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## **Information and guidance for primary care sites on how to localise a project document.**

The purpose of this guide is to provide primary care sites with guidance on how to localise participant facing study documentation within a research project.

### **1. What is localisation of study documents?**

Localisation of study documents means adding local information to participant facing study documents prior to using them. The local information usually required is the practice header and name/contact details of the study team.

### **2. Which documents are usually localised?**

Any participant facing study documents that have received Health Research Authority (HRA) approval e.g. Participant Information Sheet (PIS), Informed Consent Form (ICF) and letters of invitation. If a study has a poster or flyer contact details for the local study team can be added to these too.

### **3. Why do we need to localise a project document?**

These documents are localised to make them specific to the research site/GP practice and shows potential participants where the information has been sent from.

### **4. How should we localise a study document?**

Documents are localised by adding the practice information into the header without obstructing any other logos that may already be in the header. Sometimes adding the Information – Primary Care localising a project document. V1.0

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practice header can affect the formatting of documents so study teams may offer to localise them for you. The practice header is usually only added to the first page of each document and you should check that all the local information is accurate before using the documents.

#### **5. Is any other information required to localise documents?**

Each study PIS needs to include information about who participants should contact if they have a problem or if they wish to make a complaint. This is usually the study team at the practice but the contact for complaints in primary care can also be added.

#### **6. Who do I contact if I have further questions?**

For any questions, please email: [rdu@shsc.nhs.uk](mailto:rdu@shsc.nhs.uk)