

	NON-COMPLIANCE BY INVESTIGATORS			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	4.03	02.08.2020	4.8, 5.16	03.25.2019

Non-compliance is defined as any deviation from approved protocol specifications or violations of federal policies or the policies outlined in the present document by an investigator or study team member. Serious non-compliance consists of deviations that place study subjects at increased risk, whether physical, emotional, or to their protected health information. Continuing non-compliance occurs whenever such practices are not corrected by the investigators but are perpetuated.

Non-compliance that is neither serious nor continuing is dealt with administratively by the IRB. The investigators are made aware of the problem and agree to correct it. The IRB confirms this through review of revised practices and documentation.

The most common lapses in investigator compliance include unreported changes in protocols, misuse or non-use of the informed consent document, and failure to submit revised protocols, modifications to a protocol, and applications for continuing approval of studies to the IRB in a timely fashion. Problems such as these are often caused by communication difficulties. With the full cooperation of the investigator, these cases can be resolved by the IRB without jeopardizing the welfare of research subjects.

Occasionally, an investigator will either avoid or ignore an IRB request. Such cases present a more serious challenge to the IRB and to the institution. Regardless of investigator intent, unapproved research involving human subjects places those subjects at an unacceptable risk. When unapproved research is discovered, the IRB and the institution will act promptly to halt the research, assure remedial action regarding any breach of regulatory or institutional human subjects protection requirements, and address the question of the investigator's fitness to conduct human subjects research.

Any protocol deviation or violation is required to be reported by the study team to the IRB via the [Notification of Protocol Deviations/Violations Form](#). Any employee who suspects an issue of non-compliance has a duty to report either directly to the Compliance Office or to the IRB, and can do so anonymously. Due consideration will be given to any information provided, and either resolved administratively or investigated for further corrective action. Issues of non-compliance may be discovered during the study Self-evaluation audit process or a Compliance Office program audit. These are provided to the IRB.

When the IRB learns of an issue of alleged non-compliance with IRB policies and regulations, the Chair will contact the PI and/or other study team members to evaluate whether the occurrence may actually involve non-compliance. If, in the estimation of the Chair that is a case of serious or ongoing non-compliance, the Chair will send a "Letter of Inquiry" to all investigators listed as participating in the study. If the study in question is still open, the Chair will also make an immediate, initial determination as to whether subjects are being placed at risk as a result of the alleged non-compliance. In most circumstances, the Chair will confer with other Board members before making this determination. If the Chair determines that this is a case of serious and/or continuing non-compliance and subjects are being placed at risk, then the study will be administratively suspended. When study approval is suspended or terminated, the Chair considers actions to protect the rights and welfare of currently-enrolled participants. The Chair considers whether procedures for withdrawal of enrolled participants take into account their rights and welfare (e.g., making arrangements for medical care outside of a research study, transfer to another researcher, and continuation in the research under independent monitoring), and considers informing current participants of the termination or suspension. The Chair will also have any adverse events or outcomes

reported to the IRB. All study-related activity, including new accrual, must be halted until completion of further investigation. If it is determined that subject safety may be compromised by termination of research activities, then intervention may continue per the approved protocol after consultation with the IRB.

The principal investigator must respond to a "Letter of Inquiry" within the time period specified in the "Letter". The "Letter" will open an inquiry, and based on the response from the principal investigator the matter will either be concluded and the "Letter" revoked or a full investigation will be conducted by the IRB. Usually a committee of the Board will be appointed by the Chair to assist in conducting an investigation. During this investigation, all study team members will be questioned by the IRB and documents related to the study will be reviewed.

Management by the convened IRB is initiated at the conclusion of the investigation; the results of the interviews and the audit are presented to the Board by the committee of the Board at a convened meeting of the IRB. IRB members receive a copy of the "Letter of Inquiry" if sent by the Chair along with any response from the investigators. The IRB may then conclude the investigation and develop a corrective action plan that must be completed by all study team members as required by the IRB. If appropriate, the IRB may require modifications to the protocol or to the information disclosed during consenting, additional information to be provided to past participants, current subjects to be re-consented, modifications to the continuing review schedule, monitoring of the research or the consent process, or referral to other organizational entities. The IRB may terminate approval for the study and/or take action against any or all of the investigators on the study. These actions may include, but are not limited to, warning, reprimand, censure, or suspension, or prohibition from conducting further human subjects research at LSUHSC-NO. Current participants are notified when such information might relate to their willingness to continue to take part in the research. Additional action may be taken by the Institution at the discretion of the Chancellor. All actions of the Board are communicated to the investigators involved and to the Vice-Chancellor for Academic Affairs. All actions of the Board may be appealed by contacting the Vice-Chancellor for Academic Affairs in writing within two weeks of receipt of the Board's decisions. As part of the appeal, investigators may request an appearance before the Board.

Likewise, suspensions and terminations by someone other than the convened IRB must be reported to and reviewed by the convened IRB.

Per federal policy, any serious or on-going non-compliance with DHHS human subjects regulations or the determinations of the IRB, including termination of IRB approval, must be reported to the sponsor of the study, institutional officials, OHRP, and, if applicable, the FDA. The maximum time allowed between the recognition of a reportable event and fulfilling reporting requirements is less than 30 days.

Anyone may report (and everyone is encouraged and expected to do so) any suspected non-compliance of researchers and study team members. This includes reporting by investigators, study team members, research participants, or other observers of human subjects research conducted by this institution and its ethical review process and oversight of these activities. Any allegations must be reported upon discovery. Reports may be made anonymously to the Chancellor's office, the Vice-Chancellor for Academic Affairs, the Office of Compliance Programs or the Chair of the IRB.

A thorough investigation will be initiated by the Chair of the IRB when the Chair receives notification of concerns directly, or via the Chancellor, Vice-Chancellor for Academic Affairs or Office of Compliance Programs. If the concern is expressed by a research subject, that participant will be contacted directly by

the Chair to discuss the situation. The procedure for handling the investigation follows the steps detailed earlier in this section. At the conclusion of the investigation and deliberation by the IRB and Vice-Chancellor for Academic Affairs, if appropriate, any conclusions and/or actions taken by the IRB and/or institution will be communicated to the participant.