

# Research Integrity and Protection Newsletter

November 2019

## PRIM&R Advancing Ethical Research (AER) VIRTUAL CONFERENCE at Ascension Wisconsin Nov. 17-20, 2019

Ascension Wisconsin is registered for the AER19 Virtual Conference occurring November 17-20, 2019.

All AWRI staff, IRB members and researchers will have access to view sessions streaming from the conference. Attendance is not mandatory, and you can view as few or as many sessions as you'd like. There are up to 63 CE credits available.

No registration is required, and no additional meeting invites will be sent.

Research Integrity and Protection will also host follow up discussion sessions.

Learn more about the Virtual Conference, sessions, CE credits, and how to join [here](#).

If you have questions, contact [Jackie Kirchen](#).

## Good Clinical Practice(GCP) Q&As

Test your GCP knowledge! Click the links to review the answers.

**Q)** Do CVs expire in the same way a medical license does when collecting these documents to support investigators listed on the 1572? [answer](#)

**Q)** Suppose that a study protocol calls for a physician to conduct study-related physical examinations, but that a state's law permits nurse practitioners to perform exams under a physician's supervision. What takes precedence in this case? [answer](#)

**Q)** Is it acceptable for a CRA or sponsor/CRO auditor to have direct access to an investigator site's electronic medical record system (using a unique user ID and password) if the system is unable to limit this access to only those patients participating in the trial that is being monitored/audited? [answer](#)

## RI&P Releases New Guidance Documents

- [Data and Safety Monitoring Plan Guidelines](#) provide researchers with guidance on creating and submitting a DSMP.
- [Preparing Research Data in a Spreadsheet](#) outlines tips and examples for data. Entry into spreadsheets to ensure collected data can be easily and accurately imported into a statistical software package.
- [Corrective Action Preventive Action Plan \(CAPA\) Guidance](#) provides tips and a template to help study sites create complete CAPA plans.

As a reminder, all IRB Guidance documents can be found on the SOP and Guidance [webpage](#). All REQM Guides and Templates for study teams are found on the Quality Management [webpage](#).

## IRB Membership Updates

**New IRB Vice-Chair:** The AWRI IRB Vice- Chair, Maureen Greene, PhD, APN, RN has resigned after nearly 15 years serving on the Ascension WI and legacy IRBs. We are grateful for her service and wish her the best. We are also happy to announce our new IRB Vice-Chair, Chris Dykstra, PharmD, MBA. Chris is a Regional Director of Pharmacy for Ascension Wisconsin and has served on the Ascension WI and legacy IRBs for over five years.

**IRB Seeks a Nurse Member:** The AWRI is accepting nominations and applications for a nurse IRB member. The ideal candidate would have an advanced degree and a research background, but not necessarily IRB expertise. The IRB meets monthly and the total time commitment for the meeting, reviews and education is approximately 4-6 hours per month.

[Contact us](#) if you're interested.

### UPDATE: IRB Meeting Schedule

The [2020 IRB Full Board Meeting Schedule and FAQ](#) is now available on the IRB [website](#).

### UPDATE: IRB Rosters

Updated IRB Rosters (11/1/19) are available under "IRB Rosters" on the IRB [website](#).