

Feasibility Review Question Prompts

Study overview

- List of activities (clinical and non-clinical), identifying which are conducted as routine care vs. required for the protocol (as described within the IRAs application)
- Which service support areas are involved?
- Who is doing the work? Are they trained to perform the work? Are they in post?
- Where will the research take place; e.g. OP clinics, wards, CRF, A&E, primary care, labs/theatres, satellite units, campus
- When, and for how long, will the work be conducted; e.g during a clinic, out of hrs, 24/7,

Recruitment

- Do you have this cohort and do they meet the inclusion criteria?
- Are there competing studies? Are they linked or overlapping?
- Is it practicable to recruit? Is this study attractive to your population? Is there a burden to the participant?
- What is your target and your timeline? Can you achieve it? Can you meet the 70 day metric?
- Can the protocol be readily integrated into routine care? What do you need to do to change ways of working? Are there barriers?

Funding

- Is there money attached to the project, and what till it cover?
- Does it cover all activities, clinical and non-clinical, including statistics and archiving?
- If there is a shortfall, how will it be covered?

Regulations

- CTIMP or device? MHRA or other body involved?
- Data storage and handling
 - Do the researchers have appropriate expertise?
 - Is statistical support needed/included?
- Tissue handling, storage, shipping
- Are there specific requirements i.e. working with children or incapacitated adults