Complying with Geisinger Consent Form Requirements when Geisinger is a Relying Institution

Introduction

In 2015, Geisinger Research Leadership formed several workgroups to assess the current state of engaging individuals in research and develop strategies to improve this engagement. An outcome of this initiative was the formation of a working group charged with improving accessibility of research informed consent. This group developed standards for informed consent documents that Geisinger IRB follows today to better align research interactions with community standards and education level.

Geisinger IRB adheres to strict consent form requirements for all non-exempt research in which Geisinger or a Geisinger affiliated site is engaged. Generally, with few exceptions, consent forms used at Geisinger or Geisinger affiliated sites are required to comply with the following formatting and readability requirements:

- Flesch-Kincaid Grade Level = 6-8; or
- Flesch Reading Ease >60
- Font = Arial
- Spacing = multiple @1.15

When Geisinger cedes IRB oversight to an external IRB, enforcing these requirements presents several challenges and can delay IRB approval at Geisinger sites. Reviewing IRBs, sponsors and prime institutions may not allow site specific changes to consent forms when the modifications extend beyond local context issues. The purpose of this document is to provide a hierarchy of methods that must be followed by local investigators and research teams in order to satisfy the local Geisinger consent form requirements.

Hierarchy of Options When Relying on External IRB Other Than NCI CIRB

1. Discuss Geisinger local consent form requirements with the reviewing IRB and sponsor or the prime institution, and seek permission for consent revisions that would allow the consent form to meet Geisinger requirements. This is the strongly preferred option. If

any other option is used, the investigator must provide documentation of IRB, sponsor or prime site refusal to allow consent form revisions necessary to align with Geisinger requirements.

2. Develop a Key Information *sheet* that meets Geisinger requirements to be reviewed during the consent process. If the consent form contains a "Key Information" or "Overview" summary section at the beginning of the document that meets the Geisinger IRB consent form readability requirements, the consent form can be used at Geisinger sites as long as the Geisinger IRB feels it adequately covers the study details. A copy of the Key Information Sheet must be given to the participant, and the Investigator must document that the Key Information sheet was used in the consent process. The participant must sign and date the consent form and receive a copy. The local Investigator must confirm with the reviewing IRB that this document is acceptable and determine if IRB review and approval is required prior to its use.
3. Develop a Key Information *script* to be used during the consent process that meets Geisinger requirements. If the reviewing IRB allows the script to be given to participants, then one should be provided at the time of consent. The Investigator must document that the Key Information script was used in the consent process. The participant must sign and date the consent form and receive a copy. The local Investigator must confirm with the reviewing IRB that the script is acceptable and determine if IRB review and approval are required prior to its use.
4. If one of the first three options is not possible, then the local investigator will need to submit a mitigation plan to Geisinger IRB. An example of a mitigation plan might be a list of questions asked during the consent process to assess and confirm patient comprehension of the study, its risks, and benefits. The Geisinger IRB will evaluate the consent form and the mitigation plan and determine if they are acceptable for use at Geisinger sites. In making this determination, the Geisinger IRB will consider the following:
    a. The risk level of the study
    b. How much the reading level exceeds Geisinger requirements
    c. How well the consent form explains and defines complex words and topics
    d. How well the proposed mitigation plan counters the reading level of the consent form and ensures participant comprehension
    e. Any other criteria that the Geisinger IRB determines to be essential to protecting participants

    The Geisinger IRB may rely on IRB staff, IRB members, IRB Leadership members, and members of the local community to assess the appropriateness of any consent form that does not comply with the required readability standards. If it is determined that the consent form is acceptable despite the reading level exceeding local standards, Geisinger IRB will allow the study to continue through the ceding process.

Hierarchy of Options When Relying on NCI CIRB

Since NCI CIRB strictly limits the modifications that can be made to the template consent form at local sites, meeting the Geisinger consent requirements is typically not feasible unless the template consent form already meets these standards. For studies relying on NCI CIRB, if the consent form exceeds requirements, the following hierarchy of methods must be followed by local investigators:

1. If the consent form contains a "Key Information" or "Overview" summary section at the beginning of the document that meets the Geisinger IRB consent form readability requirements, the consent form can be used at Geisinger sites as long as the Geisinger IRB feels it adequately covers the study details.
2. Develop a Key Information *sheet* that meets Geisinger requirements to be used during the consent process. This document must be submitted on the Study Specific Worksheet and approved by the NCI CIRB prior to use. A copy of the Key Information sheet must be given to the participant and the Investigator must document that the Key Information sheet was used in the consent process. The participant must sign and date the consent form and receive a copy. If the NCI CIRB does not approve the use of the Key Information sheet, Option 3 (below) should be followed.
3. Develop a Key Information *script* that meets Geisinger requirements to be used during the consent process. This document must be submitted on the Study Specific Worksheet and approved by the NCI CIRB prior to use. If the NCI CIRB allows the script to be given to participants, then one must be provided at the time of consent. The Investigator must document that the Key Information script was used in the consent process. The participant must sign and date the consent form and receive a copy. If the NCI CIRB does not approve the use of the script, Option 4 (below) should be followed.
4. If one of the first three options is not possible, then the local investigator must submit a mitigation plan to Geisinger IRB. An example of a mitigation plan might be a list of question asked during the consent process to assess and confirm patient comprehension of the study, its risks and benefits. Geisinger IRB will evaluate the consent form and the mitigation plan and determine if they are acceptable for use at Geisinger sites. In making this determination, the Geisinger IRB will consider the following:
    a. The risk level of the study
    b. How much the reading level exceeds Geisinger requirements
    c. How well the consent form explains and defines complex words and topics
    d. How well the proposed mitigation plan counters the reading level of the consent form and ensures participant comprehension
    e. Any other criteria that the Geisinger IRB determines to be essential to protecting participants

    The Geisinger IRB may rely on IRB staff, IRB members, IRB Leadership members, and members of the local community to assess the appropriateness of any consent form

that does not comply with the required readability standards. If it is determined that the consent form is acceptable despite the reading level exceeding local standards, when coupled with the investigator mitigation plan, Geisinger IRB will allow the study to continue through the ceding process.