NHG RESEARCH EDUCATION

Qualité

Education to facilitate high standards of research conduct

Issue 27, July 2017

Monitoring for HBR (Exempt & Expedited) Studies

Synopsis

Effective March 2017, new Principal Investigators (PI) in NHG conducting expedited reviewed Human Biomedical Research (HBR) studies involving consent procedures will be required to monitor their studies using the PI Self-Assessment Form.

Background

Human Biomedical Research Act (HBRA), part 5, section 23(2) requires each Research Institution to proactively monitor its HBR studies. In NHG, a monitoring framework is being developed to meet this legal requirement. This article describes the approved monitoring program and resources for exempt and expedited reviewed studies. More information on the monitoring program for Full Board reviewed studies will be released in subsequent articles.

PI Self-Assessment Form (PISAF)

The PISAF is a tool that will be used for the monitoring of exempt and expedited reviewed studies. The PISAF is a self-assessment form that contains a set of questions about DSRB and regulatory requirements. With this tool, PIs can self-monitor their study progress, identify and rectify gaps. Some examples of PISAF questions are:

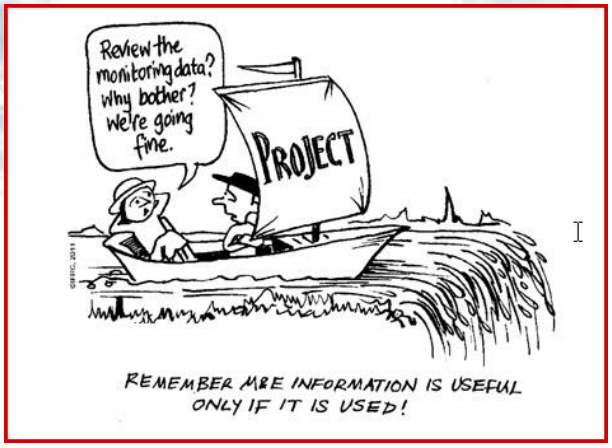
1. Have you recorded relevant trainings for all study team members and filed the records in the investigator file? E.g. training record form/log to record the training on the study, CITI/GCP certs, CVs.
This question reminds the PI of the responsibility to maintain all team members' training certs as well as a training record form for the protocol specific trainings such as consent taking, study design.

2. Did you document study specific roles and responsibilities (including consent taking by team members approved by DSRB) in the study responsibility/ delegation log?
This question reminds the PI of the responsibility to maintain a signed and dated study delegation log containing team members' roles and responsibilities. Help resources are also linked so that the PI can refer to the relevant policy readily.

3. Was the ICF and/or translated short consent form personally signed and dated by all relevant parties where appropriate?
This question reminds the PI of the responsibility to ensure that all parties involved in the consent process should sign and date personally. A help link to the PCR SOP 501-C01 (Informed Consent Form and Process) is provided for ease of reference on how proper informed consent for subjects should be taken.

Self-Monitoring of Exempt Studies

PIs conducting exempt reviewed studies can freely access the PISAF as a tool to monitor their studies periodically. These forms may be voluntarily submitted to the NHG Research Quality Management (RQM) team for an independent review.



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Monitoring of Expedited studies

Expedited studies carry some risks. To help first time investigators understand their roles and carry out their responsibilities more effectively, a subgroup of PIs will be selected to use the PISAF as a mandatory form of monitoring effective March 2017.

The selected New NHG PIs will be informed by the Research Quality Management Team to complete the PISAF for its review.

Issues Identified Through PISAF

Through the use of the PISAF, PIs get to self-monitor and rectify issues in research conduct early.
Examples of common errors identified and resolved timely through this program include:

1. Study documents are only stored electronically. This practice is not encouraged unless an audit trail is captured within the electronic filing system.

2. Lack of a delegation log. At minimum, if the PI is the only study team member, a PI sample signature log would be required. This allows for data attribution, which means the person who made the data entry can be verified against the endorsed signature.

3. Lack of documentation of the informed consent process. Informed Consent is not a one-time action of signing and dating on the document; it is a process. In the informed consent process, person who took consent should explain the content of the informed consent form, engage an impartial witness or translator where appropriate, and provide a copy of the signed consent document to the subject. After each consent action, there should be proper documentation in the source document. For many studies, this refers to the subjects' medical records.

Conclusion

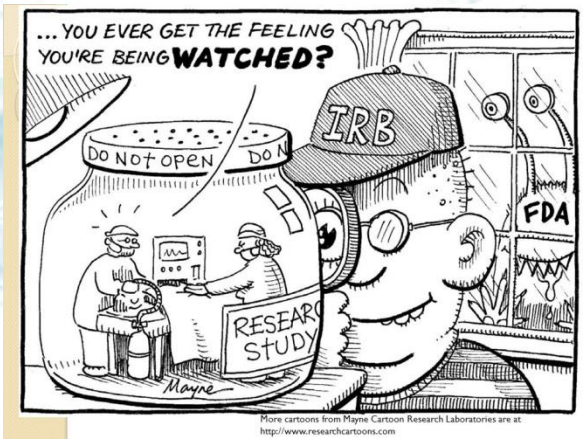
New PIs are highly encouraged to use the tool to monitor their studies so that they can become familiar with key regulatory requirements. This will benefit the conduct of their current and future studies. Seasoned PIs too can opt to use the tool regularly as a quick and easy method of tracking essential documentations and check on consent processes, so as to maintain a high quality of research conduct.

The PISAF is openly accessible on the NHG Research website for all investigators and study team members to download and use.

PISAF Research Website Link:
https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/02+ethics+and+quality/research+quality/self+assessment

Contact Details

If you have any feedback or enquiries on the monitoring program, please contact us at **researchquality@nhg.com.sg**.



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