RISK MANAGEMENT PLAN FOR RESEARCH ON THE ALFRED CAMPUS

1. The context

The Alfred campus is one of Australia's leading centres in clinical and biomedical research. Several of the campus research groups are regarded as international leaders.

Research is a core activity of all the institutions on The Alfred campus. For example, it is essential for The Alfred, as a leading teaching hospital, to have strong research programs in place to ensure continuous improvements in patient care and clinical outcomes. The importance of research to the hospital is demonstrated by its inclusion as a key component of the Bayside Health Strategic Plan 2002-2005. Specifically, it is planned to increase the knowledge base of Bayside Health by improving research output, and leading and fostering research activities across all clinical disciplines. Measurable progress has been made thus far.

Experience in other institutions around the world has demonstrated that serious misadventure in research activities may have far reaching repercussions and bring disrepute to the entire organisation, possibly compromising activities in other affiliated institutions. It is for this reason that this Risk Management Plan has been devised.

The aim is to identify the major risks faced in the conduct of research on The Alfred campus, and to analyse and manage them effectively. The plan is to apply to research conducted by staff of all institutions on The Alfred Campus: The Alfred hospital, the Monash University Central and Eastern Clinical School, the Baker Heart Research Institute and the Burnet Institute. It will also apply to nursing and physiotherapy research conducted in conjunction with La Trobe and Deakin Universities.

This plan is intended to supplement legislation, regulations and guidelines under which research is conducted. Those undertaking research must adhere to requirements regarding:

- Good research practice
- Human research ethics (including privacy)
- Animal experimentation ethics
- Intellectual property management (see Appendix 1 regarding maintenance of laboratory notebooks)
- Genetic manipulation of organisms
- Use of carcinogenic or highly toxic chemicals

2. Identification of risks

In the development of this plan, heads of departments / institutes undertaking research on the campus were provided with a copy of a draft risk management plan prepared by Professor John McNeil, Monash University Department of Epidemiology and Preventive Medicine, and invited to submit their comments and suggestions.

The risks identified in the current document (see Table 1) are those that were included in the draft risk management plan, as well as several others identified by the respondents.

Further risks that may be identified in the future will be added to later versions of this document.

The potential risks identified relate to:

- Fraud in collection of data
- Serious errors in analysis of data
- Loss of data due to inadequate back-up procedures
- Serious breach of protocol or ethics committee requirements
- Serious breach of confidentiality
- Failure to identify and follow up an abnormal pathology result
- Failure of monitoring or emergency procedures leading to death or serious injury to a study participant
- Attack on research personnel or other dangers to personal safety especially when visiting outside the hospital
- Perceived coercion of subjects to enrol in research studies
- Undeclared conflicts of interest

3. Risk analysis

The risk analysis was carried out according to the approach described in the Australian and New Zealand Standard on Risk Management, AS/NZS 4360:1999, and in the Bayside Health Risk Management Guidelines (September 2002).

The likelihood of occurrence of each event was rated on a scale of 1-5 (Table 2). The consequences were also ranked in degree of severity on a scale of 1-5 (Table 3), and the overall level of risk was determined by combining the consequence rating and the likelihood rating (Table 4).

4. Conclusions of the risk assessment

All of the risks identified require strategies to reduce the likelihood of occurrence. It is not feasible to eliminate any of the risks by disallowing the activities.

A summary of the risk assessment is shown in Table 1. The detailed analysis for each individual risk is contained in Appendix 2.

5. Risk management

Strategies to manage each identified risk are shown in Table 1 as well as in the detailed risk analysis (Appendix 2).

The risks associated with research on The Alfred campus can, to a large extent, be managed by the following actions:

- Development of Good Research Practice Guidelines that are distributed to all research staff and which set a standard for research activities conducted on the campus;

- Development of a course in Good Research Practice to be attended by all staff who are new to research;

- Appointment of a research auditor to be responsible for review of clinical research projects to ensure compliance with the Good Research Practice Guidelines.

These major components must be supplemented by additional specific actions aimed at managing all of the risks identified in the risk assessment (see Table 1 and Appendix 2).

6. Monitoring and review

The Risk Management Plan for Research on The Alfred Campus will be distributed to all departments/institutes undertaking research and will be made available for access on institutional intranets.

Responsibility for monitoring and review rests with institution / department heads.

Table 1 Summary of risk assessment and risk management plan.

Risks identified	Assessment of risk level[combines 'likelihood (L)' and 'consequence (C)]			Major consequences if risk not managed	Risk management strategies
	L	C	R		
Fraud in collection of data	3	3-4	H-E (high to extreme risk)	• Study data may be negated resulting in unreportable and unpublishable results • Published article may require retraction • Study may need to be repeated at considerable cost and effort • If NHMRC funding involved, NHMRC would need to be advised with likelihood of criticism of level of supervision and adverse effect on future funding • Ethics committee needs to be notified	• Develop strong culture emphasising care and accuracy in data collection • Ensure staff receive adequate training prior to embarking on research activities • Require research protocols to have adequate quality control procedures which are likely to detect falsified data • Require all new staff to be adequately briefed on the need for accuracy in data collection by the study directors and research auditor • Ensure that standard operating procedures are in place for most key data collection procedures including quality control procedures • Establish a sub-committee of the Medical Research Council to deal with potential research fraud
Serious errors in analysis of data	3	3-4	H-E (high to extreme risk)	• Study data may be negated resulting in unreportable and unpublishable results • If already published, article may require retraction	• Ensure that all key research data is analysed by two independent persons, with a statistician involved
Loss of data due to inadequate back-up procedures	5	3	H (high risk)	• Irretrievable loss of essential data • Expenditure of considerable expense and time in reconstructing database • Other funding implications (eg. cost of repeating study or withdrawal or non payment if no 'outcome' or report prepared)	• Develop detailed standard operating procedures relating to data management • Provide training in data management procedures via short course and postgraduate programs • Research auditor to review data management procedures • Back up data files daily
Serious breach of protocol or ethics committee requirements	4	4-5	E (extreme risk)	• Research may progress without ethics committee approval with the consequence that investigators lose the protection of their institution and insurer • Adverse events affecting a participant could lead to serious adverse publicity and threaten other activities in that country, legal liability and loss of insurance cover	• Insist on adequate training of research staff (inc. participation in course in Good Research Practice) • Research auditor to monitor compliance with ethics committee requirements

Risks identified	Assessment of risk level[combines 'likelihood (L)' and 'consequence (C)]			Major consequences if risk not managed	Risk management strategies
	L	C	R		
Serious breach of confidentiality	4	3-4	H-E (high to extreme risk)	• Could result in adverse publicity for institution • May lead to legal action from individuals whose privacy has been breached • Threaten other activities in that country	• Require all research staff to sign privacy / confidentiality declarations annually • Require all staff new to research to attend course in Good Research Practice • Unit heads and research auditor to emphasise requirement for privacy to staff • Research auditor to review data storage during audits • Senior management to create a culture of confidentiality
Failure to identify and follow up an abnormal pathology result	4	3	H (high risk)	• Failure to include efficient procedures to pass on important clinical information may mean that a potentially curable illness is not detected • May lead to significant legal action for negligence	• All studies involving physiological measurement or laboratory testing to include specific procedures to review abnormal results • Research auditor to monitor adherence to these procedures
Failure of monitoring or emergency procedures leading to death or serious injury to study participant	3	4	E (extreme risk)	May lead to • death or serious injury to participant • serious legal action against researchers • serious adverse publicity for institution	• Ensure that detailed standard operating procedures are developed • Adherence to standard operating procedures to be reviewed by research auditor
Attack on research personnel or other danger to personal safety especially when visiting outside the hospital	3	3	H (high risk)	• Physical injury to staff member • Staff member may become seriously ill	• Research staff to contact participants by telephone in advance of visit (to assess acceptability of visit) • If any concerns, visits to be undertaken with companion and during daylight hours • All research staff undertaking such visits to be provided with a mobile phone and personal alert and to call a designated individual before and after the visit • Staff visiting countries in which there is a danger to personal safety are to be provided with a mobile phone and appropriate travel medications, and clear procedures in case of emergencies
Perceived coercion of subjects to enrol in research studies	3	3	H (high risk)	• May lead to significant legal action if participant suffers adverse effects	• Provide potential participants with a balanced and fair verbal explanation • Make available 'cooling off period' and/or independent adviser when appropriate / or when requested by Ethics Committee
Undeclared conflicts	4	4	E	• The reputation of the department and	• Ethics Committee must seek complete information regarding financial

Risks identified	Assessment of risk level[combines 'likelihood (L)' and 'consequence (C)]			Major consequences if risk not managed	Risk management strategies
	L	C	R		
of interest			(extreme risk)	institution could be significantly damaged	arrangements for all research projects • All research funds to be handled transparently and in accordance with hospital policy • Research funds should be subject to audit and scrutiny as with all other hospital accounts

Table 2 Likelihood of occurrence

Score	Descriptor	Likelihood rating before considering
5	Almost certain	The event is very likely to occur
4	Likely	The event will probably occur
3	Occasionally	The event could occur at some time
2	Unlikely	The event has not occurred but could occur
1	Rare	The event may occur in some exceptional circumstances

Table 3 Consequence

Level	Descriptor	Detail description
5	Extreme	• Unexpected/unplanned loss of life, or permanent impairment of quality of life on a multiple scale • Multiple significant programs terminated • Substantial loss of reputation and loss of confidence in the hospital/institutional management by the public and media • Result in a parliamentary enquiry and loss of government confidence
4	Major	• Unexpected/unplanned loss of life, or permanent impairment of quality of life on a single scale • Threaten continued effective function or survival of a division or divisions • Result in loss of >5% of research revenue • Result in serious adverse publicity for institution and significant loss of reputation, require retraction of published article • Lead to serious legal action against researchers and institution • Result in research progressing without ethics committee approval (researchers lose protection of institution and insurers)
3	Moderate	• Unexpected/unplanned health impairments to patients and staff • Be serious for the organisation/institution or its divisions either financially or politically • Result in need for study to be repeated at considerable cost and effort • Result in irreversible loss of essential data; may require considerable time and expenditure to reconstruct database • Would not threaten survival of a program, but could be subject to significant review or changed way of operating • Result in negation of study data with results being unreportable and unpublishable • Result in necessity to notify ethics committee • Adverse media coverage • Lead to significant legal action against researchers and institution
2	Minor	• Minor health impairments to patients and staff • Threaten the efficiency or effectiveness of some aspects of a department • Financial loss that would impact on the research group • Be dealt with internally

1	Insignificant	• Complaints that can be dealt with routinely • Financial loss that comes within the relevant financial delegation level • Political enquiries resolved by routine management procedures • The consequences are dealt with by routine operations

Table 4 Calculation of level of risk

		CONSEQUENCE				
	LIKELIHOOD	**Insignificant 1**	**Minor 2**	**Moderate 3**	**Major 4**	**Extreme 5**
5	Almost certain	L	M	H	E	E
4	Likely	L	M	H	E	E
3	Occasionally	L	M	H	E	E
2	Unlikely	L	L	M	H	H
1	Rare	L	L	M	M	H

Key E = Extreme risk; immediate action required/needs active management now
H = High risk; senior management attention needed/regular monitoring (half yearly/quarterly)
M = Moderate; management responsibility must be specified/at least annual monitoring
L = low risk; manage by routine procedures/no major concern

Appendix 1: Laboratory book maintenance policy

The following are guidelines for staff and students in relation to laboratory book maintenance:

- Use notebooks with non-removable, sequentially pre-numbered pages.
- Commence a new experiment on a new page.
- Record the experiment title and date.
- Use black or blue biro only.
- Do not erase or use correction fluid – line out mistakes with a single line and initial and date new entry.
- Do not leave blank spaces; draw a line through such spaces.
- Sign and date each page.
- Have all pages witnessed regularly (at least once a week) by a non-supervisory colleague.
- Record all results and observations. (Any additional raw data in hard copy form can be adhered in the notebook with permanent pH neutral archival glue).
- Material that is added must be signed across the edge of the insertion.
- Material that is added must be witnessed.

Appendix 2: Detailed risk analysis

Fraud in collection of data

1 *Description of risk*:

- Researcher responsible for interviewing patients in their homes invents data rather than meeting the rigours required by the protocol
- Researcher 'adjusts' subject characteristics to make them meet eligibility criteria for a study
- Researcher alters data to make the results more likely to fit his/her preconceived idea of what results should show

2 *Likely circumstances*:

- Where research personnel collect data from external sources without close supervision
- Where research personnel employed on a study are new to research and have not been appropriately trained and briefed
- Where research personnel operate without likelihood of their data being checked
- Where senior staff are overcommitted and do not have sufficient time to discharge their supervisory responsibilities

3 *Likelihood of occurrence*:

- Occasionally, in appropriate circumstances (**3**)

4 *Likely consequences*:

- Negation of study data resulting in results being unreportable and unpublishable. If article already published, may require withdrawal with risk of severe embarrassment to researchers and department.
- Study may have to be repeated at cost to the department; delay in results becoming available may lead to breach of contract and liability to damages, especially if study is critical for the development of a drug or device.
- If NHMRC funding involved, the fact would need to be reported to NHMRC with likelihood of severe criticism of level of supervision and adverse effect on future funding. Requirement to review previous data collected by the researcher may lead to possibility of further adverse findings
- Ethics committees would have to be notified

5 *Approach in other industries*:

- The pharmaceutical industry pays particular attention to this risk because such an event could delay the program of development of a new agent resulting in large financial losses. Regulators also require rigorous data validation because of previous occurrences of fraudulent data collection.
- As a result of these concerns many pharmaceutical studies are accompanied by rigorous data validation procedures. Monitors employed by the pharmaceutical company or by contract monitoring companies periodically visit participating centres and carry out source data verification. This involves the matching of trial data with information from patients' medical records, original pathology laboratories etc.
- Pharmaceutical companies also require units undertaking early phase drug studies to have a series of standard operating procedures that specify the procedures to be undertaken in deriving and recording all data elements

6 *Risk management strategies*:

All departments/institutes on The Alfred campus must establish a strong culture that emphasises care and accuracy in data-collection. This involves:

- ensuring that all new staff are adequately trained in research methods/ethics. Those without a strong research background should be required to attend courses in research methods
- requiring all new research staff to attend the short course in Good Research Practice
- requiring all research protocols to have adequate quality control procedures that would be likely to detect falsified data. All chief investigators should be required to have regular study meetings with their research team in which data-collection forms, procedures involved in the collection and handling of data, and quality control measures are reviewed.
- requiring that all new staff are adequately briefed in the need for accuracy in data collection by the study directors and the research auditor
- ensuring that standard operating procedures are in place for most key data collection procedures, including quality control procedures
- establishing a sub-committee of the Medical Research Council to deal with potential research fraud

Serious errors in analysis of data

1 *Description of risk*:

- Serious error made in analysis of a data set leading to the need to retract a published article or correct a report. Under worst circumstances this could alter outcomes of research that had already been acted upon at considerable cost and lead to substantial legal liability. This could seriously affect the scientific career of a researcher and his/her colleagues and/or threaten the financial viability of the department/institution.
- Researcher may fraudulently alter results to fit preconceived hypothesis or to increase the likelihood of publication of the results. After discovery, this could mandate review of previously published work, require retractions and raise spectre of legal action as above. Colleagues involved in current and previous research could have their reputations tarnished.

2 *Likely circumstances*:

- Analysis of large data sets by computer requires high levels of expertise gained only from experience under adequate supervision. Mistakes are easy to make and may be difficult to detect because intuitive feel for data is less that with small paper-based data sets. Serious errors are more likely if analysis of large data sets is unsupervised and conducted by relatively junior researchers
- Much research data requires sophisticated statistical analysis. Computer packages allow these analyses to be undertaken with relative ease by inexperienced people but there is a high risk of inappropriate application.
- Fraud in data analysis is unlikely with large data sets because their size makes them resistant to manipulation. However, an inadequate research culture and poor supervision would make it possible

3 *Likelihood of occurrence*:

- Occasionally, in appropriate circumstances, especially when full responsibility for data analysis is delegated to a relatively junior researcher or research student (**3**)

4 *Likely consequences*:

- Negation of study data resulting in results being unreportable and unpublishable. If already published article, may require withdrawal with risk of severe embarrassment to researchers and department.

5 *Approach in other industries*:

- It is increasingly common in the pharmaceutical industry for all data to be independently analysed by two statisticians

6 *Risk management strategies*:

- All research data requiring analysis should be analysed by two independent persons, with a statistician involved. No original results should be published without the senior researcher being able to certify that either (a) a statistician has undertaken the analysis or (b) that the analysis of the data has been checked by a statistician or (c) a statistician has reported to the senior investigator that the head of biostatistics has sufficient confidence in the researcher undertaking the analysis to warrant that the requirements for checking are not necessary
- All PhD students should have key results checked by a statistician

Loss of data due to inadequate back-up procedures

1 *Description of risk*:

- Clinical and public health research commonly involves the use of large computer databases which are continuously being updated as new data is added and older data is checked and edited. A highly organised and systematic process is needed to ensure that changes are being made to the appropriate (ie. The latest) copy of the database and that the most current copy of the database is backed-up regularly and kept in a secure location.
- It is often a prolonged and expensive process to reconstruct a database that is destroyed in a computer 'crash' or in the unlikely event of a fire or theft. For this reason, systematic processes are needed with frequent checks that the procedures are being adhered to.

2 *Likely circumstances*:

- The risk is greatest when databases are established and maintained by researchers without the close support of an experienced programmer or database manager.
- The risk is greater in large data sets where databases are constantly being updated, especially if more than one person is involved in data entry or if different people are involved in data entry and data editing.
- A high risk exists in the data checking/editing stage where it may be easy to lose track of which is the most current version of the database.
- A substantial risk of data loss due to theft, malicious destruction or fire may occur if all copies of a database are kept in the one location or on the same computer

3 *Likelihood of occurrence*:

- Almost certain, unless specific precautions are taken (**5**)

4 *Likely consequences*:

- The likely consequences may range from irreversible loss of essential data to an expensive and time consuming process in reconstructing a database. If not recognised or remedied, this could lead to the publication of inaccurate data.

- There may be other funding implications, such as the cost of repeating the study or withdrawal or non payment if there is no 'outcome' or report prepared.

5 *Risk management strategies*:

Because of the high likelihood of this problem arising, it is necessary to have detailed procedures in place to lessen the risk. These include:

- development of detailed standard operating procedures related to data management which are incorporated into the Good Research Practice Guidelines
- provision of training in data management procedures via short course and postgraduate programs
- review of data management procedures as an essential component of reviews conducted by the research auditor
- daily back up of data files

There is a general recognition that this problem will not be adequately addressed until a data management unit is established that can provide advice and support for all departments/institutions on the campus.

Serious breach of protocol or ethics committee requirements

1 *Description of risk*:

All research involving humans must be endorsed by an appropriate ethics committee. Ethics approvals are specific to the particular protocol (including plain language information statements and data collection sheets). Entry of patients to a study whose personal characteristics do not meet those of the approved entry and exclusion criteria is a breach of the condition of ethics approval. It may also lead to a breach of contract with a study sponsor. If an individual who was ineligible for entry to a study experiences an adverse event, they may have grounds for legal action that would not be covered by the institution's insurers.

Ethics committees pay particular attention to circumstances of consent. They require all study participants to be provided with an approved 'plain language' information sheet and to sign an approval form that signifies their preparedness to participate in the project. These forms must be carefully filed and made available for scrutiny by auditors operating on behalf of the ethics committee or the study sponsors. Should an individual claim that they had not been adequately informed of the risks and benefits of participation, this documentation provides an important line of defence for investigators. Entry of patients to a study without consent is an egregious error which could lead to severe sanctions and highly adverse publicity.

Serious adverse events affecting any study participant, and considered reasonably likely to have resulted from study participation, must be notified urgently to study sponsors and the appropriate ethics committee. Failure to do this may lead to sanctions by either of these agencies.

2 *Likely circumstances*:

- The areas of greatest risk are studies involving significant risk to participants, such as drug trials and invasive studies, or where study is in an environment with different social and cultural 'norms'.
- The risk is higher in investigator initiated research where there is no program of independent monitoring by a study sponsor.

- The risk is also likely to be higher in units with research programs where senior staff are too busy to provide adequate supervision of their research programs.
- Failure to meet ethics committee requirements is usually a result of lack of knowledge of an ethics committee's role in the regulation and monitoring of an institution's research program. Thus, it is more likely amongst those who have not undertaken formal research training.

3 *Likelihood of occurrence*:

Likely (**4**)

4 *Likely consequences*:

- If significant alterations are made without ethics committee approval, the research may effectively be progressing without ethics approval. Under such circumstances the investigators may lose the protection of their institution and their insurers. They may lose the confidence of their local ethics committee and the management of their institution.
- Adverse events affecting an individual admitted to a research project without permission could lead to serious adverse publicity and serious legal liability as well as a loss of insurance cover.
- Other activities / programs in a particular country may be threatened.

5 *Risk management strategies*:

- Insistence on adequate training of all research staff (including participation in course in Good Research Practice)
- Research auditor to monitor compliance with ethics committee requirements and check that:
    - consent forms are available for all studies
    - approved plain language sheet is provided to participants
    - all serious adverse events have been reported
    - all participants in studies meet approved entry and exclusion criteria.

Serious breach of confidentiality

1 *Description of risk*:

Clinical and public health research commonly collects information of considerable sensitivity, which is divulged only because of guarantees of confidentiality provided by the researchers. In other instances ethics committees may approve the use of health-related data without the consent of individuals when the public benefit is considered to substantially outweigh concerns regarding privacy.

Ethics committees approve the collection of personal health-related data for research purposes only if they are assured that the data will be maintained under strict conditions that protect the confidentiality of the subject participants.

Privacy requirements to be observed by researchers have recently become more explicit with the adoption of new legislation that must be observed by all those involved in the collection of personal data. Breaches of these requirements may result in criminal penalties.

Components of the procedures required for privacy protection include:

- restriction of access to personal data to a small number of individuals with a need for access
- training of researchers at all levels in the issues related to data confidentiality

- provision of secure storage of confidential data which includes restricted access to areas where such data is stored, separation of identifying data from the other data elements, secure password access to data in computers and development of a specific protocol for destruction of identifying data when no further need exists to retain this information.
- requirement for all staff involved in data collection or processing to sign a confidentiality declaration at yearly intervals

2 *Likely circumstances*:

- Breaches of privacy are most likely in cases where there has been little attempt to create a culture of confidentiality and reinforce it.
- Privacy breaches are also more likely where new researchers who have not been adequately educated about the rationale for confidential data handling are given responsibilities in this area.
- A specific instance of risk is where a research staff member handles data from an individual known to the researcher and is tempted to mention this outside the department

3 *Likelihood of occurrence*:

Likely (**4**)

4 *Likely consequences*:

- A serious breach of confidentiality could result in serious adverse publicity that could significantly lessen the likelihood of future participants providing confidential information.
- It would probably reduce the likelihood of gaining ethics approval for future projects requiring collection of personal data.
- It might lead to legal action from the individuals whose privacy has been breached.
- It might jeopardise other activities / programs.

5 Risk management strategies:

- Requirement for all research staff to sign privacy/confidentiality declarations annually
- Requirement for all new research staff to attend course in Good Research Practice
- Requirement for privacy to be emphasised to new staff by unit heads and research auditor
- Data storage for all studies to be reviewed periodically by research auditor during audit
- Obligation on senior management to create a culture of confidentiality

Failure to identify and follow up an abnormal pathology result

1 *Description of risk*:

Many research studies involve the measurement of physiological variables (such as blood pressure) and the undertaking of various pathology tests (such as full blood examinations or liver function tests). When large numbers of individuals are tested, there is a strong possibility of finding abnormalities of clinical significance that may not be known to the individual or his/her medical practitioner. In some instances, recognition of the abnormality may allow effective treatment to be introduced.

2 *Likely circumstances*:

- The primary risk setting is where screening tests are being done on large numbers of individuals either as part of eligibility screening for a research study or as part of an epidemiological study

3 *Likelihood of occurrence*:

Likely, unless anticipated and a highly organised approach is developed to assess and handle abnormal results (**4**)

4 Likely consequences

- Failure to include efficient procedures to pass on important clinical information may mean that a potentially curable illness is not detected. This could lead to significant legal action for negligence.

5 *Risk management strategies*:

- All studies involving physiological measurement or laboratory testing must include specific procedures to review all abnormal results.
- These procedures must be documented in the protocol and procedure manual and adherence monitored by the research auditor.

Failure of monitoring or emergency procedures leading to death or serious injury to a study participant

1 *Description of risk*:

Some clinical research projects, particularly those conducted on patients with conditions such as asthma or hypertension, may require special attention to monitoring and the availability of emergency care. For example, clinical trials of new drugs may require withdrawal of usual therapy with clinical monitoring to ensure the detection of deterioration. The risk of medical complications resulting from such actions may be sufficiently high as to mandate the availability of urgent medical assessment and/or emergency care.

If such emergency care was not immediately available and, as a result, a study participant died or developed serious complications, serious repercussions would follow for both the investigator and the institution.

2 *Likely circumstances*:

- This risk is most likely to be encountered in drug trials and in physiological studies. The risk is greater when studies are supervised by inexperienced staff and when senior clinical investigators are unavailable or not able to be contacted.

3 *Likelihood of occurrence*:

Occasionally (**3**)

4 *Likely consequences*:

May lead to

- Death or serious injury to participant
- Serious legal action against researcher/s
- Serious adverse publicity

5 *Risk management strategies*:

- Ensure that detailed standard operating procedures are developed
- Adherence to standard operating procedures to be reviewed by research auditor

Attack on research personnel or other danger to personal safety especially when visiting outside the hospital

1 *Description of risk*:

Some research studies involve visits to participants' homes to conduct interviews or to collect samples. Often these visits are conducted by research nurses after hours. Under these circumstances there is a risk to the safety of the research staff.

Research conducted in under developed countries may expose research personnel to an increased risk of contracting exotic diseases or, because of deficiencies in law and order, to risks of bodily harm.

2 *Likely circumstances*:

- After hours visits by lone research nurse
- When research personnel working in under developed countries fail to take appropriate precautions to avoid contracting diseases/illnesses or to avert physical attack

3 *Likelihood of occurrence*:

Occasionally (**3**)

4 *Likely consequences*:

- Physical injury to staff member, with the senior management accountable for lack of appropriate preventive action
- Staff member becomes seriously ill and requires hospital treatment or evacuation

5 *Risk management strategies*:

- Research staff to contact participants by telephone in advance of visit to assess acceptability of visit
- If any concerns, visits to be undertaken with companion and during daylight hours.
- The institution / department involved will provide all research staff undertaking such visits with mobile phones and personal alerts. They will call a designated individual before and after the visit.
- Ensure the availability of adequate travel medicines, mobile phones, etc. for those staff members travelling to countries in which there may be increased dangers to personal safety; have in place clear procedures in case of emergencies.
- Adherence to this protocol to be checked by the research auditor.

Perceived coercion of subjects to enrol in research studies

1 *Description of risk*:

It may be perceived that some subjects, particularly those with a long-standing reliance on a particular clinician (for example, with cystic fibrosis or lung transplantation), have been coerced into taking part in a research study.

2 *Likely circumstances*:

When subjects have had a professional relationship with a clinician over a prolonged period, often for several years, they may believe that their clinical care will be jeopardised if they fail to participate in a research study.

3 *Likelihood of occurrence*:

Occasionally (**3**)

4 *Likely consequences*:

- May result in signficant legal action if patient suffers adverse effects from treatment under trial.

5 *Risk management strategies*:

- Provide potential participants with a balanced and fair verbal explanation
- Make available 'cooling off period' and/or independent adviser when appropriate / or when requested by Ethics Committee

Undeclared conflicts of interest

1 *Description of risk*

If a treatment under evaluation in a research study has a high potential commercial value, there is the possibility of significant financial inducement by a pharmaceutical company (or a venture capitalist) to investigators to participate and recruit participants.

2 *Likely circumstances*

This may occur where a particular treatment may have a high commercial value but the science may not be comparably strong, making the proposed trial relatively unattractive to a potential study centre. Agreeing to recruit participants for the study may be based on undue financial inducements.

3 *Likelihood of occurrence*

Likely (**4**)

4 *Likely consequences*

- Damage to the reputation of the department and institution

5 *Risk management strategies*

- Ethics committees must seek complete information regarding financial arrangements for all research projects
- All research funds are to be handled transparently and in accordance with hospital policies
- Research funds should be subject to audit and scrutiny as with all other hospital accounts