

Scenario	Category	Why	Comment	HR Arrangements
<p>A HEI researcher wants to attend Great Ormond Street Children's Hospital for 3 consecutive days to interview staff about their experience of a new treatment programme for childhood diabetes. The researcher will not have any patient contact during their visits nor will they have access to any health records.</p>	<p>Regulated Controlled Neither</p>	<p>Specified place Frequency</p>	<p>NB no direct contact with children and vulnerable adults, but activity is in a specified place (children's hospital), therefore regulated.</p>	<p>Research Passport Version 2 (regulated activity), LoA Version 2</p> <p>Enhanced CRB and check against ISA children's barred list needed (between 12 October 2009 and 26 July 2010)</p> <p>Enhanced CRB and ISA registration available from 26 July 2010 and mandatory from November 2010.</p>
<p>A NHS Dr wishes to conduct a new CTIMP at two District General Hospitals across two Trusts. At both Trusts the member of staff will be overseeing patients' treatment in accordance with the study protocol. The trial will run for 3 months.</p>	<p>Regulated Controlled Neither</p>	<p>Specified position / Specified activity / Frequency</p>	<p>Activity involves treatment to vulnerable adults. Whether the NHS researcher is an existing member of staff, or a new starter or member of staff changing role (i.e. undertaking research for the first time) will determine which checks the employer carries out, and which NHS to NHS LoA to be issued</p>	<p>NHS to NHS arrangements:</p> <p>New enhanced CRB check and ISA registration will be required, but NHS employer will bring the Dr into the scheme in line with phasing arrangements.</p> <p>NHS to NHS LOA Version 2 to be issued</p>
<p>A HEI researcher with an existing Research Passport wants to attend the hospital records department to examine patients' hospital notes to identify potential patients for a new CTIMP. The patients have already given consent for the researcher to do this. The records are located in a Mental Health Trust and the researcher will only need to attend for one day, however will have access to the information obtained there rafter</p>	<p>Regulated Controlled Neither</p>	<p>Specified activity / Frequency</p>	<p>Access to identifiable health records of vulnerable adults. Researcher not supervised. Researcher extracts and retains identifiable health record data.</p>	<p><b><i>N.B. New regulations relating to Controlled Activity come into place in April 2010, and guidance on the specific procedures to be followed will be provided nearer the time.</i></b></p> <p><b><i>Activity currently only eligible for a basic disclosure.</i></b></p> <p><b>Existing staff:</b> Continuation of Research Passport Version 1 – new project / new site added to the Appendix. <b>New staff:</b> Research Passport Version 2 LoA Version 2</p>

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<p>A group of HEI researchers want to have a questionnaire handed out from a GP surgery by Practice staff. The questionnaire will collect information about children's diet and physical activity levels. The questionnaires will contain children's names and addresses and if the patients choose to complete it, the questionnaire will be returned to the HEI for analysis. The HEI will then write to the children with a follow-up questionnaire.</p>	<p>Regulated Controlled Neither</p>	<p>No direct contact. No access to health records</p>	<p>Questionnaire data does not constitute a health record Completing the questionnaire is a voluntary activity. Families are self selecting Controlled activity refers to health or social care records only</p>	<p>None - PIC Study HEI responsibility for ensuring researchers are suitable, data is anonymised for analysis etc</p>
<p>A newly HEI employed network research nurse will be conducting study assessments for a large observational study. This role will involve direct contact with patients on a daily basis.</p>	<p>Regulated Controlled Neither</p>	<p>Direct Contact - VA Specified activity Frequency</p>		<p>Research Passport Version 2 Enhanced CRB Enhanced CRB and check against ISA adult's barred list needed (between 12 October 2009 and 26 July 2010) Enhanced CRB and ISA registration available from 26 July 2010 and mandatory from November 2010.</p>
<p>A researcher will attend an acute Trust to interview staff for 3 consecutive days. The researcher will not have any patient contact during their visits nor will they have access to any health records.</p>	<p>Regulated Controlled Neither</p>	<p>No direct contact with children / VA Not a specified place</p>	<p>Difference between this and example one is that the site is not a "specified place"</p>	<p>Research Passport Version 2 LoA</p>