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

Signatory Institution: Yale University

Dear Monika Lau,

On November 29, 2017, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for Yale University received on November 28, 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**

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>HIC #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding Source:</td>
<td></td>
</tr>
<tr>
<td>Sponsor ICF Template</td>
<td></td>
</tr>
<tr>
<td>Version:</td>
<td></td>
</tr>
<tr>
<td>Sponsor ICF Template</td>
<td></td>
</tr>
<tr>
<td>Date:</td>
<td></td>
</tr>
</tbody>
</table>

2. **Footer of the consent form**

Page x of x
YCC v# (dd_mmm--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/LAWRENCE AND MEMORIAL HOSPITAL

Study Title: [Insert title of the study.]
Principal Investigator: [Insert name]
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 Yale Human Research Protection Program
- 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].

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 Research Protection Program at (203) 785-4688.

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

<table>
<thead>
<tr>
<th>Person obtaining consent (print name)</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Interpreter/ Witness (print name)</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>– only if applicable, otherwise blank</td>
<td>-----------</td>
<td>------</td>
</tr>
</tbody>
</table>
11. Reproductive risks for Saint Francis Hospital and Medical Center (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.

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.

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. The “Risks 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 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.
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
  - Hindi
  - Hebrew
  - Yiddish

- Recruitment Flyer (ETCTN)

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