Section B - DSRB Application Form FAQs

QB1. Should I submit an Exempt or Non Exempt DSRB Application Form?

You should use Application Form 2 – Exempt category if your research activity qualifies for Exempt review. The Exempt Categories can be found in the DSRB Application Form Guidebook.

You should use Application Form 1 – Non Exempt category if your research activity does not qualify for Exempt review. Submissions using Application Form 1 will be reviewed via the Full Board or Expedited route.

NOTE: If the application is submitted via Application Form 2 but does not fall under any of the Exempt Categories, it has to be re-submitted using Application Form 1 for Non Exempt review.

QB2. Section E1: Who should 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 any injury or illness arising from their participation in the study.

You may contact your institutional research office / clinical research unit on whether your institution is declared for insurance under the National Clinical Trial (CT) Group Insurance Policy or for information on other available insurance coverage options.

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, according to the Association of British Pharmaceutical Industry (ABPI) guidelines, or offer a no-fault compensation to research subjects. The PI should check to ensure that pharma-sponsors have in place the necessary CT Policies, including coverage to the PIs and the Sites.

In the event of any injury or illness to research subjects arising from their participation in the trials, the pharma-sponsors' CT Policies shall be the primary policies to provide compensation to the research subjects.

QB3. Section F8: What details should I provide about the experimental design and procedures of my research study?

The DSRB application should include information on blinding, randomization, number of study arms, phase of trial, approximate time to complete study recruitment, expected duration of subject participation, sequence and duration of all trial periods (including follow up), changes in scheduling, single or multi centre, healthy or sick population, in or outpatient, etc.

If your study involves a retrospective medical records review, please specify the period of data collection. All data should already be in existence and not be prospectively collected.

If your study involves the administration of an anonymous survey, please describe how the questionnaire / demographic data collection form will be distributed and re-collected to ensure anonymity (e.g. the questionnaire / demographic data collection forms will be given to participants at the clinic and they can return the completed forms via a collection box or by using the return envelope provided).

QB4. Section F9: I am doing a pilot study and there is no sample size calculation. Does DSRB need any further information?

If you are conducting a pilot study and no sample size calculation is performed, you need to explain how the recruitment target is determined (e.g. based on literature or expected number of cases that will be seen in the study period).

QB5. Section F19: Is it mandatory to take informed consent from all subjects? Can I apply for a waiver? What if my research study involves both prospective recruitment of subjects and a retrospective medical records review?

Written informed consent should be obtained from all subjects and documented prior to their participation in any research, unless the DSRB approves the waiver of consent or waiver of documentation of consent. Consent cannot be waived for US FDA-regulated studies and clinical trials regulated by the Medicines Act and Health Products Act.

The DSRB may waive consent or waive the documentation of consent if you are able to justify that all the criteria for waiver of consent or the waiver of documentation of consent are met. The criteria are different if you are conducting a human biomedical research study that is regulated by the Human Biomedical Research Act. You may refer to the different criteria stated under Question B9.

If you would like to request for a waiver of consent, please select ‘Waiver of Informed Consent is

requested for all study subjects' and provide your justification in Section Q.

If you would like to request for a waiver of documentation of consent, please select 'Informed Consent will be taken for all study subjects' and provide your justification in Section P9.

If your research study involves both prospective recruitment of subjects and a retrospective medical records review, please select 'A combination of both Informed Consent and Waiver of Consent is required for different study populations', You need to elaborate why a combination of both informed consent and waiver of consent is required, and which population(s) will require waiver of consent and which population(s) will be able to give informed consent.

QB6. Section P1: When should the consent process take place with the potential subject?

Informed Consent should be obtained before initiation of the study, i.e. before any procedures being performed solely for the research.

Subjects should not be approached when they are under duress. For example, it would not be appropriate to approach a subject immediately before a procedure or surgery, while in labour, while under sedation and any other situation where a subject might feel compromised.

You need to describe an appropriate time when you will conduct the informed consent process with your subjects.

QB7. Section P2: Where should the consent process take place with the potential subject?

Subjects should be approached in a quiet and conducive environment. It would not be appropriate to approach a subject in an Operating Theatre for a study when he/she is getting ready for a procedure, even if the study is not related to the procedure.

You should also consider the location's appropriateness to protect the subject's privacy (e.g. when approaching subjects for survey involving sexually transmitted diseases, approaching the subject in the Waiting Area of a General Clinic may violate the subject's privacy).

You need to describe an appropriate place where you would conduct the informed consent process with your subjects.

QB8. Section P4: How should the consent process be conducted to minimise the possibility of coercion or undue influence?

In the process of obtaining consent from subjects, the time and place must be suitable and comfortable for the subject to discuss the research with you, and he/she must not be compelled to participate. The subject must also have sufficient time to decide whether or not to participate, and have the option of further discussing with their family members before making the decision.

It is also advisable for consent not to be obtained by the subject's attending physician as the subject may feel obliged to join the research, or may be more willing to participate because of a heightened sense of faith and trust in their own physician.

If you are conducting a human biomedical research study that is regulated by the Human Biomedical Research Act, appropriate consent must be taken in the presence of a witness –

(a) who is 21 years of age or older;
(b) who has mental capacity; and
(c) who must not be the same individual taking the appropriate consent.

The witness must take reasonable steps to ascertain –

(a) the identity of the individual giving the appropriate consent; and
(b) that the consent was given voluntarily without any coercion or intimidation.

The witness may be a study team member unless the situation requires an impartial witness to be present (e.g. subjects who are unable to read). Please refer to the NHG Investigator's Manual here for more information on when an impartial witness is required.

The requirement for a witness is exempted where the human biomedical research study is —

(a) not invasive;
(b) not interventional; and
(c) not restricted human biomedical research.

Human biomedical research study that comprises solely of a survey or collection of information from the research subjects is treated as not invasive and not interventional.

This applies to all new human biomedical research studies that are approved by DSRB from 1 November 2017 and ongoing human biomedical research studies that are expected to continue recruitment beyond 31 October 2018.

Reference: Human Biomedical Research Act section 6(d) and Human Biomedical Research Regulations 2017 sections 25 and 26

QB9. Section Q: Does my research study qualify for a waiver of consent?

The DSRB may waive the requirement to obtain informed consent if the study meets the following criteria:

- The study poses no more than minimal risk to research subjects (e.g. The information collected are not sensitive in nature, and the data are derived from clinically indicated

procedures)

- Waiver of informed consent will not adversely affect the rights and welfare of research subjects (e.g. None of the information collected would affect the clinical decisions about the individual's care, and patients are not being deprived of clinical care to which they would normally be entitled to)

- The study cannot be practically conducted without the waiver of informed consent. (e.g. the subjects are no longer on follow-up, lost to follow-up or deceased)

- Whenever appropriate, the research subjects will be provided with additional pertinent information after participation.

If you are conducting a human biomedical research study that is regulated by the Human Biomedical Research Act, the criteria for the waiver of appropriate consent are as follows and shall be applied accordingly.

3 3. Where the institutional review board is satisfied that –

(a) the research cannot reasonably be carried out without the use of the human biological material or health information in an individually-identifiable form;

(aa) the process of obtaining consent from the person, to which the individually-identifiable human biological material or health information relates, will involve a disproportionate amount of effort and resources relative to the research requirements;

(b) the use of the individually-identifiable human biological material or health information, as the case may be, involves no more than minimal risk to the research subject or donor;

(c) the waiver concerned will not otherwise adversely affect the rights and welfare of the research subject or donor; and

(d) the human biomedical research or health information research would reasonably be considered to contribute to the greater public good.

3A. Where the institutional review board is satisfied that –

(a) the individually-identifiable health information was obtained or compiled before 1 November 2017;

(b) the research cannot reasonably be carried out without the use of the health information in an individually-identifiable form;

(c) the use of the individually-identifiable health information involves no more than minimal risk to the research subject;

(d) the waiver concerned will not otherwise adversely affect the rights and welfare of the research subject; and

(e) the process of obtaining consent from the person, to which the individually-identifiable health information relates, will involve a disproportionate amount of effort and resources relative to the research requirements.

3B. Where the institutional review board is satisfied that –

(a) the individually-identifiable human biological material was obtained or compiled before 1 November 2017;

(b) the research cannot reasonably be carried out without the use of the human biological material in an individually-identifiable form;

(c) the use of the individually-identifiable human biological material involves no more than minimal risk to the research subject;

(d) the waiver concerned will not otherwise adversely affect the rights and welfare of the research subject; and

(e) reasonable effort has been made to re-contact the person to which the individually-identifiable human biological material relates for the purpose of obtaining his or her consent.

This applies to all new human biomedical research studies that are approved by DSRB from 1 November 2017.

Reference: Human Biomedical Research Act Fifth Schedule (Part 2) and Amendment of the Fifth Schedule Order 2017

QB10. Section R: How should I store the research data to protect its confidentiality?

You may store the records in a locked file cabinet, in a locked office, on a computer protected by a password (which should be changed periodically), or on a computer that is not linked onto a network. You could also code the data with an identifier, and keep the key to the code located in another physical location or on a separate computer.

Access to the study data should be limited to authorised study team members in order to maintain the confidentiality of the research data and subjects' identities.