
Office of Human Research Affairs**OneAegis IRB System Transition FAQs****1. What is OneAegis?**

[OneAegis](#) is an electronic IRB submission system that will replace iRIS for the submission and review of Einstein IRB protocols. It is part of the same electronic system the Office of Human Research Affairs (OHRA) has used for conflict of interest (COI) disclosure submissions since December 2024. It is also the same system that is already in use by BRANY, so the look and feel will be familiar to those of you who submit BRANY IRB protocols as well.

2. Why is a new IRB system being implemented?

OneAegis allows greater functionality than iRIS, offers a streamlined approach for IRB submissions, and allows integration with COI review.

3. When will OneAegis be available for IRB submissions?

OneAegis will go live on Thursday, 6/25. You will be able to submit new studies and post-approval submissions (e.g., amendments, continuing reviews, etc.) for open studies that were previously approved in iRIS.

4. How do I access the OneAegis system once it goes live?

OneAegis may be accessed at <https://einsteinmed.oneaegis.com>. You can log in using your Einstein or Montefiore email address and password. Anyone with an Einstein or Montefiore email address can log into the system without prior activation. You do not need a separate username or password to access the system.

5. Will I continue to be able to submit new IRB protocols and submissions in iRIS during the transition?

As we transition to OneAegis, there will be a 10-day blackout period during which we cannot accept new IRB submissions, including progress reports and amendments. This blackout period will begin on Monday, 6/15 at 6 pm EST. A blackout period is necessary to transfer electronic records for thousands of protocols from iRIS to OneAegis. Please plan accordingly and submit any urgent IRB submissions prior to this date.

Exceptions will only be made on a case-by-case basis for submissions related to immediate patient safety concerns or NIH funding requirements (e.g. Just-in-Time submissions). These exceptions include emergency use, single patient treatment INDs or IDEs, reportable events, and protocol exception requests to continue necessary research treatments during a lapse of IRB approval. Please contact Stefanie Juell, Executive Director, at stefanie.juell@einsteinmed.edu, if you need to submit an emergency submission.

6. What will happen to my pending submissions in iRIS?

Any new submissions that *have been submitted on or before 6 pm EST on 6/15* will be processed in iRIS. Please plan accordingly when submitting, as all department chair and other signoffs must occur before the submission is received by the IRB.

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Any submissions that are currently pending a response to stipulations in iRIS must be returned to the IRB with the stipulations addressed no later than 6 pm EST on Sunday, 7/5.

7. Can we continue to use iRIS for IRB submissions after the transition?

No, iRIS may not be utilized for IRB submissions on or after the OneAegis implementation date. Active IRB protocol records will be transferred to the new system. iRIS will be deactivated after the transition is complete.

8. What will happen to my existing active and closed studies in iRIS?

Records of existing active and closed studies, inclusive of study documents, will be converted over to OneAegis.

9. Are there any changes in COI disclosure requirements for IRB submissions?

We have simplified the COI disclosure process for personnel on IRB submissions. At the time of submission, you will automatically be informed if any investigators do not have a current COI disclosure on file. There will be no more surprise “COI denials” that occur after you have submitted a protocol.

Please note, only individuals listed as Principal Investigator or Co-Investigator are required to have a COI disclosure on file. Regulatory coordinators, research assistants, students/trainees, and study site coordinators are not required to submit COI disclosures for IRB submissions.

10. Will training on the new system be offered?

The OHRA will offer Zoom training sessions in the month of June beginning on Monday, 6/8. A mix of in-person and Zoom training sessions will be offered in the month of July. Advance registration is required. To view the training schedule and register for a session, please click [here](#).

11. Who do I contact with questions?

Please contact the Office of Human Research Affairs at irb@einsteinmed.edu or call 718-430-2237. OHRA staff are also available for questions via the bookings tool listed in all our email signatures. Please click [here](#) to make a booking.

12. How do I download current study documents for my studies in iRIS?

Please contact the Office of Human Research Affairs at irb@einsteinmed.edu or call 718-430-2237 if you need assistance obtaining study documents from your studies in iRIS.