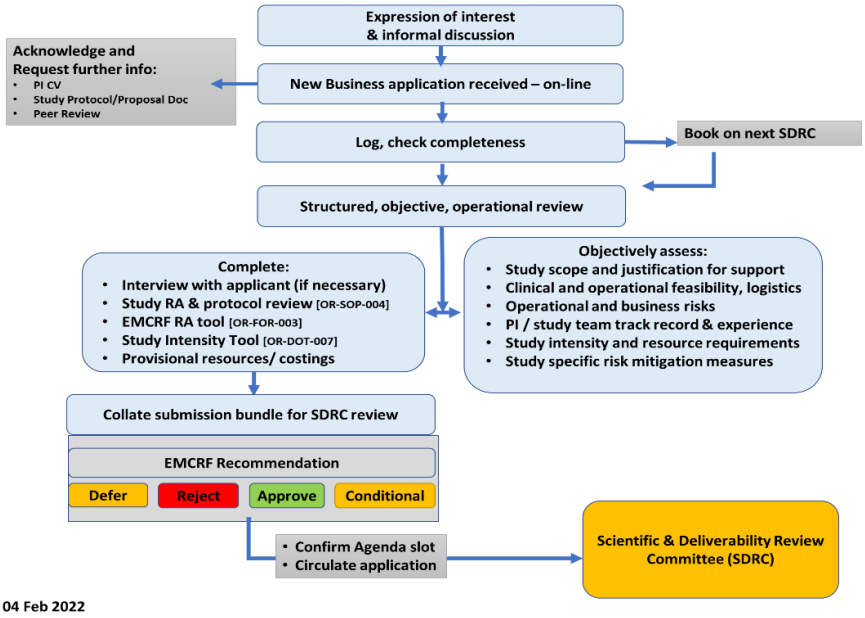
Guidance and instructions for applicants

EMCRF Review 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.

Oxford University Hospitals NHS Foundation Trust Management Approval (OUH TMA)

OUH TMA is required for all studies taking place in EMCRF. Review of the studies will be proportionate to the level of involvement of Trust resources and patients. Alongside the EMCRF Application, study teams need to complete the OUH Research & Development Feasibility Form. Information about OUH TMA and the link to their feasibility form can be found in the link below:

https://www.ouh.nhs.uk/researchers/approvals/capacity-capability/

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.

Costs

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

Additional charges may apply to studies, these include:

- Overnight charges
- Research Nurse support (industry sponsored studies)
- Study set-up support

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. This involves core SOP/WI training via iPassport and a physical induction of the facility. Information about how to proceed with this will be provided with the outcome of this application review.