

A close-up photograph of a person's right arm, showing a tattoo on the shoulder and upper arm. The tattoo consists of the letters 'HRRP' in a large, bold, serif font, with the word 'Accredited' written below it in a smaller, cursive script. The person is wearing a black tank top. The background is a gradient from white to grey, with a red diagonal shape on the left side.

HRRP
Accredited

Seeking Accreditation For Your Human Research Protection Program (HRPP)

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Unlike institutional animal care and use programs, for which accreditation was granted over 45 years ago (“About AAALAC History,” 2014); accreditation of human research protection programs (HRPPs) began less than 15 years ago.

The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), the largest HRPP accrediting body, was founded in 2001. As of February 2014, 192 organizations were accredited, including 86 academic institutions, across the U.S. and internationally including Canada, China, India, and Taiwan (“AAHRPP Accredited Organizations,” 2014).

Alion Science and Technology Corporation started HRPP accreditation services in 2013. Alion recently awarded its first accreditation to the University of Nebraska Medical Center (Alion Science and Technology, 2013).

Institutions interested in seeking accreditation for their HRPP now have two options - AAHRPP and Alion. Both have similar accreditation processes that involve self-assessment, application preparation, application review, and on-site evaluation.

AAHRPP and Alion both provide applicant institutions with evaluation instruments. To achieve accreditation, an institution must meet all the accreditation standards.

On-site evaluations include interviews with key stakeholders including senior leadership, IRB members and staff, investigators and research coordinators, as well as members and staff of Sponsored Research Administration and the Conflict of Interests Committee and other members of the HRPP.

Here are a few application preparation tips based on our AAHRPP accreditation experience:

Tips for Preparing the Application

Establish a deadline for submitting your application. Start early. The self-assessment process involves comparing your institution's policies and procedures to the accreditation standards. This process is critical and will take longer than expected.

Gather a team of experts to conduct the self-assessment. Since both AAHRPP and Alion look beyond the IRB, be sure you have the appropriate experts on your team.

Use the resources provided by the accrediting body:

- Review their websites <http://www.aahrpp.org> and <http://www.alionhrpp.com>, both provide a wealth of information about the process.
- Review their evaluation instruments and tip sheets.
- Establish a dialogue with your assigned Accreditation Contact and ask questions. S/he may not be able to provide specific answers but will point you in the right direction.

Communicate:

- Keep key stakeholders informed about the self-assessment process. Send out short email blasts or develop a dedicated web page.
- Educate the research community about new and revised policies and procedures.
- Reach out to colleagues at accredited institutions. Ask how they met specific requirements and prepared for the on-site visit.

Once you submit your application, expect to receive feedback in four to six weeks. Re-assemble the team to address any comments and concerns, which may involve revising policies and procedures and/or providing additional documents. If unclear about the feedback, call your Accreditation Contact.

References:

History - Association for Assessment and Accreditation of Laboratory Animal Care (AALAC). Retrieved March 24, 2014 from AALAC website: <http://www.aalac.org/about/history.cfm>

Accredited Organizations - The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). Retrieved March 24, 2014 from AAHRPP website: <http://www.aahrpp.org/learn/find-an-accredited-organization>

Alion Science and Technology. (2013). Alion Awards HRPP Accreditation to University of Nebraska Medical Center [Press Release]. Retrieved from <http://www.alionhrpp.com/alion-awards-hrpp-accreditation-to-university-of-nebraska-medical-center>

Next comes the On-Site Evaluation. This phase of the process involves the accreditation agency interviewing key HRPP stakeholders, reviewing HRPP documentation including IRB rosters, minutes, research protocols and related contracts, and possibly attending an IRB meeting. You will receive a detailed schedule in advance of the site visit.

Tips for Preparing for the On-Site Evaluation

Notify interviewees as soon as possible, giving them sufficient time to adjust their calendars.

Prepare interviewees as questions are not provided ahead of time. Questions are geared toward an institution's application of its policies and procedures regarding the protection on human subjects rather than a recitation of the ethical principles and federal and state regulations.

- Create a guidance document that includes potential interview questions.
- Prepare individuals in the same group (e.g., IRB members, clinical research coordinators, etc.) together in an orientation-like setting.
- Perform a mock site visit where interviewees can practice prior to the actual site visit.

During the site visit, debrief the interviewees after their site visitor meeting to understand the focus of the interviews and what questions are being asked. This is helpful information for those yet to be interviewed as well as for anticipating areas of concern in the Site Visit Report.

After the site visit the institution will receive a Site Visit Report that includes observations and areas of concern. Respond to any misunderstanding of procedures and address each concern. Responses should be specific and measurable. The Site Visit Report, along with your response, will be reviewed to determine whether your institution's HRPP receives accreditation. ■



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