



*National Institute for
Health Research*

Research in the NHS: HR Good Practice Resource Pack

The Research Passport: Vetting and Barring Scheme Guidance

WORKING WITH CHILDREN AND VULNERABLE ADULTS

THE VETTING AND BARRING SCHEME (VBS)

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 2006¹, 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 VBS², and a different timescale for implementation, but the two schemes

¹ Safeguarding Vulnerable Groups Act 2006 (c.47)
http://www.opsi.gov.uk/ACTS/acts2006/ukpga_20060047_en_1

² 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.

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 2 am – 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 Guidance³, 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.

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:

³The 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.

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 2006⁴).

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;
- 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.

⁴ Safeguarding Vulnerable Groups Act 2006
http://www.opsi.gov.uk/ACTS/acts2006/ukpga_20060047_en_1

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

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.

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.

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**⁵ 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.

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

⁵ **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.**

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's⁶ and CRB's⁷ websites

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 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.

⁶ Independent Safeguarding Authority
<http://www.isa.gov.uk/default.aspx?page=0>

⁷ Criminal Records Bureau
<http://www.crb.homeoffice.gov.uk/>

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? ⁸	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

Algorithm continued on next page.

⁸ 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? ⁸	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 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
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

⁸ 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	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.
1 April 2011	Existing employees and volunteers undertaking regulated activity can register with the ISA	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

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 2006⁹.

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.

UNIVERSITY RESEARCHERS

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:

- **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).

⁹ Safeguarding Vulnerable Groups Act 2006
http://www.opsi.gov.uk/ACTS/acts2006/ukpga_20060047_en_1

- **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.

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 for first time applicants above, would then need to be followed by the host NHS site(s).

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 for first time applicants 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.

NHS RESEARCHERS

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.

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.

RESEARCH STAFF FROM COMMERCIAL ORGANISATIONS

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.

INDEPENDENT CONTRACTORS WHO UNDERTAKE RESEARCH

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 for NHS researchers above, as appropriate to the individual circumstances.

Independent contractors who undertake research under separate contract with an HEI will be dealt with as described for University researchers above, as appropriate to the individual circumstances.