Cardiovascular CTU Core Resources

Core Resource	Name	Duties
Director	Interim: Amrita Ahluwalia	Recommend adoption of study to Barts CTU Inform CI of adoption Provisional letters of adoption Chair Scientific Committee Development of Unit providing strategic vision Facilitates external grant income to support the Unit and its research
Manager	Vivienne Monk	**Providing assistance to PIs:** Assist PIs with protocol development Proof reading and correcting documents including application forms Ensure all relevant paperwork is completed Review and approve new submissions/amendments to ethics committees, regulatory bodies, JRMO, the HRA and where applicable to the MHRA **Individual Trial related tasks:** Perform risk assessment Complete CTU collaboration request proforma Prepare costings in conjunction with JRMO Assist with recruitment and staff appointments Representative on TMCs of all trials Document sign-off Determine cost of CTU resources to cover additional costs incurred by CTU in overseeing study Be a member of all TMGs of all portfolio trials (monthly meetings) Ensure staff working on trials are up to date with their SOP reading and training requirements Cover for trial-specific staff **Overall Trial related tasks:** Chair the Resource Committee Provide information to Barts CTU Head/Director: summary of findings/decisions made by CV CTU committees, draft CI delegation to Barts CTU, copy of the research costing, draft risk assessment, form for 'document sign-off) Monitor recruitment and management of all trials Regular contact with Barts CTU Head General oversight role Meet monthly with project managers on all trials. Copies of meeting minutes to be sent to Barts CTU Head/QA Manager.

		General management of Unit: Development of business plans Project management Monitoring research budgets
Senior Statistician	Vacant	Advise on study design, sample size & statistics
Quality Assurance Officer	Vacant	Regular contact with Barts CTU QA Manager Checking documents provide specialist advice Regulations and governance Quality assurance and control Ensure that relevant staff are fully aware of and comply with trial regulations Check and monitor compliance and training Audit portfolio trials to measure compliance Regular contact with Barts CTU QA Manager Checking documents through TMF Reviews Monitoring projects Implementation and training of regulations and governance First point of contact for CV CTU staff Ensure that relevant staff are fully aware of and comply with trial regulations through training, STASH checks etc. Assisting the Barts CTU auditors (as identified by the QA Manager) with internal audits Assisting the Barts CTU QA Manager with external audits and inspections as required Responsibilities left with the Barts CTU QA Manager as below: Audit of the trials on the portfolio Providing specialist advice First point of contact for the MHRA Adding staff to STASH
Scientific Committee	Chair: CTU Director (AA) Members: Clinical Lead: David Collier Senior statistician WHRI Director or nominee An appropriate clinical expert (dependent on study being reviewed) Chair of BHC Peer Review	Review study Recommend adoption Review scientific excellence and appropriateness of proposed study Review capability and capacity

	BHC Research Director Other members co-opted as necessary	
Resource Committee	Chair: CTU Head (VM) QA Officer QA Manager CRC Nurse Manager CRC: Anne Zak Database manager BHC representative	Approval before submission to funder Review: Type of study and implications Recruitment strategy and projected accrual Risk assessment Resources requested and draft costing
Clinical Lead	David Collier	Member of Scientific Committee Medical review of SAEs Provide expert clinical opinion as required on individual applications Protocol advice Advice on Patient Information Sheets and Informed Consent Forms