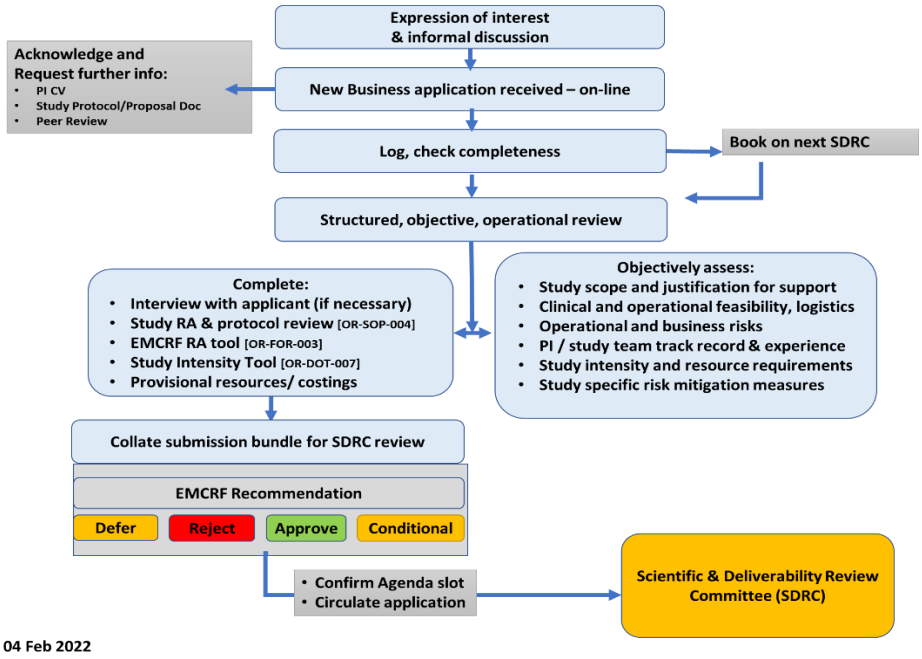
Guidance and instructions for applicants

Application process



The application form is completed on-line via the EMCRF website: [Using the Facility — Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (ox.ac.uk)]

Prior to submitting your application, please contact the EMCRF Operational Lead about your application and for any informal advice required: oxcrf@ndorms.ox.ac.uk Subject Heading: *New Study Application*

Within one week of submission arrangements will be made for you to meet with the Operational Lead (or delegate) to discuss your application.

Applications should detail:

- Which facility resources are being requested to run the study (e.g. day bed, oscopy suite, laboratory)?
- Measures of intensity of use, including number of patients, and resources required
- Essential equipment required for the study, whether study specific provided or not standard?
- Any requests for EMCRF core staff (list by roles or tasks)

Additional documents will be requested, these may include the following:

☐ Protocol or equivalent document if not yet available (ie: funding application, synopsis)

☐ Investigator Brochure/SmPC/Clinical Investigation Plan (if appropriate)

☐ PI's CV and current GCP certificate

☐ Peer review of study proposal (if available)

☐ Specialist protocols (if applicable)

Application Assessment

The assessment of your application will include the following elements:

- Scope of the study – in relation to the CRF objectives and operational policies
- The study's scientific validity considering study design and operational conduct/ logistic issues;
- PI track record and evidence current team has capacity and skill mix to deliver the study e.g. if unable to confirm key staff or needs significant facility cover;
- Study intensity and resource requirements as measured by completion of the SIT;
- Risks associated with the study conduct using the UKCRF RA tool; and

- Other relevant factors including the completeness of the application and supporting documents

Applicants will receive notification via email of the outcome of their submission and instructions of next steps.

Timelines

EMCRF will seek to complete, review and activate the study at site within 8 weeks of submission, if possible. Study specific timelines will be agreed depending on the circumstances of the project and current capacity. In all cases, early application is encouraged to reduce the potential for site set up delays. The timelines below are an estimated guide only.

Development stage	CRF involvement	Timeline to complete
Protocol in development	Support for funding application or approvals submission	>28 days before submission deadline.
Acceptance by CRF	SDRC review	≥ 5 working days prior to SDRC meeting
Final draft protocol and study agreement	CRF set up	≤ 4 weeks
Final, fully approved protocol	Site initiation & green light	≤14 days (if CRF involved draft stage and able to pre-plan)

Costs

Costs to cover the oversight and completion of the study activity in the CRF are required. These include:

- Cost of the core staff who facilitate and oversee the work in the facility
- Facility maintenance and utility costs
- Space charges (for rooms, beds, etc)
- Service charges (eg: lab processing)
- Overnight charges
- Any research nurse support charges
- Additional costs will be applied if the CRF team are required to input into your study design and development (including PPI support).

EMCRF costs will be provided to you and your department following approval of the application.

Patient and Public Involvement

PPI is an important part of study development and conduct. EMCRF strive to ensure all studies coming through the facility have a PPI strategy. Further information about EMCRFs own PPI work and ideas for how you can involve patients and public in your research are available on the website www.oxcrf.ndorms.ox.ac.uk

Further information:

- **Green Light Review**
  Studies can only commence once the CRF Green Light review is completed. Applicants will receive formal notification of this via email.

- **Booking of facility space and resources**
  Booking of space and resources cannot occur until the study has been given the Green Light.

- **CRF Induction**
  Induction to the CRF, for first time users, must be completed before the study can commence in the facility. Information about how to proceed with this will be provided with the outcome of this application review.

- **Division of Responsibilities**
  EMCRF have a standard DoR for study teams to follow. Modifications to the responsibility delegation can occur to correlate with study protocol and team requirements.