Research Ethical-Risk Screening Tool

Please read the Companion Guide to the Research Ethical-Risk Screening Tool and answer all **four questions**. If the response is '**YES**' to any of the following questions, the study requires **Full Review** by the **REC.**

1.Consent	**YES**
Does your research have the potential to compromise the informed consent process or require a consent declaration? *Examples include the following:* • Research involving participants who may lacking decision-making capacity to provide consent. • The use of data and biological samples beyond the scope of existing consent (except Retrospective Chart Reviews where the data protection risk to the participant is low). • Deferred consent in emergency situations where participants are not able to consent in the first instance but will be asked to consent once they regain capacity. • Covert research where no consent is obtained from participants or information is withheld.	☐
2.Participants	**YES**
Does your research involve participants who are experiencing vulnerabilities in relation to their situation or circumstance that may impact on their ability to make decisions freely, protect their own interests or understand the research? *Examples include the following:* • Studies involving neonates and/or children (except Retrospective Chart Reviews where the data protection risk to the participant is low). • The study population is vulnerable or there are individuals or groups, in vulnerable situations or circumstances. • Power imbalances that exert an undue level of influence or pressure on an individual to participate. • Disproportionate incentives that undermine voluntary participation.	☐
3.Risk of Harm	**YES**
Does your research pose a risk of harm to participants i.e. is there a potential to harm participants? *Examples include the following:* • Research that poses more than a minimal risk of physical, psychological, and/ or social harm. • Research that poses risk of disfigurement or disability. • Research investigating highly sensitive research topics. • Studies that change a pre-existing care plan including, but not limited to, the withholding of usual medication. • Research that may compromise participants' dignity or privacy. • Studies where there is potential for incidental findings from research procedures. • Overly arduous or burdensome procedures in studies that relate solely to participation in the research. • Research where more than minimally invasive biological samples are collected beyond clinical treatment indications. • Research settings that may raise ethical concerns related to privacy, consent, participant and researcher vulnerabilities.	☐
4.Research Design	**YES**
Does your research involve a complex design or additional burden to participants? *Examples include the following:* • Placebo-based studies involving an inactive substance or treatment with no therapeutic effect. • Randomised Controlled Trials (RCTs) comparing different treatments or interventions where participants are randomised to one group or the other. • Complex interventional studies that contain several interactive components. • Studies investigating the safety or efficacy of non-established therapy, device or drug treatment. • Genetic or genomic studies that have potential to identify the participant or specific elements of their genome. • Studies relating to emerging technologies including new technologies and Artificial Intelligence (AI) • Establishment of research biobanks of human biological materials due to extended duration and/ or burden on participants over time. • Establishment of longitudinal studies due to extended duration and/ or burden on participants over time. • Establishment of research registries/ research databases due to study extended duration and/ or burden on participants over time.	☐