NHG RESEARCH EDUCATION

Qualité

Issue 24, September 2016

Education to facilitate high standards of research conduct

DSRB SOP Updates in Alignment to Human Biomedical Research Act (HBRA)

Background

The Human Biomedical Research Act (HBRA) was passed and enacted in Parliament in August 2015. The Act provides a legal framework for key areas of human biomedical research in Singapore. These include safeguards for research subjects from the loss of identifiable information, a comprehensive range of requirements on informed consent as well as regulations for human tissue related activities. The Act will come into effect gradually in stages.

This article summarises key DSRB SOP updates to align with the HBRA. These changes will be made effective in phases from 1 Nov 2016 onwards.

(1) New Informed Consent Requirements for Human Tissue Related Activities

A new SOP covering Informed Consent Requirements for the Removal, Collection and Use of Human Tissue has been developed. This covers:

1) New information on compulsion to donate tissue
2) Consent for research or removal or use of tissue for research in case of deceased persons
3) Consent for removal or use of tissue for research involving adults who lack mental capacity
4) Consent for removal or use of tissue for research from minors
5) Restrictions on disclosure of information on tissue donor and;
6) Required Elements of Informed Consent

Key elements are outlined in the following table:

Informed Consent Requirements for the Removal, Collection and Use of Human Tissues	HBRA Reference
1. New information on compulsion to donate tissue	**Section 38**
Consent must be voluntarily given by the subject. Any person who- (a) by means of coercion or intimidation, compels another person against that person's will to allow his or her tissue to be removed from his or her body; (b) by means of coercion or intimidation, compels another person (A) against A's will to give A's consent or to refrain from withdrawing A's consent for the removal of tissue from the body of another person (B); (c) by means of deception or misrepresentation, causes another person to allow or continue to allow his or her tissue to be removed from his or her body; (d) by means of deception or misrepresentation, causes another person (A) to give A's consent or to refrain from withdrawing A's consent for the removal of tissue from the body of another person (B), shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $100,000 or to imprisonment for a term not exceeding 10 years or to both, under the Human Biomedical Research Act (HBRA).	
2. Consent for research or removal or use of tissue for research in case of deceased persons	**Section 11**
Where the prospective research subject or tissue donor is a deceased person, the appropriate consent —	

NHG RESEARCH EDUCATION

Qualité

Issue 24, September 2016

Education to facilitate high standards of research conduct

DSRB SOP Updates in Alignment to Human Biomedical Research Act (HBRA)

Informed Consent Requirements for the Removal, Collection and Use of Human Tissues	HBRA Reference
(a) for the use of the deceased person's individually identifiable — (i) biological material; (ii) body or any part of the body; or (iii) health information; or (b) for the removal or use of human tissue for research from the deceased person, must be obtained from any of the following persons in the order of priority stated, when persons in prior classes are not available at the time of death, and in the absence of actual notice of contrary indications by the deceased person, or actual notice of opposition of a member of the same class or a prior class: (i) the spouse; (ii) an adult son or daughter; (iii) either parent or a guardian of the deceased person at the time of the person's death; (iv) an adult brother or sister; (v) the administrator or executor of the estate of the deceased person; (vi) any other person authorised or under obligation to dispose of the body of the deceased person. The person specified in the above segment must, in determining whether to give appropriate consent, have regard to such matters, considerations and procedures as may be prescribed.	
3. Consent for removal or use of tissue for research involving adults who lack mental capacity	**Section 9**
An adult is assumed to have capacity to give consent unless it is established that he or she lacks capacity. Where the prospective tissue donor is an adult who lacks mental capacity to consent to the removal or use of any human tissue and the removal of human tissue from that adult is primarily for a therapeutic or diagnostic purpose, the appropriate consent must be obtained from the following persons in the following circumstances: (a) where there is a donee or deputy who is authorised to give consent to the removal or use of the tissue on behalf of the adult, consent is obtained from the donee or deputy; (b) where there is no donee or deputy who is authorised to give consent to the removal or use of the tissue on behalf of the adult, consent is obtained from any of the following persons in the order of priority stated, when persons in prior classes are not available, and in the absence of actual notice of contrary indications by the adult, or actual notice of opposition of a member of the same class or a prior class: (i) the spouse; (ii) an adult son or daughter; (iii) either parent or a guardian; (iv) an adult brother or sister; (v) any other person named by the adult as someone to be consulted on the matter in question or on matters of that kind. Where a donee is a person specified in section (b)(i) to (iv) but there is an express provision in the lasting power of attorney that the donee is not authorised to give consent to the removal or use of tissue on behalf of the adult lacking mental capacity, that donee is not authorised to give consent.	

NHG RESEARCH EDUCATION

Qualité

Issue 24, September 2016

Education to facilitate high standards of research conduct

DSRB SOP Updates in Alignment to Human Biomedical Research Act (HBRA)

Informed Consent Requirements for the Removal, Collection and Use of Human Tissues	HBRA Reference
The donee or deputy of an adult lacking mental capacity or a person specified in subsection (b)(i) to (iv) must, in determining whether to give consent, have regard to such matters, considerations and procedures as may be prescribed.	
4. Consent for removal or use of tissue for research from minors	**Section 10**
Where the prospective tissue donor is a minor, the appropriate consent for the removal or use of human tissue must be obtained from the following persons in the following circumstances: (a) where the minor has sufficient understanding and intelligence to enable the minor to understand what is proposed in the procedure, consent is obtained from both the minor and at least one adult parent or guardian of the minor; (b) where the minor does not have sufficient understanding and intelligence to enable the minor to understand what is proposed in the procedure and the removal of the tissue is primarily for a therapeutic or diagnostic purpose, consent is obtained from at least one adult parent or guardian of the minor; (c) where the minor lacks mental capacity and the removal of the tissue is primarily for a therapeutic or diagnostic purpose, consent is obtained from — (i) a deputy who is authorised to give consent for the removal or use of the tissue on behalf of the minor; or (ii) at least one adult parent or guardian of the minor. For the purposes of this section, the deputy, adult parent or guardian of a minor must, in determining whether to give consent under that subsection, have regard to such matters, considerations and procedures as may be prescribed.	
5. Restrictions on disclosure of information on tissue donor	**Sections 28 & 29**
Individuals should not attempt to re-identify anonymised information or biological material, or disclose any individually-identifiable information of a research subject except – (a) with the consent of the research subject or the person authorised to give consent on the research subject's behalf; (b) when it is necessary to do so in connection with the administration or execution of anything under the HBRA; (c) when ordered to do so by a court; (d) where the information is publicly available; (e) for the purpose of providing the identity/information to any person or class of persons to whom, in the opinion of the Director of Medical Services, it is in the public interest that the information be disclosed; (f) where it is permitted or provided for under the HBRA or any other written law or rule of law; or (g) in such other circumstances and to such persons as may be prescribed. Individuals receiving individually-identifiable information or human biomedical material of a research subject should not disclose any individually-identifiable information of the research subject, if at the time when the individuals receive the information or material, they knew or had reasonable grounds to believe that it had been communicated or supplied to them in a manner that breaches the HBRA or any other applicable law.	

NHG RESEARCH EDUCATION

Qualité

Issue 24, September 2016

Education to facilitate high standards of research conduct

DSRB SOP Updates in Alignment to Human Biomedical Research Act (HBRA)

Informed Consent Requirements for the Removal, Collection and Use of Human Tissues	HBRA Reference
6. Required Elements of Informed Consent (Additional Required Information)	**Section 12**

In this case of the removal, donation or use of human tissue for human biomedical research, the following elements must be present in the consent form:

- A statement about whether, and the circumstances under which, the donor or the person authorised to give consent, will be contacted for further consent.
- A statement about whether the tissue will be used in restricted human biomedical research involving human-animal combinations.
- A statement about whether the donor or the person authorised to give consent would wish to be re identified in the case of an incidental finding if the future research expressly provides for such re-identification.

(2) Informed Consent Requirements Involving Cognitively Impaired Persons

All Human Biomedical Research (HBR) of no more than minimal risk & more than minimal risk, involving adults who lack mental capacity will need to obtain consent from an appropriate person, according to a specified order as spelt out in the HBRA.

Current Practice	Revision of SOP to align with HBRA	Key changes
When the research poses no more than minimal risk, the investigator may obtain consent from family members of cognitively impaired persons. For research involving more than minimal risk and clinical trials (under Medicines (CT) Regulations), informed consent of the subject who is incapable of exercising rational judgment shall not be required if : (a) The principal investigator and a doctor who is not otherwise participating in the clinical trial certify in writing that – i. that person is incapable of exercising rational judgment; and ii. it is not likely that the person will be capable of	*HBRA reference: Sections 7 & 9* For human biomedical research where the prospective research subject is an adult who lacks mental capacity and there are reasonable grounds for believing that biomedical research of comparable effectiveness cannot be carried out without the participation of the class of persons to which the adult belongs, the appropriate consent for the adult must be obtained from the following persons in the following circumstances: (a) where there is a donee or deputy who is authorised to give consent to the biomedical research on behalf of the adult, consent is obtained from the donee or deputy; (b) where there is no donee or deputy who is authorised to give consent to the biomedical research on behalf of the adult, consent is obtained from any of the following persons in the order of priority stated, when persons in prior classes are not available, and in the absence of actual	All HBR involving adults who lack mental capacity will need to obtain consent from an appropriate person, according to a specified order. *(An update on the informed consent requirements for research involving more than minimal risk and clinical trials will be provided subsequently).*

NHG RESEARCH EDUCATION

Qualité

Issue 24, September 2016

Education to facilitate high standards of research conduct

DSRB SOP Updates in Alignment to Human Biomedical Research Act (HBRA)

Current Practice	Revision of SOP to align with HBRA	Key changes
exercising rational judgment within the window period; (b) Consent has been obtained from – i. that person's spouse, parent, guardian (if there is no parent) or any other person having charge of him; and ii. if different from (i) above, that person's legal representative; and (c) There is a reasonable prospect that participation in the clinical trial will directly benefit that person; and (d) The trial cannot be practicably carried out in subjects who can give their own consent.	notice of contrary indications by the adult, or actual notice of opposition of a member of the same class or a prior class: i. the spouse; ii. an adult son or daughter; iii. either parent or a guardian; iv. an adult brother or sister; v. any other person named by the adult **The same consent requirement also applies to research that involves the removal or use of tissue for research involving adults who lack mental capacity.*	

(3) Informed Consent Requirements Involving Minors

Current Practice	Revision of SOP to align with HBRA	Key changes
The Investigator shall obtain the consent of the child as follows: (a) In the case of a child below the age of 21 years who is married, the consent should be obtained from that child; (b) In the case of a child below the age of 21 years who is not married, the consent of the child	*HBRA reference: Sections 8* *"Minor" means a person who is below 21 years of age and who has never been married.* For human biomedical research where the prospective research subject is a minor, the appropriate consent must be obtained from the following persons in the following circumstances: (a) where the minor has sufficient understanding and	For a minor who has sufficient understanding and intelligence to understand what is proposed in the HBR, if the DSRB has waived the requirement to obtain consent from the adult parent of guardian of the minor, only the minor needs to give

NHG RESEARCH EDUCATION

Qualité

Issue 24, September 2016

Education to facilitate high standards of research conduct

DSRB SOP Updates in Alignment to Human Biomedical Research Act (HBRA)

(3) Informed Consent Requirements Involving Minors

Current Practice	Revision of SOP to align with HBRA	Key changes
and i. the consent of the child's parent or guardian; and ii. if different from (i), the consent of the child's legal representative. (c) The consent of a child below the age of 21 years who is not married is not required if: i. The child lacks sufficient understanding to give such consent; and ii. There is a reasonable prospect that participation in the clinical trial will directly benefit that child.	intelligence to enable the minor to understand what is proposed in the biomedical research, consent is obtained from both the minor and at least one adult parent or guardian of the minor; (b) where the minor has sufficient understanding and intelligence to enable the minor to understand biomedical research and the DSRB has waived the requirement to obtain the consent of at least one adult parent or guardian of the minor, consent is obtained from the minor; (c) where the minor does not have sufficient understanding and intelligence to enable the minor to understand what is proposed in the research and there are reasonable grounds for believing that biomedical research of comparable effectiveness cannot be carried out without the participation of the class of minors to which the minor belongs, consent is obtained from at least one parent or guardian of the minor; (d) where the minor lacks mental capacity and there are reasonable grounds for believing that biomedical research of comparable effectiveness cannot be carried out without the participation of the class of minors to which the minor belongs, consent is obtained from i. deputy who is authorised to give consent to the biomedical research on behalf of the minor; or ii. at least one adult parent or guardian of the minor.	consent. Where the minor lacks mental capacity, consent needs to be taken from the deputy or at least one adult parent or guardian of the minor.

NHG RESEARCH EDUCATION

Qualité

Issue 24, September 2016

Education to facilitate high standards of research conduct

DSRB SOP Updates in Alignment to Human Biomedical Research Act (HBRA)

(4) Data Collection and Handling

Current Practice	Revision of SOP to align with HBRA	Key changes
No explicit guidelines on re-identification of anonymised information or biological material or disclosure of individually identifiable information of a research subject.	*HBRA reference: Sections 28 & 29* Individuals should not attempt to re-identify anonymised information or biological material, or disclose any individually-identifiable information of a research subject except – (a) with the consent of the research subject or the person authorised to give consent on the research subject's behalf; (b) when it is necessary to do so in connection with the administration or execution of anything under the HBRA; (c) when ordered to do so by a court; (d) where the information is publicly available; (e) for the purpose of providing the identity/information to any person or class of persons to whom, in the opinion of the Director of Medical Services, it is in the public interest that the information be disclosed; (f) where it is permitted or provided for under the HBRA or any other written law or rule of law; or (g) in such other circumstances and to such persons as may be prescribed.	New requirements as listed.
No explicit guidelines on handling of identifiable information or human biomedical material of a research subject where it is suspected to be received in a manner that breaches any applicable law.	*HBRA reference: Section 29* Individuals receiving individually-identifiable information or human biomedical material of a research subject should not disclose any individually-identifiable information of the research subject, if at the time when the individuals receive the information or material, they knew or had reasonable grounds to believe that it had been communicated or supplied to them in a manner that breaches the HBRA or any other applicable law.	New requirement as listed.

References:

- *The Human Biomedical Research (HBR) Act passed, 21st August 2015.*

Maggie Lee
Senior Executive, Research Quality Management
National Healthcare Group
Nantha Kumar S/O Sivanathan
Executive, Domain Specific Review Board (DSRB)
National Healthcare Group