

WCMC-NY & WCMC-Q Institutional Review Board (IRB) Authorization Agreement

The WCMC-NY and WCMC-Q IRBs are listed on the same FWA. Regulations of the Qatar Supreme Council of Health (SCH) require that research in or funded by Qatar be reviewed by an IRB in Qatar under a valid Assurance, such as the one held by WCMC-Q.

All of the following conditions apply to those protocols that are conducted in collaboration between WCMC-NY and any Qatari institution.

1. Certifications that projects funded by or conducted in Qatar are not human subjects research or are exempt from IRB review must be made by or in consultation with the WCMC-Q Human Research Protection Program.
 - a. Such a certification by one Human Research Protection Program (HRPP) may be considered valid for both campuses upon mutual agreement by the HRPPs.
 - b. Human subjects research that is not exempt from IRB review will be reviewed in accordance with Sections 2-8.
2. The WCMC-Q IRB will be the IRB of record and perform a collaborative review for any project funded by a Qatar-based funding entity (such as the Qatar National Research Fund).

NOTE: Sections 3-5 refer only to those projects not covered by Section 2 above.

3. The WCMC-Q IRB will be the IRB of record and perform a collaborative review for those projects with subjects only in Qatar (or materials obtained only from subjects in Qatar).
4. The WCMC-NY IRB will be the IRB of record and perform a collaborative review for those projects with no subjects (or materials) in Qatar.
5. The WCMC-Q IRB and WCMC-NY IRB will each perform a review and serve as the IRB of record for the respective campus for those projects with subjects (or materials) both in Qatar and elsewhere.
 - a. As needed, the HRPPs shall determine how best to distribute responsibility for subjects in locations other than Qatar or New York.
 - b. The HRPPs shall coordinate their reviews to the extent possible in order to minimize discrepancies between protocols and duplication of work for investigators.
 - c. The HRPPs may institute a collaborative review and designate one IRB of record on a case-by-case basis and by mutual agreement.
6. If changes are made to a protocol currently approved by one IRB such that the other IRB should be the IRB of record (for example, the addition of

funding from a Qatar-based entity to a protocol that was previously approved by the WCMC-NY IRB, the IRB of record will:

- a. Conduct collaborative reviews of that amendment and all subsequent submissions until the next scheduled continuing review.
- b. Transfer responsibility for the protocol to the other IRB at the next continuing review, with all subsequent reviews conducted according to the terms of this agreement.

7. Collaborative reviews will be conducted as follows:

- a. Investigators will submit protocols for review according to the methods and procedures of the IRB of record.
- b. Once a protocol has been reviewed and approved by the IRB of record, all subsequent submissions, reviews and approvals for that protocol will be done through that IRB.
- c. At least one IRB member from the other campus will be assigned as a reviewer on the protocol with full access to protocol materials.
 - i. By mutual agreement, the other campus may forego this step and rely fully on the IRB of record (except in cases where the project poses greater-than-minimal risk).
- d. Both campuses are required to comply with the terms of the Federalwide Assurance filed with the US Office for Human Research Protections.
 - i. Activities in or funded by Qatar must also be in compliance with the terms of the Assurance filed by WCMC-Q with the SCH.
 - ii. Any differences between US and Qatari subject protections shall be resolved in favor of the more stringent protection.
- e. The HRPP of either campus may opt out of collaborative review on a case-by-case basis, with notice to the other HRPP, in order to conduct an independent review.

8. Either campus may limit its participation in a given research protocol based on the local context.

Administrative Issues

1. The WCMC Institutional Official and QA/QI coordinator will have full access to WCMC-Q IRB records.
2. The director of the WCMC HRPP will serve as an alternate member of the WCMC-Q IRB, and will be given reviewer level access to WCMC-Q protocols.
3. The WCMC-Q director of research compliance will serve as an alternate member of the WCMC-NY IRB.

We the undersigned, as the signatory officials to the US Federalwide Assurance and the Qatar Supreme Council of Health Assurance respectively, agree to the arrangements described .