Research Study Risk Checklist

Date –

Project Title –

Principal Investigator –

Please consider the points below when reviewing each research study

Governance Check	Key Question & Procedure	Yes	No	Unclear	N/A
Clinical Oversight					
Principal Investigator	Has a Principal Investigator been identified? Process: • Identification will be within the study proposal and participant information				
Sponsor	Has the sponsor of the study been clearly identified? Process: • Written confirmation of sponsorship should have been received				
Ethics					
Approval	Has a copy of the ethical approval letter been received?				
Participant Information Sheet	Does the study have a copy of the Patient Information Sheet / Consent Form approved by ethics? Process: • Participation Information Sheet / Consent Form contains the correct local details and is presented on the letterhead of the local organisation				
Resources					
Emergency/ Back up/ Support arrangements	Where appropriate, has the Principal Investigator (PI) at the participating site confirmed that appropriate arrangements for emergency or back up support for Participants are in place, and are the relevant staff aware of these arrangements? Process: • Refer to the study documents to confirm that arrangements are in place				
Expenses	Are there any travel expenses involved i.e. for the researcher/patient?				
Assessment of the adequacy of facilities	Are the local resources, equipment & facilities suitable for the study? Process: • Refer to the study documents				
Principal Investigator/ Research team arrangements in place	Are the employers of the PI / Research team aware of the research activity? Process: • Will the project affect the flow of routine work? • Will the project be conducted in the researcher's own time? • Will the work be carried out during normal working hours?				
Skills					
Appropriate Consenting procedure	Are the individuals who will be seeking consent appropriately trained & experienced? Process: • Written evidence of training should be obtained e.g. GCP certificate				

Governance Check	Key Question & Procedure	Yes	No	Unclear	N/A
Principal Investigator (PI) / Research team CVs	Do CVs demonstrate that the PI / Research team are suitability trained, qualified & experienced? Process: • Indicate that the individuals are suitably trained, qualified and experienced				
Legal/Regulatory					
Data protection/ Guardian issues reviewed	Are arrangements in accordance with your organisations' confidentiality policy? Process: • The protocol and study documents should be reviewed to determine if any data protection or confidentiality issues have been highlighted or are likely				
Access to Medical Records	Are arrangements for medical records to be accessed by people outside of the clinical care team acceptable to your organisation? Process: • Refer to the protocol and ethics letter to determine if medical records might be accessed by people outside of the clinical care team. Also ensure this is reflected in the Patient Information Sheet and Consent Form				
Honorary Research Contracts (HRCs) or Letters of Access	Where required, does the organisation have appropriate HR systems in place to ensure that Honorary Research Contracts or Letters of Access are issued?				
Mental Capacity Act – arrangements for assessing capacity	Are the procedures for assessing capacity suitable to the locality? Are those involved in assessing capacity suitably trained / experienced in the particular client group? Process: • Refer to study documentation and research team CVs to confirm that procedures and those involved assessing capacity are suitable				
Reporting Participant Safety Incidents	Are there arrangements to report participant safety incidents to the host care organisation? Process: • Ensure the PI is aware of safety incident reporting procedures identified in the Protocol and by the Sponsor and Ethics committee				

	Yes	No
Is the project ok to go ahead?		
Additional comments		

Name…….

Signed…… Date……

Role…….