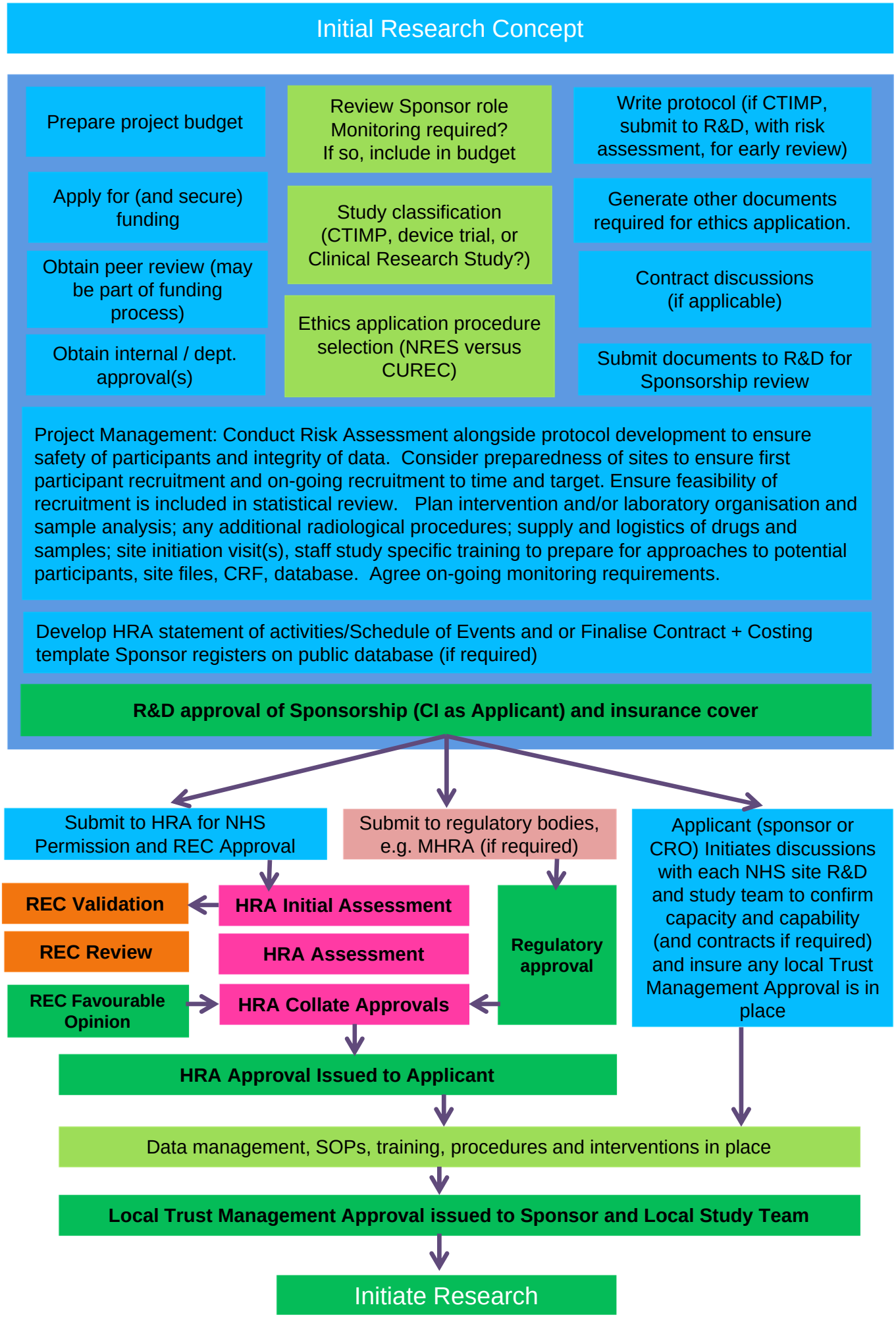
Initial Research Concept
Prepare project budget
Review Sponsor role
Monitoring required?
If so, include in budget
Write protocol (if CTIMP, submit to R&D, with risk assessment, for early review)
Apply for (and secure) funding
Study classification (CTIMP, device trial, or Clinical Research Study?)
Generate other documents required for ethics application.
Obtain peer review (may be part of funding process)
Contract discussions (if applicable)
Obtain internal / dept. approval(s)
Ethics application procedure selection (NRES versus CUREC)
Submit documents to R&D for Sponsorship review
Project Management: Conduct Risk Assessment alongside protocol development to ensure safety of participants and integrity of data. Consider preparedness of sites to ensure first participant recruitment and on-going recruitment to time and target. Ensure feasibility of recruitment is included in statistical review. Plan intervention and/or laboratory organisation and sample analysis; any additional radiological procedures; supply and logistics of drugs and samples; site initiation visit(s), staff study specific training to prepare for approaches to potential participants, site files, CRF, database. Agree on-going monitoring requirements.
Develop HRA statement of activities/Schedule of Events and or Finalise Contract + Costing template Sponsor registers on public database (if required)
R&D approval of Sponsorship (CI as Applicant) and insurance cover
Submit to HRA for NHS Permission and REC Approval
Submit to regulatory bodies, e.g. MHRA (if required)
Applicant (sponsor or CRO) Initiates discussions with each NHS site R&D and study team to confirm capacity and capability (and contracts if required) and insure any local Trust Management Approval is in place
REC Validation
HRA Initial Assessment
REC Review
HRA Assessment
REC Favourable Opinion
HRA Collate Approvals
Regulatory approval
HRA Approval Issued to Applicant
Data management, SOPs, training, procedures and interventions in place
Local Trust Management Approval issued to Sponsor and Local Study Team
Initiate Research