

## IRAS Form guidance for Queen Mary and Barts Health

General points:

- Ensure consistency across all documents (IRAS, Protocol, PIS etc.). Vitrally important that all details such as Protocol version and date, inclusion and exclusion criteria, samples size, study interventions etc. are consistent across documents.
- Do not just copy and paste from the Protocol or other documents. The IRAS form needs to be completed in lay language and be very clear about responsibilities and roles.
- Ensure all sites (including unconfirmed potential sites) are listed in Part C.
- Justify in full any change in standard clinical care or any additional invasive intervention proposed.

### Question-specific answers

The following is question-specific standard wording to include in your IRAS form,

#### Question A4

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#### Question A42

This should be the Chief Investigator

#### Question A44

20 years

#### Question A45

The research data will be archived for 20 years according to Queen Mary University of London/ Barts Health NHS Trust policy. The data will be archived in the Barts Health Corporate Records Facility.

#### Question A64

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#### **Question A68-1**

***ONLY WHEN BARTS HEALTH NHS TRUST IS THE LEAD RESEARCH SITE IN THE STUDY (AND LISTED IN PART C):***

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#### **Question A74**

The Sponsor or delegate retains the right to audit any study, study site or central facility. In addition, any part of the study may be audited by the funders where applicable.

#### **Question A76-1**

*QM Sponsored:*

Select "Other insurance or indemnity arrangements will apply".

Add the following sentence:

The insurance that Queen Mary University of London has in place provides "No-Fault Compensation" for participants which indemnify a research participant for negligent and non-negligent harm.

*BH Sponsored:*

Select "NHS indemnity scheme will apply"

#### **Question A76-2**

*QM Sponsored:*

Select "Other insurance or indemnity arrangements will apply".

Add the following sentence:

The insurance that Queen Mary University of London has in place provides "No-Fault Compensation" for participants which indemnify a research participant for negligent and non-negligent harm.

*BH Sponsored:*

Select "NHS indemnity scheme will apply"

#### **Question A76-3**

- Research conducted at NHS site(s) only: tick NHS box
- Research conducted at both NHS and non-NHS site(s): tick both boxes

- Research conducted at a non-NHS site(s) only: tick non-NHS box

To access full guidance on the IRAS form visit the [Help section of the MyResearch website](#).