

Frequently Asked Questions (FAQs) for HBR Essential Research Conduct (ERC) Online V.2

GENERAL

1. What is the HBR Essential Research Conduct (ERC) Course about?

The HBR ERC Course aim to equip all NHG Researchers and research staff with the knowledge of regulations and institutional policies to perform research properly so as to reduce the common recurring HBR Non-Compliances committed.

2. Who is required to complete the HBR ERC Online Course V2 for?

The HBR ERC Online course is to be completed as part of the NHG HBR Minimum Training Requirement for all **NHG Institution staff (PIs, Site-PIs, Co-Investigators and study team members)** involved in the design, conduct or reporting of new HBR studies / sites* approved by a NHG appointed IRB.

This requirement is also applicable to NHG-based MOHH residents/doctors and NHG-based SAF staff/doctors* who are participating in HBR studies (approved by NHG appointed IRB) in the capacity of NHG PI/Co-I or study team member.

*Staff with formal appointment with NHG Institutions (including affiliate or joint appointments.

<u>Note:</u> Non-NHG staff (e.g. non-NHG collaborators or Study Team members) will NOT be required to complete this training. (refer to point #8 for more information)

Click <u>here</u> for more information <u>or</u> go to <u>https://www.research.nhg.com.sg</u> > *Conducting Research* > *Minimum Training Requirement* > *HBR Essential Research Conduct (ERC) Course.*

3. When should the HBR ERC Course be completed?

The HBR ERC Online course must be completed prior to the commencement of HBR study involvement.

Click <u>here</u> for more information <u>or</u> go to <u>https://www.research.nhg.com.sg</u> > Conducting Research > Minimum Training Requirements > HBR Essential Research Conduct (ERC) Course.

4. [NEW] I've completed the HBR ERC Course before. Do I need to re-do the HBR ERC Online V.2?

Existing HBR PI & Study Team members who completed past version of the online course do NOT need to repeat V.2 online course to meet the minimum training requirements, but may do so for refresher or enhanced learning purposes.

All new HBR PI & Study team members will only need to complete the (updated) HBR ERC Online V.2.

Click <u>here</u> for more information <u>or</u> go to <u>https://www.research.nhg.com.sg</u> > Conducting Research > Minimum Training Requirements > HBR Essential Research Conduct (ERC) Course.

5. Are NHG-based MOHH residents or *NHG-based SAF staff/doctors required to complete the NHG HBR Minimum Training Requirements if they had already completed a HBRA minimum training course from another institution?

*NHG-based SAF staff/ doctors (with formal NHG Appointment with NHG Institutions including affiliate or joint appointments).



If they had already completed a HBRA minimum training course from SingHealth, NUHS or NUS Cluster or NTU, it will be recognized by NHG. Please file a copy of the training certificate in the study's Investigator File. (see Item 23 – Mutual Recognition of HBRA Minimum Trainings)

6. How do NHG-based MOHH residents or *NHG-based SAF Staff/doctors in NHG institutions (i.e. TTSH) who are PI/ Co-I or Study team member request access to complete the HBR ERC Online Course?

*SAF-NHG staff/ doctors (with formal NHG Appointment with NHG Institutions including affiliate or joint appointments).

They may use the "Request to access HBR ERC Online V.2" template and write to the course administrator (research_courseadmin@nhg.com.sg); copying their NHG Reporting Officer/HOD and provide the following information:

- Name of MOHH resident/requestor OR *NHG-based SAF (Staff/doctor) requestor:
- Department:
- Study/IRB Ref number:
- Role in the study (e.g. Principal Investigator/ Co-investigator, Collaborator, Study Team Member):
- The period/duration of your involvement in the study:
- eLEARN User ID (if any):

Upon successful approval, the NHG based MOHH residents or NHG-based SAF Staff/doctor will be granted 1-month access to complete the online course.

Kindly be reminded to retain a copy of the certificate in the study file.

Note:

- 1. The "Request to access HBR ERC Online V.2" <u>template</u> can be found on our research website, https://www.research.com.sg > Conducting Research > Minimum Training Requirements > HBR Essential Research Conduct (ERC) Course.
- 2. An email notification will be sent after approval is granted. If you did not receive the email notification within 1-2 working days after requesting for access, please login to eLEARN to check if you are able to access the HBR ERC Online Course.
- 7. If a Visiting Consultant (who had been granted approval by a NHG institution to conduct a HBR research or be PI of HBR research as a VC), would he/ she also be required to comply with the NHG HBR Minimum Training Requirements?

From 1 Nov 2019, visiting consultant of newly approved studies will be required to complete the ERC in order to meet the NHG HBR Minimum Training Requirements. The Visiting Consultant will also need to have a NHG appointment.

(Reference: NHG Investigator's Manual, Chapter 3.1 Who Can Be a Principal Investigator?)

8. Are Coordinators/ vendors/ volunteers whom are non-NHG staff required to complete the NHG HBR Minimum Training Requirements?

No, as the NHG HBR Minimum Training Requirements is a NHG RI requirement and extends only to NHG Staff. Such staff should check with and complete their respective Institution's HBR minimum training requirement (if available).



The NHG PI is still responsible for training them to perform their delegated roles/tasks per NHG PCR SOP 501-A02: Responsibilities of the Research Team, Section 4.2 Ensure adequate resources are available to conduct study.

9. Is there any registration fees involved?

No registration fees required.

10. How long will it take to grant for access to be granted for the HBR ERC Online Course V2 upon registration?

Direct access to the course on eLEARN for all NHG Institutions Staff had been made available. Once you have successfully logged into eLEARN, you may commence the course immediately.

However if you encounter logging in difficulties, kindly contact the eLEARN Technical Support team at lmssupport@wizlearn.com or contact them at +65 6777 9661 (Monday – Friday: 7.30am – 9pm) for further assistance.

Alternatively, you may contact your institutions' eLEARN representatives.

11. Is there any timeline for completing the HBR ERC Online Course V2 after self-registering for it?

<u>For NHG Staff</u> who self-registered for the course, there is no deadline for completing the HBR ERC Online V.2. However, the course <u>must</u> be completed (with e-Certificate issued) <u>before</u> the start /commencement of study involvement. If not, it is considered a non-compliance and is reportable to NHG DSRB.

<u>For NHG-based MOHH Residents & *NHG-based SAF staff/ doctors</u> who have submitted their request to register for the HBR ERC Online V.2, they will be granted 1-month access (from the date of approval) to complete the course. The course must be completed (with e-Certificate issued) <u>before</u> the start / commencement of study involvement. If not, it is considered a non-compliance and is reportable to NHG DSRB.

*NHG-based staff/ doctors (with formal NHG Appointment with NHG Institutions including affiliate or joint appointments).

12. Can I be Exempted from doing the HBR ERC Course?

If you fulfil the Exemption criteria, you may be exempted from completing the HBR ERC Course.

Click <u>here</u> for more information <u>or</u> go to <u>https://www.research.nhg.com.sg</u> > Conducting Research > Minimum Training Requirements > HBR Essential Research Conduct (ERC) Course.

13. Can I be Waived from doing the HBR ERC Course?

If you fulfil the Waiver criteria, you may apply for a waiver from completing the HBR ERC Course.

Click <u>here</u> for more information <u>or</u> go to <u>https://www.research.com.sg</u> > Conducting Research > Minimum Training Requirements > (HBR) Essential Research Conduct (ERC) Course.



14. I've completed other research ethics training programmes (i.e. CITI, FCOI, ICH-GCP), can I use it to waive the completion of the HBR ERC Course?

No. You are still required to complete the HBR ERC Course.

For more information on the minimum training requirements, click <u>here</u>.

15. [UPDATED] I am a NHG Researcher and I have completed the HBR ERC Online Course. I will be carrying out research involving human tissue. Do I need to complete the NHG Human Tissue Framework (HTF) Course?

The completion of the NHG Human Tissue Framework (HTF) course is mandatory for all Custodians and Tissue Bank Team Members in NHG. This also includes all NHG-based MOHH Residents/Doctors who have been delegated as Tissue Bank Custodians or Tissue Bank Team Members.

Only NHG custodians and tissue collection applicants (TCA) who had completed or been granted a waiver to complete the ERC course may be considered for a waiver of this minimum training requirement (refer to Tissue Compliance Circular Issue 1-2023_06Feb2023).

Click <u>here</u> for more information <u>or</u> go to <u>https://www.research.com.sg</u> > Conducting Research > Minimum Training Requirements > HBRA – Human Tissue Framework Course

16. Are there any reading materials for me to read if I've been granted a waiver or had been exempted from completing the HBR ERC Course?

You are encouraged to read the following Supplementary reading materials:

- Information on Human Biomedical Research Act (HBRA) Regulatory Framework & Requirements
- ii. NHG Research Data Policy
- iii. HBRA Case Studies
- iv. NHG RQM Common Study Review Findings
- v. HBRA Human Tissue Framework
- vi. NHG Policy for Tissue Bank Management and Release of Human Tissue Specimen

These are available at https://www.research.nhg.com.sg > Conducting Research > Minimum Training Requirements > HBR Essential Research Conduct (ERC) Course.

17. What if the HBR ERC Course is not completed as required under the NHG Minimum Training Requirement for HBR?

If it is not completed before the required due date, the Principal Investigator (PI), Site PI/ Co-I and / or study team member is required to submit a Non-Compliance Report (NCR) to the NHG DSRB and complete the course (unless the NHG staff had been granted a waiver by the NHG Research Institution (RI) Principal Person In Charge (PIC) from completing the HBR ERC Course). The NCR will be reviewed by the NHG Research Institution (RI).

18. How do I receive my certificate after completing the HBR ERC Online V.2?

When you have completed the HBR ERC Online V.2 (reading materials and quiz) and obtained a passing grade of \geq 75%, you will be issued an e-Certificate of Completion. The certificate is downloadable from eLEARN.



(Refer to the <u>eLEARN LMS Navigation Guide for HBR ERC Online Course</u> more information.)

19. Where do I file my certificates after completion of courses?

The certificates should be filed in the Investigator File for each HBR study protocol. Random audits may be conducted.

Note: If is not completed, the Principal Investigator (PI) and/ or study team member is required to submit a non-compliance report to the NHG DSRB.

20. [NEW] What happened to the previous HBR ERC Classroom Workshop and HBR ERC Alternative Online Assessment?

Both the HBR ERC Classroom Workshop and HBR ERC Alternative Online Assessment have ceased after the launch of the new (upgraded) HBR ERC Online (V.2) interactive online module.

All NHG CRCs, Research Assistant (RAs) and other supporting Study Team members involved in the subject recruitment and informed consent process for HBR studies will **no** longer be required to complete the HBR ERC Workshop / Alternative Online Assessment to meet the minimum NHG HBRA minimum training requirements.

21. [NEW] Are the e-Certificates and/or hard copy certificate obtained from previous HBR ERC Classroom Workshops and HBR ERC Alternative Online Assessment still valid?

Yes, they are still valid. However, you are encouraged to complete the HBR ERC Online V.2 for refresher or enhanced learning purposes.

22. Is there an expiration date for the HBR ERC Course certification?

There is no expiration for the HBR ERC Course certification. However, if there are major updates to the course contents, individuals whom have completed the course will be notified to read the updated materials, and/ or may be required to re-do the course.

23. [UPDATED] If I have already completed HBRA Minimum Training from another Healthcare Cluster / Research Institution, will be accepted by NHG? (Mutual Recognition of HBRA Minimum Trainings)

If you had already completed HBRA minimum training course from SingHealth, NUHS / NUS Cluster, or NTU, it can be recognised by NHG.

Please remember to file a copy of the training certificate in your Investigator File.

To familiarise with NHG specific policies and requirements, you are encouraged to read the following Supplementary reading materials:

- Information on Human Biomedical Research Act (HBRA) Regulatory Framework & Requirements
- ii. NHG Research Data Policy
- iii. HBRA Case Studies
- iv. NHG RQM Common Study Review Findings
- v. HBRA Human Tissue Framework
- vi. NHG Policy for Tissue Bank Management and Release of Human Tissue Specimen

These are available at https://www.research.nhg.com.sg > Conducting Research > Minimum Training Requirements > HBR Essential Research Conduct (ERC) Course.



HBR ERC ONLINE V.2 via eLEARN

24. How do I access the HBR ERC Online V.2?

The HBR ERC Online V.2, has been made available to all NHG Institutions Staff. To access the HBR ERC Online Course:

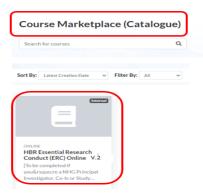
- 1. Go to https://elearn.sg/nhg
- 2. Login with your ADID and password for eLEARN



3. Go to "Marketplace" as shown.



4. On the "Course Marketplace (Catalogue)", click on HBR ERC Online V.2 and begin the course.



For more details, refer to the <u>eLEARN LMS Navigation Guide for HBR Online Course</u> available on the website <u>https://www.research.nhg.com.sq</u> > Conducting Research > Who can be a Principal Investigator > Minimum Training Requirements > HBR Essential Research Conduct (ERC) Course.

25. I'm able to login to eLEARN but unable to locate/ search for the course.

You can try logging in again via this link https://elearn.sg/nhg using your ADID and your password to eLEARN.

If you are still unable to access eLEARN, please contact the eLEARN Technical Support team at lmssupport@wizlearn.com or contact them at +65 6777 9661 (Monday – Friday: 7.30am – 9pm).

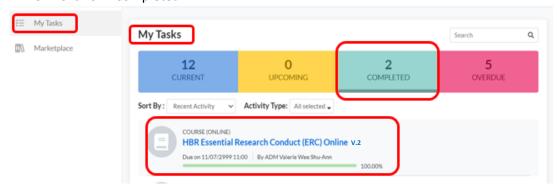


Alternatively, you may contact your institutions' eLEARN representatives.

26. Am I able to review the online content after I have completed the course?

Yes. To access the online content, follow these steps:

- 1. Log into https://elearn.sg/nhg
- 2. Go to "My Tasks"
- 3. Click on "Completed"



4. Click on the "HBR Essential Research Conduct (ERC) Online V.2" to review the content



27. I've completed my online course but I did not download a copy of my cert/ or I'm unable to locate my cert/ how can I re-print my cert?

To reprint/ download or locate your cert, follow these steps:

- 1. Log into https://elearn.sg/nhg
- 2. Go to "Completed Tasks" and search for HBR ERC Online (refer to above point, #26)
- 3. Click on the "HBR Essential Research Conduct (ERC) Online V.2"
- 4. On the left slide of screen, scroll all the way to the top left corner until you see "View your progress"
- 5. Click on "Download Certificate" and save a copy of it and remember to save a copy of it in the investigator file.





28. Can I view the HBR ERC Online V.2 on eLEARN using my mobile device?

Yes. You may do so by down loading the eLEARN LMS app available on the App Store (iPhones) and Play Store (Android).

Note: Mobile data charges applies.