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| **SOP Number** | 01 |
| **SOP Title** | The Pre-hospital Environment SOP |
| **Version** | 1.0 |
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|  | **NAME** | **TITLE** | **SIGNATURE** | **DATE** |
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1. **PURPOSE**

To outline the tasks that need to be completed in the pre-hospital environment. This is to ensure that all tasks are completed so that the integrity of the PRESTO study is not compromised and that the data collected is of good quality and to ensure that all potential participants are being told the same thing across each Ambulance Service and that the important parts of the PIS are covered. It applies to all paramedics that have signed the signature log and are approaching potential participants for the PRESTO study.

1. **SCOPE**

This SOP will cover the tasks that need to be done by paramedics in the pre-hospital environment for the PRESTO study. To make this easier in the field, we have developed a checklist that is to be completed, dated and signed by the paramedic who is approaching the potential PRESTO participant. The SOP will also cover the discussion about the study between the potential participant and the paramedic. We have developed a discussion crib sheet to aid paramedics with approaching potential participants about the PRESTO study.

1. **DEFINITIONS**

PRESTO – The Pre-hospital Evaluation of Sensitive Troponin study

SOP – Standard Operating Procedure

PIS – Patient Information Sheet

ACS – Acute Coronary Syndromes

GCP – Good Clinical Practice

1. **SPECIFIC PROCEDURES**
2. Before you can begin approaching potential participants for the PRESTO study, you must ensure that you have completed your protocol training, your Research Fundamentals training and that you have signed the signature log.
3. Transfer patient to ambulance and complete standard care.
4. If you suspect that the chest pain/discomfort felt by the patient is due to ACS, then check to see if the hospital that the patient is being transferred to is open to recruitment. Some of the hospitals are not using their central laboratories for sample processing and so recruitment can only occur between the research nurses’ working hours. Please check the relevant table provided at the end of this SOP to ensure that the patient can be recruited on to the study. If the hospital is not open, do not approach patient about the study.
5. If hospital is open, check inclusion and exclusion criteria to determine whether patient is potentially eligible for the PRESTO study. If patient does not meet inclusion and exclusion criteria, do not approach patient about PRESTO study. An enlarged version of the eligibility criteria has been provided at the end of this SOP for printing out to be used in the field.
6. If patient meets all eligibility criteria, then approach patient about the PRESTO study. We have provided a crib sheet for the points to mention when discussing the study with the patient. This is to ensure that the information given to potential participants is standardised across the different ambulance services.
7. Even though the patient may not be in any state to read the PIS, please hand the copy provided in the study pack to them as this is in alignment with GCP and Research Fundamentals. The research nurses will have extra copies if they lose it and will go through it with them at the hospital.
8. Complete the eligibility criteria (printed on blue paper), which is in front of the Pre-hospital CRF.
9. Draw blood sample. This could be done at the same time as inserting an intravenous cannula as part of the patient’s clinical care. Everything needed to do this is provided in the study pack, in the biohazard bag labelled ‘Ambulance’. Included should be a 4.5mL lithium heparin tube, a cannula adapter, pre-labelled cryovials and a sample processing log.
10. Once filled, please label the blood sample on the label with date and time, place bag in biohazard bag and seal the bag. Place sealed bag back in study pack to leave with patient at the hospital.
11. Complete Pre-hospital CRF (blue sheet behind eligibility criteria). If any mistakes are made, please put one line through the mistake, initial and date.
12. Complete Emergency Department handover letter. There are two included in the pack – one for hospitals that are using their central labs for sample processing and one for hospitals where the research nurses are processing the samples themselves. Please check which one is relevant to the hospital where the patient is being transferred using the relevant sheet attached to this SOP. Fill in the patient’s details in the spaces provided, as well as the date and time the blood sample was taken.
13. After the checklist has been completed, print, sign and date at the bottom. This checklist should be taken back to the ambulance station with the eligibility criteria and the Pre-hospital CRF (blue sheets of paper). The study pack, along with the pre-hospital blood sample, should be left with the patient at the hospital.

PRESTO Paramedic Checklist

Please tick each box once the task has been completed.

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|  |  | Standard care given to patient |
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|  |  | Check that hospital patient being transferred to is open to recruitment |
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|  |  | Check that patient eligible for PRESTO study against criteria |
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|  |  | Discuss the PRESTO study with patient using crib sheet |
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|  |  | Give patient copy of Participant Information Sheet |
|  |  |  |
|  |  | Obtain verbal consent from patient to proceed with study and blood draw |
|  |  |  |
|  |  | Complete eligibility criteria (blue sheet) |
|  |  |  |
|  |  | Take blood sample |
|  |  |  |
|  |  | Label blood sample with date and time (24hr clock) |
|  |  |  |
|  |  | Complete Pre-hospital CRF (blue sheet) |
|  |  |  |
|  |  | Complete Emergency Department Handover Form – incl. date and time of  |
|  |  | blood draw |

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| --- | --- |
| Name: |  |
|  |  |
| Signature: |  |
|  |  |
| Date:  |  |

PRESTO hospitals in North West

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| --- | --- | --- | --- |
| **Hospital** | **Research Team contact** | **Recruitment times** | **Sample Processing** |
| Manchester Royal Infirmary | Fiona Pomeroy (Research Nurse) | Monday-Friday, 1am-7pm | Research nurses |
| Salford Royal | Angiy Michael (Lead Research Nurse) | 24/7 | Central labs |
| Royal Bolton Hospital | Emma McKenna (Lead Research Nurse) | Monday-Friday, 9am-5pm | Research nurses |

PRESTO hospitals in West Midlands

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| --- | --- | --- | --- |
| **Hospital** | **Research Team contact** | **Recruitment times** | **Sample Processing** |
| Royal Stoke University Hospital |  | 24/7 | Central labs |
| University Hospital (Coventry) | Pam Bremmer (Lead Research Nurse) | Monday-Friday, 8:15am-5pm | Research nurses |
| Warwick Hospital | Penny Parsons (Lead Research Nurse) |  |  |

PRESTO hospitals in South West

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| --- | --- | --- | --- |
| **Hospital** | **Research Team contact** | **Recruitment times** | **Sample Processing** |
| Southmead Hospital | Emma Gendall (Lead Research Nurse) | 24/7 | Central labs |
| Wonford Hospital | Sam Keenan (Lead Research Nurse) | 24/7 | Central labs |
| Derriford Hospital | Rosalyn Squire (Lead Research Nurse) | 24/7 | Central labs |
| Musgrove Park Hospital | Jayne Foot (Lead Research Nurse) | Monday-Friday, 8am-4pm | Research nurses |

**Eligibility Criteria**

**Inclusion Criteria**

1. Age 18 or over
2. Pain or discomfort in the:
	1. Chest
	2. Epigastrium
	3. Neck
	4. Jaw
	5. Upper limb
3. Suspect that symptoms could be ACS

**Exclusion criteria**

1. Obvious STEMI
2. Patient needs to go to hospital for another reason
3. Symptoms did not occur within the last 24 hrs
4. Does not have capacity to provide consent

PRESTO Discussion Crib Sheet

* It’s called the PRESTO study, which is being run by the research team at Manchester Royal Infirmary
* Asking those who have called an ambulance due to pain/discomfort in the chest to take part
* When people suffer from chest pain, we are often worried that the pain may be coming from a heart problem such as a heart attack
* Currently patients with chest pain are usually taken to hospital for further investigations, including at least two blood tests to look for signs of heart damage
* These can take up to 2 hours to come back, however there are new devices that can allow us to test for signs of heart damage in the ambulance
* The PRESTO study is looking at whether the results from the tests in the ambulance are as accurate as the results we get from the hospital laboratory
* If you agree to take part, I will take a blood sample from you now, through the cannula, and record some of your medical information on a study form
* Everything is **anonymous** so your name won’t appear on any of the blood samples or the data we collect
* Taking part is **voluntary**, so even if you decide to take part now, but decide to withdraw later on, that is okay
* Once we take you to hospital, one of the research nurses will usually come and see you in the hospital to go through the study with you in more detail. If they don’t, another paramedic will contact you at a later stage
* If you decide to withdraw at this point, we will destroy any samples and information that we have collected from you
* If you decide to go ahead with the study, the research nurse or paramedic will go through a consent form with you and take another blood sample
* Someone from the research team will then follow up with your GP after 30 days to see how you are doing
* Here is more detailed information about the study for you to have a read through in your own time – the research nurses will go through this with you at the hospital