

Procedure	
Title:	Ethical and Religious Directives - Language for Informed Consent Forms - Research
Maintained by:	Baylor St. Luke's Medical Center Research Office
Reviewed by:	Baylor St. Luke's Medical Center Research Office
Approved by:	Director of Research Compliance at Catholic Health Initiatives/CHAN
Effective date:	February 2022
Next review date:	February 2025

REVISION SUMMARY

Date	Referenced Section(s)	Change
March 2017	Full document	New

SCOPE

Applicable to:
 CHI St. Luke's Health–Baylor St. Luke's Medical Center

Department(s):
 Baylor St. Luke's Medical Center (BSLMC) Research Office
 All groups involved in research activities at BSLMC

DEFINITION(S)

Administrative Application – BSLMC requires submission and approval of an administrative application before research activities may be conducted in BSLMC space or with BSLMC protected health information (PHI).

Ethical and Religious Directives – Ethical and Religious Directives (ERD) guide healthcare conduct at BSLMC.

POLICY

- A. Research studies which consent subjects in BSLMC space, and which may present potential risks to the fetus if a female subject should become pregnant, shall allow for abstinence as a form of birth control, as reasonably applicable.

PROCEDURES

- A. As part of the research compliance process, the BSLMC Research Office will verify research informed consent forms meet ERD Article 52 requirements for all applicable studies.
- B. Applicable studies may adhere to ERD by use of approved template language or by receiving approval for alternative language.

- a. Applicable studies utilizing the template language, or receiving approval for alternative language in the research informed consent form(s), will be routed for BSLMC administrative approval.
- b. Applicable studies that do not utilize the template language and have not received approval for alternative research informed consent form language are not eligible for BSLMC administrative approval.

C. Use of template language:

- a. To comply with ERD requirements, the following template language has been approved for use in applicable studies' research informed consent form(s):

Birth control methods, even when used consistently and correctly, are not perfect. If abstinence is your usual and preferred lifestyle and you and your study doctor agree that it is your selected method of birth control, it should be strictly followed or you may become pregnant. Complete abstinence is the only method of birth control that is 100% effective.

- b. During the BSLMC administrative approval process, the BSLMC Research Office will verify inclusion of template language for applicable studies.

D. Use of alternative language:

- a. If an applicable study's research informed consent form does not include the approved template ERD language, the BSLMC Research Office will review the form's birth control language for compliance with ERD requirements.
- b. If ERD requirements are insufficiently met, the BSLMC Research Office will work with the study team and mission leadership to reach consensus on consent language regarding birth control.
- c. The BSLMC Research Office will notify the study team of approval or disapproval of the research informed consent form(s).

CROSS-REFERENCE(S)

Policy and Procedure, *Protocol Administrative Review – Research*

RELATED DOCUMENTS

Ethical and Religious Directives for Catholic Health Care Services, Article 52.
Guide to Conducting Clinical Research at BSLMC