



## **PAINTED** Frequently Asked Questions

This information and FAQs document is intended for sites interested in participating in the PAINTED study. It contains important information about the anticipated operation of the study and the patient pathway in a pandemic situation.

### **Q. Do we get paid for participation in PAINTED?**

*Sites are not strictly paid for participation in the PAINTED study. As PAINTED is not a clinical trial there is no fee payable per patient 'recruited'. However, part of the funding for PAINTED includes allocated support costs payable to your Comprehensive Local Research Network (These costs are £9 per patient based on estimates of the time it takes to identify completed Pandemic Influenza Forms (PIFs), retrieve them and upload the data to the Prospect online database) As a portfolio study CLRN staff are able to offer support to run this study. Please contact your local CLRN to discuss your department's needs.*

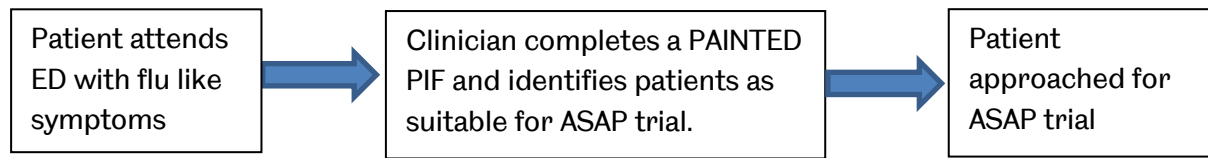
### **Q. What if we already have several active research projects within the department?**

*At present this is obviously not an issue as there is no pandemic. Pre-Pandemic PAINTED is in 'hibernation' and sites are not required to do anything beyond a simple yearly check/update. It is recognised by the National Institute for health Research (NIHR) that there will be insufficient time to recruit new staff to support any of the pandemic studies when a pandemic strikes. The NIHR have therefore agreed that when the NIHR pandemic portfolio is activated, CLRN support for pandemic studies would be prioritised. Therefore, it is anticipated that research support for this study will most likely come from the re-deployment of existing resources. It is recommended that potential PI's have conversations with their local CLRNs, all CLRNs have urgent public health plans to support the activation of these studies.*

You can find key contacts for your CLRN here:  
[http://www.crncc.nihr.ac.uk/about\\_us/ccrn](http://www.crncc.nihr.ac.uk/about_us/ccrn)

### **Q. What if we are already running one of the pandemic studies within the ED?**

*There are no barriers to running more than one of the pandemic studies within your department. In fact the chief investigators from all pandemic portfolio studies have agreed mutual support in principle. Moreover some of the studies can work synergistically. The ASAP Trial (Adjuvant Steroids in Adults with Pandemic Influenza) trial will recruit patients with an influenza-like illness, thus it is likely that patients for which the PAINTED PIF is completed will also be identified as a potential patient for the ASAP trial. Co-enrolment to both studies is therefore actively encouraged.*



### **Q. Who fills in the Pandemic Influenza Form (PIF) ?**

*Anyone within the emergency department who may routinely fill in clinical assessment forms as part of their work should use the PIF to assess patients who meet these clinical diagnostic criteria: (1) fever (pyrexia  $\geq 38^{\circ}\text{C}$ ) or a history of fever and (2) influenza-like illness (two or more of cough, sore throat, rhinorrhoea, limb or joint pain, headache, vomiting or diarrhoea) or severe and/or life-threatening illness suggestive of an infectious process.*

### **Q. Can we use the form now?**

*Yes. We have developed and refined the triage tool so that it contains current, relevant and evidence based clinical items necessary to guide clinicians when assessing suspected influenza. As such we recommend you use the PIF for both seasonal and pandemic influenza.*

*FOR CURRENT SITES: We have contacted the lead for pandemic planning within your trust to promote the PIF's incorporation into your Emergency Department's overall Pandemic Planning policies and procedures.*

### **Q. Do we need to seek consent from the patient in order to use PIF?**

*No. We have approval from the Confidentiality Advisory Group (CAG – formally the NIGB) Section 251, to record patient identifiers, namely the NHS number without seeking patient consent. Section 251 enables the common law duty of confidentiality to be overridden to enable disclosure of confidential patient information for medical purposes. Please see <http://www.hra.nhs.uk/hra-confidentiality-advisory-group/what-is-section-251/> for more information.*

*\*PAINTED does have child, adolescent and adult leaflets which must be given to patients (parents or guardians) whilst completing the PIF offering the patient the opportunity to withdraw their data from the study. There is a section (left hand side) of the PIF to record this.*

*\*Please note this is not applicable in Scotland.*



**Q. How do we report our 'recruitment' of patients into PAINTED?**

*As patients are not strictly 'recruited' to PAINTED (RECRUITMENT is defined as a patient freely giving consent to partake in a study) there are no accruals to record as there are for trials. CLRN research staff are advised to complete an 'exception report' to record the patients collected as a means of evidencing the work done.*

**Q. How do we ensure we meet NHS and CLRN targets?**

*PAINTED is one of eight projects within the CSP portfolio of pandemic studies commissioned with the specific purpose to be 'pandemic ready', with all necessary governance and approvals in place prior to a pandemic. As such we require all participating trusts to proceed through the full process towards approval in advance. The target of 30 days for the time taken to recruit the first patient into an NIHR CRN study, once NHS permission has been issued does not apply. This NIHR High Level Objective 5 (first patient, first visit within 30 days) is measured at study level and therefore PAINTED 1 (pilot 2012/13) met this target. New sites will not be affected by this metric.*

**Q. What do we do with the completed PIFs?**

*As the PIF doubles up as clinical notes then we advise that they are left within the ED patient records. A photocopy may then be taken by the research staff member and removed to a safe and secure place. We advise that this is done on a frequent and routine basis during the pandemic to ensure both that forms are not lost, misplaced, move into other wards, or are scanned into other formats prior to retrieval.*

*A screen cast demonstration shows how to access the PAINTED database from a computer terminal and how to upload data from the forms online.*

**Q. Can prisoners or young offenders take part in PAINTED?**

*PAINTED neither seeks to include nor exclude them. PAINTED PIFs may be used with all persons attending the ED regardless of whether they are offenders or not.*

*For any further information on the PAINTED study please contact the Project Management team, e-mail: [painteds@sheffield.ac.uk](mailto:painteds@sheffield.ac.uk). Alternatively, you can contact the Chief investigator for the study Professor Steve Goodacre. E-mail: [steve.goodacre@sth.nhs.uk](mailto:steve.goodacre@sth.nhs.uk), [s.goodacre@sheffield.ac.uk](mailto:s.goodacre@sheffield.ac.uk)*