

Site Source Documents and Location

Site _____

The following requires source documents. Please record the location where the source documents can be found at your site.

Data	Location of source documentation
Study related lab reports	
Study questionnaires completed by the participants	
Coronary artery disease or peripheral artery disease inclusion criteria which makes the participant eligible for the study	
Primary and secondary outcomes	
Serious Adverse Events	

Source documents are not required for data mentioned in the table below and may be entered directly into the eCRF. In some cases, if the data is **not** entered directly into the eCRF, you may use a worksheet; however, we strongly discourage this. If you require a worksheet we suggest that you record below where they can be located.

Data	Entered directly in eCRF YES/NO	If No, location of data if not entered directly into the eCRF
Age		
Blood pressure		
Anthropometric measurements (height, waist, and hip)		
Demographic data		
Vital signs obtained at study visits		
Concomitant medications		
Any assessment of adherence to medication (which may include pill count)		
Medical history provided by the		

Data	Entered directly in eCRF YES/NO	If No, location of data if not entered directly into the eCRF
participant (inclusion criteria and exclusion criteria [if they exist]) should be documented		
Study questionnaires completed by study staff(dietary assessment and physical activity)		
Adverse Events		