

July 25, 2019

Terry Thomas MS CCRC
[via Email]

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

Signatory Institution: **Dignity Health**

Dear Terry Thomas MS CCRC,

On July 19, 2019, the NCI Adult CIRB - Late Phase Emphasis reviewed and approved the Annual Signatory Institution Worksheet About Local Context for Dignity Health received on May 28, 2019. The information contained in this Worksheet contributes toward establishing the Institution's local context considerations for the CIRB. The review conducted by NCI Adult CIRB - Late Phase Emphasis 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:

BNI - Dignity letterhead



letterhead for consents



NCI CIRB Boilerplate Language:
Dignity Health

Reproductive risks?

If you are pregnant or breastfeeding, you cannot take part in this study. You may be required to have a blood and/or urine test to see if you are pregnant before you begin this study treatment. If you are sexually active, it is important that you not become pregnant for this medication may be harmful to your unborn child. You must discuss your pregnancy plans with your doctor before enrolling in this study and agree that you will take the appropriate precautions not to become pregnant while enrolled in the study. The treatment in the study may make you unable to have children in the future. Women of childbearing age can ask their doctor for information about pre-treatment or post-treatment reproductive or fertility options prior to agreeing to participate in the study. For women, if you become pregnant or have reason to believe you might be pregnant, please inform your doctor immediately. Once you are no longer receiving this study treatment, discuss with your doctor when it might be safe to become pregnant or become a new father.

OR

If you are pregnant or breast-feeding, you cannot take part in this study. You may be required to have a blood and/or urine test to see if you are pregnant before you begin and during this study treatment. You must not become pregnant while in this study. If you are sexually active, you and your partner must take precautions to avoid the possibility of becoming pregnant or of becoming a new father because this treatment may affect an unborn child. The treatment in the study may make you unable to have children in the future. Women of childbearing age can ask their doctor for information about pre-treatment or post-treatment reproductive or fertility options prior to agreeing to participate in the study.

For women, if you become pregnant or have reason to believe you are pregnant, you must inform your study doctor immediately. If you are a man and your partner becomes pregnant, you must inform your study doctor immediately.

If you are a man participating in this study, you must use effective methods to ensure you do not father a child while in the study and inform your study doctor if your partner becomes pregnant. You should avoid fathering a child or donate sperm for _____ months after your last study treatment. If your partner becomes pregnant during the study you should tell the study doctor right away.

Once you are no longer receiving this treatment, discuss with your study doctor when it might be appropriate to become pregnant or father a child.

Where can I get more information?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ at 602-406-8222 or write to University of Arizona Cancer Center, 625 N. 6th St., Phoenix, AZ 85004.

OR

You can talk to the study doctor about any questions or concerns you have about this study or to report side

effects or injuries. Contact the study doctor _____ at _____ or write to St. Joseph's Hospital and Medical Center, Department _____ at _____ W. Thomas Rd., Phoenix, AZ 85013.

For questions about your rights while in this study, call the St. Joseph's Hospital and Medical Center's Institutional Review Board (IRB) at 602-406-8051.

What happens if I am injured because I took part in this study?

If you experience an injury or adverse event, please call the Principal Investigator _____ or a member of your study team at _____ immediately.

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:

- We are a Catholic based hospital and therefore the pregnancy language needs to be about risks and new verbiage was just issued from Corporate and is included in template.

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	Saint Joseph's Hospital and Medical Center (AZ009)
2	Saint Joseph's Westgate Medical Center (AZ159)
3	University of Arizona Cancer Center at Saint Joseph's (AZ151)

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:

None

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 Adult CIRB - Late Phase Emphasis

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