Risk Register for:
Name of Project (Example)

CO Research Trust
EVIDENCE • SAFETY • HEALTH

ID	Risk Type	Description	Mitigation Strategy	Probability (0 - 5)	Impact (0 - 5)	Residual Risk (Probability x Impact)
1	Study	Ethics Committee do not approve study.	Ensure application is reviewed by consultant physician and consultant toxicologist prior to submission. Ensure sufficient contingency within experimental schedule to deal with delays caused by resubmissions. Probability of not gaining approval is low due to team's track record and adherence to GCP guidelines. Re-submission of revised protocol is allowed, so the impact would be limited.	1	3	3
2	Study	Incorrect dosage of carbon monoxide during exposure.	Concentration of CO in all exposure bags will be checked prior to use and by an alarmed, in-line detector during use.	1	5	5
3	Study	Exposure to carbon monoxide elicits adverse reaction due to underlying health condition.	Maximum dose of CO to be below WHO safety levels for acute exposure. Volunteers to be screened against exclusion criteria by consultant physician prior to recruitment into study. Advanced first aiders, oxygen and AEDs (automated external defibrillators) to be present at all times during exposures. All participants to be monitored (ECG and pulse CO-Oximetry) during exposures.	1	5	5
4	COVID	Infected individual transmits virus to other participants or research staff.	Use existing COVID infection control standard operating procedure (including local COVID-19 policy) to prevent individuals with signs or symptoms from attending the experimental facility. Use disposable equipment to prevent cross-contamination. Clean all equipment between use. Use disposable mouth pieces and demand valves for CO exposures. Participants and research staff to wear face coverings at all times.	2	3	6
5	COVID	Closure of research facility due to local council or government infection control measures.	Highly unlikely, as facility has key worker status. Alternative facility has been identified for temporary use if necessary.	1	4	4
6	COVID	Temporary loss of key staff due to infection or isolation.	Ensure availability of fully trained, replacement staff (currently have X additional staff available as temporary replacements). The research facility operates a strict COVID-19 policy which will further reduce this risk.	2	2	4
7	COVID	Participants withdraw due to infection or isolation.	Experimental schedule includes contingency for 20% attrition rate.	2	2	4
8	Data	Loss of server data due to IT malfunction or malicious activity.	Facility operates an extensive IT standard operating facility and has control measures in place, including immediate encryption, frequent (hourly) data back-ups on secondary internal storage system and daily (24 hour) back-ups to a secure, off-site storage facility.	1	3	3
9	Data	Theft of data from server.	Facility operates an extensive IT standard operating facility and has control measures in	1	3	3

			place, including fully encrypted data storage and multiple-level security systems.			
10	Data	Loss or theft of data from initial data capture devices.	All devices will be secured with a password and local storage will be immediately encrypted using industry standard software (e.g. FileVault). Data on all stand-alone devices will be transferred to server each day in accordance with existing University IT policies, local SOPs and GCP.	1	3	3
11	Participant	Insufficient number of volunteers identified prior to informed consent.	"Expressions of interest" can begin before ethical approval to expand number individuals on facility's volunteer register. Recruitment is generally high as research facility is embedded within local community.	1	4	4
12	Participant	High drop-out rate following informed consent.	Ensure volunteer reimbursement is sufficient and that time spent at research facility is a pleasant experience. Provide leaflets for present participants to share with friends and family to promote additional recruitment.	2	2	4
13	Funding	Contribution from University is cut.	Highly unlikely, as funding is based on five year cycle and contribution is earmarked within current cycle.	1	5	5
14	Funding	Cancellation of project (for any reason).	Reimbursement of any funds not spent would be fully reimbursed.	1	5	5
15	COVID	Lack of availability of equipment due to backlog of patients.	This element of the study has been scheduled to provide the maximum possible delay after the project start date to allow any potential backlog to be cleared. Delaying this to start of Workstream 5 would be an option to circumvent this risk should a delay be unavoidable.	1	3	3

Residual Risk	Score Range
Low	1 to 4
Elevated	5 to 9
Medium	10 to 14
Substantial	15 to 19
High	20 to 25