

Policy Number	CIIACC 021
Title	Reporting Research Non-Compliance to the Office of Human Subject Research Protection Program (OHSRPP)
Department/Division	Research/IRB - General Administration
Owner	System Director of Research
Approvers	Dr. Bagchi, Pukar Ratti, Phyllis Everage, Francis Kanayo
Review Frequency	Every 3 years
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Purpose

In an effort to comply with 45 CFR 46.103(b), this policy requires research stakeholders within CHRISTUS Health to report research related non-compliance to the Office of Human Subject Research Protection Program (OHSRPP). This policy also delineates the process designed to handle allegations of non-compliance.

Definitions

- (1) **Allegation of non-compliance** is an unproven assertion or report of non-compliance.
- (2) **Non-compliance** is the failure to follow federal, state, or local regulations governing human subject research, institutional policies related to human subject research, or the requirements or determinations of the IRB. This may pertain to the principal investigator, research staff, or third party groups (contracted) or research stakeholders within or affiliated with CHRISTUS Health

Two types of Non-compliance

a. Serious Non-compliance:

Non-compliance that creates an increase in risks to subjects adversely affects the rights, welfare and safety of the research subjects or adversely affects the scientific integrity of the study. Willful violation of policies and/or federal regulations may also constitute serious non-compliance.

b. Continuing Non-compliance:

A pattern of non-compliance that if allowed to continue is likely to increase risk to subjects, adversely affect the rights, welfare and safety of research subjects, or adversely affect the scientific integrity of the study.

Policy Statement

1. It is the policy of CHRISTUS research Health that all investigators, research staff, affiliated institutions and other stakeholders are required to report any potential, observed, suspected, or apparent non-compliance to the Office of Human Subject Research Protection Program (OHSRPP).
2. It is the policy of CHRISTUS Health to prohibit retaliation against employed or those who participate in the report of non-compliance to OHSRPP or CHRISTUS Health.

Guidelines

A. Requirements for reporting allegations of non-compliance

All forms of non-compliance are reportable. All institutional members, research participants, and others are encouraged to report any observed, suspected, or apparent non-compliance. Reports of non-compliance may also occur as a result of internal or external audits, as a result of IRB review or from discussion with chairs, supervisors, or colleagues. Reports of non-compliance must contain enough specific information to

determine whether the report is credible so that an investigation of non-compliance may be thoroughly conducted.

B. Handling allegations of non-compliance

All allegations of non-compliance are to be referred to the IRB Chair or designee. Within one week of receiving a report of non-compliance Chair or designee will determine whether the allegation has a factual basis. If circumstances warrant a longer period, the chair or designee may approve an extension. The reason for the extension will be documented. If they conclude that the allegations have a factual basis, the process "Handling non-compliance" will be followed. Otherwise, no further action will be necessary. The matter may be referred to other institutional entities for evaluation and management as deemed appropriate.

C. Handling non-compliance

All non-compliance with a factual basis will be reviewed by the IRB Chair or designee. Within 30 days of determining the allegation has a basis in fact, the Chair or designee will evaluate the report and determine whether the non-compliance represents serious and/or continuing non-compliance. The Chair or designee will establish a process for conducting an investigation and appoint a representative to conduct and complete the investigation within 30 days. If circumstances warrant, the Institutional Official (IO) or designee may approve an extension. The reason for the extension will be documented.

If the Chair or designee determines the non-compliance is neither serious nor continuing, the process under "Non-compliance that is determined to be neither serious nor continuing" is followed.

If the Chair or designee determines the non-compliance to be serious and/or continuing, the process under "Non-compliance that is determined to be serious or continuing" is followed.

D. Non-compliance that is determined to be neither serious nor continuing

If the non-compliance is considered to be neither serious nor continuing non-compliance, the Chair or designee will determine whether any corrective actions are needed, and if so communicate those to the involved individual(s) and ensure all corrective actions are completed. The Chair or designee will work with the involved individuals to implement the corrective action plan and will monitor the completion of all required corrective actions. If the Chair of the IRB or designee is unable to work with the involved individuals to implement the corrective action plan, the matter will be considered to be continuing non-compliance and the procedures in "Non-compliance that is determined to potentially be serious or continuing" will be followed. The completed investigative report should then be submitted and reviewed by CHRISTUS Health IRB.

E. Non-compliance that is determined to be serious or continuing

If the non-compliance is considered to represent serious or continuing non-compliance, the Chair or designee will notify the Institutional Official (IO), and investigate the non-compliance. The investigation, including preparation of any reports should be completed within 60 calendar days of initiation of the investigation. The report will contain a description of the non-compliance being evaluated, a description of the investigation, the basis for recommending that non-compliance is or is not serious and/or continuing and any recommended corrective actions. The report will be provided to the individual(s) involved in the non-compliance who will have 7 calendar days to provide a written response. If circumstances warrant a longer investigation or response period, the Institutional Official (IO) or designee may approve an extension. The reason for the extension will be documented as part of the final report. The report will be sent to the (IO) or designee. If the non-compliance is considered by the Institutional Official (IO) or designee and an IRB Chair to be serious and/or continuing, it is referred to a convened IRB for review and action. If the non-compliance is considered to be neither serious nor continuing, the process under "Non-compliance that is determined to be neither serious nor continuing" is followed.

F. Information provided to the IRB for review of serious or continuing non-compliance

A primary reviewer will be assigned to present non-compliance that is referred to a convened IRB for review and action. The primary reviewer will have access to all documents and information gathered during the investigation. All materials that are gathered as a part of the investigation, including the final report and response will be provided to all members attending the IRB meeting. In addition, all members will be

provided with a copy of the IRB application, the currently approved protocol summary, and currently approved consent documents. All members will be expected to review these materials.

G. Actions of the convened IRB

The convened IRB will confirm by vote whether the non-compliance is serious and/or continuing. The IRB may request to hear from or ask questions of all individuals involved in the non-compliance or the investigation of the non-compliance. All individuals involved in the non-compliance will be provided the opportunity to present their response to the convened IRB. The IRB Chair for the meeting will establish appropriate and reasonable parameters for the presentation, including length. It will be the responsibility of the individuals wishing to present a response to be available for the scheduled meeting. Once the response has been presented and questions from the IRB answered, the individuals involved in the non-compliance will be excused from the meeting.

If the IRB does not find the non-compliance to be serious or continuing, the non-compliance along with any recommendations will be referred back to the IRB Chair or designee and the process for "Non-compliance that is determined to be neither serious nor continuing" is followed.

If the convened IRB finds that the non-compliance is serious or continuing, it may immediately suspend the research if it finds that doing so is necessary to eliminate immediate hazards to the research subject. The IRB will specify any required corrective actions which may include:

- Suspension of the research
- Termination of the research
- Notification of current participants (required when such information might relate to participant's willingness to continue to take part in the research)
- Modification of the research protocol
- Modification of the information disclosed during the consent process
- Additional information provided to past participants
- Requirement that current participants re-consent to participation
- Modification of the continuing review schedule
- Monitoring of the research
- Monitoring of the consent
- Obtaining more information pending a final decision
- Referral to other organizational entities such as legal counsel, risk management, human resources, the privacy office or the IO
- Providing additional recommendations to the IO
- Other actions appropriate for the local context

The IRB Chair or designee will work with the individuals involved in the non-compliance to implement the corrective action plan and will monitor the completion of all required corrective actions.

H. Final Authority

The IO has the final authority to confirm the IRB's determination of serious and/or continuing non-compliance, or to make a determination of serious and/or continuing non-compliance when the IRB did not make such a determination. However, the IO does not have the authority to reverse the IRB's determination of either serious or continuing non-compliance. The IO may constitute additional investigative groups with members drawn from appropriate divisions across CHRISTUS Health System. This group will report its findings to the IO in a time frame prescribed by the IO.

I. Reporting

A final written determination that includes any required corrective actions will be provided to the individuals involved in the non-compliance. The IO or designee, with assistance of the IRB Chair or designee, will report the institution's determination and findings to all appropriate entities within CHRISTUS Health System and to relevant regulatory agencies, as described in the policy titled "Reporting of IRB Findings to Institutional Officials and Federal Regulatory Agencies". All correspondence will be filed in the IRB's protocol file

Addendum

Report a research non-compliance issue form.

Approved By:



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System Director of Research

30 JULY 2018

Date

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8/14/18

Date