# Adventist HealthCare

# Institutional Review Board Newsletter

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## Annual Research Conference

The IRB Office hosted the 8ᵗʰ annual Research Conference on Friday, October 19. Presentations by industry experts explained common deficiencies the FDA finds when performing routine study audits and how to prevent them from occurring. In addition, attendees gained insights on how to run an efficient research site that sponsors will return to with clinical research opportunities.

Award-winning author of *A Life Everlasting: The Extraordinary Story of One Boy's Gift to Medical Science* and TED speaker Sarah Gray spoke about donating her newborn son's tissue to research. Her talk, which was an audience favorite, can be seen as a TED talk.

If you would like a copy of the presentations, please contact the IRB Office.

## IRBManager: Go Live on April 1, 2019

The IRB Office will be transitioning to IRBManager, an electronic platform for IRB application submission and management with a Go Live date of April 1, 2019. Training sessions and reference materials are forthcoming.

**Beginning April 1, 2019, no paper IRB forms will be accepted.**

## Revised Reportable Event Process

In concert with current regulatory standards and guidance, reportable events found to be serious, related to the research, and unexpected are required to be reported as soon as possible or within 1 week of discovery utilizing the Reportable Event Reporting Form and Reportable Event Cumulative Table. All other reportable events should be logged on the Cumulative Table and reported at the time of continuing review. Please see the Unanticipated Problems policy in the Policy Library or contact the IRB Office for more information.

## Finalized Research Policies

All content from the IRB Handbook is now located in the Research Policies under the Policy Library.