CTU collaborates to support trial development, conduct analysis and oversight. JRO insurance funding applied.

Final check, sponsor sign off and oversight of high risk activity.

High Risk Investigation defined as: invasive procedure, radiological assessment, where risk is greater than in routine care.

Does it involve a high risk investigation?

JRO/RDS

Support to develop study, secure funding and address practical issues and methodology.

Entry Questionnaire

ICTM Review Group

Review group to consider risk and determine if most suitable with JRO or in a CTU.

Is it a clinical trial?

ICTM

Considerations for adoption: Feasibility, Cost, Design, CI, Risk assessment, Timelines, Capacity, etc. If academic: Head of Institute/Division – priority, feasibility, costs if not externally funded.

Clinical Trial defined as: testing the activity and/or safety of an investigational medicinal product (IMP-drug, vaccine, immunological or biological product), or a medical device, or an advanced therapy or other type of intervention such as surgery, physiotherapy or complex intervention.

Is it a clinical trial?

ICTM

Rejected, if first rejection then CI can amend and resubmit, or appeal to FRED.

CTU

CTU collaborates to support trial development, conduct analysis and oversight. JRO insurance funding applied.

FRED

PI can accept rejection and do nothing, amend and resubmit, or appeal to FRED, i.e. SLMS Deans.