

# FREQUENTLY ASKED QUESTIONS ON AAHRPP RE-ACCREDITATION AND SITE VISIT

## Abbreviations

AAHRPP	Association for the Accreditation of Human Research Protection Programs, Inc
CEO	Chief Executive Officer
DSRB	Domain Specific Review Board
HRPP	Human Research Protection Programme
NHG	National Healthcare Group
OHRPP	Office of Human Research Protection Programme
P&O	Partnerships and Outreach
PCR	Proper Conduct of Research
RE	Research Education
RQM	Research Quality Management
SOP	Standard Operating Procedures

## Frequently Asked Questions (FAQ)

<b>1.</b>	<p><b>What is AAHRPP?</b></p> <p>AAHRPP is an independent, non-profit accrediting body that promotes high-quality research through an accreditation process that helps organisations worldwide strengthen their HRPPs. AAHRPP adopts a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection.</p> <p>The goals of accreditation are to:</p> <ul style="list-style-type: none"><li>• Improve the systems that protect the rights and welfare of individuals who participate in research;</li><li>• Communicate to the public the strength of an organisation's commitment to the protection of human research participants.</li></ul> <p>To date, AAHRPP has accredited 258 organizations across the United States, Belgium, Brazil, Canada, China, India, Jordan, Mexico, Republic of Korea, Saudi Arabia, Singapore, South Africa, Taiwan and Thailand.</p> <p>All major U.S. independent institutional review boards have earned AAHRPP accreditation. In addition, more than 70 percent of U.S. medical colleges and 85 percent of the top National Institutes of Health-funded academic medical centers are either AAHRPP accredited or have begun the accreditation process. To earn accreditation, organisations are required to provide tangible evidence — through policies, procedures and practices — of their commitment to scientifically and ethically sound research and to continuous improvement.</p> <p>You may obtain more information about AAHRPP at <a href="http://www.aahrpp.org">www.aahrpp.org</a>.</p>
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**2. Why is AAHRPP accreditation important for NHG?**

NHG's HRPP was first awarded AAHRPP accreditation in March 2007, and subsequently received re-accreditations in March 2010 and March 2015. Attaining accreditation has brought to NHG the following benefits:

**(a) Better risk management programmes**

The RQM framework was developed to encompass a systematic study review programme to guide investigators on the proper methods of conducting research. The RE framework was also established to provide upstream training and education to researchers. These frameworks ensure that the research community is adequately trained and qualified to perform research.

**(b) Better regulatory compliance**

The establishment of the RQM study review and RE educational frameworks has led to better awareness and compliance with local regulations and guidelines governing human subject research.

**(c) Improved research quality**

The PCR SOPs and templates developed have provided investigators with clear guidance on how research should be conducted. This has helped to reduce the incidence of non-compliances in research studies.

AAHRPP accreditation has also provided additional networking platforms with other AAHRPP-accredited organisations to share best practices, which in turn translates to better research quality.

**(d) Ability to attract collaborative research, sponsors, high quality investigators and research subjects**

The comprehensive research frameworks that NHG has established has attracted an increasing number of institutions who wish to collaborate with NHG. To date, the NHG OHRPP provides research support services to 11 non-NHG institutions. The increased collaboration with other institutions has resulted in a larger number of investigators submitting studies to the DSRB.

AAHRPP accreditation and its associated rigorous standards have also increased sponsors' confidence in working with NHG. The establishment of the P&O unit within OHRPP has also enabled NHG to reach out to potential research subjects, educating them on their rights and expectations when participating in research studies.

**(e) Increased efficiency and reduced costs**

NHG OHRPP has also developed comprehensive research policies, SOPs and templates, which are widely used by investigators across NHG and affiliated

	<p>institutions. This eliminates duplicate efforts in developing research resources, thus reducing manpower and costs.</p>
<b>3.</b>	<p><b>What is the re-accreditation process like?</b></p> <p>The initial step, or the Step 1 review, in the re-accreditation process requires NHG OHRPP to perform a rigorous self-assessment, to identify and correct any process deficiencies. This includes a review of existing policies and procedures within NHG, as well as scrutinising current practices to assess compliance with regulations and applicable guidelines. The results of the step 1 review have been submitted to AAHRPP in May 2019.</p> <p>This is followed by the Step 2 application and site visit, where AAHRPP site visitors will review the application materials and conduct an on-site evaluation at NHG. The on-site evaluation will involve the site visitors reviewing NHG facilities, relevant records, policies, procedures and study files.</p> <p>Following the site visit, AAHRPP will send a Draft Site Visit Report to NHG, which will require NHG's response within the required time frame. The AAHRPP Council on Accreditation will review the application, Draft Site Visit Report and NHG's response to make a determination regarding accreditation.</p> <p>NHG, NUHS and NUS are looking to achieve joint re-accreditation in March 2020.</p>
<b>4.</b>	<p><b>When will the site visit occur and how long will it be?</b></p> <p>The site visit will be a 2 day visit, which has been scheduled on the 16 and 17 January 2020.</p>
<b>5.</b>	<p><b>How many site visitors will there be, and who are they?</b></p> <p>The number of site visitors assigned will depend on the size and complexity of the HRPP being reviewed. There were 2 site visitors for the 2015 re-accreditation site visit to NHG.</p> <p>Site visitors are selected by AAHRPP based on their experience, and generally come from different backgrounds. AAHRPP will tailor the site visit team to the needs of the organisation undergoing accreditation. The site visitors will have appropriate expertise on the research setting and type of research being conducted within the organisation.</p>
<b>6.</b>	<p><b>Who will be involved in the site visit?</b></p> <p>All staff of NHG, NUHS and NUS who are involved in human subject research may be involved. These can include (but are not limited to):</p> <ul style="list-style-type: none"> <li>• Organisational officials – CEO, Chairman Medical Board, Directors of Research, Institutional Representatives.</li> <li>• Clinical research unit / research office staff</li> </ul>

	<ul style="list-style-type: none"> <li>• DSRB chairpersons, members and administrators</li> <li>• Investigators, clinical research coordinators and all members of the study team.</li> </ul>
<b>7.</b>	<p><b>What will happen during the site visit?</b></p> <p>The site visit will commence with introductions between the site visitors and representatives from NHG. Subsequently, the main activities taking place during the site visit will comprise of record reviews and interviews.</p> <p>Record reviews will involve review of ethics applications and protocol files, among others, for compliance with applicable regulations, policies and ethical principles. Interviews will be held with the various HRPP stakeholders within NHG, including organisational officials, DSRB members, principal investigators and research staff.</p>
<b>8.</b>	<p><b>How are individuals selected for interviews with AAHRPP? What will I be asked about if I am selected and how do I prepare for the interview?</b></p> <p>Closer to the site visit date, AAHRPP will select the individuals they wish to interview, although NHG may also propose to AAHRPP the individuals to be interviewed. Research studies will be selected based on information on ongoing studies provided to AAHRPP. The selection criteria will be based on the experience of the principal investigator, number of ongoing studies concurrently managed by the principal investigator, the nature of the research study as well as its risk level. Any member of the study team may be selected for interview, including the principal investigator, co-investigators, clinical research coordinators and other study staff. For DSRB members, interview selections will be based on your role(s) within DSRB, e.g. scientific member, layperson, legal, etc.</p> <p>If you have been selected for the AAHRPP interview, you will be contacted by NHG OHRPP or the respective Institution Clinical Research Unit. You will be provided with materials to prepare for the interview such as brief information on AAHRPP, and a list of possible questions that may be asked by AAHRPP interviewers. These questions have been compiled based on previous accreditation / re-accreditation cycles. If required, a mock interview session can also be scheduled with you to help prepare you for the interview.</p>
<b>9.</b>	<p><b>How is NHG preparing for the re-accreditation and site visit?</b></p> <p>NHG OHRPP staff will be working with the Institutional Representatives, Directors of Research and Clinical Research Units / Research Offices of each institution to ensure that all research staff are adequately informed about the site visit. Some of the means through which OHRPP will be reaching out to sites include providing information about AAHRPP through the NHG Research Website and scheduling mock interviews with selected individuals (where needed).</p>
<b>10.</b>	<p><b>How is the AAHRPP re-accreditation process different from a study audit?</b></p>

	<p>The scope of the AAHRPP site visit will encompass all aspects of human subject research conducted within the NHG, NUHS and NUS including (but not limited to) research oversight, research staff, study conduct, research-related documents and dealings with study subjects. As long as your research study has been reviewed by the DSRB, it will fall under the ambit of NHG's HRPP. As such, you may be invited to attend an interview with the AAHRPP site visitors, who may ask you questions about your role in research and how your studies are managed.</p> <p>It should be noted that the AAHRPP site visit is an inherently different process from the routine study reviews (audits) conducted by NHG's RQM team. The objectives of the re-accreditation process and site visit seek to recognise high-quality HRPPs within institutions. On the other hand, the purpose of NHG RQM study reviews is to assess the compliance of research study conduct with applicable regulations and guidelines.</p> <p>As such, while the site visitors may ask you questions about your research studies, these questions will relate to your awareness of the responsibilities and ethical principles governing research and protection of human subjects, rather than on the specific details of how you conduct your study (e.g. maintaining the investigator file, as would be asked during a routine RQM audit).</p>
<p><b>11.</b></p>	<p><b>Where can I obtain more information about the re-accreditation process and site visit?</b></p> <p>For more information about AAHRPP re-accreditation and your role in this process, please refer to the NHG research website (<a href="https://www.research.nhg.com.sg">https://www.research.nhg.com.sg</a>) → Home → Accreditation.</p> <p>Alternatively, you may contact the following individuals for further enquiries or assistance:</p> <p><b>For General Enquiries</b>  Ms Hu Liqin  Senior Executive  Research Quality Management  Email: <a href="mailto:Liqin_HU@nhg.com.sg">Liqin_HU@nhg.com.sg</a></p> <p><b>For Educational Materials related Enquiries</b>  Ms Valerie Wee  Senior Executive  Research Education  Email: <a href="mailto:valerie_sa_wee@nhg.com.sg">valerie_sa_wee@nhg.com.sg</a></p>