

Competency	Evaluation Criteria
<b>1. Capability</b>	
Appropriate infrastructure providing a distinct, research dedicated space for doing investigative clinical science	Does the facility comprise a distinct, research dedicated space for conducting clinical research?
	Does the facility conduct early clinical research (experimental medicine or/ and early phase clinical trials)?
	Evidence that the facility is an integral part of the local, national and/or international clinical research environment, as appropriate.
	Evidence of the strategic importance of the facility in the planned future development of the local, national and/or international clinical research environment, as appropriate.
Appropriate capacity/ scale of operation	Does the facility have more than 2 research dedicated beds/ couches?
	Does the facility have more than 30 study subjects through the facility each month.
Dedicated specialist facilities	Evidence of dedicated research resources such as imaging or human performance equipment.
	Evidence of facilities which are nationally notable or comparable to those of other institutions already included on the <i>UKCRC Experimental Medicine Resources</i> site.
	Evidence of the facilities and equipment complying with appropriate accreditation requirements (e.g. GMP, GLP) and standard operating procedures.
Appropriate leadership and management structures	Is there an oversight committee such as a scientific advisory board?
	Is there a management team or committee?
	Evidence of the competence of these structures to perform their required function.
A multi-disciplinary, well trained and experienced team	Does the facility have dedicated research staff?
	Can facility staff accommodate a range of studies?
Systems and processes in place for continuing professional development	Evidence of appropriate training e.g. ICH-GCP and resuscitation?
	Evidence of a functional process for staff training.
Appropriate and defined reporting structures	Is the facility's performance reviewed?
	Evidence of defined and appropriate metrics for the evaluation of the facility's performance.
	Evidence that the facilities performance is regularly monitored.
<b>2. Safety</b>	
Systems and process in place to ensure that staff work to appropriate guidelines and standards	<p>1. For facilities conducting participant (patients, healthy volunteers or controls) research requiring MHRA Clinical Trial Authorisation (CTA)</p> <p>Evidence that the most recent MHRA GCP/GCLP inspection was favourable (i.e. a copy of the report findings)</p> <p>2. For facilities <b>solely</b> conducting experimental medicine research not requiring MHRA CTA:</p> <p>Evidence of the most recent GCP/GLP/GCLP/GMP inspection/ audit or equivalent. A favourable report is essential for approval.</p> <p>3. Evidence of compliance with GxP and other accredited bodies, as appropriate.</p>
Systems and process in place to meet appropriate regulations and legislation (e.g. the principles of ICH-GCP, the NHS Research Governance Framework, the Data Protection Act and the UK Regulations that implement the EU Directive for Clinical Trials)	
Robust and secure information systems	
Systems and processes in place for risk assessment to guide appropriate monitoring of research studies.	
<b>3. Availability</b>	
A clearly defined process in place through which eligible investigators can access the facility	Agreement that the facility is available to external researchers
	Evidence of clearly defined standard terms of access, including any procedures, restrictions and fees which apply