Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

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	Name and Position	Signature	Date
Author:	Mrs Louise Dunlop Head of Research Governance		8/2/17
Reviewed by:	Professor James McElnay, Chair Research Governance and Integrity Committee		09-02-2017
Approved by:	Mr Scott Rutherford Director, Research and Enterprise		8.2.2017

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* For all University sponsored research recorded as risk category level 4, including IMP studies
# For all other University sponsored research involving human participants

Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Final v 1.0	10/11/09	Annual Review	Draft v 2.0
Draft v 2.0	03/05/10	Update following MHRA GCP Inspection	Final v 2.0
Final v 2.0	10/11/10	Update following consideration by RGSG	Final v 3.0
Final v 3.0	17/8/12	Periodic Review	Final v 4.0
Final v 4.0	29/10/12	Amended to include human tissue research	Final v 5.0
Final v 5.0	06/10/2014	Periodic Review	Final v 6.0
Final v6.0	18/02/2015	Update on consent from minors	Final v 7.0
Final v7.0	19/09/2015	Periodic Review	Final v 8.0

1. Purpose

This Standard Operating Procedure (SOP) describes the process for obtaining informed consent from a research participant. It outlines the informed consent procedures for adults, who are able to give informed consent and the procedures to be followed for vulnerable participants, such as children and adults, who are unable to consent for themselves.

2. Introduction

Paragraph 3(1) of Part 1 of Schedule 1 to the Medicines for Human Use (Clinical Trials) Regulations, 2004, implementing Article 2(j) of the EU Directive 2001/20/EC, gives the following definition of informed consent:

A person gives informed consent to take part in research, in particular a clinical trial, only if his/her decision:

- *Is given freely after that person is informed of the nature, significance, implications and risk of the trial; and*
- *Either:*
  - *i Is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his/her consent, or*
  - *ii If the person is unable to sign or to mark a document so as to indicate his consent, is given orally in the presence of at least one witness and recorded in writing.*

Informed consent is the fundamental principle of the Human Tissue Act 2004 (HT Act). The Act requires consent to be obtained for the storage and use of human tissue – defined as '*relevant material*' – from the living for:

i. research in connection with disorders or the functioning of the human body, *or,*
ii. obtaining scientific or medical information which may be relevant to any person including a future person.

Informed consent is also required for the removal, storage and use relevant material from the deceased. Relevant material is defined as material that has come from the human body and consists of or includes human cells.

Informed consent is at the heart of ethical research, and a core ethical principal is that every researcher must respect each individual research participant. Therefore diversity and level of understanding must be respected when obtaining informed consent.

All participants entering into a research project/clinical study must have given their informed consent before they can become involved in the research study. In addition, researchers must remember that informed consent is an ongoing requirement, so they must ensure that participants:

- continue to understand the information relating to the study and any changes in that information;
- continue to consent to participate throughout the duration of the study.

3. Scope

This SOP applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff, and students who are conducting research within or on behalf of the University, including research regulated by the Human Tissue Act 2004 (HT Act).
Note: The Northern Ireland Biobank will have their own procedures and requirements and should not follow this SOP.

4. Responsibilities

4.1 Chief Investigator

Overall responsibility for all elements of research activity, including gaining informed consent, rests with the Chief Investigator (CI) although each individual member of the research team is responsible for their own specific actions. As CI you may delegate the task of obtaining informed consent to another appropriately qualified member of the research team, but this delegation must be clearly documented, and the person gaining informed consent must sign the consent form when required. To sign a consent form when you have not personally been involved is fraudulent.

The CI must ensure that the study is logged onto the Human Subjects Database and that the correct level of risk is designated to the proposed research. The risk levels are detailed in the below table.

Risk	Descriptor
Level 1	Those projects which although involving human subjects are in no way associated with a medicinal purpose or do not involve issues such as alcohol and illicit drug use or higher risk sexual behaviour. Level 1 projects essentially involve research into, for example, behaviour, attitudes, rights and education issues. These projects do not include an intervention[1].
Level 2	Those projects that have more relevance to healthcare and include, for example, survey work on access to health care or issues, such as alcohol and illicit drug use or higher risk sexual behaviour. These projects do not include an intervention[1].
Level 3	These projects essentially involve research involving collecting data (including risk factor data) in human subjects and correlating this with, for example, health status, and advances in diagnostics. The projects do not involve altering treatment regimens or the standard of routine care that these individuals receive. These projects do not include an intervention[1].
Level 4	These studies generally either involve an intervention which has the aim of changing health status or behaviour or involve procedures that are generally more invasive in nature, but do not have the attributes/characteristics of Level 4b studies.
Level 4b	These studies involve Clinical trials of Investigational Medicinal Products or clinical trials into medical devices or involve procedures which aim to induce illness or other conditions (eg inflammation) in study subjects for the purpose of testing the efficacy of new treatment approaches.

[1]An intervention is classed as a change directly related to the study that may alter the research subject's health, physically or mentally and includes any potential to alter behaviour as a result of participation.

The Insurance Database will be audited subject to an annual audit and any discrepancies will be reported back.

4.2 Investigators

The ICH GCP guideline states that *"The investigator, or a person designated by the Investigator, should fully inform the subject or,.....the subject's legally acceptable representative"* (ICH GCP 4.8.5) and *"the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative"*. (ICH GCP 4.8.8)

The delegation of informed consent to an appropriate, suitably qualified member of the research team should be considered on a case-by-case basis. If staff, other than the CI are to accept responsibility for the informed consent process, it is important that the following criteria are met by the researcher:

- They are prepared to take on the additional responsibility and are confident with seeking informed consent, in line with their professional body/organisational guidelines;
- They have a full understanding of the study, the potential risks/benefits and the associated area. This knowledge can be gained through experience and/or appropriate training. All training must be documented;
- That delegated responsibility should be documented on the log that captures each member of the study team and their individual responsibilities in the management and conduct of the study. This too is signed and date by the CI;
- The process has been reviewed and received a favourable ethical opinion by the relevant Research Ethics Committee;
- An effective communication channel is maintained between the CI who is ultimately the person responsible for the research participant's care.

When research studies involve the removal, storage or use of human tissue, the individual obtaining consent must have received suitable training as required by the Human Tissue Authority (HTA).

It is best practice for any other research personnel involved in giving information during the informed consent procedure to sign and date the informed consent form. For CITMPs, those responsible for obtaining written informed consent must have a copy of their signed and dated CVs in the Trial Master File and, must have completed the study delegation log, which is also signed and dated by the CI.

4.3 Research participants

Potential participants should understand that if they agree to take part in research they have a duty to the researchers. In giving informed consent they are agreeing to comply with the requirements of the research. However, if at any time they are unable or unwilling to do this, they can withdraw from the research. It is important to emphasise that withdrawal from a clinical study will not compromise the quality of care they receive, although their treatment may change. For example, if the study is examining a new treatment, they may go back to receiving standard treatment.

5. Procedure

5.1 Contents of Consent Form

The Informed Consent Form and Participants Information Sheet must be approved by an appropriate Research Ethics Committee, as outlined in SOP QUB-ADRE-003 on the ethical approval of research. The following must be on the informed consent form:

- It should be printed on the appropriate headed paper, depending on the Sponsorship arrangements for the specific study;
- The correct title and version number for the study should be clearly visible and relates to the written information sheet given to the participant;
- It should contain statements relating to the following items:
  - i The participant has had the study explained to them and by whom;
  - ii The risks, benefits and alternative treatments have been discussed and all the participant's questions have been answered to their satisfaction;
  - iii Their participation is voluntary and they are free to withdraw at any time, without the loss of any treatment to which they would otherwise have been entitled to;
  - iv Their medical records may be reviewed by responsible individuals from Queen's University Belfast, regulatory authorities or from the NHS Trust and information relevant to the research retained on University premises;
  - v Sample collection and future research.

An example consent from is provided in Appendix 1.

5.2 Informed Consent Process: Capable Adults

- Potential research participants should be identified and approached and given a verbal explanation of the study. Appropriate visual aids should be used, such as diagrams, to explain the study. Participants should also be provided with the up to date and approved information sheet(s) regarding the study;
- Consent is best taken in a private area, ensuring the protection of the potential participant's dignity and affording them respect. It also enables the potential participant to ask questions. Potential participants must be given the time to ask questions throughout the information process and be given adequate and appropriate answers;
- When describing the study, the designated member of the research team should explain:
  - i Why the participant has been approached and assure them that their privacy and confidentiality will be maintained throughout the study;
  - ii The purpose of the study and any relevant background information. Where a drug trial is being undertaken the potential participant must be made aware that the trial involves research;
  - iii The approximate number of participants involved in the study;
  - iv What the procedures for the study will be i.e. the number of study visits, any blood tests/investigations, including all invasive procedures;
  - v What human tissue will be collected (if any), the amount of tissue required, how it will be used (including genetic analysis, transfer abroad or commercial research), stored and disposed of as appropriate;
  - vi The potential benefits. Where there is no intended clinical benefit the participant should be made aware of this;
  - vii The foreseen risks or inconveniences to the participant;
  - viii The alternative procedure(s) or course(s) of treatment that may be available, and importantly, the potential benefits and risks;
  - ix The availability of compensation, should something go wrong;
  - x The anticipated expenses, if any, to the participant and if there are any payments to be made;
  - xi That the person's participation is voluntary and that they may refuse to participate or withdraw, at any time, without any prejudice to them or their future care;
  - xii That the study records / participants medical records will be open to audit/monitoring by the appropriately identified persons within or on behalf of the

Sponsor i.e. the University and/or Trust and the necessary regulatory authority(ies). This is to enable the verification of clinical trial procedures and/or data. The subject should be assured that their confidentiality will be maintained;

xiii That giving informed consent does not necessarily mean the participant will be enrolled into the study if it is discovered they do not meet the inclusion/exclusion criteria;

xiv Where a study is co-sponsored a copy of the signed consent form may be held by both organisations.

- When obtaining and documenting informed consent, the investigator should adhere to Good Clinical Practice (GCP) and ethical principles;
- The language used to explain the study should be as non-technical as is practical and should be understandable to the participant. In addition, an appropriate and accessible format should be used when obtaining consent;
- Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the participant ample time and opportunity to inquire about details of the trial and decide whether or not to participate;
- No unreasonable incentives or financial inducements must be given except for compensation in the event of injury or loss;
- Prior to the person's participation in the trial, the written informed consent form should be signed and personally dated by them, or by the their legally acceptable representative, and by the person who conducted the informed consent discussion;
- Once all parties have signed the written informed consent form, the participant should receive a signed and dated copy, together with the information sheet and any other written information in relation to the study. For CTIMPs a copy of the consent form must be placed in the participant's medical notes and a copy kept by the study team, in the Trial Master File. For all other studies, a copy of the consent form should be maintained in the study file, as appropriate;
- The research participant should be provided with a contact point where he/she may obtain further information about the trial;
- Neither the research participant nor their legally acceptable representative should be coerced or unduly influenced to participate in the study.

5.3 Ongoing Consent Procedures

- The consent form and any other written information to be provided to participants should be revised whenever important new information becomes available, that may be relevant to their consent. This in turn may determine their willingness to continue participating in the study;
- The communication of this information should be documented;
- Depending on the information being imparted to a study participant, it may be appropriate for them to be re-consented to continue their involvement in the study;
- Neither the investigator, nor the trial staff, should coerce or unduly influence a participant to continue with their participation in a study;
- If a capable adult gives informed consent to take part in a study in accordance with the conditions outlined in Section 5.2 above, and subsequently becomes unable to give informed consent by virtue of physical or mental incapacity, the consent previously given when capable remains legally valid;
- If a capable adult refused informed consent, and subsequently becomes unable to give informed consent, the refusal is legally binding. He or she cannot be entered into the trial by seeking consent from a legal representative.

5.4 Informed Consent of Minors and Incapacitated Adults

- Persons who are incapable of giving legal consent to clinical trials should be given special protection. Such persons may not be included in research if the same results can be obtained using persons capable of giving consent;
- Normally these persons should only be included when there are grounds for expecting that the administering of the medicinal product would be of direct benefit to the patient, thereby outweighing the risks. However, there is a need for research involving children to improve the treatment available to them;
- The definition of a legal representative varies under the Clinical Trials Regulations, 2004, depending on whether the subject is a minor or an adult with incapacity. The legal representative must not be *"a person connected with the conduct of the trial"*.

Minors

- Under the Clinical Trials Regulations, 2004, a minor is a person under the age of 16 years.
- Under the HT Act, a child is defined as a person under the age of 18 years. The Clinical Trials Regulations, 2004 definition of a minor takes precedence for clinical trials of an investigational medicinal product.
- For other research (i.e. non-clinical trial) young people aged between 16 and 18 are usually competent to give consent to treatment. If a young person under the age of 16 years, has sufficient understanding what is involved and is deemed competent of making an informed decision then he/she can give consent to take part in the proposed research, (i.e. 'Gillick competence'[1]). The involvement of those with parental responsibility in the decision should be encouraged, even if the young person is deemed competent. When a child or young person is not deemed competent, parents or those with parental responsibility can consent on their behalf. The child or young person should be informed of the nature of the research in a manner appropriate to their age and their assent obtained as well. The process by which competency is determined should be documented.
- For research involving human tissue, the HTA's Code of Practice on Consent, indicates that a young person aged between 12 and 16 years, who is able to make their own decisions can consent to the storage and use of their tissue for research purposes if they are deemed competent to do so.
- Careful consideration must be given before proceeding with the research when there is discordance between the parent/guardian and the child/young person regarding participation.
- Researchers involved in the consent and recruitment of children and young people must have appropriate consent training.
- The minor should be given information about the study according to his/her level of understanding and from staff with experience of working with the young person.
- The Participant Information Sheet should be written in age appropriate language that the minor can understand, with different versions for different age groups. There should also be a version produced for the legally acceptable representative, as appropriate.

[1] Gillick competence is the term used in medical law to describe a young person's ability to make a decision regarding consent, The Gillick case (Gillick v West Norfolk and Wisbech Health Authority) determined that where a young person has sufficient understanding to enable them to fully comprehend what is proposed, he or she can consent to treatment themselves.

Minors - Clinical Trials

- Children represent a vulnerable population with developmental, physiological and psychological differences from adults, which make age- and development-related research important for their benefit. Where clinical trials must be undertaken involving children, the best possible protection should be afforded to the participant.
- The consent procedure outlined in Sections 5.2 and 5.3 must be followed ensuring that the minor's legally acceptable representative is informed in the same manner as the participant, and gives their informed consent for the minor to participate. Minors may only be recruited onto a study, when it relates directly to an illness from which the young person suffers, or where the study can only be carried out on minors.
- It is best practice to obtain the assent of the child in addition to the consent of the legally acceptable representative (i.e. parent/guardian). If the child is deemed competent to understand the research being explained, then a signature should be obtained from both the minor and the legally acceptable representative.

Minors – Emergency Situations

- The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality Amendment Regulations 2008 made additional provision relating to trials involving minors in emergency situations. Where the treatment to be given to a minor as part of the trial needs to be administered urgently, time may not allow for the written consent of a person with parental responsibility or a legal representative to be obtained first. The Amendment Regulations allow for minors to be entered into a trial prior to informed consent being obtained provided that:
  - i Having regard to the nature of the trial and the particular circumstances of the case, it is necessary to take action for the purpose of the trial as a matter of urgency, but
  - ii It is not reasonably practicable to obtain informed consent prior to entering the subject, and
  - iii The action to be taken is carried out in accordance with a procedure approved by the ethics committee.

- Where a minor is recruited in an emergency situation without prior informed consent, steps must be taken to seek informed consent from a person with parental responsibility or a legal representative as soon as practicable after the initial emergency has passed. Where consent is withheld, the subject must be withdrawn from the trial.

5.5 Informed consent of incapacitated adults

- An incapacitated adult has been defined in the Regulations as "*an adult unable by virtue of physical or mental incapacity to give informed consent*". Therefore recruiting persons with dementia or psychiatric conditions should be even more restrictive. Consent should be sought, in the same process as outlined in Sections 5.2 and 5.3 of the person's legal representative, be they personal or professional;
- A personal legal representative is a person, not connected with the conduct of the trial that is suitable to act as the legal representative by virtue of their relationship with the adult, and is available and willing to do so;
- A professional legal representative is a person not connected with the conduct of the trial who is:
  - i the doctor primarily responsible for the adult's medical treatment, or
  - ii a person nominated by the relevant health care provider.

A professional legal representative may be approached if no suitable personal legal representative is available.

- Adults incapable of giving informed consent may be recruited onto a study where:
  i There are grounds to expect that administering the trial drug will produce a benefit to the subject outweighing the risks;
  ii The clinical trial is essential to validate trial data, and
  iii The clinical trial relates directly to a life-threatening, debilitating clinical condition from which the subject suffers.
- The participant must receive information according to his/her capacity of understanding regarding the trial, its risks and its benefits. However, the decision on whether to consent to (or refuse) participation in a study must be taken by a legal representative;
- The participant's representative must have the objectives, risk, inconveniences/discomforts and associated conditions for the study explained to them. The representative must be informed of their rights to withdraw the participant at any time, resulting in no detriment to the care or treatment for the subject. They must then give informed consent on behalf of the subject.

Incapacitated Adults - Emergency Situations

- The Medicines for Human Use (Clinical Trials) (Amendment No. 2) Regulations 2006 made additional provision relating to trials involving incapacitated adults in emergency situations. Where the treatment to be given to an incapacitated adult as part of the trial needs to be administered urgently, time may not allow for the written consent of a person with legal representative to be obtained first. The amendment allows incapacitated adults to be entered into a trial prior to informed consent being obtained from a legal representative provided that:
  i Having regard to the nature of the trial and the particular circumstances of the case, it is necessary to take action for the purpose of the trial as a matter of urgency, but
  ii It is not reasonably practicable to obtain informed consent prior to entering the subject, and
  iii The action to be taken is carried out in accordance with a procedure approved by the ethics committee.
- Where an incapacitated adult is recruited in an emergency situation without prior informed consent, steps must be taken to seek informed consent from the subject (if capacity has been recovered) or from a legal representative as soon as practicable after the initial emergency has passed. Where consent is withheld, the subject must be withdrawn from the trial.

Medical Devices

- Consent for studies of medical devices which are not covered by the Clinical Trials Regulations, 2004, will require consent to be obtained in line with the legal requirements for obtaining consent in patients without capacity in England and Wales (Mental Capacity Act 2005), and in Scotland (Adults With Incapacity (Scotland) Act 2000). Consent processes in Northern Ireland follow common law.
- In England/Wales/NI consent must be taken from a Personal Consultee prior to inclusion or randomisation. A trained authorised staff member/researcher must provide them with a Personal Consultee Information Sheet. In the event that a Personal Consultee is not available to provide consent, then an independent doctor not involved with the patient's care may be consulted and informed about the trial by an authorised staff member/researcher and given a copy of the Information Sheet. If the independent doctor agrees, the authorised staff member/researcher may recruit

the patient into the trial. In the event that a patient is randomised in the study via an independent doctor, the Personal Consultee must be informed at the earliest opportunity and consent to continue will be sought.

5.6 HT Act, enduring consent and consent exceptions

The HT Act permits the seeking of enduring and generic consent to facilitate the use of human tissue in future research. Where possible the participant information sheet should inform the participant of the likely nature of the future research (eg disease states to be studied or genetic analysis) and if the tissue could be shared with other collaborators or commercial partners (within the UK and abroad). The participant should also be informed if the tissue samples will be anoymised and that any future research will be subject to ethical approval. Where enduring consent has been obtained ethical approval for future research projects may be sought from School Research Ethics Committees if appropriate. Consent forms providing enduring and generic consent must be retained for the same duration as the human tissue samples are stored under the HTA licence.

There are exceptions to consent requirements under the HT Act. Consent for research is not required if:

- The material is an 'existing holding' (i.e. collected prior to the 1st September 2006);
- The material is imported;
- The material is from a living person and the researcher is unable to identify the person and the specific research project is approved by a recognised REC (i.e. ORECNI or the equivalent statutory REC). University RECs are not considered to be recognised RECs for this purpose.

It should be noted although consent is not required for imported material, mechanisms must be in place to provide assurance that the tissue has been obtained with valid consent.

Research involving the use of previously collected tissue (or information) from which individual past or present NHS/HSC users could be identified must be approved by a recognised REC.

6. References

International Conference on Harmonisation (ICH) Harmonisation Tripartite Guideline: Guideline for Good Clinical Practice E6 (R1) (last accessed October 2014): http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html

HRA; Clinical Trials Regulations – informed consent v. 3 01-05-08 http://www.hra.nhs.uk/documents/2013/09/informed-consent-in-ctimps.pdf

Declaration of Helsinki, 1996 (last accessed October 2014) http://www.wma.net/en/30publications/10policies/b3/

The Medicines for Human Use (Clinical Trials) (Amendment No. 2) Regulations 2006 The Medicines for Human Use (Clinical Trials) (Amendment No. 2) Regulations 2006

Human Tissue Authority Code of Practice 1 Consent and Code of Practice 9 Research http://www.hta.gov.uk/ (last accessed October 2014)

7. Appendix

Appendix 1 - Consent Form Template
(Consent forms may vary according to the nature of the study. The template consent form is suitable for most studies but may require alteration. Text in red or within square brackets indicates wording that should be included if appropriate for the study).

CONFIDENTIAL

Queen's University Belfast

CONSENT FORM

Participant Identification Number:_____

Title of Project:	
Chief Investigator:	
Study Number:	

Please initial box

1. I confirm that I have read, or had read to me, and understand the information sheet dated dd/mm/yyyy, version xx for the above study. I have had the opportunity to ask questions and these have been answered fully. ☐

2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason and without my legal rights [or medical care] being affected. ☐

3. I understand the study is being conducted by researchers from Queen's University Belfast and that my personal information will be held securely on University [or Trust] premises and handled in accordance with the provisions of the Data Protection Act 1998. ☐

4. I understand that data collected as part of this study [and relevant sections of my medical records] may be looked at by authorized individuals from Queen's University Belfast [and] regulatory authorities [or NHS/HSC Trust] where it is relevant to my taking part in this research. I give permission for these individuals to have access to this information. ☐

5. I agree to take part in the above study. ☐

X. I agree to my GP being informed of my participation in the study [and to my GP/Consultant being informed of any abnormal test results]. ☐

X. I understand that the information I provide may be published as a report. Confidentiality and anonymity will be maintained and it will not be possible to identify me from any publications. ☐

X. I understand that this study is confidential but there are limits to this confidentiality. Revelations that are criminal [or in clear breach of good medical practice] may require confidentiality to be broken by the researchers. ☐

X. I understand that what is discussed during the [interviews or observations or focus group] is confidential with the exception that if I disclose information that indicates that I am at risk of harming myself or others, or in danger of being harmed by someone else, the researcher is legally obliged to pass on this information to [insert appropriate persons]. ☐

X. I understand the [interviews or observations or focus group] will be [tape recorded or video recorded] and there is a possibility of direct quotation being used in publications. ☐

X. I agree to gift my samples to Queen's University Belfast and I consent to the storage and use of my sample for future research, including genetic analysis and commercial research. I understand that I will not benefit financially from any research. ☐

X. The potential benefits of keeping my [blood or other tissues] for future research have been explained to me and I consent to the storage and use of my [blood or other tissues] for future research, including genetic analysis and commercial research. I understand that I will not benefit financially from any research. ☐

X. The potential benefits of keeping my blood or other tissues for future research have been explained to me and (please choose <u>one</u>)

(i) I consent to the storage and use of my blood or other tissues for future research, including genetic analysis and commercial research. ☐

<u>OR</u>

(ii) I do not wish my blood or other tissues to be used for any purpose other than this study ☐

X. I agree to being contacted at a later date and invited to take part in future studies of a similar nature. I understand that I am only agreeing to receive information and I am under no obligation to take part in any future studies. If you decide not to consent to being contacted in the future it will not have any influence on your involvement in this particular research study [and will not affect any standard of care that you receive]. ☐

Name of Participant (please print)	Signature	Date
Name of Person Taking Consent (please print)	Signature	Date

Chief Investigator or Researcher Contact details: