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Weill Cornell Medicine

WCM & WCM-Q Institutional Review Board (IRB) Procedural Agreement

WCM and WCM-Q hold separate Federal Wide Assurance (FWA) filed with the United States Office of Human Research Protections (OHRP). The WCM-NY and WCM-Q IRBs are listed on the same IRB Registration with OHRP. Regulations of the Qatar Ministry of Public Health (MoPH) requires each institution that is engaged in human subjects' research to have a valid Assurance with Department of Research of MoPH. Review by a local IRB in Qatar is a must when there is collaboration with a foreign engaged institution for projects either funded by or conducted in Qatar. Currently WCM-Q and WCM-NY have and will maintain separate assurances active with MoPH.

All of the following conditions apply to those protocols conducted in collaboration between WCM-NY and WCM-Q. "WCM Faculty employee investigator" refers to faculty, employees, or students at either WCM-Q or WCM-NY.

1. Certifications that projects funded by or conducted in Qatar by WCM-Q investigator are not human subject research or are exempt from IRB review must be made by the WCM-Q Human Research Protection Program (HRPP).

    a. Such a certification by one HRPP may be considered valid for both campuses upon mutual agreement by the HRPPs.
    b. Human subject research that is not exempt from IRB review will be reviewed in accordance with Sections 2-8.

2. WCM-Q IRB will be the IRB of record and perform a collaborative review for any project with a WCM-Q investigator funded by a Qatar-based funding entity (such as the Qatar National Research Fund or Qatar Foundation). If research subjects for this study reside both in Qatar and elsewhere, review by the WCM-NY IRB may also be indicated (see item 6 below).

    NOTE: Sections 3-6 refer only to those projects not covered by Section 2 above.

3. WCM-Q IRB will be the IRB of record and perform a collaborative review for those projects with a WCM-Q investigator(s) and with subjects only in Qatar (or materials obtained only from subjects in Qatar).

4. The WCM-NY IRB will be the IRB of record and perform a collaborative review for those projects conducted by a WCM-Q or WCM-NY investigator whose subjects (or material) are in the United States, with no subjects (or materials) in Qatar.

5. WCM-Q IRB and WCM-NY IRB will each perform a review and serve as the IRB of record for the respective campus for those projects with subjects in both Qatar and elsewhere.

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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 switch to a collaborative review and designate one IRB of record on a case-by-case basis 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 WCM-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. This transfer may require re-review of the protocol by either WCM-Q or WCM-NY IRB.

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 FWA filed with the United States OHRP in all research
        i. WCM-Q is also required to comply with the terms of Assurance filed with the MoPH in Qatar. WCM-NY is also required to comply with the terms of MoPH assurance only when WCM-NY is engaged in HSR funded by Qatar or when its' employees intervene or interact with human subjects for research purposes in Qatar or when WCM-NY obtains from Qatar individually identifiable private information about human subjects for research purposes.
        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 cultural and political context.

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Administrative Issues

1. Timothy Wilkin, as the Institutional Official for WCM-NY, Javaid Sheikh as the Institutional Official of WCM-Q and Rayaz Malik as the Organizational Official of WCM-Q will have full access to the WCM-Q IRB online system.
2. The WCM-Q IRB will be comprised of members from both WCM-NY and WCM-Q, as well as community members from Qatar and if desired, NYC. The composition of the WCM-Q IRB is subject to approval by MoPH in Qatar
   All protocols requiring full-board review submitted to the WCM-Q IRB will be reviewed by two reviewers, one from NYC and one from Qatar. The convened board must be notified of all expedited protocols approved since the last convened meeting
3. Amal Robay will be added to the WCM-NY IRB rosters as an alternate scientific member.

Timothy Wilkin, M.D
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Weill Cornell Medicine, New York

Signature: DocuSigned by: CB4F4733A13D473...

Date: 6/16/2021

Javaid I. Sheikh, M.D., M.B.A.
Dean and Professor
Weill Cornell Medicine-Qatar

Signature:

Date: June 21st, 2021