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Self-Assessment of Human Subjects Protection Programs

By Eric Allen

Institutions that conduct research with human participants are subject to oversight of their human research protection (HRP) programs by one or more of the following:

- Office of Human Research Protections (OHRP)
- Food and Drug Administration (FDA) and their equivalents in other countries
- State and local agencies

The rules and their interpretation are complex and always changing, so good practice requires periodic assessment of HRP programs for ethical compliance. Self-assessment can be much less painful than OHRP and FDA inspections, especially an aggressive for-cause inspection or a broad-ranging not-for-cause inspection. In addition to ethical duties and compliance requirements, self-assessments can protect against litigation, public relations problems, and other risks.

Assessments should cover all of the main elements of an HRP compliance program:

- Rules (regulations, guidances, policies, etc.)
- Procedures
- Personnel
- Training
- Implementation

Self-Assessment Process

The steps in a self-assessment process are as follows:

1. If self-assessment is not already a standard practice, justify it to management to obtain authorization, resources and strong support.
2. Create a representative team, team charter, project timeline, procedures for tracking progress, etc.
3. Compile a "baseline" library of relevant policies, procedures, reports, memos and other documentation of current practices and expectations. Also document important unwritten policies and procedures, including practices that are known to deviate from the standard. Describe the compliance culture.
4. Optionally, survey faculty, staff, physicians, administrators and any other individuals that may be involved with your institution's human research program. The survey should include yes/no, multiple-choice, and open-ended questions. Affordable online survey tools are available. Since you will be surveying different types of people, the survey tool should be able to present questions based on demographics and previous answers.
5. Review the documentation in detail to identify likely gaps, weaknesses, inconsistencies, problems and questions to be resolved.
6. If it has not been done already, determine the features of an HRP that would meet the institution's standards.
7. Set priorities for addressing issues.
8. Write report with findings, recommendations and corrective and preventative action (CAPA) plans.

The last step in this process is also the first step in the process of correcting any deficiencies.

External Resources

Although resources are scarce in today's economy, there are several no-cost options available that can be quite beneficial.

OHRP

OHRP's Division of Education and Development (DED) has developed a QA Self-Assessment Tool as part of its Quality Improvement Program, available at www.hhs.gov/ohrp/education/qip/index.html. The tool provides a guided self-assessment for either biomedical or social behavioral human research programs. The tool consists of approximately 100 mostly yes/no questions. The questions cover general and administrative processes, resources and workloads, training, institutional review board (IRB) committee structure, the review process, and documentation.

After answering the questions, you can ask DED to review it on a confidential and non-punitive basis. DED will also review your IRB's standard operating procedures and minutes from three recent IRB meetings. Following DED's review, it will provide consultation by teleconference, video conference, or onsite meeting.

AAHRPP

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) is a non-profit organization that accredits HRP programs. It has made available an Evaluation Instrument for Accreditation at http://www.aahrpp.org/www.aspx?PageID=221. This self-assessment tool is extremely informative. The questions are very detailed, consisting of approximately 110 pages of information and questions that cover general IRB topics, administrative issues, education, committee structure, protocol review process, and related offices (e.g., sponsored programs). Because of the scope and detail of the questions, answering them all can take weeks, so setting priorities is in order.

AAHRPP's website (www.aahrpp.org) provides other relevant resources, including a list of accredited organizations. The websites of these organizations, in turn, provide policies, standard operating procedures, and other useful HRP documents.

Other

HRP experts from other institutions can provide useful advice during the self-assessment process. Colleagues at other institutions are the first people to ask. The professional association Public Responsibility in Medicine and Research (PRIM&R) operates a mentoring program that can match you with a suitable expert. Professional consultants are available from organizations like HRP Consulting Group (www.thehrpconsultinggroup.com), Huron Consulting Group (www.huronconsultinggroup.com), and Polaris Compliance Consultants (www.polarisconsultants.com). These organizations can provide advice, lead the self-assessment program, or anything in between. As with any advisor or consultant, their contributions will depend on their expertise and your specific requirements.

Common Areas for Improvement

HRP program self-assessment can identify numerous areas for improvement. Some common findings are as follows:

- Ensure compliance with standard operating procedures.

- Develop more efficient procedures.
- Improve understanding of IRB review processes by researchers and administrators outside the HRP department.
- Increase transparency of IRB submission requirements, deadlines and activities.
- Implement ongoing training of IRB members.
- Replace burdensome paper-based protocol review processes with a streamlined electronic system.
- Add HRP staff to bring capacity in line with increased responsibilities.

Conclusion

There is no point starting a self-assessment program that runs out of gas part way through. The institution must therefore be willing to commit to the program, prioritize and persevere. The result will probably be a significant improvement in human subjects protection at your institution, along with the satisfaction that your institution's investment in HRP is productive.

Author

Eric Allen is Director of Office of Research Compliance at the University of North Carolina, Greensboro. Contact him at 1.336.256.1482 or eric_allen@uncg.edu.