

## Guidance Notes – Statement of Activity for Research Passports

The Research Passport application is the application process for approval to work with NHS information or patients. There are two possible outcomes of the research passport – either a letter of access or an honorary contract. The outcome is determined by the NHS Research & Development Office based on the activities being carried out and the level of clearance needed.

A statement of activity is required for your research passport application in order to help us determine which level of Disclosure check suits the type of research activity you will be undertaking, and whether or not you will require an Occupational Health Check. Please note that registration with the PVG (Protection of Vulnerable Groups) Scheme may be required.

### Things to note about the research passport process:

- **The statement of activity template can be completed prior to confirmation of NHS ethics approval as it will allow for the confirmation of the appropriate clearance check and will ultimately speed up the process. Disclosure checks do expire so no disclosure check application will be submitted until it can be seen that NHS approval is forthcoming.**
- **If you have already registered for the PVG scheme for working with children a separate application may be required for working with protected adults depending on the activities you are carrying out.**
- **It is important that the statement of activity is in line with the description of activity included in the ethics submission so please make sure that you refer to the ethics submission when completing this form. Any major differences can result in your research passport application being rejected or further amendments being needed for the ethics submission.**
- **It is not possible to submit a research passport application until the NHS ethics approval has been confirmed.**
- **It is not possible for a research passport application to be fully processed until the R&D approval has been confirmed for the project however it is possible for both research passport and R&D approval to be completed simultaneously.**

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### Notes for the completion of the statement of activity form:

#### Section 1: Project Details

- 1.1 **Project Title/Working Title.** If your project is already in the final stages of approval or has been approved, then please insert the title of the project here. If the project is still in the design stage, please type in the working title.
- 1.2 Please provide us with the name of the **Principal Investigator and/or the lead academic.** We recommend the contact name you give us is the best person who will be able to verify your activities and role within the project.
- 1.3 Please indicate here if your project has received **ethical approval** from the Research Ethics Committee. If so, please enter the approval number. If not yet approved, please indicate what stage the approval is at.
- 1.4 Please indicate here if your project has received **NHS Management/R&D approval** from the NHS Lothian Research and Development. If so, please enter the approval number. If not yet approved, please indicate what stage the approval is at.

#### Section 2: Location of Research

- 2.1 Please indicate here **where your research will take place.** This could be on NHS premises, University of Edinburgh premises, in patient's homes, a GP surgery, another location or a combination of places. Please indicate all locations where you will undertake activities relating to this project.

**NB: If your activities will take place on NHS premises we will require permission from the local NHS manager responsible for the department. Please indicate this person's name and title on the form.**

### Section 3: Research Activities and Supervision

- 3.1 Please indicate here whether you will undertake the **research activities alone, under supervision, or alongside several people**. Please include their job titles and their role in the project.
- 3.2 Will you be providing a clinical service to the patient(s)? This is a key question in determining what level of Disclosure check you will require. Will you be taking blood samples, operating on patients or undertaking cognitive testing?

Examples:

Clinical Care (Eligible for PVG)	Not classed as 'Clinical care' (Eligible for Standard Disclosure)
Taking blood samples	Interviewing patients
Taking other types of samples from patients	Providing information to obtain informed consent
Visual field assessments	Taking samples from theatre i.e. where the samples have been taken from patient previously by a health care professional
Specialist practitioner roles, e.g. orthopaedic	Development of screening tools

**NB: Researchers requiring access to patient data solely may not require a Disclosure check to be undertaken. Please discuss your statement of activity with the appropriate contact person to ensure you have disclosed all activities you will be undertaking.**

### Section 4: Can you explain in lay terms the nature of the research?

I.e. can you explain in a manner that a non-specialist in your field will understand? You should clarify what is involved e.g. how will the test be delivered (e.g. use of equipment, taking of samples, verbal delivery) and how is the participant expected to respond. Can you outline the frequency and duration of the activity(ies)? Do you require any specific training or guidance in order to undertake specific tests for the research e.g. you will be trained to use a certain piece of equipment to go ahead with the research?

**NB: Please remember to refer to the ethics submission in order to ensure that the activities you outline are the same as those included in the ethics application.**

### Section 5: Target Group

This will help us determine whether or not you are working with a group of protected adults, or with children. Please specify e.g. whether your target group is healthy, or whether they have a specific condition. Do they already attend a healthcare provider for regular treatment of a pre-existing condition? Will you have controls for the experiment? How will you recruit participants?

### Section 6: Participant Consent

Please let us know how patient consent will be gained. Will you, or someone else be asking for consent?