pregnancy and to get the support of an adult. If your daughter is under age 13 and has a positive pregnancy test, we will report the pregnancy to the Department of Children and Families.

8. HIPAA Research Authorization if Compound Authorization is used

The protected health information that will be collected in this study includes *[list information to be collected from calendar of events in protocol or procedure listing above: i.e., demographics, medical history, physical examinations, routine lab tests, review of adverse events and medications you take (past and present), vital signs, eye examinations, MRI scans, CT scans, ECHOs or MUGAs, pregnancy tests, blood samples for research purposes, information recorded in study questionnaires, survival follow-up information and records about any study drug(s) that you received.]*

Information about you and your health which might identify you may be used by or given to:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University and the Human Investigation Committee (the committee or Institutional Review Board that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential
- Your providers who are participants in the Electronic Medical Record (EMR) system
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The study doctor, *[enter PI name]*, and the Yale study team
- The U.S. Food and Drug Administration (FDA). This is done so that the FDA can review information about the new drug product involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
- The study sponsor or manufacturer of study drug, *[enter Sponsor name]* and/ or their representatives *[if a CRO has been identified, you can identify them by name here]*
- Drug regulatory agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study *[delete if not applicable]*

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and [Specify health care facility, e.g., Yale-New Haven Hospital, the Connecticut Mental Health Center] are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to *[Enter name and address of the data repository's principal investigator]* at the Yale University _____New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

9. Contact Information for Authorization and Permission

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919 [Add country code, if applicable].

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator [cite name and full telephone number]. 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 Investigation Committee at (203) 785-4688.

10. Signature Lines to be added in addition to the participant's signature:

_____	_____	_____
Person obtaining consent (print name)	Signature	Date

Interpreter/ Witness (print name) – only if applicable, otherwise blank	Signature	Date

11. <u>Reproductive risks for Saint Francis Hospital and Medical Center</u> (This section can be used as a separate sheet)

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.

Saint Francis Hospital and Medical Center is 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. Saint Francis Hospital and Medical Center 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 Section" may also discuss options to preserve you 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 institution, Saint Francis Hospital and Medical Center abides by the Ethical and Religious Directives for Catholic Health Care Services, as determined by the United States Conference of Catholic Bishops. As such, Saint Francis Hospital and Medical Center neither endorses nor provides medical practices and/or procedures that contradict the moral teachings of the Roman Catholic Church.

Patient Initials _____

This section can be used as a separate sheet:

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.

Saint Francis Hospital and Medical Center is 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. Saint Francis Hospital and Medical Center 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 institution, Saint Francis Hospital and Medical Center abides by the Ethical and Religious Directives for Catholic Health Care Services, as determined by the United States Conference of Catholic Bishops. As such, Saint Francis Hospital and Medical Center neither endorses nor provides medical practices and/or procedures that contradict the moral teachings of the Roman Catholic Church.

Patient Initials _____

- **Child Assent**

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

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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

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:

- 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

- At Yale documentation of assent from minor subjects (7-17) is required.

- Adult consent form can be used for obtaining assent from adolescents (13-17).

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:

1	Yale University (CT018)

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

Sincerely,

NCI Pediatric CIRB

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