



*National Institute for
Health Research*

Research in the NHS: HR Good Practice Resource Pack

Frequently Asked Questions
Full Supplement

HUMAN RESOURCES (HR) AND CONTRACTUAL ARRANGEMENTS

1. **The HR Good Practice Resource Pack states that honorary research contracts (HRCs) should only be issued when the researcher's activity has a direct bearing on the quality of patient care. What does this mean?**

Researchers require an HRC only if:

- the research is hosted in the NHS **and**
- they have no contractual relationship with the NHS **and**
- the activities which the researcher plans to undertake in the host NHS site involve interacting with individual patients in a way that has a direct bearing on the quality of their care.

A researcher's activity may be deemed to have a direct bearing on the quality of patient care if:

- the researcher's activity could directly influence decisions made on:
 - a patient's access to care
 - the care pathway which the patient followed
 - the type, quality or extent of prevention, diagnosis or treatment of illness.
- the researcher's action could foreseeably cause injury or loss to patients or service users to whom the NHS organisation has a duty of care, leading to a possible case of clinical negligence being made against the NHS organisation.

Examples of activities that could have a direct impact on care include:

- taking consent for an interventional study (as this will determine an individual's access to a specific treatment)
- delivering a treatment that forms part of the research study
- performing phlebotomy on trial patients (as this is an invasive procedure which could lead to injury or infection).

Activities that would not have a direct impact on care include:

- some types of interview study, where information from the study will NOT feed into the patient's care plan or decision-making in relation to the care of the patient
- undertaking the randomisation procedure to allocate trial patients to a specific treatment, as this is preceded by the consent process. Randomisation is considered a research procedure.

By issuing an HRC, the NHS organisation ensures that:

1. Patients in receipt of these research procedures come under the NHS duty of care and the NHS indemnity scheme applies to the researchers and their activities.
2. The researcher is accountable to the NHS organisation for their activities, explicit supervision arrangements are in place, and the researcher is made aware of the relevant NHS policies with which they must comply in their activities.
3. The researcher's substantive employer understands the research activities and has undertaken all the necessary checks in relation to the researcher's suitability to carry out those activities.

2. Shouldn't we issue an HRC to all researchers to make sure that we have a way of controlling their activities so that we minimise the risk to the NHS?

The Department of Health (DH) previously advised that researchers who do not have a substantive contract with an NHS body, but whose research involves NHS staff or patients, their organs, tissue or data, should have an honorary contract with an NHS body. The advice was withdrawn some years ago.

The UK Research Governance Frameworks make it clear that appropriate allocation of responsibility, and hence liability, is fundamental to good overall governance of research. Higher Education Institutions (HEIs) must accept their responsibilities as employers of researchers, because it is only the employer that can be responsible ultimately for ensuring the suitability of the individual in terms of training, experience and conduct.

HEI substantive employers must retain accountability and liability for the actions of researchers that are outside the core responsibility of NHS organisations, i.e. actions that do not relate to the legal duty of quality and the common law duty of care of the NHS organisation. NHS organisations should not lay claim to responsibility, and hence liability, for issues that are outside their ability to fully discharge.

HEIs, as employers, are responsible for ensuring that staff conducting research within the NHS have been subject to appropriate pre-engagement checks commensurate with their proposed research activity in the NHS (and in line with NHS standards in this area), are appropriately trained to carry out their research activity and to handle confidential information, and that disciplinary arrangements are in place for handling breaches of confidentiality.

The Research Passport system provides for information-sharing between the NHS organisation and the substantive HEI employer to ensure that overall governance arrangements are in place to support researchers and their activity.

3. In what circumstances should a Letter of Access (LoA) be issued instead of an HRC?

The HR Good Practice Resource Pack contains three types of LoAs, these should be issued in the following circumstances:

For HEI researchers, the [Example letter of access for university researchers who do not require an HRC \(DOC\)](#) should be issued in the following circumstances:

- where the research is hosted by the NHS **and**
- the researcher needs to access NHS facilities or patients or data to undertake their research **and**
- it is judged that the researcher's activity will **not** have a direct bearing on patient care.

For HEI researchers, the [Example letter for university researchers, where the NHS site accepts an existing HRC](#) should be issued in the following circumstances:

- where the lead NHS organisation has already validated a Research Passport form, **and**
- the lead NHS organisation judged that the research activity had a direct bearing on patient care, **and**
- the lead NHS organisation issued an HRC, **and**
- the researcher now needs to undertake the same research activity in a different NHS organisation.

For **NHS** researchers and clinical academics¹ the [Example NHS to NHS LoA \(DOC\)](#) should be issued following the procedures outlined below

- Researchers with an existing substantive NHS or honorary clinical contract do not require an HRC
- The NHS organisation which hosts their research can accept their existing relationship with the NHS
- The [NHS to NHS LoA](#) gives permission for any types of research activity to be undertaken at the host site
- The researcher's substantive NHS employer remains fully responsible for undertaking and updating the pre-engagement checks.

The procedure for researchers who require an NHS to NHS LoA has been revised as follows:

A new [NHS to NHS \(LoA\) – proforma confirmation of pre-engagement checks](#) has been developed. The R&D office for the employing Trust is responsible for ensuring this confirmation is issued by their Trust for all staff requiring NHS to NHS LoAs. For clinical academics, the Trust holding the honorary clinical contract may need to liaise with the HEI who is the substantive employer, in order to issue the signed proforma.

The NHS researcher/clinical academic can then submit this declaration, along with their CV, to all NHS organisations who are hosting their research. The host site can accept this declaration as confirmation that the required pre-engagement checks have been undertaken by the employer and issue the [Example NHS to NHS LoA \(DOC\)](#) to the researcher, copied to the researcher's substantive employer. The copy NHS to NHS LoA sent to the employer will also be accompanied by a copy of the proforma confirming completion of pre-engagement checks submitted to the host organisation.

4. Who needs a Research Passport?

If you have no contractual relationship with the NHS, you *may* need a Research Passport, which enables the NHS to decide whether or not you need an HRC or LoA to enable you to undertake your research within NHS facilities. A Research Passport is valid for a period of three years and may be project-specific or may cover a number of projects. The Research Passport may be used for both single-site and multi-site studies.

5. Why is the Research Passport form not completed for NHS employees who need to carry out their research activity in a different NHS Trust?

Throughout the NHS there is a level of assurance with regard to the standards and the processes in place to support HR arrangements as applied at individual NHS organisations. With the introduction of the Vetting and Barring Scheme (VBS), the employer as the Regulated Activity Provider is responsible for the management and control of that person's activity, and for making the arrangements for their employees to work in that activity.

The NHS Employment Check Standards² have been developed with key stakeholders including the DH, the Centre for the Protection of the National Infrastructure (CPNI), and employers in the NHS, and includes all pre-appointment checks that are required by law, those that are mandated by DH policy, and those that are required for access to the NHS

¹ Clinical academics hold joint appointments across NHS and HEI organisations to conduct clinical activity, teaching and research. <http://www.academicmedicine.ac.uk/uploads/folletreview.pdf>

² NHS Employers Check Standards
<http://www.nhsemployers.org/RECRUITMENTANDRETENTION/EMPLOYMENT-CHECKS/EMPLOYMENT-CHECK-STANDARDS/Pages/Employment-Check-Standards.aspx>

Care Record Service. Furthermore, employer organisations in the NHS need to evidence their compliance of these standards as part of the Care Quality Commission's (CQC) Annual Health Check (formerly the Healthcare Commission).

In addition, there are existing processes and systems in place to facilitate the movement of highly mobile staff within the NHS as a whole, for example from October 2009, the Electronic Staff Record (ESR) contains details of pre-engagement occupational health screening and has replaced the Occupational Health Smart Card (OHSC) system. On this basis, the advice in the HR Good Practice Resource Pack in relation to those with a substantive or honorary clinical NHS contract is that the Research Passport system is not required when sharing information.

The [NHS to NHS LoA](#) should be issued, which:

- accepts the employee's existing NHS contract
- accepts confirmation from the substantive employer that the pre-engagement checks and associated contractual obligations are in place (through receipt of the [NHS to NHS LoA – proforma confirmation of pre-engagement checks](#))
- places the obligation fully on the substantive NHS employer to ensure these checks continue to be in place for the role to be undertaken in the NHS organisation hosting the employee's research activity.

6. Does the letter of agreement between NHS organisations HAVE to be in place between NHS organisations, to support NHS to NHS LoAs?

Where NHS organisations can demonstrate that they are effectively managing and implementing the Research Passport system within the UK Clinical Research Networks, then it is not necessary to put an additional [letter of agreement between NHS organisations](#) in place to cover cross-institutional working between the organisations. In England, NHS organisations can check through their NIHR Comprehensive Local Research Networks whether individual NHS organisations are implementing the Research Passport system. In Scotland, Wales and Northern Ireland, NHS organisations can contact the nominated Research Passport lead from their Health Department³. Where there is any doubt with regard to the substantive employer's compliance with the scheme, host organisations can issue the [letter of agreement between NHS organisations](#) alongside the [NHS to NHS LoA](#).

7. The Research Passport form does not provide the relevant information relating to the start and end-date of a researcher's substantive contract. How can I ensure that the duration of the Research Passport and the associated HRC or LoA does not run beyond a researcher's contract end-date?

The Research Passport form (Version 2) has been amended to include this information. For NHS to NHS arrangements the [NHS to NHS LoA – proforma confirmation of pre-engagement checks](#) also requires that the substantive employer confirms the contract end-date. Working with the current application form (Research Passport form (Version 1)), there are a number of additional principles and safeguards available to address this issue:

1) The substantive employer is responsible for the actions of their employee

In order to fulfil this responsibility, the substantive employer should ensure that they have established an appropriate process for notifying and monitoring changes to the content of their employee's Research Passport (or the conditions of their employment for NHS staff and clinical academics) and that this process is documented in the organisation's procedures and policies. The CLRN in England and the Health Departments of the Devolved Nations are

³ <http://www.ukcrc.org/regulationgovernance/researchpassport/>

working with academic and healthcare organisations to ensure that substantive employers are aware of this requirement.

2) The Research Passport holder is obliged to notify Trusts of changes in their situation

Similarly, the substantive employer should ensure that they have established an appropriate process to actively manage the researchers they employ. In addition, HRCs and LoAs place an obligation on the researcher to provide details of any changes to the terms on which the HRC or LoA was issued to the host organisation.

3) Limit the dates of the Research Passport or HRC to coincide with the substantive contract

The organisation validating the Research Passport can contact the researcher or their employer to confirm the contract details and where the duration of an applicant's substantive contract is less than the duration of the project, organisations may choose to limit the dates of the validity of a Research Passport (and any HRC or LoA issued following the validation of a Research Passport) or stipulate a review date to coincide with the terms of the substantive contract. The latter would enable an extension or new HRC/LoA to be issued if appropriate, and would ensure appropriate tracking. A similar approach can be applied to researchers working under NHS to NHS arrangements.

8. How does the Research Passport system apply to the staff who work for Independent Contractors, for example GPs or practice nurses, when they are carrying out research in the NHS?

A PCT, like all NHS Trusts, has a duty of care to its patients, including those who are cared for by a GP. Therefore a PCT retains vicarious liability for patients who receive care from a GP or their staff, and for patients who are participants in research undertaken during provision of NHS services through their GP. Although the new NHS Contract⁴ defines staff employed by Independent Contractors (e.g. practice nurses) as NHS staff, NHS indemnity arrangements (the Clinical Negligence Scheme of Trusts (CNST)) specifically do not extend to Independent Contractors (or their staff) working under contract for services to a PCT. Therefore, the issuing of an NHS honorary contract to this group of practitioners does not bring them within the scope of NHS indemnity arrangements.

This means that PCTs should not extend HRCs to practice staff if they are conducting research as part of their NHS practice. However, the PCT may wish to highlight that compliance with research governance is a contractual obligation for such staff as part of the broader obligation to comply with the PCT's corporate risk management arrangements.

Medical defence organisations (MDOs) provide cover for clinical negligence to GPs for the service they (and their staff) are contracted to provide to the NHS. If they undertake research as part of their routine activity, their professional indemnity arrangements would normally provide adequate cover for that activity. However, this should be confirmed with their MDO before starting the research⁵.

If a GP or practice nurse is supporting research activity that is not considered part of the services under the NHS contract, the PCT will need to ascertain whether it owes a duty of care

⁴ Annex F3, Delivering Investment in General Practice. Implementing the new GMS contract Department of Health, December 2003

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4070242

⁵ Research in the NHS: indemnity arrangements

Gateway reference: 5957

Department of Health, December 2005

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4125281

to the study participants with respect to the research activity. If this is the case, then the GP or practice nurse is operating within the vicarious liability of the PCT and arrangements should be made to include these staff under CNST arrangements. Such arrangements would involve the organisation responsible for the research, either the PCT or HEI, putting in place a contract for services with the GP or practice nurse relating to these additional research activities⁶. If the organisation responsible is the HEI, then the Research Passport system could then be used to obtain an HRC or LoA as applicable. If the organisation responsible is the PCT, the PCT is encouraged to accept the pre-engagement checks undertaken by the GP practice, though it can request its own pre-engagement checks if warranted following a proportionate risk assessment. NHS to NHS arrangements as described in the HR Good Practice Resource Pack would then cover any additional movement of these staff to other participating NHS organisations.

Where the research activity and involvement of the GP or practice nurse is commercially funded, the commercial company should hold adequate insurance to indemnify the research, covering negligent and non-negligent harm and provide this cover for the GP/practice nurse.

Although the specific example used in this guidance refers to GPs and practice nurses, the same also applies to other Independent Contractors based in primary care including dentists, ophthalmologists, community pharmacists and podiatrists.

9. How does the Research Passport system apply to students?

The research activities of undergraduate and postgraduate students who conduct research as part of their healthcare placements will come under the memorandum of understanding between the HEI and the NHS organisation which governs healthcare placements. This confirms the accountability arrangements between the organisations. Students on healthcare placements also have the appropriate pre-engagement checks conducted before they can commence a course which includes a healthcare placement⁷. NHS organisations can delegate the verification of identity and issue of a Smartcard (within the Registration Authority governance framework) to educational establishments. Any research conducted as part of healthcare placements should come under the existing arrangements for such students. Therefore **students conducting research as part of their healthcare placements should not be issued with HRCs or letters of access by the NHS organisation.**

Where students are undertaking research as part of a Masters or PhD, and that course is not subject to a healthcare placement agreement with clinical supervision, then the Research Passport system should be applied. For students, the HEI would need to ensure that the student admissions section was able to complete the sections of the Research Passport normally completed by HR for employed staff. On submission of a complete and validated Research Passport, the NHS organisation may issue the student with an HRC or LoA, depending on the nature of the research activity.

10. How does the Research Passport apply to visiting international researchers that are not formally employed by the hosting university?

⁶ Indemnity arrangements within Primary Care – who is responsible for what?
NHS R&D Forum, Primary Care Working Party
http://www.rdforum.nhs.uk/workgroups/primary/indemnity_arrangements.doc

⁷ NHS Employers' Check Standards
<http://www.nhsemployers.org/RecruitmentAndRetention/Employment-checks/Employment-Check-Standards/Pages/Employment-Check-Standards.aspx>

Medical student access to patient records
NHS Employers
http://www.nhsemployers.org/PlanningYourWorkforce/MedicalWorkforce/Medical_Education_and_training/Pages/MedicalstudentsCRS.aspx

In situations such as these, the university hosting the researcher would need to complete the Research Passport form. Where there is no formal employment contract in place between the researcher and the hosting university, a suitable honorary academic contract should be put in place to ensure that there is clear accountability between the hosting university and the researcher.

The hosting university should then undertake the necessary pre-engagement checks to support the completion of the Research Passport. Any associated cost would be allocated in accordance with local policy and the researcher's funding source.

Where an international researcher presents occupational evidence from their country of origin, the hosting university would need to assess the evidence, bearing in mind any differences in clinical or regulatory practice compared with the UK, and determine whether this evidence could be used to support completion of the Research Passport form. Checks should be repeated where considered necessary.

The completed Research Passport would be presented to the Lead NHS organisation for validation in the usual manner.

11. How does the Research Passport system apply to trial data monitors?

It is the role of the sponsor (and the data monitor's employer, if different) to take responsibility for the actions of any trial data monitor. The suite of model agreements for use in both commercial and non-commercial clinical trials provides specific information relating to the activities of trial data monitors including issues of access and confidentiality. For trial data monitors, a clinical trial agreement should be put in place addressing the issues relating to their activities and a Research Passport and subsequent HRC or LoA should not be used.

Any NHS organisation that has any concerns about the conduct of a trial data monitor must inform the sponsor (and their employer, if different), as this may be a matter of misconduct that the employer must follow up.

12. How does the Research Passport system apply to staff such as research nurses provided to the NHS Trust by Contract Research Organisations (CROs), to undertake research activities in the Trust which form part of a commercial study

In commercially sponsored trials, commercial research staff should not be given a Research Passport, or issued with an HRC or LoA or any other document that could be construed as indicating that the NHS organisation is accepting liability for their actions.

With the exception of clinical study data monitors, the UKCRC model agreements do not cover issues relating to commercial organisations providing staff to undertake commercial research activities in the host NHS site (e.g. commercial research nurses). Therefore, the host organisation needs to ensure that a contract for the provision of these services is put in place with the commercial organisation. This contract should address all issues relating to the activities and suitability of the commercial staff (e.g. pre-engagement check requirements (Criminal Records Bureau (CRB), occupational health, professional registration, right-to work, qualification etc), training, accountability and management arrangements, insurance for negligent actions etc).³⁹

The host organisation's legal, HR or procurement departments may be familiar with standard contracts for services that address these issues and may have appropriate templates available for use in these circumstances. In many cases, the CRO may provide a template agreement that can be amended by your Trust as appropriate.

Please also see guidance under QUESTION 39.

13. How does the Research Passport system apply to contract research staff who undertake research activities forming part of a non-commercial study sponsored either by the university, the NHS or a non-commercial funder?

There is a distinction to be made when the research is being sponsored and led by a non-commercial organisation, compared with a situation when the study is wholly commercially sponsored. In the former situation the CRO staff are being contracted by the university to undertake non-commercial research. Therefore the university should ensure it has appropriate agreements in place with the CRO governing the provision of services for the study, which appropriately address indemnity issues and the requirement for and sharing of information on pre-engagement checks, where both organisations agree to follow the requirements of the HR Good Practice Resource Pack. On this basis, the university can then provide assurance to the Trust about the suitability of these individuals, and the Trust can deal with these individuals as though they were university researchers.

The Implementation Project and the HR Good Practice Resource Pack present a risk management framework to support the decision to accept pre-engagement checks undertaken by others. In practice, the university could complete a Research Passport form for the nurse. If they felt it was appropriate, they could use evidence of pre-engagement checks undertaken by the CRO to support this application. (NB where the research involves regulated activity, the HEI would need to initiate Independent Safeguarding Authority (ISA) registration and register their interest in the individual concerned – see section on VBS below). Similarly, the Trust receiving the Research Passport should apply an appropriate and proportionate risk assessment to the evidence provided in deciding whether it is comfortable accepting these checks. If risk assessment demonstrates that it is warranted, the Trust can request that the University repeats the checks undertaken by the CRO or the Trust can request its own.

Depending on the nature of the clinical trial and the activity involved, an HRC or LoA may be issued. The RP issued by the university and the HRC or LoA issued by the NHS would be project-specific and time-limited.

14. Bank nurses seem to present some considerable challenges to the Research Passport system. Is there any national guidance on bank nurses?

With regard to the handling of bank nurses, if the nurses are recruited to the bank in accordance with current NHS Employment Checks Standards⁸, and are then involved in research roles as NHS staff, these bank staff can be handled using the NHS to NHS arrangements described in the HR Good Practice Resource Pack. They should not use the Research Passport form.

If, however, bank nurses have an HEI as their substantive employer, the Research Passport system will apply. The Research Passport form includes an Appendix which allows new projects to be added, or additional information regarding amendments to agreed research activities to be documented.

15. Can a project-specific passport be converted into a multi-project/generic passport?

The ideal situation would be for researchers to apply for the multi-project/generic three-year passport, rather than the project-specific Research Passport at the outset. However,

⁸ NHS Employers' Check Standards
<http://www.nhsemployers.org/RECRUITMENTANDRETENTION/EMPLOYMENT-CHECKS/EMPLOYMENT-CHECK-STANDARDS/Pages/Employment-Check-Standards.aspx>

researchers in possession of a valid project-specific Research Passport, who then find that they need to work on more than one project, can at a later stage submit an amendment to their project-specific Research Passport, by completing the relevant details in the Appendix to the application form and submitting this to the Lead NHS organisation for approval. The Lead NHS organisation then needs to ensure that the pre-engagement checks in place are also valid for the new activity. If so, the Lead NHS organisation can convert the project-specific Research Passport into a multi-project/generic three-year Research Passport. In addition, the researcher is required to inform all NHS organisations that have received their original Research Passport of any changes to information within the Research Passport. Having alerted the other NHS organisations of the change in their Research Passport from project-specific to multi/project generic, the researcher can then provide details of additional studies and/sites as would be the case for a multi-project/generic three year Research Passport

16. A researcher with an NHS substantive contract wishes to carry out research in a different Trust, but their NHS employer states that they cannot be responsible for this person's research activity. What can be done in this circumstance?

In a case such as this, it is important to determine if the researcher is undertaking this activity as part of their contracted working hours/job description, or whether it is completely outside their contracted responsibilities. This issue needs to be clarified and agreed between the employer, employee and the NHS Trust hosting the research, in order to enable the appropriate arrangements to be put in place.

If the activity is being undertaken as part of the researcher's substantive contracted hours and job role, and they are being paid by their substantive employer whilst completing this activity, the substantive employer will remain responsible for the researcher's activity, as they will continue to have a duty of care towards their employee even if the research is not directly related to the substantive Trust. In this case, the NHS to NHS agreements described in Question 3 (above) and the HR Good Practice Resource Pack should be followed, and the [NHS to NHS LoA](#) should be issued by the host NHS Trust to the researcher and their NHS employer.

If the researcher is undertaking this activity independently and not in the course of their paid employment, they should ensure that they have appropriate professional indemnity in place to cover the research activity. Evidence of this would need to be reviewed as part of the research governance review and a suitable agreement put in place between the Trust hosting the research and the researcher (e.g. a contract for services).

If the researcher is undertaking this activity completely outside their contracted hours, the Trust hosting the research may enter a separate contract with this researcher enabling them to undertake research sessions in the host Trust. In this case, the host Trust becomes responsible for the researcher's activity and would be encouraged to accept the existing pre-engagement checks undertaken by the substantive employer following a proportionate risk assessment rather than undertaking its own.

It should be noted that if the host Trust issues an HRC, then liability for the researcher's activity is transferred from the employing Trust to the host Trust.

17. Does the Research Passport system apply to researchers who are not employed either by the NHS or by a university (e.g staff employed by social care organisations or the voluntary sector)?

In this situation it is important firstly to clarify that the research is hosted through the NHS. If so, it is then important to establish to whom the researcher is affiliated in respect of the research activity being undertaken. For example, in an HEI sponsored non-commercial trial, if the HEI sponsor sub-contracts staff to assist in the delivery of the research, the organisation responsible for the research, i.e. the HEI, should put in place a contract with the individual(s)

relating to these additional research activities. Once this is done, the Research Passport system can be used to obtain an HRC or LoA as applicable. Similarly, if an NHS Trust is responsible for the conduct of the study, they could put in place a contract for the additional research activities with the researcher and then NHS to NHS arrangements would apply.

Where individuals are employed by organisations which have no formal agreements in place to operate the Research Passport system, and therefore there is no established method for sharing information, NHS organisations hosting research may need to undertake appropriate checks on the researchers and claim the costs of such checks from the employer or research funder.

NHS organisations can establish local arrangements with other organisations in addition to HEIs, e.g. public sector research partners such as local authorities or charities, where those organisations can also undertake to implement the Research Passport system, in order to facilitate methods for sharing information on researchers where their research is hosted through the NHS.

Please also see guidance under QUESTION 10 for commercially sponsored research and QUESTION 13 for Bank Nurses.

MANAGING AND MONITORING THE RESEARCH PASSPORT SYSTEM

18. Who should process and validate Research Passports, and then issue HRCs or LoAs for NHS organisations: R&D office staff or HR staff?

The Research Passport system relies on a combination of HR and R&D skills, where effective systems can support timely and efficient processing, and good communication. It is for local agreement within an NHS organisation how responsibility for tasks should be allocated, depending upon the resource and expertise available, to achieve the level of streamlining that the Research Passport system can provide.

In England, the Comprehensive Local Research Networks (CLRNs) of the National Institute for Health Research (NIHR) have adopted the Research Passport system as standard practice, and working procedures among local partners are being developed.

The expectation within the CLRN is that effective operating procedures to support implementation of the Research Passport system are agreed between HR and R&D departments, but that implementation is delegated to R&D departments.

19. A research nurse employed by a university needs to conduct research in a number of NHS Trusts. S/he is already undertaking this activity in one NHS Trust, who have reviewed and validated her/his Research Passport, and issued an HRC. What can the second and subsequent NHS Trusts do?

The Research Passport system is intended to streamline HR processes for researchers working across the NHS. Where NHS and HEI organisations can demonstrate that they are effectively managing and implementing the system within the UK research networks, then, following a proportionate risk assessment, an organisation can choose to accept checks carried out by others without needing to see all the original documents.

The Lead NHS organisation is responsible for reviewing the Research Passport when it is first submitted to the NHS and if it is accurately completed, for validating it by completing Section 8. Once the Research Passport is validated, subsequent Trusts can accept the checks and validation undertaken by the Lead NHS organisation. Where there is no difference in the activity that will be undertaken at each Trust, the options are as follows:-

- Requesting to see the existing HRC only
- Requesting a copy of the passport only
- Requesting the original passport only
- Requesting the original passport and photocopies of the supporting documents
- Requesting the original passport with the researcher's original copies of any supporting documentation

The second and subsequent Trusts can then either issue their own **HRC** or they can issue a **letter accepting the terms of the HRC** issued by the Trust that validated the Research Passport.

In any case, the organisation responsible for care will always retain the right to request additional information where there is uncertainty about the information received or where risk assessment indicates that this is necessary.

20. Is an HRC or LoA necessary where a university research team is undertaking university research in NHS office space? For example, when a GP practice acts as a participant identification centre (PIC) to refer patients to a university based study.

The university researchers will take consent and perform all research activities, however, the location of the research is based on the participant's preference and may include university premises, the participant's home, the town hall or sometimes the GP practice.

As outlined in paragraph 3.10.3 of the Research Governance Framework for Health and Social Care⁹, HRCs are required where a researcher who is not employed by any NHS organisation interacts with individuals (to whom the NHS organisation owes a duty of care) in a way that has direct bearing on the quality of their care. Therefore, if the NHS organisation does not have a duty of care to the participants in respect of the research activity an HRC should not be issued. In this example, if the NHS organisation is simply renting or providing space to the university research team to undertake research that is the explicit responsibility of the university then it would not be appropriate to issue HRCs to the university researchers.

In addition, to the governance requirements relating to its role as a PIC, the NHS organisation will need to consider the appropriateness of and the arrangements for use of NHS premises for the research activities. In authorising the use of its facilities the NHS organisation would need to clarify issues such as the period of access, any fees and liability in relation to the use of facilities. A standard contract to cover the hire of facilities/rooms would address these issues. It would not be appropriate to issue a LoA.

From a wider governance perspective, what is really important in these situations is for the application to the Research Ethics Committee (REC) to set out clearly which organisation is the research site and what the role of the NHS is, and for the information on indemnity/insurance to be consistent with that. The REC and R&D applications should make clear:

- that NHS PICs are involved
- that the research site is non-NHS and therefore NHS indemnity does not apply
- that the university has appropriate insurance to cover the conduct of the study including any clinical interventions
- that if NHS or other premises are locations where research activities are conducted that this research remains the responsibility of the university and that appropriate contracts are in place
- that the patient information is explicitly clear about who is responsible for the research (including making sure that NHS headed paper is NOT used) and arrangements for compensation.

Where this has not been made clear in an application and incorrect information on indemnity and insurance has been provided which is uncovered by an R&D office, then a substantial amendment needs to be submitted to the REC.

21. Sometimes researchers employed by a university will conduct research with NHS organisations a long way from their university and their only contact with participants is one visit. Where the activity will require pre-engagement checks to be completed, how do we handle viewing the original criminal record disclosure or conducting occupational health checks that cannot be completed by the employer?

Where it would be difficult for a researcher to present her/his Research Passport to the NHS organisation in person, there are three options:

⁹ Research Governance Framework for Health and Social Care
Department of Health, Second edition, 2005
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4122427.pdf

- working through their local CLRN, the researcher can ask a Lead NHS organisation within their local network to validate their Research Passport, having viewed the original documentation and then subsequent NHS organisations can proceed as described in question 19.
- the Research Passport can be processed based on photocopies as long as the issuing of the HRC or LoA is conditional upon the NHS organisation viewing the original documents prior to the researcher conducting the research activity.
- the researcher may post the documents and request that they be posted back when they have been processed (using appropriate secure postage).

22. What monitoring systems should I put in place to support the implementation of the Research Passport system?

In relation to ensuring the Research Passport system is operated to a high standard, the systems should be developed to measure and monitor:

- Time from submission of complete application to issue of HRC or LOA
- Whether additional pre-engagement checks are being requested.

The NIHR Clinical Research Network Coordinating Centre will support CLRNs to develop appropriate information systems to monitor and report on performance management of the Research Passport system.

For management purposes, the following systems should be in place to monitor:

- the duration of the Research Passport
- the duration of the accompanying pre-engagement checks
- the duration of the HRC or LoA which have been issued following the validation of the Research Passport
- the researcher's activity as new projects are added to a Research Passport, to ensure that the original pre-engagement checks apply also to new projects, and to ensure enhanced checks are carried out if required.

The following monitoring mechanisms therefore need to be in place:

Substantive employer

- Monitoring employment contract start and end-dates
- Monitoring CRB disclosure certificate dates and triggering periodic re-checks (prior to the introduction of ISA registration)
- Monitoring occupational health test dates and triggering periodic re-checks/updates
- Monitoring changes in activity and triggering additional checks
- Monitoring changes in personal/professional circumstances and assessing impact on Research Passport.

Host site

- Monitoring HRC/LoA start and end-dates
- Monitoring CRB disclosure certificate dates and triggering periodic re-checks (prior to the introduction of ISA registration)
- Monitoring occupational health test dates and triggering requests for periodic re-checks/updates
- Assessing impact of changes in activity and triggering requests to substantive employer for additional checks

23. Where a researcher is recruiting through the prison healthcare service is it necessary for the healthcare provider to issue an HRC or LoA to the researcher or will the researcher's suitability be considered solely by the prison service and an equivalent document issued?

For prison research that is health related, the permission of the healthcare provider is required. This is usually the PCT and their permission is required where the research is related to the provision of care by the care organisation (i.e. where the research activity comes under the vicarious liability of the PCT). The PCT should follow its standard governance processes, which would include an assessment of the researcher's suitability. The Research Passport system or the NHS to NHS arrangements described in the HR Good Practice Resource Pack should be applied as appropriate. The PCT should issue an HRC or LoA appropriate to the nature of the research activity, which clarifies the location of the research and the accountability arrangements.

Researchers should note that it is the Prison Governor's responsibility to give final approval for the research and to allow the researcher access to the prison. The researcher can ask the prison to accept the Research Passport arrangements, whereby the researcher can provide a copy of their Research Passport and HRC or LoA to the Prison Governor. However, researchers should be aware that the decision to accept evidence of existing pre-engagement checks rests with the prison. Researchers should liaise with both the PCT and the prison at an early stage to clarify their requirements and minimise unnecessary delays. For further information about permissions for prison research, please refer to the Offender Health Research Network tool kit¹⁰.

¹⁰ Offender Health Research Network Toolkit, January 2010
<http://www.ohrn.nhs.uk/toolkit/Toolkit4thEdition.pdf>

THE RESEARCH PASSPORT AND PRE-ENGAGEMENT CHECKS

CHECKS ON THE SUITABILITY OF THE RESEARCHER – Training and Experience

24. Why doesn't the Research Passport application request references?

The Research Passport system does not require additional references for researchers as the substantive employer signs off the form confirming that standard pre-employment procedures have been followed. This includes confirmation that the substantive employer will normally have checked references as part of their own pre-employment procedures. NHS organisations will also want to be satisfied that the researcher is suitably qualified and experienced for the research s/he is to undertake. The Research Passport form includes a section for the researcher's line manager to confirm that the researcher is appropriately qualified, trained and experienced to carry out the proposed research activity. This should also be indicated in the CV supplied. The standard format of CV (i.e. the version submitted as part of the Integrated Research Application System (IRAS) application¹¹) requested in the Research Passport form covers this.

25. What is meant by a verified reference? Do substantive employers need to check qualifications with the awarding body or accept that any certificate(s) provided by the applicant are authentic?

A verified reference means that references were taken up when the individual was appointed by the HEI and this is confirmed by the HEI HR department when they complete the Research Passport form.

Substantive employers are expected to follow good employment practice to satisfy themselves that the individual has attained the qualifications that s/he has claimed. This will include a visual check and recording of certificates of qualification and current registration with professional bodies.

26. Do substantive employers need to check with the professional body to ensure that the applicant is currently registered or simply accept that the applicant is still registered with the stated body?

Where an HEI is employing someone who is required to be a registered professional (this is normally included as an essential criterion in the job/person specification), the HEI would be expected to check that the individual is registered. The Research Passport form also prompts the substantive employer to check that *current* professional registration is in place at the time of completion of the Research Passport form. The registration should be valid, in date and without any restrictions to undertake the research in question. For NHS organisations using ESR, registration information is already linked to the register information held by the General Medical Council, and registration status changes are automatically notified to ESR.

¹¹ Integrated Research Approvals System
<https://www.myresearchproject.org.uk/>

IDENTITY VERIFICATION and RIGHT TO WORK CHECKS

27. Does the NHS organisation need to undertake its own identity checks when the Research Passport form is first presented for validation?

No. Identity checks are a central part of the pre-engagement checking process in both the NHS and Higher Education settings. Within the NHS, the Verification of Identity Check Standard¹² and the Right to Work Standard¹³ outline the mandated requirements of employers to verify the identity of all prospective employees in the NHS. Therefore for NHS to NHS arrangements, the substantive employer will have completed the checks outlined in these standards.

For HEI researchers, the Research Passport form enables the substantive employer to confirm that they have verified the researcher's identity, to the standard required by NHS Employers (to include acceptable photographic and non-photographic proof of identification, and address), and they have completed the appropriate checks confirming that they have viewed and stored a copy of the relevant documentation to corroborate the researcher's legal right to work in the UK, in line with the requirements of the British Immigration Authority.

Therefore, for either group of researchers it is not necessary for subsequent Trusts to repeat this process in full. However, at a practical level, to ensure that the person who turns up is actually the one to whom the Research Passport and associated employer assurances relate, an organisation could ask the researcher to report on their first day of activity at the NHS organisation with their ID badge from the substantive employer, or another acceptable form of photo ID, along with their LoA, as proof that they are the individual that the NHS organisation is permitting to conduct research.

¹² NHS Employers' - Verification of identity checks standard
<http://www.nhsemployers.org/Aboutus/Publications/Documents/Verification%20of%20identity%20checks.pdf>

¹³ NHS Employers' - Right to work check standards
<http://www.nhsemployers.org/Aboutus/Publications/Documents/Right%20to%20work%20checks.pdf>

WORKING WITH CHILDREN AND VULNERABLE ADULTS

THE VETTING AND BARRING SCHEME (VBS)

28. What does the VBS involve?

The core purpose of the scheme is to prevent unsuitable people from working or volunteering with children or vulnerable adults. With the introduction of the VBS on 12 October 2009, it becomes unlawful knowingly to employ a person to work with children or vulnerable adults if that person is barred from working in such positions, and there is a legal duty to refer people to the Independent Safeguarding Authority (ISA) if they have harmed or demonstrated a potential to harm children or vulnerable adults.

The VBS, enacted by the Safeguarding Vulnerable Groups Act 2006¹⁴, is being **implemented on a phased basis over a five year period**. It puts in place a range of procedures to safeguard vulnerable groups through:

- a **legal duty to refer** information on an individual who has harmed or demonstrated a potential to harm children or vulnerable adults to the ISA
- new **barred lists** of those prevented from working with children or vulnerable adults
- the creation of a **register** of those able to work with vulnerable adults and children
- **continuous monitoring** of registration status against the barred list of those who are prevented from working with children and vulnerable adults
- the **introduction of regulated and controlled** activities. It is unlawful to employ a person to work in a position which involves regulated activities, if they are barred from working with children or vulnerable adults.

Once the scheme is **fully implemented**:

- all individuals working or volunteering with children or vulnerable adults in regulated or controlled activities in the NHS must be registered with the ISA (a legal requirement) and their details must be checked against the lists of those who are barred from working with children and vulnerable adults.
- those who work or volunteer in a role that is defined as a regulated or controlled activity must undertake a CRB check in accordance with the NHS Employment Check Standards. Regulated or controlled activity will require an enhanced disclosure to be undertaken.
- employers, social services and professional bodies are legally obliged to notify the ISA of all relevant information on individuals who pose a risk to children or vulnerable adults
- once registered, individuals will be continuously monitored and reassessed against any new information which comes to light
- ISA will alert employers who are subscribed to the scheme in the event of the status of an individual on the ISA register changing, so that they are barred from working with children or vulnerable adults.
- there will be criminal penalties for barred individuals who seek or undertake work with children and vulnerable adults, and for employers who knowingly take them on.

The ISA is responsible for decision-making and maintenance of the two barred lists in England, Wales and Northern Ireland. The CRB is responsible for the application process, the criminal records checks and monitoring features of the VBS in England and Wales. Access NI provides access to the service in Northern Ireland. Scotland has its own equivalent Scottish VBS¹⁵, and a different timescale for implementation, but the two schemes

¹⁴ Safeguarding Vulnerable Groups Act 2006 (c.47)
http://www.opsi.gov.uk/ACTS/acts2006/ukpga_20060047_en_1

¹⁵ Protection of Vulnerable Groups (Scotland) Act 2007
http://www.opsi.gov.uk/legislation/scotland/acts2007/asp_20070014_en_1

are aligned, share information and recognise each others' bars. Disclosure Scotland will manage and operate the VBS in Scotland.

New starters who undertake a regulated activity can register with the ISA from July 2010, through the updated disclosure request process. Once an individual is registered with the ISA, the employer can register an interest in that person through the ISA's online checking facility, and will be notified of any changes in the employee's status. Employers cannot permit a member of staff to undertake a regulated activity if that individual is barred.

29. How is regulated activity defined?

The concept of a **regulated activity** is introduced from 12 October 2009. Regulated activity involves contact with children or vulnerable adults where because of their role, the person undertaking the activity may develop a relationship of trust with the child or vulnerable adult. It includes:

- **Activity of a specified nature** – this includes advice, guidance, assistance, health or social care, supervision, or treatment or therapy

OR

- **ANY activity in a specified place** – N.B specified place is clearly defined in the legislation. In relation to health research, specified places cover children's hospitals or adult care homes, schools, as these provide opportunity for contact with a child or vulnerable adult

AND INVOLVES

- Frequent contact (once a month or more), OR
- Intensive contact (three or more occasions in a period of 30 days) OR
- Overnight contact (between 2am – 6 am)

Regulated activity also includes Fostering and 'Defined Office Holders'.

NB. In December 2009, the Government accepted the recommendations of Sir Roger Singleton to redefine the definitions of "frequent" and "intensive". The way that these are to be implemented in Health and Social Care will be communicated once the relevant legislation has been passed.

You can find more information in the VBS Generic Guidance¹⁶, that can be viewed or downloaded from the ISA website. A section of the guidance 'Coverage of the Scheme' explains which people, settings and activities are covered. It also provides details and examples of those activities that are regulated and controlled. Sector-specific guidance for Higher Education Institutions and Health and Social Care settings is also to be published on how to define whether an activity is regulated.

New starters in the NHS and those who change role, whose role includes regulated activity, may register with the scheme from July 2010. The mechanism to do this will be an application via the CRB.

30. How is controlled activity defined?

Controlled activity is more limited than regulated activity. The key difference is that it is ancillary to the provision of services and it applies in the following areas:

¹⁶The Vetting and Barring Scheme Guidance, HM Government, October 2009
http://www.isa.gov.org.uk/PDF/VBS_Guidance.pdf

- primary care
- hospital services
- domiciliary care
- making arrangements for an adult placement scheme
- making provision for community care services
- making arrangements for direct payments

Controlled activity applies when a person has

- the opportunity to have any form of contact with a child or vulnerable adult
or
- the opportunity to have access to health records or social services records

The contact with the child or vulnerable adult or with their health or social services records must be frequent or intensive.

New regulations relating to controlled activity are expected to come into place in April 2010 and guidance on the specific procedures to be followed will be provided nearer the time.

From **July 2014**, members of the current workforce and volunteers who are undertaking a controlled activity may start registering with the ISA and have their status checked against the barred lists operated by the ISA. The mechanism to do this will be an application via the CRB.

31. How is a vulnerable adult defined for the purposes of defining a regulated or controlled activity?

The Safeguarding Vulnerable Groups Act 2006 extends the definition of vulnerable adult for the purposes of the VBS. The eligibility criteria for an enhanced CRB check have also been extended accordingly.

The term is defined according to the service, setting or situation where staff or volunteers are in a position of trust and people have a right to expect that this trust will not be abused (see Section 59 of the Safeguarding Vulnerable Groups Act 2006¹⁷).

For the purposes of the VBS, people are deemed to be vulnerable adults, when they have reached the age of 18 years and they are:

- living in residential accommodation, such as a care home or a residential special school;
- living in sheltered housing;
- receiving domiciliary care in their own home;
- receiving any form of healthcare;
- detained in a prison, remand centre, young offender institution, secure training centre or attendance centre, or under the powers of the Immigration and Asylum Act 1999;
- in contact with probation services;
- receiving support, assistance or advice to help them live independently, for example through the Supporting People programme;
- receiving a service or participating in an activity that is specifically targeted at people with age-related needs, disabilities or are expectant or nursing mothers in residential accommodation;

¹⁷ Safeguarding Vulnerable Groups Act 2006
http://www.opsi.gov.uk/ACTS/acts2006/ukpga_20060047_en_1

- receiving direct payments from a local authority/HSS body in lieu of social care services; or
- requires assistance in the conduct of their own affairs.

The full legal definition is included in the Generic Guidance available on the ISA website at www.isa.gov.org.uk

32. How is a child defined?

A child is defined as a young person under the age of 18, except in employment settings, where the age limit is 16.

33. Is an individual's ISA registration transferable to a different employer or organisation?

Yes. ISA registration involves a one-off application, and will apply to any future setting where the person is working with children or vulnerable adults. The individual has to demonstrate they are registered with the ISA to be able to work in a regulated activity. The employer(s) can register an interest in the individual, check a person's ISA registration status on-line, and the ISA can advise the employer if that person is no longer ISA-registered.

34. How do I assess whether a research activity meets the criteria for regulated activity?

A new algorithm, describing the main types of activities undertaken by healthcare researchers as part of the Research Passport system, and whether or not these are regulated or controlled activities, is provided with this guidance. When assessing whether or not an activity is regulated:

- First assess whether one or more of the **frequency criteria**¹⁸ are met:
 - Frequent contact (once a month or more), OR
 - Intensive contact (three or more occasions in a period of 30 days) OR
 - Overnight contact (between 2am – 6 am)

When assessing the frequency criteria, the Lead NHS site should look at the activity in its totality, and across all sites where the research is planned. This is because at the point of submitting a Research Passport form which involves multi-centre research, it is hard to predict the frequency of an activity at an individual site. If the activity does not meet the frequency criteria at all, then the research cannot be defined as a regulated activity.

- Having identified whether the activity meets the **frequency criteria**, you should then assess whether the activity is being undertaken in a **specified place**. NB all activity undertaken in a children's hospital (a specified place), will be classified regulated activity, as long as the frequency criteria are met, because the location of the work provides an *opportunity* to have contact. Therefore, even where the researcher's activity may not involve care for or direct contact with children, if they are accessing a children's hospital to undertake their work, they are deemed to have the opportunity to have contact with children, and therefore their activity becomes regulated activity.

¹⁸ **NB. In December 2009, the Government accepted the recommendations of Sir Roger Singleton to redefine the definitions of "frequent" and "intensive".** The way that these are to be implemented in Health and Social Care will be communicated once the relevant legislation has been passed.

NB children's wards within a general hospital are not a specified place. Mental Health Hospitals are not a specified place either.

- If the research activity meets the **frequency criteria** but is not being undertaken in a specified place, you will then need to assess whether the activity falls within the definition of a **specified activity**. Where the research activity includes advice, guidance, assistance, health or social care, supervision, or treatment or therapy, or the research is undertaken in the context of a patient's treatment or therapy, then the research activity is defined as regulated activity. Further guidance is available on the ISA's¹⁹ and CRB's²⁰ websites

35. How do I assess whether a research activity meets the criteria for controlled activity?

New regulations relating to controlled activity are expected to come into place in April 2010, and guidance on the specific procedures to be followed will be provided nearer the time.

- a. Again and as for regulated activity, first assess whether the **frequency criteria** are met. If the activity does not meet the frequency criteria then the research cannot be defined as a controlled activity.
- b. Then assess whether in undertaking the research activity in the NHS:
 - the researcher has **opportunity to have any form of contact with children or vulnerable adults** even though the research activity itself does not include direct contact with children or vulnerable adults (e.g. the research involves interviews with paediatric nurses, taking place in the children's ward of a hospital).

OR

- the research activity involves **access to identifiable health or social services records**. A health record is defined as a record consisting of information about the physical or mental health or condition of an identifiable individual made by or on behalf of a health professional in connection with the care of that individual. A social services record means a record obtained or held by a local authority in the exercise of its social services functions.

HOW IS THE VBS APPLIED TO THE RESEARCH PASSPORT?

With regard to the VBS, research projects are no different to any other type of work. The Regulated Activity Provider (i.e. the employer of the researcher) has a responsibility to provide the appropriate evidence that staff who are undertaking regulated activity when carrying out their research within the NHS are not barred from working with vulnerable adults or children. This may be done through a Research Passport, or through a normal NHS contract.

In summary, the HEI or NHS researcher who is undertaking regulated activity will be subject to monitoring by their substantive HEI or NHS employer. The employer, as the Regulated Activity Provider, will maintain their obligation to undertake the necessary checks and monitoring, and to withdraw their employee from undertaking regulated activity, if the

¹⁹ Independent Safeguarding Authority
<http://www.isa.gov.uk/default.aspx?page=0>

²⁰ Criminal Records Bureau
<http://www.crb.homeoffice.gov.uk/>

employee's registration status changes. The Research Passport system provides the mechanism for employers to provide the required reassurances about their employees across NHS organisations and to demonstrate that the appropriate pre-engagement checks are in place. It also provides the mechanism whereby researchers can be monitored and withdrawn from a regulated activity should their status change, providing the researcher continues to have a substantive contract of employment with the HEI or NHS, who will remain the Regulated Activity Provider.

The Research Passport has been amended to align with the requirements of the VBS. Table 1 below describes:

- types of research activity
- whether they can be classified as regulated activity
- what kind of CRB checks are needed
- whether an HRC or LoA is required
- whether an occupational health check is required

DH have previously provided the following statement which provides a Summary of the Research Passport system, and how it aligns with the VBS:

The use of the Research passport scheme for researchers who need to access NHS patients, facilities or data has been agreed with Higher Education Institutions and NHS Employers. The Research Passport scheme provides the mechanism whereby the HEI substantive employer undertakes the necessary pre-engagement checks, and the Research Passport form is used to confirm to the NHS host organisation that these checks have been undertaken to the safer recruitment standards required by NHS Employers. The Research Passport form is validated by the first (lead) NHS organisation and a Letter of Access or Honorary Research Contract is then issued. On the basis of the Research Passport having been validated, subsequent NHS organisations can accept the arrangements agreed with the first NHS organisation and either issue their own HRC / Letter of Access or accept the HRC / LoA issued by the lead NHS organisation. Where there is any uncertainty about the validity of a Research Passport, or the appropriateness of the pre-engagement checks that have been carried out, NHS organisations who are hosting the research can request to see the original documentation, and can request new or additional checks to be undertaken, in line with the activity to be undertaken at their site.

The Research Passport form is not required for researchers who already hold a substantive employment contract with one NHS organisation. For NHS-to-NHS arrangements the organisation which employs the researcher must ensure that the researcher has all the employment checks required (as set out below), specific to the type of research to be undertaken. This is the basis on which the NHS Letter of Access is issued by the NHS organisation(s) who host NHS researchers to the researchers and their NHS employers.

The Research Passport scheme continues once the VBS scheme comes into place. As the Regulated Activity Provider (or Responsible Person for controlled activity), the HEI or NHS employer of the researcher will continue to be the body responsible for ensuring the appropriate checks have been undertaken on the researcher, in line with whether or not their research involves a regulated activity or controlled activity (see revised schedule of pre-engagement checks for researchers in Table 1 below).

The HEI or NHS employer will retain their responsibility for monitoring the status of their researchers, and if they are alerted of any change in the researcher's status by the ISA, they must notify the NHS host site(s) immediately, and withdraw their researcher from working in the regulated activity.

Where local arrangements have been made to implement the principles of the HR Good Practice Resource Pack for research within Social Care (or other settings) the principles of when a person should be subject to monitoring remain the same.

In relation to controlled activity, the employer will be the Responsible Person. New regulations relating to controlled activity are expected to come into place in April 2010, and guidance on the specific procedures to be followed will be provided nearer the time.

Table 1 – RESEARCH PASSPORT ALGORITHM

Shaded rows highlight the adjustments made to the Research Passport system in response to the requirements of the VBS. Staff with an existing Research Passport can continue current arrangements until their Research Passport needs renewal, unless their research role changes significantly (e.g. they start to work with children where previously they worked only with adults).

Type of research activity researcher will be conducting	Criminal record check necessary? ²¹	Is this likely to be regulated or controlled activity, which is subject to monitoring? NB MUST be undertaken frequently, intensively or overnight	LoA or HRC	Occupational health check necessary?
Direct contact with adult patients/service users (i.e. vulnerable adults) and providing prevention, diagnosis or treatment	Yes, enhanced	Yes – regulated activity	HRC	Yes
Direct contact with children and providing prevention, diagnosis or treatment	Yes, enhanced	Yes – regulated activity	HRC	Yes
Direct contact with patients/service users (vulnerable adults or children) as part of the care team	Yes, enhanced	Yes – regulated activity	LoA	Yes
Direct or indirect contact in a specified place (e.g. children's hospital)	Yes, enhanced	Yes – regulated activity	HRC or LoA	Yes, if there is direct contact
Indirect contact with patients/service users (vulnerable adults or children) and providing prevention, diagnosis or treatment (e.g. some types of telephone interviews)	Yes, enhanced	Yes – regulated activity	HRC	No
Indirect contact with patients/service users but not providing prevention, diagnosis or treatment (e.g. some telephone interviews, access to health records which have not been anonymised)	Yes, enhanced timescale & procedures to be confirmed	Yes – controlled activity: access to identifiable health records or opportunity to have any form of contact with children or vulnerable adults	LoA	No
Access to identifiable patient data derived from health records, tissues or organs with likely impact on prevention, diagnosis or treatment	Yes, enhanced timescale & procedures to be confirmed	Yes – controlled activity: access to identifiable health records or opportunity to have any form of contact with children or vulnerable adults	HRC	Yes, if working with tissues or organs in NHS labs
Access to identifiable patient data derived from health records, tissues or organs with no likely impact on prevention, diagnosis or treatment	Yes, enhanced Timescale & procedures to be confirmed	Yes – controlled activity: access to identifiable health records or opportunity to have any form of contact with children or vulnerable adults	LoA	Yes, if working with tissues or organs

Algorithm continued on next page.

²¹ Please refer to http://www.crb.homeoffice.gov.uk/guidance/rb_guidance/eligible_posts.aspx for guidance on specific activities which are eligible for a CRB disclosure.

Type of research activity researcher will be conducting	Criminal record check necessary? ²¹	Is this likely to be regulated or controlled activity, which is subject to monitoring? NB MUST be undertaken frequently, intensively or overnight	LoA or HRC	Occupational health check necessary?
Access to anonymised patient data derived from health records, tissues or organs only (including by research staff analysing data)	No	No	LoA (only if records reviewed in NHS facilities)	Yes, if working with tissues or organs
Working on NHS premises (e.g. laboratory) only (no access to identifiable data, not in a specified place)	No	No	LoA (if in NHS facilities)	Yes, if working with tissues or organs
Direct contact with staff only (e.g. interviews) (No access to patients or patient data, not in a specified place)	No	No	LoA (if in NHS facilities)	No
Access to identifiable staff data only (Not in a specified place)	No	No	LoA (if in NHS facilities)	No
Access to anonymised staff data only (Not in a specified place)	No	No	LoA (if in NHS facilities)	No

²¹ Please refer to http://www.crb.homeoffice.gov.uk/guidance/rb_guidance/eligible_posts.aspx for guidance on specific activities which are eligible for a CRB disclosure.

PHASED IMPLEMENTATION OF THE VBS

The implementation of the VBS is phased over a five year period, and the phasing strategy is determined by risk-based assessment. The Research Passport system has been adapted in line with a model of good practice adapted in the NHS for phasing-in the VBS, and this is described in Table 2 below.

Table 2

Key Dates	Phasing of VBS	Phasing of Research Passport system
12 October 2009	VBS introduced. Unlawful knowingly to employ a person who is barred from working with children or vulnerable adults into regulated activity. Legal duty to refer people to the ISA if they have harmed or demonstrated a potential to harm a child or vulnerable adult.	Researchers requiring a Research Passport or NHS to NHS LoA for the first time will follow the revised procedures for a Research Passport.
July 2010	All new employees, those moving jobs and volunteers who will undertake regulated activity can register with the ISA.	Researchers requiring renewal of their Research Passport because its three-year period has come to an end will follow the revised procedures for a Research Passport.
November 2010	All new employees and volunteers undertaking regulated activity must register before they can start work	
1 April 2011	Existing employees and volunteers undertaking regulated activity can register with the ISA	Researchers with a three year Research Passport issued before 12 October 2009 may continue to work in the NHS, but will become subject to Vetting and Barring procedures when their Research Passport needs to be renewed. Researchers whose research role changes significantly (e.g. activity involves direct contact with children where previously there was none) will need to renew their Research Passport, using the revised procedures (Research Passport Version 2)
26 July 2014	Existing employees and volunteers in controlled activity can register with the ISA (except in Wales)	By July 2013, all university researchers working in the NHS under the procedures of the Research Passport system and who undertake regulated activity will be part of the ISA registration process.
25 July 2015	All employees and volunteers working with children and vulnerable adults must be registered with ISA	All NHS researchers working through an NHS to NHS LoA will have been phased in to the scheme, and the new NHS to NHS LoA (Version 2) will have been issued to them.

From 12 October 2009

- Regulated activity providers have a duty to make referrals to the ISA where an individual has harmed or risks harming a child or vulnerable adult. This duty applies to paid and unpaid employment
- Duty to refer extends to health and social care bodies, local authorities and regulatory bodies such as the GMC, GDC, NMC, etc. and CQC
- It is an offence *knowingly* to employ a person barred by the ISA.

New regulations relating to controlled activity are expected to come into place in April 2010 and guidance on the specific procedures to be followed will be provided nearer the time.

From 26 July 2010

- **new starters and those moving jobs who are working in regulated activity** will be able to register with the ISA, and have their ISA registration status checked as part of an employment decision.
- Employers will be able to check the ISA registration online and register an interest in an individual's status and thus receive updates if the person's status changes.
- New CRB application form introduced, which includes option to request ISA registration. Old forms will no longer be accepted after this date.
- Applications can be made for ISA registration.
- All new workers engaged in regulated activity require enhanced CRB checks.
- Standard CRB checks will not include a search of the barred lists, but will continue to provide details held on the Police National Computer (PNC), therefore standard CRB checks are not available for those undertaking regulated activity.

From November 2010

- New entrants must be ISA-registered before they start in their posts if the post is in the category of regulated activity (NB taking place frequently, intensively or overnight).
- It becomes a legal requirement for employers to check the ISA registration status of employees entering the workforce or changing jobs into a regulated activity for the first time.

From April 2011

- Existing staff engaged in regulated activity in any organisation can start to register with the scheme.
- ISA registration for existing staff will be carried out in phases over a four year period (from April 2011 to July 2015), based on a risk assessment approach decided by each individual employer

From January 2014

- **existing staff** working in **controlled activity** will be invited to join the ISA registration scheme between January 2014 and July 2015.

New regulations relating to controlled activity are expected to come into place in April 2010 and guidance on the specific procedures to be followed will be provided nearer the time.

**Phasing of the VBS for existing staff in the NHS:
a model of good practice**

Step 1 - existing staff who are not changing jobs, but who are working in regulated activity and who **have never had a CRB check before** will be phased in to the scheme. Pre-engagement checks must include carrying out an enhanced CRB check, registration with ISA, and having the staff member's details checked against the ISA barred lists on a continuous basis.

Step 2 – existing staff who are working in regulated activity and **whose CRB check is over three years old** will undergo an enhanced CRB check, will be registered with ISA and their details will be continuously checked against the ISA barred lists.

Step 3 - existing staff who are working in regulated activity, who have not changed jobs and who have a **CRB check undertaken less than 3 years ago** will undergo an enhanced CRB check, will be registered with ISA and their details will be continuously checked against the ISA barred lists.

Step 4 – the remainder of existing staff who are already working within regulated activity and have had a **more recent CRB check** will be registered with ISA, will undergo an enhanced CRB check and their details will be continuously checked against the ISA lists.

2014 – Staff working in **controlled activity** will be invited to join the ISA registration scheme between January 2014 and July 2015. All **existing staff** working in **regulated activity**, who have not already joined, will be invited to join the ISA registration scheme between January 2014 and July 2015.

25 July 2015 – all employees and volunteers working in regulated or controlled activity with children and vulnerable adults must be registered with the ISA

36. IMPACT OF ISA REGISTRATION ON THE RESEARCH PASSPORT SYSTEM

ISA registration is fully portable. Once an individual is registered, their ISA status is continually monitored and updated. Employers are notified of changes to an individual's ISA registration, and employers are LEGALLY OBLIGED to withdraw a member of staff from a regulated activity if their registration status changes. New employers can use an individual's current registration data to undertake free on-line checks of their status (i.e. without having to request a new CRB check).

In terms of the impact on the Research Passport system, the principal points to be aware of are:

1. The phasing-in programme for the VBS applies equally to current Research Passport holders and to all NHS-employed researchers.
2. Researchers can continue working under the arrangements of their existing validated Research Passport as long as the research activity remains similar to that for which the original Research Passport was issued and validated.

3. Researchers who need a Research Passport for the first time, or whose Research Passport needs renewal, or whose research activity changes significantly, will need to obtain a new Research Passport from their HEI employer, using the Research Passport form (Version 2). This will need to be validated by the Lead NHS site, and Version 2 of the HRC or LoA (as appropriate) would need to be issued.
4. Because the Research Passport requires renewal at three years, all HEI researchers will comply with the requirements of the VBS by November 2013.
5. NHS researchers will be phased in to the scheme in accordance with NHS Employers' guidance, and all NHS employees and volunteers working with children and vulnerable adults must be registered with the ISA by 26 July 2015.
6. The criteria for requesting an enhanced CRB check are extended to include regulated activity, as defined by the Safeguarding Vulnerable Groups Act 2006²².

New regulations relating to Controlled Activity are expected to come into place in April 2010, and guidance on the specific procedures to be followed will be provided nearer the time.

7. The requirement for existing NHS staff undertaking controlled activity to be registered with the scheme comes into force towards the end of the phasing-in period in 2014.
8. The Research Passport form (Version 2) and HRC/LoA documentation (Version 2) are updated to allow confirmation that the individual is ISA registered (where this is required), that the employer has registered an interest in the individual, and that the employer is legally obliged to withdraw the individual from working in a regulated activity, or if they are notified of a change in their registration status, or of any circumstances which may affect the individual's registration status.

ADJUSTMENT TO RESEARCH PASSPORT PROCEDURES TO COMPLY WITH THE VBS

New regulations relating to controlled activity are expected to come into place in April 2010 and guidance on the specific procedures to be followed will be provided nearer the time.

37. UNIVERSITY RESEARCHERS

37.1 What are the implications for university researchers who require a Research Passport and HRC or LoA for the first time from the NHS from 12 October 2009 onwards?

For all those new university researchers who need to access NHS facilities for the first time, as from 12 October 2009, the **Research Passport form (Version 2)** needs to be completed by the HEI. The NHS can only validate Research Passport forms (Version 2) for this category of HEI researchers, and the NHS must issue **Version 2** of the:

- Example HRC, or
- Example LoA for university researchers who do not require an HRC, or
- Example letter accepting an existing HRC.

The Research Passport form (Version 2) enables:

²² Safeguarding Vulnerable Groups Act 2006
http://www.opsi.gov.uk/ACTS/acts2006/ukpga_20060047_en_1

- **HEI researchers** to:
 - give their consent for the details from the form and accompanying documents to be processed, recorded and stored by the NHS organisation hosting their research
 - provide the necessary information to enable confirmation of whether their research activity within the NHS involves regulated activity.

See Section 3 of the Research Passport form (Version 2).

- **The line manager** of HEI researchers to state whether or not the activity to be undertaken by the researcher in the NHS meets criteria which include regulated activity

See Section 7a of the Research Passport form (Version 2).

- **HR within the HEI** to confirm:
 - whether or not the research is a regulated activity
 - that a CRB check at an appropriate level has been completed (must be enhanced disclosure where engaged in regulated).
 - For applications submitted after 12 October 2009 but before 26 July 2010, where the activity is a regulated activity, that a check against the appropriate ISA barred list(s) has been completed.
 - For applications submitted after 26 July 2010, where the activity is a regulated that the employer has registered the individual with the ISA. NB this is mandatory from November 2010.
 - that as from 26 July 2010, the employer will use ISA procedures to monitor the status of the individual, will withdraw the individual from undertaking any regulated activity if their status changes, and in such cases will immediately withdraw them from working in any NHS site. NB this is mandatory from November 2010.
 - that a Research Passport form is NOT being submitted for a person who is barred from working with vulnerable adults or children
 - the date, and reference number of the CRB disclosure certificate
 - from 26 July 2010 onwards, the ISA unique reference number. NB this is mandatory from November 2010.

See Section 8 of the Research Passport Form (Version 2).

The NHS R&D Office to confirm and record:

- The CRB disclosure certificate date and number
- The ISA registration number. NB this is mandatory from November 2010.

Once the Research Passport form (Version 2) has been validated, the appropriate HRC (Version 2) or LoA (Version 2) can be issued.

- Example HRC (Version 2)
- Example LoA for university researchers who do not require an HRC (Version 2)
- Example letter accepting an existing HRC (Version 2)

are also now available. These have been amended to clarify that:

- the employer is legally obliged to check and monitor the researcher's ISA registration status. NB not mandatory for new starters until November 2010.
- the employer will withdraw the researcher immediately if they are notified that the researcher is barred from working in regulated activity
- the researcher's HRC (Version 2) or appropriate LoA (Version 2) will be terminated forthwith if their ISA registration ceases.

37.2 What are the implications for university researchers who already have a validated Research Passport (Version 1)?

a) Researchers whose activity remains the same (same project(s) same site(s)) and whose Research Passport was validated prior to 12 October 2009

If there is no change in circumstance from when the Research Passport was first issued and validated, the Research Passport (Version 1) remains valid for its duration, and the researcher can continue working on the same terms as an existing member of NHS staff. No further action is needed until the Research Passport needs to be renewed.

b) Researchers who need to carry out the same project(s) in a new NHS site, where the activity to be undertaken at the new site is of a similar nature to those for which the Research Passport was validated prior to 12 October 2009

From 12 October 2009, where the researcher needs to undertake their research activity in a new NHS site, and the activity carried out within the additional project is similar to the activity for which the Research Passport was originally validated, the existing Research Passport (Version 1) can be presented to the new NHS site. The researcher would be treated in the same way as an existing member of NHS staff with regard to the phasing of the VBS. No new checks would be required at this point and the new NHS site can process the validated Research Passport form (Version 1) and related documentation in the usual way.

c) Need to add a new project to the Research Passport where the activity to be undertaken in that project is of a similar nature to that for which the Research Passport was validated prior to 12 October 2009

From 12 October 2009, where the researcher needs to add a new project(s) to their Research Passport, and the activity carried out within the additional project is similar to the activity for which the Research Passport was originally validated, the existing Research Passport (Version 1) can be presented to the new NHS site. The researcher would be treated in the same way as an existing member of NHS staff with regard to the phasing of the VBS. No new checks would be required at this point and the new NHS site can process the validated Research Passport form (Version 1) and related documentation in the usual way.

When the current Research Passport needs renewal: Researchers holding a project-specific or multi-project/generic Research Passport who need to continue their research beyond the end of the original three year period would need to obtain a new Research Passport (Version 2) from their HEI. If the researcher is engaged in regulated activity, the Research Passport (Version 2) meets the requirements of the VBS and the revised procedures for validating a Research Passport, described in 37.1 above, would then need to be followed by the host NHS site(s).

37.3 What are the implications for university researchers with an existing validated Research Passport whose activity changes in such a way that they would be classified as changing employment within the NHS e.g. moving to a position where their research involves direct contact with children where previously they worked only with adults, or a direct impact on care, where previously this was not the case.

Where researchers' activity involves a *significant* change of role (equivalent to being a new starter), then they would need to obtain a new Research Passport (Version 2) and follow the procedures described in 37.1 above, which ensures that researchers are brought into the VBS in line with the NHS's phasing of the scheme for staff who change employment.

38. NHS RESEARCHERS

38.1 What are the implications for NHS researchers or clinical academics whose job role changes so that they commence research for the first time after 12 October 2009 and the research includes regulated activity?

Where a researcher becomes a clinical academic or an NHS researcher by explicitly changing employment and starting a new job which includes research and regulated activity for the first time, they will be treated by their employer either as a new employee to that NHS organisation, or as an existing NHS employee who is starting in a new role. The requirements of the VBS would therefore apply, and the substantive employer would need to undertake a new enhanced CRB and a check against the barred list(s), as appropriate, on the individual concerned. From July 2010, the substantive employer would also register new starters or staff changing roles into regulated activity with the ISA.

Where an NHS researcher then requires an NHS to NHS LoA to undertake their research activities in other NHS sites, **they will submit their CV to the R&D office of the NHS site hosting their research, along with a signed confirmation from their substantive employer that the required pre-engagement checks have been undertaken, (see [NHS to NHS LoA – proforma confirmation of pre-engagement checks](#)).**

The R&D office for the employing Trust is responsible for ensuring this confirmation is issued by their Trust for all staff requiring NHS to NHS LoA. For clinical academics, the Trust holding the honorary clinical contract may need to liaise with the HEI which is the substantive employer, in order to issue the signed pro-forma confirmation of pre-engagement checks.

The host site can accept this declaration as confirmation that the required pre-engagement checks have been undertaken by the employer and issue the NHS to NHS LoA (Version 2) to the researcher, copied to the researcher's substantive employer. The copy of the NHS to NHS LoA sent to the employer will be accompanied by a copy of the proforma confirming completion of pre-engagement checks submitted to the host organisation. The NHS to NHS LoA (Version 2) has been amended to make it clear that:

- in line with the phasing of the VBS within the NHS, where the NHS researcher's role includes regulated activity, there is a mandated requirement to undertake an enhanced CRB check, their employer **MUST** undertake a new enhanced CRB check, **MUST** ensure that the researcher was checked against the two new ISA barred lists and **MUST** enter them into the ISA registration scheme
- the substantive employer **MUST** withdraw the researcher from undertaking a regulated activity in any NHS site if they become aware of any change in the researcher's registration status.

38.2 What are the implications for existing NHS researchers and clinical academics whose research activities include their working across a number of NHS sites, and who are supported by the NHS to NHS LoA issued before 12 October 2009?

Where a researcher is a clinical academic or an NHS researcher needing to access another organisation to carry out their research and they already have a NHS to NHS LoA (Version 1), they will be treated as existing staff continuing to work in the same role. Their existing NHS to NHS LoA (Version 1) can remain current.

As NHS researchers move to new sites, they will submit their CV to the R&D office of the NHS site hosting their research, along with a signed confirmation from their substantive employer that the required pre-engagement checks have been undertaken.

The R&D office for the employing Trust is responsible for ensuring this confirmation is issued by their Trust for all staff requiring NHS to NHS Letters of Access. For clinical academics, the Trust holding the honorary clinical contract may need to liaise with the HEI which is the substantive employer in order to issue the signed proforma confirmation of pre-engagement checks.

The host site can accept this declaration as confirmation that the required pre-engagement checks have been undertaken by the employer and issue the NHS to NHS LoA (Version 2) to the researcher, copied to the researcher's substantive employer. The copy of the NHS to NHS LoA sent to the employer will also be accompanied by a copy of the pro-forma confirming completion of pre-engagement checks submitted to the host organisation.

NHS researchers' substantive employer will phase existing staff into the VBS in accordance with the phasing timescale allowed in the legislation, using risk-based assessment.

By 2015, all NHS researchers should be issued with the new NHS-to-NHS LoA (Version 2) by all NHS sites hosting their research, making it clear that where their research role involves regulated activity:

- the substantive employer **MUST** undertake a new enhanced CRB check and ensure that the researcher was registered with the ISA
- the substantive employer **MUST** withdraw the researcher from undertaking a regulated activity in any NHS site if they become aware of any change in the researcher's registration status.

39. RESEARCH STAFF FROM COMMERCIAL ORGANISATIONS

39.1 What are the implications for research staff provided to the NHS by commercial organisations to undertake commercial research if they are engaged in regulated activity?

NHS indemnity does not extend to commercial research staff. This group should not therefore operate the Research Passport system, or be issued with an HRC or LoA or any other document that could be construed as indicating that the NHS organisation is accepting liability for their actions.

A contract for the provision of these services must be put in place with the commercial organisation. This contract should cover the activities and suitability of the commercial staff, including pre-engagement check requirements (CRB, occupational health, professional registration, right-to work, qualification etc), training, accountability and management arrangements, insurance for staff's negligent actions, etc.

In relation to the VBS specifically, the Regulated Activity Provider will be the employer of the commercial staff. The NHS host organisation needs to have written confirmation from the commercial employer that all relevant pre-engagement checks have been undertaken. This must include:

- details of checks against the barred lists (from 12 October 2009 up to 26 July 2010)
- confirmation of registration with the ISA (from 26 July 2010)
- enhanced CRB (if so mandated).
- specific statement that the employer **MUST** withdraw the researcher from undertaking a regulated activity in any NHS site if they become aware of any change in the researcher's registration status.

40. INDEPENDENT CONTRACTORS WHO UNDERTAKE RESEARCH

40.1 What are the implications for independent contractors who undertake research?

Independent contractors who operate under the NHS contract for services must comply with the VBS, and the phasing-in scheme applies equally to them.

The NHS should not extend HRCs to independent contractors if they are conducting research as part of their NHS practice although the host organisation may wish to highlight that compliance with research governance is a contractual obligation for such staff as part of the broader obligation to comply with the organisation's corporate risk management arrangements. Independent contractors and the host organisation should ensure that adequate professional indemnity arrangements for the research activity are in place with a MDO before starting the research. The REC should be reassured that this is in place.

Independent contractors who undertake research under separate contract with the NHS will be dealt with as described in 38 as appropriate to the individual circumstances.

Independent contractors who undertake research under separate contract with an HEI will be dealt with as described in 37 above as appropriate to the individual circumstances.

CRB Checks

This frequently asked question (FAQ) describes the new arrangements for obtaining CRB disclosures, which have been put in place as part of the implementation of the VBS. This part of the guidance should be read in conjunction with the guidance on the VBS as it applies to the Research Passport.

Summary of Key Messages

The range of positions which are eligible for an enhanced CRB disclosure²³ now only include posts involving work for a regulated activity provider, which is a regulated activity with children or vulnerable adults. In general, this type of work will involve regularly caring for, supervising, training or being in sole charge of such people. The specific categories of work which are included in the lists of those posts eligible for an enhanced CRB check are:

Any work which is defined as regulated activity relating to children within the meaning of Part 1 of Schedule 4 to the Safeguarding Vulnerable Groups Act 2006
Any work which is defined as regulated activity relating to vulnerable Adults within the meaning of Part 2 of Schedule 4 to the Safeguarding Vulnerable Groups Act 2006
Any office or employment which is concerned with the representation of, or advocacy services for, vulnerable adults by a service that has been approved by the Secretary of State or created under any enactment; and which is of such a kind as to enable a person, in the course of his normal duties, to have access to vulnerable adults in receipt of such services
Any work in a further education institution where the normal duties of that work involve regular contact with persons aged under 18

The three barring lists (POVA, POCA and List 99) are replaced by the creation of two new barred lists administered by the ISA rather than several Government departments (the ISA barred lists).

A check of the new ISA barred list(s) is available only as part of an enhanced CRB disclosure.

Enhanced CRB disclosures contain:

- the same information as Standard checks
- confirmation of the check against the new barred lists (if requested).
- any locally held police force information considered relevant to the job role, by Chief Police Officer(s).

Standard CRB checks are for people entering certain professions. For health-related activity, Standard CRB checks are available only for:

²³ List of Eligible Posts
Criminal Records Bureau
http://www.crb.homeoffice.gov.uk/guidance/rb_guidance/eligible_posts.aspx

Any employment or other work which is concerned with the provision of health services and which is of such a kind as to enable the holder to have access to persons in receipt of such services in the course of his normal duties

Standard CRB check disclosures contain the following:

- Convictions, Cautions, Reprimands and Warnings held in England and Wales on the PNC, the most of the relevant convictions in Scotland and Northern Ireland may also be included;
- Standard checks no longer include a check of the old or new barred lists from 12 October 2009.

Therefore if you are working or volunteering with children or vulnerable adults, it is important to check whether the position meets the criteria of regulated activity (see section on VBS), in which case the post is eligible for an enhanced CRB check.

There is no requirement at this point to request an enhanced CRB check for existing staff who have become eligible because of the introduction of the concept of regulated activity; they can be checked at the same time they are registered with the VBS, in line with the phasing strategy.

The Vetting and Barring scheme will initially be applied only to new employees, and a five year implementation plan will be rolled out to cover existing staff. Therefore, until required under the phasing schedule, NHS organisations do not need to undertake new checks on researchers who have a current Research Passport. Please see the guidance on the VBS above, which clarifies at which point a Research Passport needs to be renewed and how the requirements of the VBS need to be met.

The VBS will initially be applied only to new employees, and a five year implementation plan will be rolled out to cover existing staff. Therefore, until required under the phasing schedule, NHS organisations do not need to undertake new VBS checks on researchers who have a current Research Passport. Please see the guidance on the VBS below, which clarifies at which point a Research Passport needs to be renewed and how the requirements of the VBS need to be met.

41. Does the HR Good Practice Resource Pack comply with the relevant law and CRB/Disclosure Scotland guidance on requesting disclosures

Yes. The DH recommends the guidance provided in the HR Good Practice Resource Pack for use by the NHS and HEIs, on the basis that it complies with the relevant legislation²⁴, NHS Employers' Check Standards and guidance²⁵ and other relevant codes of practice and

²⁴ Data Protection Act 1998 (C.29)

http://www.opsi.gov.uk/Acts/Acts1998/ukpga_19980029_en_1

Police Act 1997 (C.50)

http://www.opsi.gov.uk/acts/acts1997/pdf/ukpga_19970050_en.pdf

Rehabilitation of Offenders Act 1974 (C.53)

http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1974/cukpga_19740053_en_1

Safeguarding Vulnerable Groups Act 2006 (C. 47)

http://www.england-legislation.hmso.gov.uk/acts/acts2006/ukpga_20060047_en_1

²⁵ NHS Employment Check Standards

<http://www.nhsemployers.org/RecruitmentAndRetention/Employment-checks/Employment-Check-Standards/Pages/Employment-Check-Standards.aspx>

guidance²⁶. The Pack describes a consistent and systematic approach to underpin the sharing of information between organisations relating to CRB and other checks and provides the NHS with a clear risk assessment and management system, to enable them to set aside the requirement to repeat pre-engagement checks, and to receive, review and validate the evidence provided by the substantive employer that appropriate checks have been carried out commensurate to the researcher's role. The systems described in the HR Good Practice Resource Pack ensure that HEI employers can meet these standards when requesting permission for their researchers to access the NHS to undertake their research. The scheme is kept under on-going review and is amended to reflect any change in employment legislation or NHS Employers' good practice guidance.

42. What are the different categories of CRB disclosure allowed under the Police Act 1997 and how can I assess which disclosure category a researcher's activity falls into?

The Police Act 1997²⁷, as amended, makes provision for three different levels of criminal record disclosure:

- Basic Disclosure
- Standard Disclosure
- Enhanced Disclosure

Basic Disclosure

This service is operated by Disclosure Scotland, but anyone in the UK can access the service. Organisations cannot request a basic disclosure on behalf of an individual. The basic disclosure may be requested only by the individual concerned. Individuals may request a basic disclosure via Disclosure Scotland for any purpose, on presentation of a fee and proof of identity.

A **basic disclosure** shows any unspent (current) convictions, and can be used when a post does not meet the criteria for a standard or an enhanced disclosure. As such, a basic disclosure can provide employers with a level of reassurance about staff who are placed in positions of trust. This can include staff who have no direct contact with patients or service users in the course of their research activities, but who may have access to sensitive or identifiable data such as patient records. NHS Employers state that organisations may if they

Circumstances for risk assessment of CRB checks

<http://www.nhsemployers.org/PlanningYourWorkforce/MedicalWorkforce/MMC/Pages/CRB-disclosures-doctors-in-training.aspx>

Medical student access to patient records

NHS Employers

http://www.nhsemployers.org/PlanningYourWorkforce/MedicalWorkforce/Medical_Education_and_training/Pages/MedicalstudentsCRS.aspx

²⁶ CRB Code of Practice

<http://www.crb.gov.uk/default.aspx?page=311>

CRB Portability Framework

<http://www.crb.gov.uk/default.aspx?page=1870>

The Vetting and Barring Scheme Guidance

<http://www.isa.gov.org.uk/default.aspx?page=402>

CRB: Vetting and Barring FAQs

http://www.crb.gov.uk/faqs/vetting_and_barring_scheme.aspx

²⁷ Police Act 1997 (C.50)

http://www.opsi.gov.uk/acts/acts1997/pdf/ukpga_19970050_en.pdf

wish request sight of a basic disclosure for staff who require access to personal data only (e.g. patient records)²⁸.

Standard and Enhanced Criminal Record Disclosures

Sections 113 and 115 of the Police Act 1997 specify the circumstances in which organisations can request a CRB disclosure. Disclosures can only be requested by Registered Bodies, who must comply with all relevant law and regulations governing requests for disclosures.

A **standard disclosure** provides information on both spent and unspent convictions including nationally held cautions, reprimands and final warnings. NB. Since 12 October 2009, it is no longer possible to request a search against the barred lists as part of a standard disclosure. Standard disclosures are available only for posts which are exempt under the Rehabilitation of Offenders Act 1974, as amended. In the context of health research it includes *any employment or other work which are concerned with the provision of health services and which are of such a kind as to enable the holder to have access to persons in receipt of such services in the course of his normal duties*.

An **enhanced disclosure** involves an additional level of checks to those carried out for a standard disclosure. Where local police records contain additional information, such as relevant non-conviction information that may be relevant to the post, the Chief Officer of Police may release such information for inclusion in an enhanced disclosure. Enhanced disclosures will also include a check against the barred lists where this has been requested. Enhanced disclosures may only be requested for posts which are exempt under the Rehabilitation of Offenders Act 1974, as amended.

Enhanced disclosures are available for:

- Any work which is defined as regulated activity relating to children within the meaning of **Part 1 of Schedule 4 to the Safeguarding Vulnerable Groups Act 2006**
- Any work which is defined as regulated activity relating to vulnerable Adults within the meaning of **Part 2 of Schedule 4 to the Safeguarding Vulnerable Groups Act 2006**
- Any office or employment which is concerned with the representation of, or advocacy services for, vulnerable adults by a service that has been approved by the Secretary of State or created under any enactment; and which is of such a kind as to enable a person, in the course of his normal duties, to have access to vulnerable adults in receipt of such services

43. Our organisation's policy is that enhanced CRB checks are required where researchers have access to sensitive or personally identifiable data. Does the Research Passport system disregard this policy?

Section 113 and 115 of the Police Act 1997²⁹, as amended provide for the issue of standard and enhanced criminal record disclosures respectively. Standard CRB disclosures are only available for the professions, offices, employments, work and occupations that are known as the exceptions to the Rehabilitation of Offenders Act 1974³⁰, as amended, In relation to health research, standard CRB disclosures are available for "*work which is concerned with the*

²⁸NHS Employers' - Criminal Records Check Standard
<http://www.nhsemployers.org/RecruitmentAndRetention/Employment-checks/Employment-Check-Standards/Pages/CriminalRecordChecks.aspx>

²⁹ Police Act 1997
http://www.opsi.gov.uk/acts/acts1997/pdf/ukpga_19970050_en.pdf

³⁰ Rehabilitation of Offenders Act 1974 (c.53)
http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1974/cukpga_19740053_en_1

provision of health services and which is of such a kind as to enable the holder to have access to persons in receipt of such services in the course of his normal duties” and enhanced CRB disclosures are available only for work which is defined as regulated activity relating to children or vulnerable adults, specific types of approved advocacy services for vulnerable adults and work in further education institutes³¹.

Where researchers have access to sensitive or personally identifiable data only in NHS settings, then, in accordance with *current* legislation, the position would not qualify for a standard or an enhanced check and this could not be requested unless the individual qualified by other means.

When the VBS is implemented in full the range of positions eligible for a CRB disclosure will be extended to include (**controlled activity**, which will include new requirements for individuals who access health or social services records relating to children and vulnerable adults (see question 43 below).

New regulations relating to controlled activity are expected to come into place in April 2010 and guidance on the specific procedures to be followed will be provided nearer the time.

Further details are available from the ISA website³². This FAQ and the HR Good Practice Resource Pack will be updated in line with any changes in the legislation.

It should be noted that section 123(2) of the Police Act 1997 states that “A person commits an offence if he knowingly makes a false statement for the purpose of obtaining, or enabling another person to obtain, a certificate under this Part”.

Where a position does not meet the criteria for either a standard or an enhanced disclosure, organisations may wish to consider the use of a basic disclosure, which may be used where an individual is appointed to a position of trust, such as access to patient records. Further information on requesting a basic disclosure is available at www.disclosurescotland.co.uk.

Employers must ensure that all checks are carried out in compliance with the Data Protection Act 1998³³ and in accordance with the CRB's Code of Practice for Registered Persons and other recipients of Disclosure Information⁴. In addition, you should note that the CRB undertakes routine checks against disclosure applications submitted and where it is found that a registered body is requesting the wrong level of check, they could ultimately be de-registered.

44. Some host organisations now ask for enhanced CRB disclosures for all researchers who will have unsupervised access. Is this correct?

As described in question 43, it is an offence under Sections 113 and 115 of the Police Act 1997 to apply for a disclosure in respect of a post which does not warrant it³⁴.

³¹ List of Eligible Posts
Criminal Records Bureau
http://www.crb.homeoffice.gov.uk/guidance/rb_guidance/eligible_posts.aspx

³² Independent Safeguarding Authority
<http://www.isa.gov.org.uk/Default.aspx?page=333>

³³ Data Protection Act 1998 (c.29)
http://www.opsi.gov.uk/Acts/Acts1998/ukpga_19980029_en_1

³⁴ Police Act 1997 (c50)
<http://www.opsi.gov.uk/acts/acts1997/1997050.htm#aofs>.

All organisations and individuals authorised to request enhanced and standard disclosure information must comply with the relevant legislation and the CRB Code of Practice³⁵ and explanatory guide to ensure that the information is used appropriately and fairly and that people are not unjustly discriminated against.

In particular, Registered Bodies must use all reasonable endeavours to ensure that they submit disclosure applications only in accordance with the disclosure eligibility criteria for relevant positions of employment. To adopt a blanket policy of requiring enhanced disclosures for all researchers, regardless of the activity to be undertaken in that post or its location, would therefore be a breach of the CRB's Code of Practice, and could mean that the Registered Body is in breach of the Police Act 1997, in that it is asking for disclosures for posts that are not exempt under the Rehabilitation of Offenders Act 1974, as amended, such as regulated activity.

Ultimately, each NHS organisation has to decide whether the activities of a researcher meet the eligibility criteria for a standard or enhanced check.

45. How should disclosures be handled? What happens if criminal conviction or police information is disclosed?

Disclosure information may be passed from the CRB only to those authorised to receive it within the Registered Body which made the request, and may only be used as part of the recruitment decision for which the CRB disclosure was requested. It must be retained securely and once a recruitment decision has been made, it must be destroyed, normally within six months of its receipt. It is a criminal offence to pass disclosure information to anyone not entitled to receive it.

Information provided in a disclosure therefore cannot be passed from the employer to an NHS organisation. The Research Passport system ensures that CRB³⁶ guidance on this is adhered to by:

- Ensuring the substantive employer who requested the criminal record disclosure confirms on the Research Passport form whether or not a clean criminal record disclosure has been obtained (i.e. a criminal record disclosure with no convictions or other police information).
- Version 2 of the Research Passport form also includes information about the date of the disclosure and the disclosure reference number
- Where the employer confirms that there is no information revealed in the disclosure, the applicant then provides her/his own copy of the disclosure document to the NHS organisation.
- In signing the Research Passport form and providing her/his own copies of pre-engagement checks, the applicant consents to the sharing of that information.

When a standard disclosure is obtained, the information obtained in the disclosure will be included on the individual's copy of the disclosure document.

When an enhanced disclosure is obtained, some information may only be provided to the Registered Body that requested the disclosure, and will not be copied to the individual. In such cases the Chief Officer of Police may in the interests of the prevention or detection of crime release 'additional' information to the Countersignatory only, in the form of a separate letter. Where the police issue a separate letter, the Countersignatory's copy of the enhanced

³⁵ CRB Code of Practice
http://www.crb.gov.uk/PDF/code_of_practice.pdf

³⁶ Handling of CRB Certificate Information
Criminal Records Bureau
http://www.crb.homeoffice.gov.uk/guidance/rb_guidance/handling_of_disclosure_info.aspx

References to CRB also apply to Disclosure Scotland

disclosure will contain the following words 'Please refer to letter sent under separate cover', printed under the 'date of issue' on the Disclosure. The information contained within the letter cannot be revealed to the applicant or be shown to the applicant or to any other person not involved with the recruitment decision.

If the response on the application form indicates that no clear criminal record disclosure has been obtained, this may be because convictions or police information were reported in the disclosure, or because no criminal record disclosure has been obtained. The NHS organisation should clarify with the researcher and her/his employer/place of study whether a disclosure was obtained. If it was obtained and the researcher confirms that it was not clear, the NHS organisation should ensure that a new criminal record disclosure is obtained with relevant and up-to-date information. The NHS organisation can then make a risk assessment in relation to the researcher's proposed activity, based on CRB information that it has obtained directly.

46. What should an HEI employer do if a criminal record check on an existing employee discloses a criminal conviction?

The employer would need to deal with each such cases on an individual basis, assessing whether the convictions on the disclosure were relevant to the work of the employee and then assessing whether it is appropriate to permit the individual to do that work. In addition, the NHS organisation would need to make its own assessment to decide whether or not to issue an HRC or LoA. In such cases, the CRB recommend that the Chartered Institute of Personnel guidance on employing ex-offenders is used³⁷. If the conviction is likely to have an impact on the individual's research activity generally then contractual issues may arise. In such cases, the advice of the employing organisation's HR department should be sought.

The same principles would apply if a researcher declared a change in her/his criminal record after a criminal record check had been completed. The NHS organisation would need to make an assessment whether to withdraw the HRC or LoA or whether to put in place additional supervision arrangements.

Where a researcher is undertaking regulated activity, their details must also be checked against the ISA barred lists. It is unlawful knowingly to employ anyone in a regulated activity if they are barred from working with children or vulnerable adults. From July 2010, registration with the ISA becomes possible, enabling the employer (the Regulated Activity Provider) to subscribe their interest in employees who are ISA registered, and to be notified of any change in their status via the ISA On-line continuous monitoring system. If notified of any change in their employee's status through ISA On-Line, employers must withdraw them from undertaking regulated activity immediately

47. How does the Research Passport system fit with guidance about portability of criminal record checks?

Improper and repeated use of CRB disclosures have been a source of frustration and wasted resources. Under the Data Protection Act 1998³⁸ it is illegal to request personal information where it is not necessary for the post.

Portability refers to the re-use of a CRB disclosure, obtained for a position in one organisation and later used for a position in another organisation. The CRB issued a revised Portability

³⁷ Employing ex-offenders: A practical guide
Chartered Institute of Personnel and Development
http://www.crb.gov.uk/PDF/CIPD_Employing_ex-offenders%20guide.pdf

³⁸ Data Protection Act 1998 (C.29)
http://www.opsi.gov.uk/Acts/Acts1998/ukpga_19980029_en_1

Framework³⁹ in November 2006. The CRB Portability Framework describes the kind of risk assessment that organisations should undertake as part of their decision to set aside their own requirement to undertake a CRB disclosure, and accept a disclosure that has been carried out by a different organisation for a different post. The CRB's advice in this area has been incorporated into the Research Passport guidance, and developed into explicit procedures. In particular, the Research Passport guidance provides a clear framework and set of procedures for employing organisations, the NHS and researchers, so that an agreed data set about a researcher is provided and shared. The NHS can use this data to undertake a comprehensive risk assessment to decide whether to accept the check carried out by the researcher's employer.

The Research Passport uses a single system to provide pre-engagement information to several NHS organisations. The application form is completed by the applicant and her/his substantive employer, and ensures that the employer and the researcher work together to provide all the information that will be needed by the NHS, using a jointly agreed systematic and consistent procedure. In particular, the Research Passport form enables evidence of the identity check, suitability of the researcher, CRB disclosure and occupational health check to be provided together. This in turn enables the NHS to match those checks with the planned research activity. One criminal record disclosure is performed as part of the single process, for a number of NHS organisations, and a specific project or numerous types of projects. In this way, the Research Passport system provides a mechanism to set aside the requirement for a new check to be undertaken by each NHS organisation.

NHS Employers have given advice to NHS organisations on handling criminal record disclosures for particular types of staff such as students, trainees, agency workers and locums, providing a balanced and proportionate approach to meeting NHS organisations' responsibilities. The provision made in the Research Passport system for researchers is in accordance with advice for doctors in training, whereby if there is evidence that a researcher has had a criminal record check by her/his employer or another NHS organisation within the previous three years, then the requirement for the checks to be repeated can be set aside.

The introduction of ISA registration, which is part of the VBS, means that the mechanisms which reassure employers about the checks in place for staff undertaking regulated activity (i.e. checks carried out against the ISA barred lists) become completely portable. ISA registration is carried out once only and registration details are fully transportable between Regulated Activity Providers. Furthermore, once a person is ISA registered their employer (the Regulated Activity Provider) can subscribe their interest in that employee via ISA On-line, and be alerted by the ISA of any change in their employee's ISA status through ISA's continuous monitoring procedures.

The Research Passport system places an obligation on researchers to inform both the employer and any relevant NHS organisations of any changes to their criminal record.

In addition to providing assurances about the researcher to the NHS, the Research Passport system also establishes a clear ongoing communication channel between the employer and the NHS organisation to address any future issues.

³⁹ CRB Portability Framework
<http://www.crb.gov.uk/default.aspx?page=1870> & <http://www.crb.gov.uk/faqs/portability.aspx>

VALIDITY AND DURATION OF THE CRB CHECK

48. Our NHS organisation's policy is that we should not accept criminal record disclosures over 6 months old. Does the Research Passport disregard this policy?

Within the NHS, provision has been made to set aside the requirement for repeat checks on each new appointment for students, trainees and highly mobile staff. The Research Passport system is in accordance with the provision for doctors in training. Once a CRB disclosure has been obtained it is relied on either for the duration of the project or for the duration of a multi-project/generic Research Passport (in either case up to three years). However it is recommended that the disclosure used to support the initial Research Passport application should be no more than 6 months old.

Once a criminal record disclosure has been obtained conducted and the individual has been issued with a Research Passport and a LoA or HRC (as appropriate), s/he is required to inform the employer and the organisation(s) with whom s/he is conducting research of any change in her/his criminal record. Therefore when the researcher produces her/his Research Passport documents when s/he needs to approach a new NHS organisation, the new organisation does not need to repeat the checks, even if the check was conducted more than 6 months previously.

Furthermore, for those researchers undertaking regulated activity, the continuous monitoring facility provided by the ISA provides employers and the NHS with additional safeguards. Under the Research Passport system, employers undertake to subscribe their interest in their employees who are ISA registered via ISA on-line. This means that ISA alerts employers of changes in an employee's ISA registration status, and in such instances the employer must immediately withdraw their employee from undertaking regulated activity.

49. How long are criminal record checks valid for?

A criminal record check carries no formal period of validity. Information revealed through a criminal record check only reflects the information available at the time of issue. A person's criminal record or other relevant information may subsequently change. Employers should, however, require employees to inform them of any change in their criminal record during the course of their employment, backed by appropriate disciplinary measures.

The advice of NHS Employers⁴⁰ in relation to the frequency of performing CRB checks on groups of mobile staff, (which is how researchers are classified), is that a check should be carried out and recorded at least every 3 years by the lead employer, so that subsequent employers might then use this information to support their risk assessments in deciding whether or not a further check is required. The same timescale also applies to HEI researchers using the research passport scheme. Where HEIs provide researchers to the NHS who are agency staff, then more frequent, annual, updating of checks may be required, in line with NHS Employers guidance for agency staff.

It is also recommended that the disclosure used to support the initial research passport application is no more than 6 months old.

In most cases, organisations will choose to align HRCs/LoA issue or review dates with the date of the CRB disclosure however the decision to do this is a local management decision and should be based on a proportionate risk assessment. For groups of stable staff, that are actively managed, for example, organisations may be happy to extend the HRC to the duration of the project. For staff that are ISA registered, it is likely that the ISA's continuous monitoring facilities will provide employers and the NHS with sufficient levels of reassurance without the need for on-going renewal of CRB checks.

⁴⁰ http://www.nhsemployers.org/SiteCollectionDocuments/Criminal_record_checks_dl270209.pdf

50. Do we need to get researchers to complete declaration forms in addition to viewing their criminal record disclosures?

No. The information supplied by the employer and the researcher through completion and sign-off of the Research Passport form or the [NHS to NHS LoA – proforma confirmation of pre-engagement checks](#), alongside the documentary evidence provided with the Research Passport form, is deemed to provide sufficient assurance.

51. Where does liability lie in relation to the checks conducted by the substantive employer?

The Police Act 1997 includes specific provision that no proceedings shall lie against the CRB⁴¹ by reason of an inaccuracy in the information made available or provided to the CRB. Organisations requesting criminal record disclosures from the CRB would be able to argue that no liability rests with them, as long as they had not knowingly made a false declaration on the application form and had complied with all guidance issued by the CRB, including the Code of Practice⁴².

If the information revealed in the criminal record disclosure is disputed by the applicant, the CRB has a procedure in place to resolve issues about accuracy. In the event of a dispute an HRC should not be issued until the investigation is completed.

The responsibility for complying with the CRB's Code of Practice rests with each recipient of the criminal record disclosure. For further details about these obligations see the Codes of Practice

The remaining checks required by the Research Passport system and conducted by the substantive employer reflect NHS Employment Check Standards⁴³, which meet legal and best practice standards in this area, provide an explicit risk assessment and management system to evaluate and decide the researcher's suitability to carry out their activity in the NHS.

It is for individual NHS bodies to satisfy themselves of the process used to carry out criminal record and other checks on researchers. If an NHS body is in any doubt about such checks, it should take such action as it considers necessary to confirm them.

Complaints or allegations against the researcher will be dealt with in accordance with her/his substantive employer's policies and procedures. The NHS organisation and the employer must work in collaboration in handling such incidents. If a claim for negligence arises the claim will be processed through the NHS trust in which the patients concerned were recruited. If during any investigation relating to that claim, it transpires that the employing trust has not done a pre-engagement check on the researcher concerned, the CNST scheme will continue to handle the claim for negligence through the NHS host site, but, as liability for the claim also rests with the employing Trust, the CNST premiums payable by the employing trust will rise the next year.

⁴¹ References to CRB also apply to Disclosure Scotland

⁴² CRB Code of Practice
http://www.crb.gov.uk/PDF/code_of_practice.pdf

⁴³ NHS Employers' Check Standards
<http://www.nhsemployers.org/RECRUITMENTANDRETENTION/EMPLOYMENT-CHECKS/EMPLOYMENT-CHECK-STANDARDS/Pages/Employment-Check-Standards.aspx>

CHECKS AGAINST THE ISA BARRED LISTS

Summary of key points

The three former barred lists, Protection of Children Act (POCA), Protection of Vulnerable Adults (POVA) and List 99, have now been replaced by the creation of two new barred lists administered by the ISA rather than several Government Departments. From now on checks of these two lists can be made as part of an enhanced CRB disclosure, for those staff undertaking regulated activity.

Legislation governing the requirements for regulated activity, in particular the requirements relating to enhanced CRB disclosure and checks against the ISA barred list(s), allow for the phasing strategy, which has been adopted to enable implementation of the VBS to take place incrementally between 2011 and 2015 for existing staff.

New staff who are undertaking regulated activity under the Safeguarding Vulnerable Groups legislation will need to undergo an enhanced CRB and a check against the relevant barred list(s). There is no requirement to repeat the enhanced CRB check or the check against the ISA barred list(s) for each new site. From July 2010, new starters in regulated activity can be registered with the ISA and their ISA status will be subject to continuous monitoring by their employer, through ISA on-line. In this way, employers and host NHS research sites can be assured about staff undertaking regulated activity.

For existing staff who are already engaged in regulated activity that previously would have required a POCA check at each site, under the Safeguarding Vulnerable Groups legislation they can continue their work without the need for new CRB checks or for new checks against the barred list(s), until they are phased in to the scheme as described in the section on VBS (above). There is no requirement to repeat the enhanced CRB check and check against the ISA barred list(s) for each new site.

52. For research involving children, before 12 October 2009, a PoCA check had to be carried out every time a researcher moved to a new host site. Is this still the case for checks against the ISA barred lists, where the employer has already undertaken a check at the appropriate level (i.e. enhanced CRB disclosure with PoCA or enhanced CRB disclosure with ISA children's list check)?

a) NHS to NHS Arrangements

Section 10 and 11 of the Safeguarding Vulnerable Groups Act 2006⁴⁴ identify certain prescribed circumstances where a Regulated Activity Provider does not commit an offence if they allow an individual to engage in regulated activity and fail to ascertain whether the individual is subject to monitoring:

1) If permission for the activity was granted prior to the relevant section of the legislation coming into force (Section 10(6) and 11(6)).

2) If immediately before that permission takes effect the individual is engaged in relevant NHS employment (this includes employment with an NHS body), and for the duration of that activity the individual continues to be engaged in relevant NHS employment and the regulated activity is also considered as relevant NHS employment (Section 10(7) and 11(4)).

In this case where an individual is an existing NHS employee currently undertaking research at other NHS sites (where research approval was issued prior to 12 October 2009) or they wish to begin research activity at another NHS site for the first time and hold an appropriate CRB check undertaken by their substantive employer, the site hosting the research does not commit an offence by failing to ascertain whether the individual is subject to monitoring

⁴⁴ Safeguarding Vulnerable Groups Act 2006 (c.47)
http://www.opsi.gov.uk/ACTS/acts2006/ukpga_20060047_en_1

It is recommended that in such circumstances researchers should be issued with the NHS to NHS LoA. Each host site would not need to repeat an enhanced level CRB check. The NHS to NHS LoA places explicit responsibility on the substantive NHS employer to undertake the required pre-engagement checks in line with the relevant legislation, NHS Employers' Standards and the VBS phasing strategy.

b) Research Passport system

As described above, sections 10 and 11 of the Safeguarding Vulnerable Groups Act 2006 identify certain prescribed circumstances where a Regulated Activity Provider does not commit an offence if they allow an individual to engage in regulated activity and fail to ascertain whether the individual is subject to monitoring. The circumstances include where permission for the activity was granted prior to the relevant section of the legislation coming into force (Section 10(6) and 11(6)). In practice, if the HEI researcher already has an HRC or LoA (for equivalent activity) there is no requirement to request a new enhanced level disclosure with a check against the ISA barred lists for children or vulnerable adults until the individual is required to join the new scheme in line with the phasing strategy.

With regard to new starters who require a Research Passport for the first time, or for those whose Research Passport needs to be renewed, the HEI substantive employer (who is the Regulated Activity Provider) is responsible for ensuring that the researcher is subject to monitoring with respect to research which involves regulated activity. Section 5 of the Research Passport form (Version 2) enables HEI employers to confirm that the relevant enhanced CRB disclosure and check against the relevant barred list(s) have been completed, and after July 2010, that the research is ISA registered and subject to monitoring.

Section 3, Schedule 5, of the Safeguarding Vulnerable Groups Act 2006⁴⁵ allows NHS host sites to accept this written assurance as evidence that the researcher is subject to monitoring. On this basis NHS organisations can issue an appropriate HRC or LoA without the requirement for each host site to repeat an enhanced level CRB check with ISA children's list check.

⁴⁵ Safeguarding Vulnerable Groups Act 2006 (c.47)
http://www.opsi.gov.uk/ACTS/acts2006/ukpga_20060047_en_1

OCCUPATIONAL HEALTH CHECKS

53. What information on occupational health checks should be expected from the substantive employer?

The substantive employer should provide the researcher with written evidence of the health checks conducted. A record of vaccinations should be included where specific immunisations are required for the research role.

The HR Good Practice Resource Pack supports HEIs to provide NHS organisations with the core information they need, confirming occupational health checks and current status. The guidance in the pack reflects NHS Employers' standards for occupational health checks⁴⁶. It includes an example of a standard occupational health check screen and record of vaccinations, which HEIs can use. The occupational health requirements described in the HR Good Practice Resource Pack take account of core NHS requirements relating to vaccination record, infection control, and exposure-prone procedures, based on requirements set out in the Green Book⁴⁷ and "Effective Management of Occupational Health and Safety Services in the NHS"⁴⁸. These are the standard checks needed for those clinical researchers who typically will be undertaking research which has a direct impact on patient care.

In some situations, it may not be possible for an employer to conduct occupational health checks for a particular research activity (e.g. where specific vaccinations are required to meet local requirements, or a discussion with the applicant is necessary). In such cases, it may be possible for the HEI to negotiate with a local NHS organisation to undertake, on behalf of the HEI, the necessary occupational health procedures on their researchers.

The occupational health check should also include workplace issues that the NHS organisation needs to be aware of, for example reasonable adjustments to meet the needs of individuals with disabilities. Where there are potential confidentiality issues, the document should explain that other matters will need to be discussed directly between the employer and NHS occupational health department, with the applicant's consent.

54. If a researcher is undertaking non-clinical face-to-face interviews with NHS patients, is it necessary to complete the full list of vaccinations listed in the sample occupational health check screen included in the HR Good Practice Resource Pack?

The DH advise that they expect NHS occupational health practice to be proportionate to the potential risks in the circumstances, and that NHS organisations should only undertake (or expect) pre-employment health screening where necessary. It is not felt beneficial to screen all staff systematically. This should be determined locally, however for the circumstance described, researchers interviewing NHS patients would not require the same level of occupational health screening as those subject to exposure-prone procedures.

⁴⁶NHS Employers' - Occupational Health Check Standard
<http://www.nhsemployers.org/Aboutus/Publications/Documents/Occupational%20health%20checks.pdf>

⁴⁷ Immunisation against infectious disease - 'The Green Book'
Gateway reference: 7523
Department of Health
http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/DH_4097254

⁴⁸ The Effective Management of Occupational Health and Safety Service in the NHS
Department of Health, 2001
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4009674?IdcService=GET_FILE&dID=26591&Rendition=Web

In accordance with the Green Book⁴⁹ “All new employees should undergo a pre-employment health assessment, which should include a review of immunisation needs” and “Staff not considered to be at risk need not routinely be offered immunisation”. The same should be applied to researchers requesting access to the NHS for their research. Section 12 of the Green Book provides specific guidance for staff involved in direct patient care and non-clinical staff in healthcare settings. In the case of the latter group, the minimum requirement is as follows:

“All staff should be up to date with their routine immunisations, e.g. tetanus, diphtheria, polio and MMR” and “Satisfactory evidence of protection would include documentation of having received two doses of MMR or having had positive antibody tests for measles and rubella”.

COSTS OF UNDERTAKING PRE-ENGAGEMENT CHECKS

55. Who bears the cost of the checks required for the Research Passport?

Individual organisations often have their own policy on who should be responsible for paying for pre-engagement checks. In some cases, individuals themselves are asked to bear the cost of CRB checks and ISA checks. For individuals employed by a HEI or enrolled as students, who are expected to undertake research as part of their role, the costs of checks should normally be borne by the HEI (the employer) or the individual. Wherever possible, costs should be built into grant applications. Where additional checks are required to implement NHS to NHS arrangements, the substantive employer would normally be responsible for ensuring that appropriate checks, commensurate to the research activity are carried out and should bear the costs of these.

⁴⁹ Immunisation against infectious disease - 'The Green Book'

Gateway reference: 7523

Department of Health

http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/DH_4097254

List of Abbreviations

CLRN	Comprehensive Local Research Network
CPNI	Centre for the Protection of National Infrastructure
CQC	Care Quality Commission
CNST	Clinical Negligence Scheme for Trusts
CRO	Contract Research Organisation
CRB	Criminal Records Bureau
CV	Curriculum Vitae
DH	Department of Health, England
ESR	Electronic Staff Record
FAQ	Frequently Asked Question
GDC	General Dental Council
GMC	General Medical Council
GP	General Practitioner
HEI	Higher Education Institution
HRC	Honorary Research Contract
HR	Human Resources
ID	Identification
ISA	Independent Safeguarding Authority
IRAS	Integrated Research Applications System
LoA	Letter of Access
MDO	Medical Defence Organisation
NIHR	National Institute of Health Research
NHS	National Health Service
NMC	Nursing and Midwifery Council
OHSC	Occupational Health Smart Card
PhD	Doctor of Philosophy
PCT	Primary Care Trust
PIC	Participant Identification Centre
PNC	Police National Computer
POCA	Protection of Children Act
POVA	Protection of Vulnerable Adults
R&D	Research and Development
REC	Research Ethics Committee
UKCRC	UK Clinical Research Collaboration
VBS	Vetting and Barring Scheme

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