Human Research Protection Program (HRPP)
Institutional Review Board (IRB)
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GEISINGER HEALTH SYSTEM

IRB Outcome Letters – Geisinger Implementation of iRIS on January 2, 2013

As of the January 2, 2013 implementation of iRIS, Geisinger outcome letters do not include original signatures.

iRIS has provided us with a tool to integrate IRB management and data collection into a web-based application that assigns specific roles and available actions for study team members, IRB members and staff. iRIS validates authentication credentials to allow only authorized individuals to generate IRB approvals. The authenticity of the IRB approver is based on his/her role and individual identification and password.

There are no federal or state regulations that require the signature of the IRB Chair on IRB approval memos/letters, and FDA does not specify the procedure that IRBs must use regarding signatures on IRB approval letters.

iRIS-generated IRB outcome letters meet the regulatory requirements and signature of the IRB Chair is not required.

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