# Deviation Guidance for Board Members

1. Does the deviation constitute **noncompliance**?

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| **Noncompliance:** | Failure to follow:<br>• applicable regulations/ policies,<br>• the IRB approved protocol, or<br>• requirements /determinations of the IRB. |

This **applies to:** research staff, research support entities, University / Hospital employees or agents, and any member of the human research protection program

2. Does the deviation constitute **serious noncompliance**?

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| **Serious Noncompliance** | • Adversely affects **welfare** of participants, including **actual** or **potential *substantive* harm;**<br>**OR**<br>• Adversely affects the **scientific integrity** of the **study;**<br>**OR**<br>• Adversely affects the **rights of participants** |

**Participant's Rights**
- To have enough time to decide whether or not to be in the research study and to make that decision without any pressure.
- To refuse to be in the study
- To **stop participating at any time**
- To be **informed of all the applicable required elements of consent**
- To receive a copy of the consent form
- To ask questions

3. Does the deviation constitute continuing noncompliance?

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| **Continuing Noncompliance** | A **pattern** of **repeated <u>serious</u> noncompliance**, including **inadequate efforts to take corrective actions** within a reasonable timeframe. |

4. Is the corrective and preventative action plan sufficient?
   a. If not, what revisions are required?

**Potential Corrective Actions**
- Informing the affected participant
- Re-consent or informing other participants (active and non-active)
- Modification to the consent or consent process
- Modification to the protocol
- Increased monitoring
- Arrangements for clinical care outside of the research or additional follow up
- Notifying other sites
- Additional training of principal investigator and/or study staff
- Voluntary enrollment hold, suspension, or termination of the research

5. Should the noncompliance be reported to FDA, OHRP, NIH, or other entity?

| **Reporting Criteria** | |
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| **Internal** | The IRB determines that noncompliance represents serious or continuing noncompliance, or both. |
| **External** | The IRB determines that the event is:<br>• **Serious non-compliance** in which a **participant experienced *substantive* harm,** or<br>• Continuing noncompliance, or<br>• Both, or<br>• There are other legal requirements to report externally. |

| **Board Recommendations**<br>***This is a 3 part decision to be made when the board has completed the review of an action item.*** | |
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| **Part 1: Decisions regarding noncompliance** | |
| • **Serious Noncompliance** | Yes or No |
| • **Continuing Noncompliance** | Yes or No |
| **Part 2: Decisions regarding event and corrective actions** | |
| • Accept<br>• Accepted pending responses (deferred pending more information or updated corrective and preventative action plan)<br>• Require earlier continuing review<br>• Suspension or termination of the research<br>• Request an audit by OCR<br>• Request observation of the research or consent process | |
| **Part 3: Decisions regarding reporting** | |
| • **Internal** | Yes or No |
| • **External** | Yes or No |