GIG CYMRU NHS WALES
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Shared Services Partnership
Welsh Risk Pool Services

Welsh Risk Pool

INDEMNITY NOTE H

INDEMNITY FOR

NHS CLINICAL RESEARCH

Title:	Indemnity for Clinical Research
Version:	2.1 *(supersedes V1.1 and Annexe document)*
Published:	29th March 2023 Approved WRPC 15th Mar 2023 subject to technical review by authoring team - which was completed 29th March 2023
Next Review:	This Technical Note will be reviewed when the All-Wales Policy on Indemnity & Insurance is reviewed (planned May 2023)

This Technical Note is intended to support the consistent and accurate application of the All-Wales Policy on Insurance and Indemnity and should be read in conjunction with the following documents

- All-Wales Policy on Indemnity & Insurance
- Scope of Welsh Risk Pooling Scheme

A member health body may raise an indemnity query using the form contained within the policy document and emailed to welsh.riskpool@wales.nhs.uk. Enquires may take up to three calendar months, particularly if the matter needs to be presented to the Welsh Risk Pool Committee.

WELSH RISK POOL TECHNICAL NOTE H

INDEMNITY FOR NHS RESEARCH

V2.1

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SUMMARY

Developing a culture of research and development in the fields of health and social care will bring short- and long-term benefits to the people of Wales. It is important that the risks associated with such activities are clearly understood and that there is clarity over the respective indemnity arrangements to ensure that risks are accepted by all parties as appropriate. This Technical Note clarifies what indemnity is available for research, hereinafter known as ("NHS Indemnity"). The principles set out for research and development are in line with those in the All Wales Policy on insurance, NHS indemnity and related risk management document, where this Technical Note H is part of, and applies to activities involving persons to whom the NHS owes a duty of care. The principles being:

i) NHS Indemnity will apply in respect of losses arising from services provided by NHS Trusts, Local University Health Boards and Local Teaching Health Board in Wales (hereinafter known as "NHS Organisation"), where a service is deemed to be directly provided by an NHS Organisation if it retains responsibility for the delivery of the service, including the overarching supervision and management arrangements.

For the purposes of this Technical Note, Sponsor is defined as per the definition in the UK Policy Framework for Health and Social Care Research as:

> *"The Sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project".*

If the NHS Organisation is co-Sponsor or joint Sponsor to research; the NHS Indemnity will only apply to the service, obligations and responsibilities directly required to be provided by the NHS Organisation.

ii) NHS Indemnity only applies to negligent harm.

iii) NHS Indemnity only covers NHS staff who, whilst undertaking research delivery, are providing services as staff of the NHS Organisations.

iv) NHS Indemnity will apply to university staff who, whilst undertaking research delivery, are providing services not as staff of the NHS Organisation but are nevertheless under the management supervision and control of the NHS Organisation.

If neither point iii or iv above apply, then NHS indemnity is not applicable.

The purpose of this document is to support research and development through the provision of a workable framework of principles which sets out the circumstances when NHS Indemnity will apply, and the actions required by NHS Organisations. Where NHS Indemnity applies, any resultant losses will automatically be within scope of the risk pooling arrangement for NHS Wales.

Queries in relation to this technical note

It is intended that this technical note will provide a workable framework for NHS Wales. However, where specific queries arise or the scope of the indemnity arrangements for Clinical Research and Trials need to be reconsidered then queries should be submitted to the Welsh Risk Pool Services using the standard indemnity query form available from the intranet site

Background

In recent years there have been significant developments and innovations in the area of clinical research and development, and it is clear that a wide range of scenarios exist which often involve joint arrangements with academic institutions. This document does not seek to amend the principles which have been in place for a number of years but updates and clarifies the application for the current models in place.

Sponsoring organisations

Research undertaken in the NHS may be Sponsored by either:

(a) Private, commercial or charity sectors including universities, or

(b) An NHS Organisation

Research Sponsored by (a) should be supported by a site agreement and/or an Organisation Information Document (or any successor equivalent) as applicable, and an indemnity certificate where required, as part of the documentation submitted for HRA/HCRW approval if in England and Wales or study wide review if in Scotland or Northern Ireland (here in after referred to as "HRA/HCRW Approval") which will provide confirmation of the insurance and indemnity arrangements that will apply to each research study. The HRA/HCRW Approvals process should confirm that the NHS is not exposed to risks associated with poor design.

For research Sponsored by (b), NHS Indemnity will apply for research which takes place within the United Kingdom.

Clinical Negligence

General

NHS Indemnity means that NHS Organisations forgo the right to recover costs and damages from their staff in respect of liabilities arising out of clinical negligence (except where that involves criminal or wilfully negligent behaviour). It covers both acts and omissions of NHS staff.

NHS Indemnity covers clinical negligence but does not extend to other liabilities such as product or employers' liability.

NHS Indemnity is Government policy: it is not a statutory obligation.

NHS Indemnity covers negligent harm to those to whom an NHS Organisation owes a duty of care, whether or not the individual causing the harm was a member of NHS staff, or an individual contracted to provide services to the NHS organisation.

Where NHS Indemnity is deemed to apply, and the activity is being delivered by an academic partner, an honorary contract for research should be in place. However, the scope of the honorary research contract should be clearly limited to approved studies for which NHS Indemnity applies.

The agreement between all parties of who owes the duty of care to the patient and/or volunteer is a key aspect of the approval process. A matrix of possible scenarios is provided in Appendix A. Where there is doubt about whether NHS Indemnity applies or to agree indemnity arrangements outside of these principles then approval should be sought from the Welsh Risk Pool Committee in advance.

Research

Research is a core NHS activity. It is therefore treated in the same way as any other NHS activity in relation to potential liabilities for clinical negligence.

For all NHS research delivery activity, whether commercial or non-commercial, liability for clinical negligence on the part of NHS Staff lies with the NHS Organisation delivering the research activities.

NHS Indemnity means that NHS Organisations forgo the right to recover costs and damages from researchers in respect of liabilities arising out of clinical negligence (except where that involves criminal or wilfully negligent behaviour, including research fraud or misconduct).

For commercial research activities, the commercial company Sponsoring the activities should provide full indemnity cover according to the Association of the British Pharmaceutical Industries (ABPI) (Code of Practice for Pharmaceutical Industry, issued by the ABPI from time to time) and/or the Association of the British Healthcare Industries (ABHI) (Code of Ethical Business Practice issued by the ABHI from time to time) appropriate to the study type; and use the appropriate UK NHS model template commercial site agreements, where a model template is available.

Liability for activities of Sponsors in designing and/ or managing research are separate from the liabilities of organisations that actually deliver the research activities. NHS

Indemnity covers negligent harm caused to patients and volunteers by NHS research delivery activities as summarised in Appendix A.

Where NHS staff undertake research across more than one NHS Organisation, the employing organisation will retain liability. Organisations should document the arrangements to provide clarity in the event of a claim being made and to clarify the management controls relating to the arrangement.

Conditions of indemnity

For NHS Indemnity to apply to individual NHS Organisations the following conditions must be met:

(a) All research studies must be submitted to an NHS Research Ethics Committee ("NHS REC") as part of the HRA/HCRW Approval, (except those studies that are specifically exempt from review under the Governance Arrangement for Research Ethics Committees (GAfREC) guidance, which NHS Indemnity will apply if either the research is NHS research or involves research activities performed by NHS staff).

(b) All research studies must be submitted for HRA/HCRW Approval which includes, but is not limited to, consideration of the appropriate levels identified in the following:

- Financial implications for the NHS Organisation.
- Service implications for the NHS Organisation, e.g. radiotherapy, pharmacy, pathology etc.
- Risk management in relation to drugs, equipment, staff involved etc.
- Identification of a member or members of staff responsible for the study, including the reporting of any adverse incidents associated with the study.
- The monitoring arrangements that will be in place to provide assurance that the study is conducted in line with the approval.

(c) Research studies with NHS Organisations, depending on the role of the NHS Organisation and the site type, may require the NHS Organisation to provide confirmation of capacity and capability from each participating NHS Organisation's NHS R&D Office, or an agreed representative appointed by the NHS R&D Office

on behalf of that NHS Organisation, as part of the study set up process. The information supporting the arrangements of the requirement for confirming capacity and capability at the research site will be clarified in the HRA/HCRW Approval letter. The intention is that the letter is an accurate reflection of the study at the time of issue. The HRA/HCRW Approval process and the confirmation of capacity and capability from the NHS research site must be able to demonstrate that relevant members of staff have been involved in this study set up process. This includes but is not limited to medical staff, pharmaceutical staff, laboratories, radiology, psychology staff, and general management staff, as appropriate dependent on the nature, type and subject matter of the research study.

Where required to do so, Research studies must be submitted and approved using the HCRW/HRA Approval process. For multi-site NHS Sponsored studies, NHS Indemnity will be limited to Sponsored multi-site research undertaken within the UK only. Where the research is undertaken outside of the UK, commercial insurance will be required if the study outside of the UK is considered income generated activity.

NHS Indemnity does not cover disciplinary investigations representations from the GMC or equivalent for nursing and Health Care Professional organisations for misconduct, for restrictions or exclusions from professional practice.

NHS Indemnity does not cover private work.

Indemnity for assurances from HRA/HCRW Approval and NHS REC opinions

NHS employers retain legal responsibility for compliance with a wide range of legislation such as the Ionising Radiation (Medical Exposure) Regulations 2017 and Medicines for Human Use (Clinical Trials) Regulations 2004.

NHS Organisations should have confidence in accepting assurances from HRA/HCRW Approvals and NHS REC opinions about the legal compliance of arrangements that are set out in protocols and related documents for individual research studies or research resources.

The HRA/HCRW Approval and NHS REC opinion provides the legal compliance, guidance and standards that should be used as the basis for assessing governance arrangements set out in protocols and related documents. Individual NHS Organisations should not therefore be required to repeat the governance reviews but have assurance in the reviews leading to the HRA/HCRW Approval, which (via Powys LHB for the HCRW

Approval as host organisation) is covered by the Welsh Risk Pool for judgements made based on the principles of the UK Policy Framework for Health and Social Care Research. Therefore, any changes to the reviews completed as part of HRA/HCRW Approval e.g., additional conditions, other than what is recommended within the approval, will no longer be indemnified by Welsh Risk Pool, as part of NHS Indemnity, but will be the liability of the NHS Organisation making those changes

The HRA/HCRW Approval staff are employed under NHS terms and conditions and are contractually obliged to comply with the legal duty of confidentiality.

This HRA/HCRW Approval is for NHS research, which is either Sponsored by the NHS, have NHS sites, involve participants whom the NHS have a duty of care for, or whereby there are NHS Staff working within the scope of their NHS employment contract working in a non-NHS setting.

NHS RECs are indemnified to review studies that are within the scope of practice. Social Care studies have not traditionally been reviewed in Wales, but there is provision to review all studies that are part of its core activity as that evolves.

Pharmacy and Radiation Assurances provided and coordinated for HRA/HCRW Approvals

It is standard practice for NHS organisations to provide and accept reasonable assurances from other organisations for pharmacy and radiation assurances as part of the HRA/HCRW Approval, rather than creating duplication and unnecessary variation by repeating activities. In this context NHS organisations should consider it reasonable and appropriate for them to accept assurances provided by appropriately qualified professionals through a nationally agreed process. Accepting such assurances will be a lower risk for an organisation than relying on the individual interpretations of their own staff. Professionals who undertake assessments as part of the HRA/HCRW Approvals are indemnified by the NHS provided the assessment is completed within the terms of the HRA/HCRW guidance and standards.

If the expert assessor is completing the review for their employing organisation rather than as part of the pharmacy or radiation expert assessment for HRA/HCRW Approval, then that employing organisation indemnifies. NHS Indemnity Schemes acknowledge that for pharmacy reviews the reviewer will be NHS employed; however, for radiation reviews, as well as NHS employed, they could also be University employed, a

commercially employed reviewer or an independent reviewer (where there is an expectancy that professional indemnity cover would be provided by that reviewer rather than through the NHS Indemnity Scheme).

Assurances provided by other NHS Organisations for contracts and costings

In Wales, we are committed to working across the NHS Organisations providing contract and costing reviews, such as UK National Contracts Value Review, where the review is completed by another NHS organisation but is accepted by Welsh NHS Organisations, and for multi–Welsh NHS sites, agreements are reviewed where possible once across the NHS Organisations with an appointed lead NHS reviewer from one of the/ or on behalf of the participating NHS Organisations, avoiding duplication and a swifter study set up.

As a risk pooling scheme, The Welsh Risk Pool does not allow for NHS Organisations to make claims from other organisations. Any claim made against an NHS Organisation that has provided assurances to another NHS Organisation or accepted assurances from another NHS Organisation will be managed through the Welsh Risk Pool.

One site Wales approach

Where the study type is determined as suitable by Health and Care Research Wales Support and Delivery Service, research may be set up in Wales for a study with a lead trial site and then other trial sites overseen by the lead trial site. For this approach, there is an expectation that the lead trial site will be the party to the study site agreement and then pass-through agreements put in place with the other trial sites; whereby the indemnity of the Sponsor is passed through.

As above, as a risk pooling scheme, The Welsh Risk Pool does not allow for NHS Organisations to make claims from other organisations. Any claim made against an NHS Organisation that has provided assurances to another NHS Organisation or accepted assurances from another NHS Organisation will be managed through the Welsh Risk Pool.

NHS Staff providing support to university sponsored research

NHS staff undertaking activities as part of their contract of employment are not required to take out separate professional indemnity. However, if a member of staff is approached by a university to provide clinical input into a study outside of the scope of the NHS Indemnity Scheme then there is an expectation that that the study will need to be subject

to the normal study approval mechanism for example HRA/HCRW Approval, individual University Research Ethics Committees etc.

NHS Staff working in Research

NHS Organisations have a duty of care and are liable for harm arising from the conduct of their activity. The responsibility (and therefore liability) for the conduct of the research activity rests with the organisation that is undertaking the activity, regardless of the physical location where the activity occurs.

NHS staff undertaking activities as part of their contract of employment, within usual care competence or standard duty of care, are not required to take out separate professional indemnity. If the NHS staff is working within the terms of their Job Description and within the scope of the NHS Indemnity and NHS Duty of Care of their substantive NHS employer, then NHS Indemnity applies through the membership of the NHS Indemnity Scheme of the NHS employing organisation.

For avoidance of doubt, NHS Organisations with staff working outside of an NHS setting are only liable for their conduct during the research in the non-NHS setting, unless the NHS employing organisation is also the NHS Sponsor for the research, in which case, NHS Indemnity also covers sponsorship responsibilities as well. This means with the exception of Sponsorship responsibilities, the employing NHS Organisation is not responsible for the conduct, study design or any other indemnity of any other non-NHS organisation setting, or staff, other than for its NHS staff (or University staff working under the management and supervision of NHS under an honorary contract). It should be clear from the information received by the participants which organisation is liable for the study.

For avoidance of doubt, non-NHS setting should be interpreted as meaning of NHS research staff conducting research activities outside of NHS premises, including but not an exhaustive list: patient homes, care homes, hospices and other charity sectors, public places such as shopping centres as part of Public Health type studies, prisons, persons in custody etc.

NHS Staff providing support to other NHS organisations

Same as in the non-NHS setting, where an NHS staff member from one NHS Organisation works in a different NHS Organisation to where their substantive employment is, the liability of the conduct of the NHS staff for the duty of care to its

patients rests with the organisation that is undertaking the research activity i.e. the substantive NHS employer of the NHS staff.

Contractors and 3rd Party and NHS Indemnity

Contractors within primary and community sector which are employed under the direction and control of the NHS will be covered by the NHS Indemnity Scheme, as per the terms of NHS staff indemnity within this technical note.

Any engagement with any 3rd Parties must have the responsibilities and evidence of appropriate indemnity clearly documented to the NHS Organisation. For avoidance of doubt, contractors working independently as expected to have in place their own professional indemnity arrangements.

GMPI Scheme and NHS Indemnity

The main change for General Medical Practices is that in relation to incidents occurring on or after 1 April 2019, the NHS Organisations in Wales will provide an indemnity arrangement and will be the named Defendant for clinical negligence litigation rather than the General Medical Practices. NWSSP - L&R will act on behalf of and seek instructions from the NHS Organisations in relation to the litigation and will seek evidence and views on the proposed strategy from General Medical Practices. Although the NHS Organisations will be the client for the purpose of the litigation, the views of all individuals involved will be taken seriously and they will be treated fairly and reasonably.

The scheme will include the provision of guidance and support for General Medical Practices in Wales and their employed or contracted staff, for actual or potential clinical negligence litigation arising from the provision of NHS Primary Medical Services. Some aspects of GP work will not be covered by the scheme, for which membership of a Medical Defence Organisation ("MDO") will remain necessary. Examples of such 'out-of-scope' activity will include private work, inquests, disciplinary issues, issues with the GMC or other Regulators and any non-clinical elements of Ombudsman referrals.

What is covered?

(a) section 41(2) (primary medical services);

(b) section 42(1) (general medical services contracts);

(c) section 50 (arrangements NHS Organisations for the provision of primary medical services).

There is an All Wales Locum Register ('AWLR') for Wales which GP locums must join in order to be captured by GMPI. There are specific requirements with which GP locums must comply in order to benefit from GMPI.

More details can be obtained from the GMPI guidance.

So what this means for research is that General Medical Practices are now eligible to be included in the NHS Indemnity Scheme based on membership application and acceptance. TOP/END

Equipment loaned to NHS Organisations for delivery of research

Where the research study involves the use of third-party equipment loaned to the NHS Organisation for the delivery of the research, it is important that the respective responsibilities and risks are agreed in advance, including completion of delivery notes and master indemnity agreements (MIAs) where appropriate; alternatively the appropriate Loaned Equipment sections of the appendices / schedules in the UK NHS model template site agreements. In respect of losses arising from its own negligence, NHS Wales is precluded from purchasing commercial insurance to cover equipment (Welsh Health Circular 04 (2000)) and therefore losses will fall to the NHS Organisation. These losses are not automatically within scope of the Risk Pooling arrangement. Equipment claims will only be paid by the Welsh Risk Pool Services upon evidence that the risk was not foreseeable and had a significant impact which could not be mitigated. In any event, successful claims will incur a £50,000 excess.

Intellectual property

The scope of this indemnity does not include liabilities arising from the commercial exploitation of clinical research and development. The commercial exploitation of knowledge is currently not within the scope of the WRPS indemnity scheme.

Non negligent clinical harm

The NHS Indemnity provided by the WRPS is limited to negligent harm only

Non-negligent clinical harm by an NHS organisation carries no legal liability.

It is ultra vires for NHS Organisations to give indemnity for compensation in the event of non-negligent clinical harm.

NHS Organisations may not offer advance indemnities or take out commercial insurance for non-negligent clinical harm.

An NHS Organisation may however consider making an ex-gratia payment in respect of non-negligent clinical harm. This is possible if the participant in the research has sustained harm and the sponsor is an NHS Organisation.

NHS Organisations should not make ex-gratia payments for non-negligent clinical harm where research is sponsored by a non-NHS body.

A HRA/HCRW Approvals governance review may decide that a study cannot go ahead unless participants are assured of compensation for non-negligent clinical harm. In that case the research can proceed, only if another non-NHS body is willing to make the required arrangements for compensation.

Data Protection Liabilities

Data controllers are obliged to comply with the the GDPR, the Data Protection Act 2018, the Privacy and Electronic Communications (EC Directive) Regulations 2003, as well as any legally enforceable NHS requirements, Codes of Practice or Guidance issued by the Information Commissioner's Office, in each case in force from time to time in England and/or Wales, the broad aims of which are to ensure that they process data lawfully and fairly.

Data controllers may seek assurances from other bodies about the legal compliance of arrangements that are set out in protocols and related documents for individual research studies or research resources.

The HRA/HCRW Approvals provides guidance and standards that should be used as the basis for assessing the compliance of arrangements set out in protocols and related documents.

Data controllers and processors are obliged to ensure that the activities within their organisation are conducted in accordance with their obligations under the Data Protection Act 2018 and that they report breaches appropriately. This obligation is primarily met through organisational policies, training and monitoring the conduct of research activities, and may include the assured arrangements and assessments.

Where personal data is shared between organisations for any purpose, a written agreement should be in place which sets out the purposes for which the data will be shared and the arrangements for ensuring that both organisations comply with the Data Protection Act in relation to the shared data; also the role of the data controller and processor. However, the need for separate Data Sharing, Data Re-Use or Data Transfer

agreements will usually be negated through the use of four nations NHS approved model template agreements provided by the sponsor for sites, where an appropriate template for the study type is available.

The Welsh Risk Pool scheme covers claims arising from breaches of the Data Protection Act and professional negligence claims, amongst other liabilities. Welsh Risk Pool does not cover prosecution for criminal offences under the Data Protection Act, e.g. the offence of knowingly or recklessly disclosing personal information without the consent of the data controller.

When researchers undertake research in NHS organisations other than their substantive employer but are handling confidential data under the instruction and direction of the organisation in which they are working, the researcher's substantive employer remains the data processor.

The HRA/HCRW Approval will provide assurances about the compliance of proposed research activities set out in the study protocol and associated documents with the Data Protection Act, and related legal codes. NHS organisations should have confidence in accepting such assurances without duplication of review of the proposed activities. Accepting assurances provided against national standards can reduce the organisation's risk of misunderstanding or misinterpreting the organisation's obligations. However, NHS organisations remain responsible, including through monitoring and training, for ensuring that the activities are conducted in accordance with the Data Protection Act 2018.

Appendix A University Research Staff

One of the purposes of an honorary research contract is to confirm to a researcher employed by an academic institution that they are indemnified by the NHS for their clinical activities. However, its primary purpose should be to bring the researcher within the accountability and management controls of the NHS organisation in order to minimise the risk of any claims arising.

An honorary research contract does not, of itself, confer indemnity for clinical activity. It is the accountability and control mechanisms plus the duty of care which matter in this respect. Furthermore, confirmation of NHS indemnity may be provided in other documents, as long as they are accompanied by mechanisms to ensure that appropriate pre-engagement checks have been conducted (in accordance with national good practice) and relevant supervision or management arrangements have been put in place.

In secondary care settings the NHS Organisation will normally issue an honorary research contract to bring the researcher within its accountability arrangements and confirm that NHS indemnity is available.

A researcher may undertake research activities across more than one NHS organisation, relying on a single confirmation of NHS indemnity and confirmation of pre-engagement checks. Honorary research contracts are therefore not required from each individual NHS organisation. Each organisation should put in place relevant supervision or management arrangements.

NHS indemnity for clinical negligence is conferred on researchers employed by university or other NHS organisations when they undertake clinical research activities on patients to whom the NHS has a duty of care. The NHS ensures that such researchers have had appropriate pre-engagement checks, and that accountability and management oversight arrangements are clarified in accordance with the Research in the NHS: Human Resource (HR) Good Practice Resource Pack. The NHS organisation responsible for the undertaking of the research activities will clarify the appropriate pre-engagement checks that should be undertaken for individual research situations for the researcher employed by the university or other NHS organisation.

Scenario	Study Sponsor	Building, Equipment, location, Site & Supplies	Participants	Delivered by	Indemnity
1	NHS	NHS/ University/Public Sector	Patients/Volunteers	NHS/Academic Staff	NHS Indemnity as duty of care rests with NHS for both design and conduct
2	University	NHS	Patients/Volunteers	NHS/Academic Staff	NHS Indemnity as duty of care rests with NHS for NHS conduct only and the University will retain liability for the design of the study and conduct issues relevant to their staff
3	University	NHS	Volunteers recruited by University or NHS (may include current patients but the study is not part of their ongoing treatment)	Academic staff	NHS Indemnity will apply to negligent losses arising from building, equipment or supplies failures only. University indemnity arrangements should apply for conduct issues relevant to their staff
4	University	NHS	Patients as part of their ongoing treatment	Academic staff	The University will retain liability for the design of the study and in respect of delivery, NHS Indemnity will apply as the study is associated with the care for patients to whom the Health Board/Trust has a duty of care

5	University	University	Patients as part of their ongoing treatment	Academic staff	NHS Indemnity will apply to negligent losses arising from the conduct of the study as the Health Board/Trust has a duty of care to the patient. The University should accept liability for losses arising from building, equipment and supplies failures and study design.
6	University	University	Volunteers	Academic staff	University indemnity should apply.
7	University	University	Patients and Volunteers (but not part of patient's treatment)	NHS Staff	NHS Indemnity should apply for the conduct of the staff only, providing NHS participation has been subject to proper approval processes (see note below). If the NHS accepts responsibility for conducting the study then this will include University Staff working under honorary contracts providing this is agreed as part of the approval process.

8	University	NHS/University	Patients and Volunteers (but not part of patient's treatment)	NHS Staff/Academic Staff	NHS Indemnity will apply to directly employed staff and also to equipment and buildings used. If the NHS accepts responsibility for conducting the study then this will include University Staff working under honorary contracts providing this is agreed as part of the approval process.