QNRF Requirements for the Certification and Assurance in Research Involving Human Subjects

I. Initial Review Certification (IRB approval letter for initial review) Requirements

The Institutional Review Board (IRB) final approval letter\(^1\) (approval letter for initial IRB review) should contain the following required information:

1. The date when the final approval letter was issued by the IRB office;
2. Title of the research study that was reviewed and approved by the IRB;
3. Name of the Lead Principal Investigator (LPI) approved by the IRB and responsible for the conduct of the study\(^2\);
4. A list of documents that were reviewed and approved by the IRB for the initial review, with the version that was reviewed and approved by the IRB. The list should include: the research study protocol; the consent form (if a request for waiver of consent; or waiver of documentation of consent were approved, please state so); recruitment materials, if any; any other materials that were reviewed and approved by the IRB during the initial review of the research study. QNRF reserves the right to access and audit the IRB files.
   i. **Note:** Recording the version of the research study protocol, consent form, and recruitment materials will help the research team, the regulatory body and funding bodies tracking the modifications of the above referenced materials after their initial review and approval; and making sure that all the modifications were approved by the IRB.
5. The type of review that was conducted by the IRB for a specific study:
   a. expedited review;
   b. full committee review (for greater than minimal risk research);
   c. exempt from IRB review\(^3\);
6. For expedited review and exempt research: the category of expedited review or exempt under which the IRB approved the expedited review request/granted the exemption;
7. For expedited review and exempt research: the name of the IRB Chair/designee who approved the expedited review request/granted the exemption;

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\(^1\) QNRF will collect (all) the IRB determination letter(s) from the submitting institution. The submitting institution must collect the IRB determination from all the submitting institution collaborators, domestic and/or foreign.

\(^2\) The Lead Principal Investigator of the grant is viewed by QNRF as the principal investigator on the IRB application and is the one responsible to receive all the IRB certifications from all her/his collaborators (for multisite studies).

\(^3\) The IRB is the only regulatory body that may grant an exemption, according with the Qatar Supreme Council of Health’s regulations for research involving human subjects.
8. For research approved under expedited review or approved by the full committee (greater than minimal risk):
   a. the approval date;
   b. the expiration date.

II. Continuing Review Certification (IRB approval letter for continuation) Requirements

1. Date when the continuation approval letter\(^4\) was issued by the IRB office;
2. Title of the research study that was reviewed and approved by the IRB;
3. Name of the Lead Principal Investigator (LPI) approved by the IRB and responsible for the conduct of the study;
4. A list of documents that were reviewed and approved by the IRB for the request for continuation review, with the version that was reviewed and approved by the IRB. The list should include: the research study protocol; the consent form (if a request for waiver of consent; or waiver of documentation of consent were approved, please state so); recruitment materials, if any; any other materials that were reviewed and approved by the IRB during the initial review of the research study;
5. New approval and expiration dates for the research study approved for continuation (for research approved under an expedited review category; or for research approved by the IRB full committee).

III. Other required IRB determination letters:

The Lead Principal Investigator responsible for the conduct of the study should notify QNRF, and include the IRB determination letter, when one or more of the following issues occur:

- a research proposal that received funding from QNRF is disapproved by the IRB;
- a serious adverse event that is unexpected, related or possibly related to participation in the study, and suggests that the research places subjects or others at a greater risks of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, and resulted in suspension of new enrollment by the IRB;
- a major study deviation\(^5\) that resulted in suspension of new enrollment by the IRB.

QNRF will hold the funding during the IRB suspension of new enrollment; if the IRB will suspend the study or the Lead Principal Investigator, QNRF will terminate the award and will take the appropriate steps based on the IRB determination letter.

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\(^4\) QNRF will collect the final approval letter only from the main awardee of the grant. It is the sole responsibility of the main awardee to collect the final IRB approval letters from all collaborators inside or outside Qatar.

\(^5\) Deviations may be classified as minor or major. The criteria for major deviations may vary but often include factors having a significant impact on consent, eligibility, treatment, reporting of toxicity, participant risk and safety, disease outcome, regulatory compliance and data quality. A major deviation may affect the outcome, analysis or interpretation of the study. A minor deviation is a deviation that does not affect the outcome, analysis or interpretation of the study and otherwise does not meet the definition of a major deviation but may still need to be described in publications. [caBIG™].
IV. Qatar Supreme Council of Health’s IRB Certification and Assurance Requirements

QNRF strictly follows the Qatar Supreme Council of Health (QSCH) regulations for research involving human subjects. QSCH regulations state that “Under no condition shall research covered by (QSCH) Policy be supported or conducted prior to receipt of the certification that the research has been reviewed and approved by the IRB.” According to the QSCH regulations, institutions conducting research with human subjects in Qatar must have an assurance filed with and approved by the QSCH.

All research conducted in Qatar must be reviewed and approved by an IRB “established in accordance with the requirements of (QSCH) policy”.

In case the institution filling a request for assurance with QSCH does not have its own IRB, the institution should contact one of the institutions with an established IRB in Qatar that conducts and reviews similar research as the institution filling the assurance request (e.g. a Social-Behavioral IRB for social-behavioral research). QSCH’s regulations require that the IRB listed on the institutional assurance should be adequate for the type of research conducted by the institution filling the assurance request; when reviewing a request for assurance, QSCH will most likely look at “…the adequacy of the proposed IRB in light of the anticipated scope of the research activities and the types of subject populations likely to be involved…”.