

Key Enhancements to the DSRB Application Form

Updated on 17 August 2016

Background

DSRB Application Forms (for Biomedical & Population Health studies) have been streamlined to make the questions and options clearer, neater and simpler.

This is to provide a user-friendly Application Form for Investigators to apply for DSRB approval.

Deployment Date: 10 August 2016

Key Enhancements (1/12)

New

Main Page

Specific descriptions for each section can be found [here](#)

Please select the appropriate form for submission to the DSRB. Please refer to the explanatory notes below if you need more information.*

- DSRB Application Form 1 - Non Exempt Category [*Click here for help](#)
- DSRB Application Form 2 - Exempt Category [*Click here for help](#)

Research activities in which the only involvement of human subjects will be in one or more of the following categories may be able to qualify for the Exempt category.

Please click on the DSRB Application Form 2 - Exempt Category option above to view the categories.

Don't know which to choose? [Click here](#)

- Enhancements have been made to refine the Help Links' contents for clarity and add new Help Links to “problematic” sections.
- E.g. There is now a direct link to the ROAM Application Guidebook that is available for download. This can be used as a companion guide when completing the DSRB Application Form. An updated version will be released in October to align with the revised Application Form.

Key Enhancements (2/12)

New

Section E - Study Funding Information

E1 Who will be responsible for the payment and compensation of injury or illness arising from participation of research participants in the study?*

- National Clinical Trial (CT) Insurance Policy (Contact your institution research office for more information)
- Sponsor
- Others

Old

E1 Who will be responsible for the payment and compensation of injury or illness arising from participation of subjects in the study?

The PI should ensure that insurance coverage is available to provide payment and compensation to research subjects for injury or illness arising from their participation in the study.

(Note: For investigator-initiated studies - Contact your OBR/CRU for more information on available NHG Clinical Trial Compensation Insurance Scheme.

For Sponsored Studies - Sponsors should be primarily responsible for ensuring that subjects receive payment and compensation in the event of injury or illness as a result of their participation in a research study.)*

NHG Clinical Trial Insurance Scheme

Text Box

- Text box has been replaced with radio buttons for ease of completion.

Key Enhancements (3/12)

New

E3 Will the funding cover all subject study-related drugs, devices, procedures, tests and visits? * [Click here for help](#)

Yes

No

Please explain how the shortfall will be made up.*

Not Applicable (No subject study-related costs)

Old

E3 Who will be responsible for research-related costs? For sponsored studies, please list the costs that will be borne by the sponsor. You may wish to attach the Financial Agreement / Clinical Trial Assurance if it is available. * [Click here for help](#)

The Grant will be responsible for all research related costs.

Text Box

Reinvestment funds grant letter.pdf

Extension_SMF.pdf

- Question has been re-designed.
- Additional information/justification is needed only when the research-related costs need to be borne by others (e.g. participants).

Key Enhancements (4/12)

New

F16 What is the estimated time needed to conduct this study?*

No. of Years *

1

No. of Months *

0

Old

F17 What is the estimated timeline for this study? [Click here for help](#)

Estimated Start Date: *

01-Aug-2012

Estimated End Date: *

31-Dec-2013

Estimated duration for this study: **1**year(s) **5**month(s)

- Question has been re-designed.
- The estimated duration of the study is more critical than the start and end date.
- PIs may under-estimate the timeline and often need to make changes to this section.

Key Enhancements (5/12)

New

H1 How will potential research participants be identified?*

- Referral by attending healthcare professional
- Persons with dependent relationship with study team (e.g. doctor-patient, employee-employer, head-subordinate, student-teacher, departmental staff relationship)

Please describe how the study team will manage the dependent relationship to prevent coercion or undue influence.*

The related sections/questions are now placed together so that PIs can answer them simultaneously.

Old

Section H - Recruitment Details

H1 How will potential subjects be identified? (Please tick all the applicable boxes)*

- Referral by attending healthcare professional
- Patients of study team
- Databases
- Other methods of subject identification

K6 Do the potential research subjects have a dependent relationship with the study team (E.g. doctor-patient, employee-employer, head-subordinate, student-teacher, departmental staff relationship)?

Note: If you have selected that subjects are 'Patients of study team' in Section H1, then the answer should be 'Yes'. * [Click here for help](#)

Yes

No

Key Enhancements (6/12)

New

Section O - Research Participant - Cognitively-Impaired Persons

O1 Please state and justify the reasons for including cognitively impaired persons in this study.*

Old

Section O - Research Participant - Cognitively-Impaired Persons

O1 Is this research relevant to this group of subjects who are cognitively-impaired?*

Yes

Please justify:*

No

- Question has been re-designed.
- This section will appear only if PI selected that the study would involve cognitively impaired persons. Hence, it was redundant to ask if the research is relevant to cognitively impaired persons; the justification was more critical.

Key Enhancements (7/12)

New

Section P - Consent Process - Consent obtained

P1 Describe when the consent process will take place with the potential research participant, including the time provided for him/her to consider his/her participation in the study. [Click here for help](#)*

a

P2 Where will consent be taken (e.g. room, ward, outpatient clinic etc)? How will privacy, freedom from intrusion and comfort be ensured? [Click here for help](#)*

a

P3 Who will take consent from potential research participants (e.g. PI, Co-Investigators etc)? [Click here for help](#)*

a

Old

P4 Please describe the consent process as follows: (i) Explain if adequate time will be given to the subject to consider their participation. (ii) Describe if the place where consent is taken, allow the subjects to have the right frame of mind to consider participation and (iii) explain how the person taking consent minimize the possibility of coercion or undue influence. * [Click here for help](#)

- Section has been streamlined.
- For example, P4 was removed and incorporated into other related sections.

Key Enhancements (8/12)

New

Section R - Research Data Confidentiality

Text Box has been replaced with radio buttons for ease of completion, minimise error and need for query.

R In general, to protect the Research Participant's confidentiality, research data should be coded, and the links between the Participant's identifiers and the codes should be stored separately from the research data.

R1 Will coded / anonymous research data be sent to the pharmaceutical sponsor?*

- No, the study team would store all research data within the institution

R1(i) Please state how the research data will be protected to ensure confidentiality and security.*

- For hardcopy data, they will be stored in designated locked cabinet(s) or room(s) that are accessible to authorized study personnel only.
- For electronic data, they will be stored on in a secured computer that is password-protected. The databases will not contain subject identifiers and the data linking subject identifiers and the subject identification codes will be stored separately. When portable media (e.g. CD, USB drives etc.) are used to store the data, subject identifiers are stored separately.

Old

i. Please state where the research data (soft copy and/or hardcopy) will be stored and indicate if the location storage is secured (i.e Password Protected PC or Laptop, data stored in physical location with lock and key access.)*

(1) The research data generated from the coded tissue specimens are stored in the PI's PC in the department office where key access is allowed only for authorized individuals; (2) the key to the coded tissue specimens are stored in a portable hard disk in the department office cupboard that is locked by key and accessible only to the PI; (3) No hard copy of the data will be stored.

Text Box

Key Enhancements (9/12)

New

iv. Will the research data be used for future research after the study is completed?*

- No, the research data will be destroyed after it has been stored for 6 years or minimum duration of retention period as specific by your institutional policy, whichever that is longer.
- Yes, the research data will be used for future research. Please register a standing database with DSRB.

Old

v. Describe what will happen to the research data when the study is completed. * [Click here for help](#)

The data will be stored for a period of 5 years, after which it will be destroyed.

Text Box

- Text box has been replaced with radio buttons for ease of completion, minimise error and need for query.

Key Enhancements (10/12)

New

Section S - Biological Materials Usage & Storage

S1 Will any biological materials (such as blood or tissue) be used as part of the study?*

- No
 Yes

i. (For prospective biological materials only). Please state the type of biological materials used and describe how they will be obtained. Please include the frequency of collection, the amount collected each time and the total amount collected for the research study.*

ii. (For existing biological materials only). Please state the type of biological materials used and the source, i.e. tissue repository, DSRB reference.*

Section has been streamlined.
The required information is now divided within 2 questions.

Old

S1 Will any biological materials (such as blood or tissue) be used as part of the study? This includes both prospectively collected and existing biological materials.*

- No
 Yes

i. Please state what biological materials are used and whether they are obtained prospectively or existing.*

Blood, urine and any other components from the cells of samples will be collected and stored.

ii. For prospective biological materials, describe how they are obtained. For existing biological materials, please state the source.*

Blood will be drawn and urine will be collected from subjects as per the protocol study schedule.

iii. With regard to the collection of biological materials, please state: (i) the frequency of collection; (ii) the amount collected each time and (iii) the total amount collected for the research study.*

Blood and urine collections will be performed according to the study schedule. Blood will be taken from the subject about 5 times during the study: once during initial screening, and once about 2 weeks, 6 weeks, 10 weeks, and 14 weeks after subject starts the study drug. At each of these times, between 1 to 2 tablespoons (15 - 30 milliliters) of blood will be collected from the subject. If the subject completes the entire study, the total amount of blood collected from the subject will be about 8 tablespoons (120 milliliters). More blood may be collected from the subject if additional testing is needed for subject's safety.

Key Enhancements (11/12)

New

Section T - Data & Safety Monitoring

T1 Who performs the data and safety monitoring? * [Click here for help](#)

- Principal Investigator and/ or Study Team
- Data Safety Monitoring Board (DSMB) (Please submit the DSMB charter)
- Others

[Attach New/Replace](#)

T2 Please state the Safety Monitoring plan, i.e. frequency of review (e.g. daily, weekly, quarterly) and type of data (e.g. adverse events/serious adverse events) will be monitored.

T3 Please state the Data Monitoring plan, i.e. frequency of review (e.g. daily, weekly, quarterly), how data integrity is assured. * [Click here for help](#)

Text box has been replaced with radio button for ease; minimise error and re-query.

Questions have been re-phrased for clarity.

Old

T1 Who performs the data and safety monitoring? If there is a Data Safety Monitoring Board (DSMB), please submit the charter of the DSMB. *

[Click here for help](#)

Text Box

T2 Please describe the frequency of review (e.g. daily, weekly, quarterly) and what data (e.g. adverse events/serious adverse events) will be monitored for safety. * [Click here for help](#)

T3 How is data integrity monitored to ensure that study data is authentic, accurate and complete, and if the data correlates with the case report forms? * [Click here for help](#)

Key Enhancements (12/12)

- Examples of questions which have been removed/added

Section F - Research Methodology

F1 Please provide an abstract of your proposed research (Up to 300 words).

Your abstract must contain: *

Aims
Methodology
Importance of proposed research to science or medicine
Potential benefits & risks

Redundant as the information can be found in other sections.

H6 What is the Recruitment Period (if applicable)? Please provide us with the approximate recruitment period.

[Click here for help](#)

Start Date: 01-Aug-2012

End Date: 30-Sep-2013

Period of study recruitment period: 1year(s) 2month(s)

Redundant and often confused with study timeline.

I3 Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.*

a

This question was missing in the Domain F App Form and reviewers have often asked the study team to explain strategies to manage potential challenges. Hence it was added to minimise additional query.