Key Enhancements to the DSRB Application Form

Updated on 17 August 2016

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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

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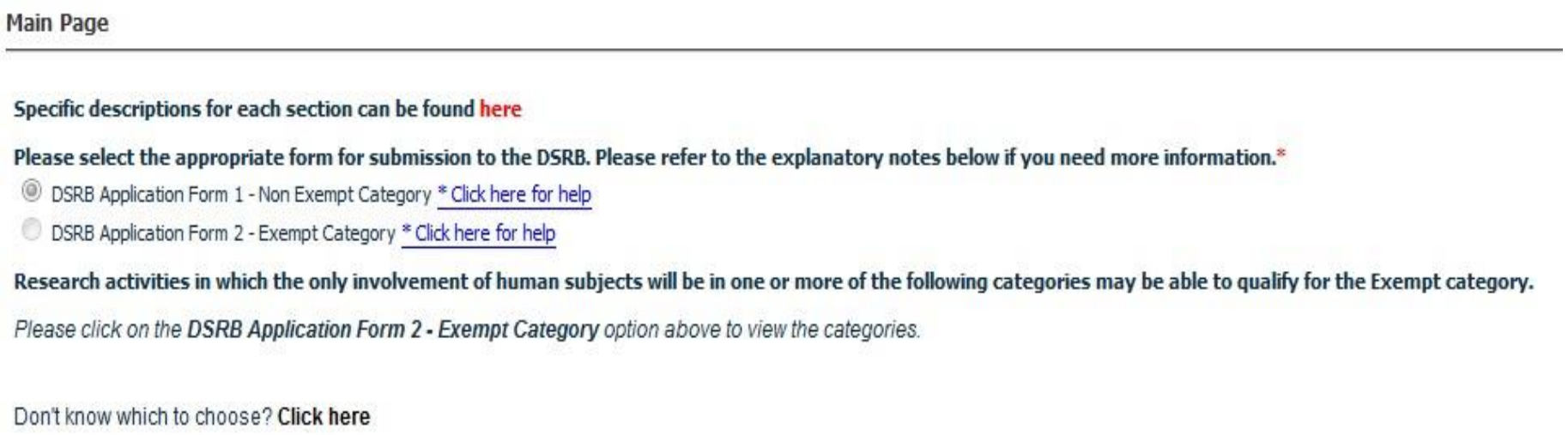
Key Enhancements (1/12)

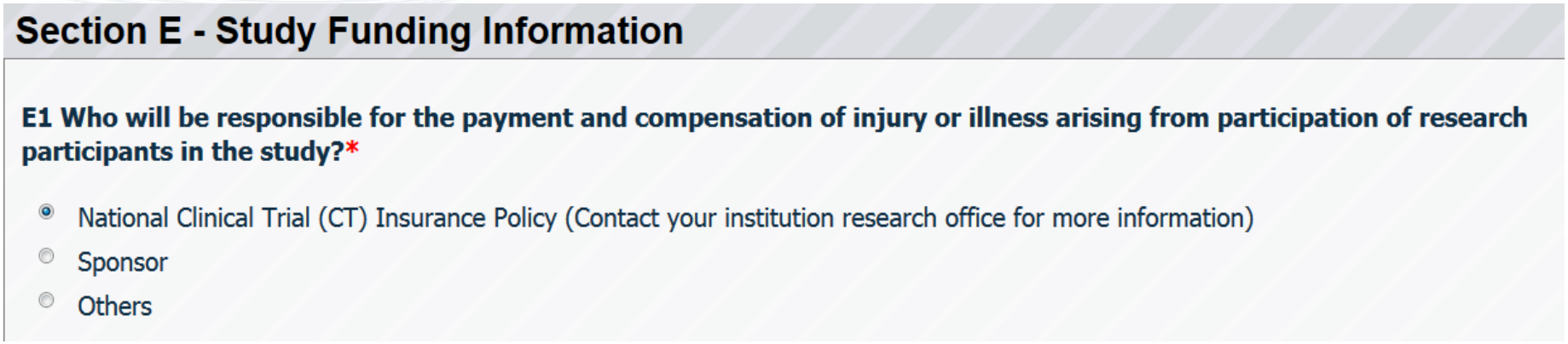
New



- 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.

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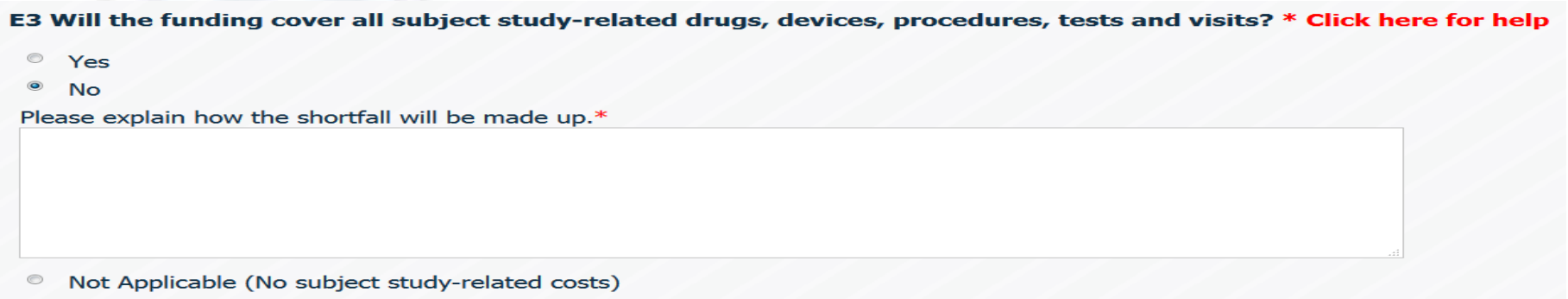
Key Enhancements (3/12)

New



Old

- 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).

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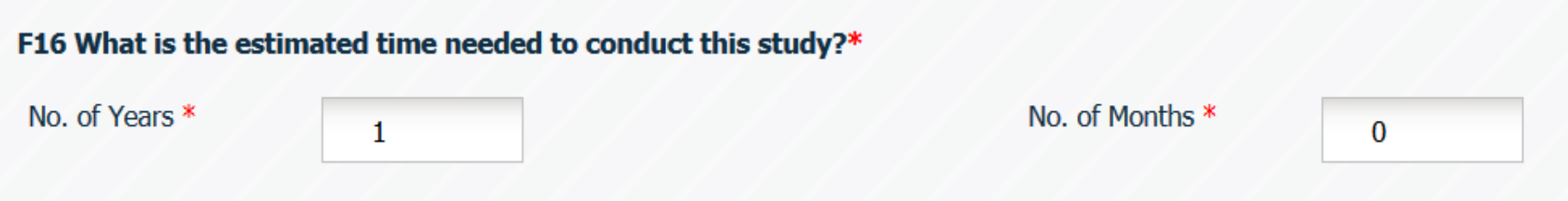
Key Enhancements (4/12)

New



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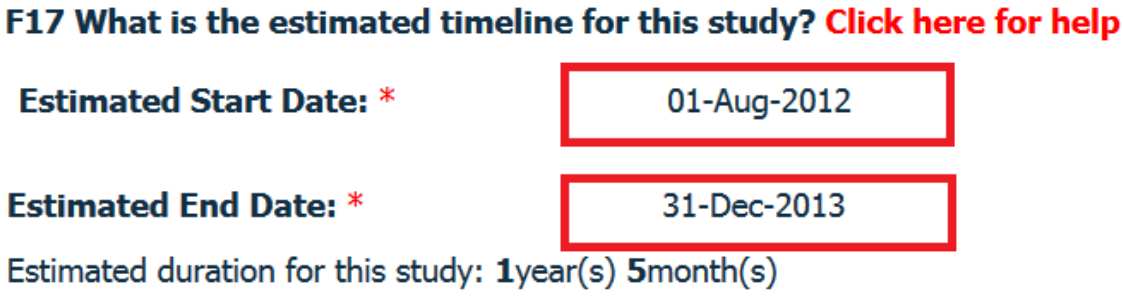

- Question has been re-designed.
- The estimated duration of the study is more critical than the start and end date.
- PIs may under-estimate the timeline and often need to make changes to this section.

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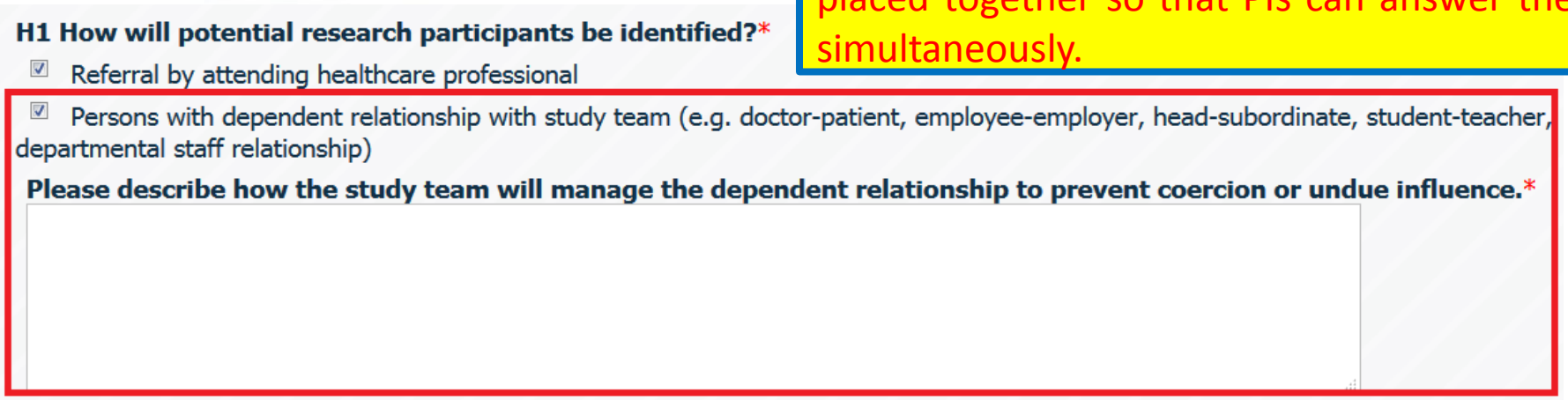
Key Enhancements (5/12)

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

New



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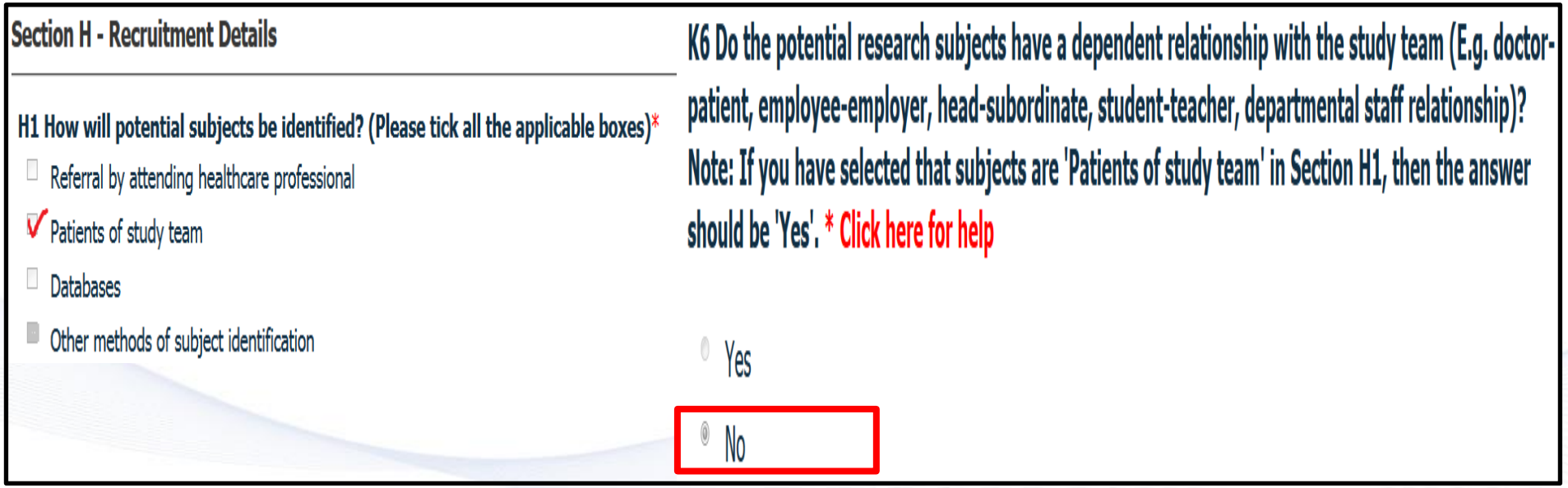
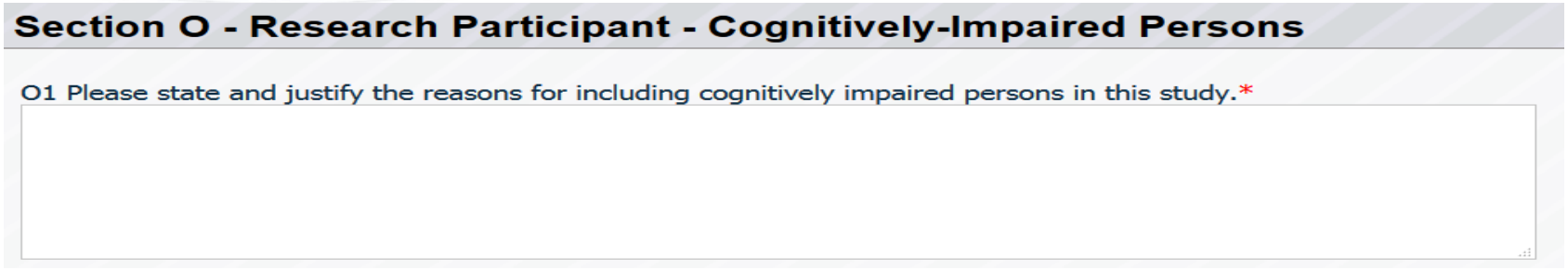


Key Enhancements (6/12)

New



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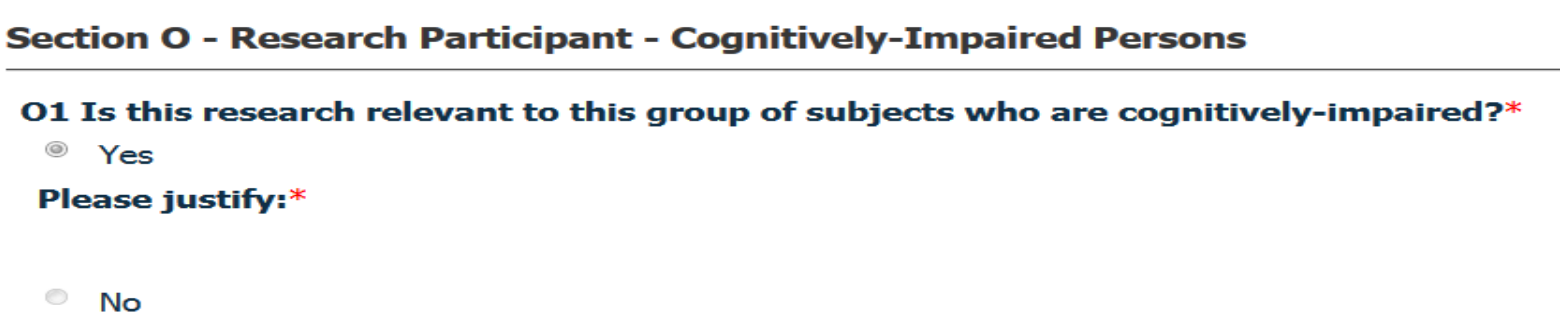

- Question has been re-designed.
- This section will appear only if PI selected that the study would involve cognitively impaired persons. Hence, it was redundant to ask if the research is relevant to cognitively impaired persons; the justification was more critical.

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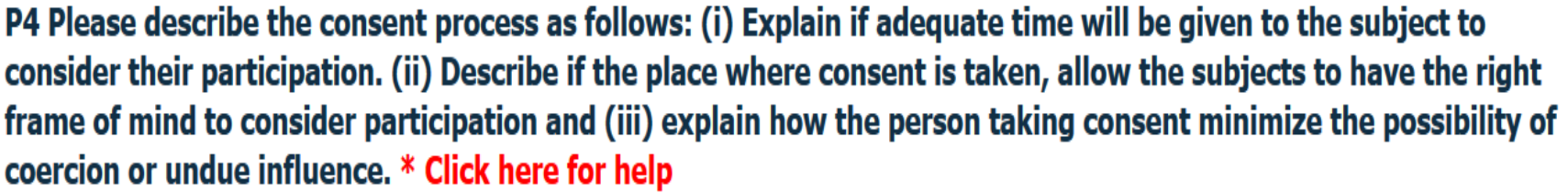
Key Enhancements (7/12)

New

Old



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

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Key Enhancements (8/12)

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

New

Section R - Research Data Confidentiality

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

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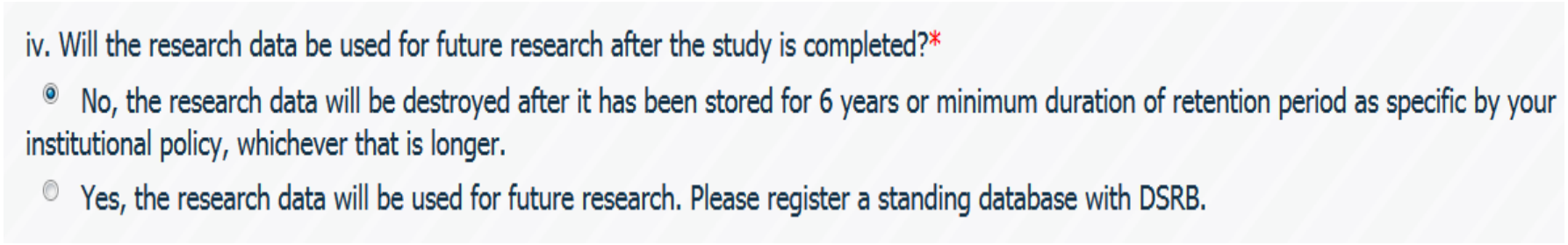
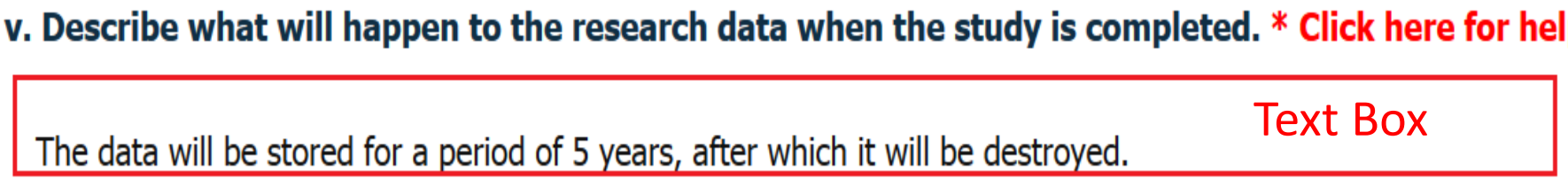
Key Enhancements (9/12)

New



Old



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

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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

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: **1**year(s) **2**month(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.