Consulting

Human Research Protection Program Services

Revitalize your human research protection program (HRPP) with customized consulting support

We know one size does not fit all. Each research program is different, with unique needs and distinct personalities. We take time to carefully understand your processes, then apply our expertise to bring out the best in your program.

Transform Your HRPP

- Keep research moving forward during vacancies, layoffs, and leaves
- Improve compliance and collaboration across your HRPP community
- Streamline institutional review board (IRB) review processes
- Achieve AAHRPP accreditation
- Navigate federal inspections, evaluations, requests, and respond to agency inspection reports with ease

Solutions for Research Sites

Transform your HRPP with solutions customized to your unique objectives.

We look beyond the IRB to evaluate the entire HRPP and provide support such as:

- Program assessment and revitalization
- Education and training
- Staffing solutions
- AAHRPP accreditation preparation and site visit support
- Assistance with federal agency visits/inspections
- Standard operating procedure (SOP) and/or policy gap analysis
- SOP and/or policy development
- Navigating communications with oversight agencies
- Ad hoc consultation

Staffing

Retaining top talent is a perpetual challenge. If you have a vacant position or need a temporary capacity boost, we can help. Advarra provides interim staffing support for IRB offices as well as other compliance programs within the HRPP. Our team is comprised of current and former IRB members, as well as former vice presidents of research, HRPP directors, IRB managers, and IRB analysts. Many of our experts are Certified IRB Professionals (CIPs) and/or Certified in Healthcare Research Compliance (CHRC). If your institution has a knowledge gap or a vacant position, let us help by providing experts to meet your needs.

HRPP Assessment

Advarra experts perform a prescribed set of assessments when evaluating your HRPP. We focus specifically on core regulatory compliance and operational effectiveness of the HRPP, enabling your organization to make informed, programmatic decisions. From COI program evaluations to HIPAA assessments, clinical trials billing compliance reviews and beyond, our team members have the expertise to ensure your HRPP is operating efficiently and effectively.

Policy and Procedure Development and Revision

The rapidly evolving regulatory landscape necessitates frequent review of and revision to policies and procedures. Let Advarra experts support your HRPP and ensure compliance with applicable regulations by conducting a gap analysis, revising existing policies, and recommending new policies where necessary.

Ad Hoc Consulting

Interpreting regulations and navigating complex ethical issues are our specialties! Advarra experts routinely provide ad hoc guidance to institutions of all types and sizes. If you need regulatory or ethical guidance on a particular topic or want to be able to contact an expert when complex issues arise, an ad hoc agreement might be a great fit for you.

> **"The team quickly assessed our research areas for improvement. Thanks to the assessment, our HRPP is on its way to being world-class."**
>
> – Executive Director, Office of Research Administration at a major health system

Ready to strengthen your human subjects protection program? Contact Consulting@advarra.com to get started.

ADVARRA

advarra.com