SPONSOR

The Sponsor of a research study is the organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project.

All health and social care research should have a sponsor. This includes all research that involve NHS patients, their tissue or information.

The sponsor is normally expected to be the employer of the chief investigator in the case of non-commercial research or the funder in the case of commercial research (the employer or funder is not automatically the sponsor; they explicitly accept the responsibilities of being the sponsor).

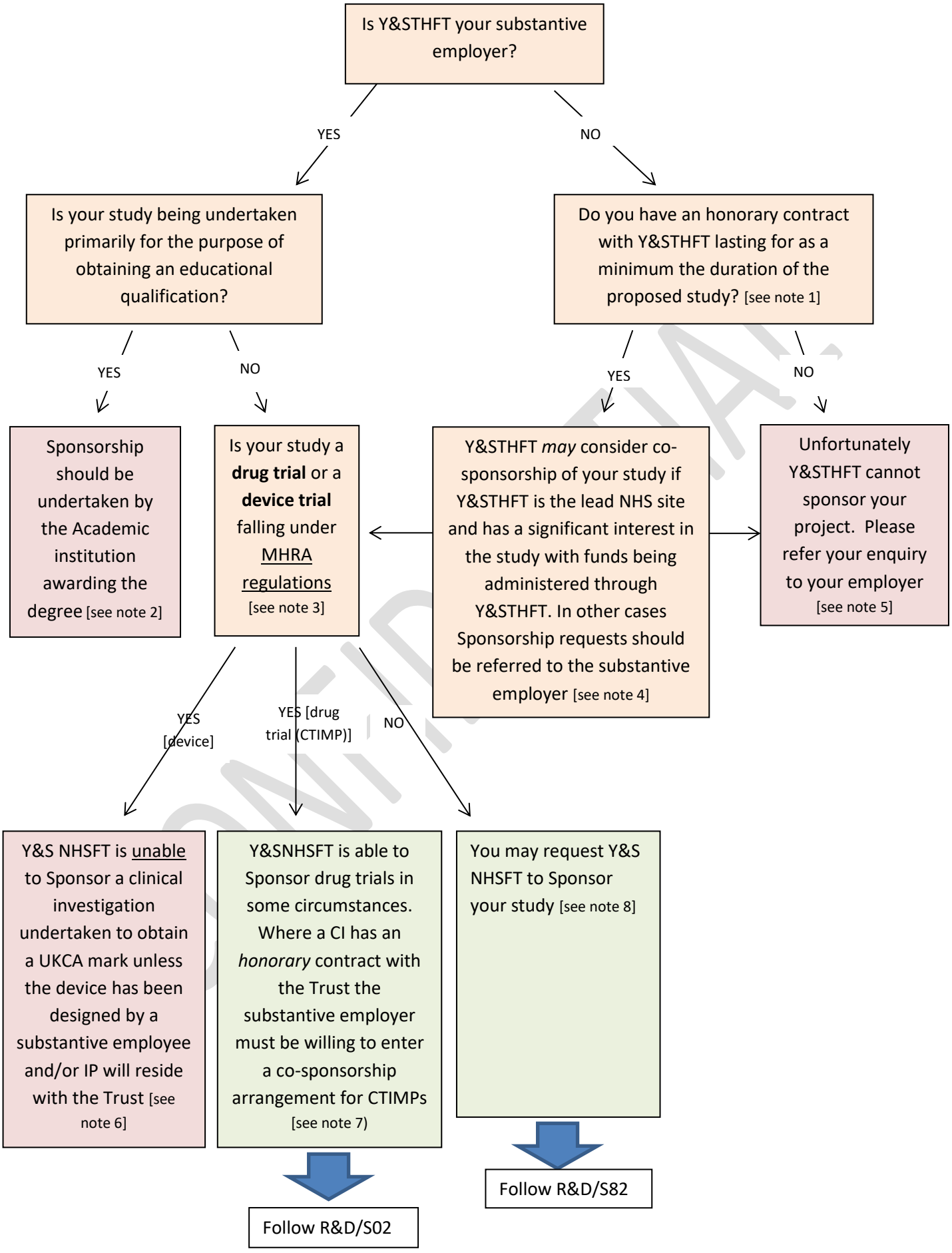
Two or more organisations may agree to act as co-sponsors or joint sponsors. Co-sponsors allocate specific sponsor responsibilities between them whilst joint sponsors each accept liability for all of the sponsor's responsibilities.

A sponsor can delegate specific tasks to any other individual or organisation that is willing and able to accept them. Any co-sponsorship, joint sponsorship or delegation of tasks to another party should be formally agreed and documented by the sponsor(s).

The Sponsor's responsibilities are set out in more detail in the UK Policy Framework for Health and Social Care Research.

York and Scarborough Teaching Hospitals NHS Foundation Trust is willing to accept the role of Sponsor when it is appropriate to do so. In most cases this will be when a Trust employee has designed the study and is acting as the Chief Investigator.

The following decision roadmap is designed to assist individuals in directing their requests for Sponsorship to the correct organisation.


Is Y&STHFT your substantive employer?
YES
NO
Is your study being undertaken primarily for the purpose of obtaining an educational qualification?
Do you have an honorary contract with Y&STHFT lasting for as a minimum the duration of the proposed study? [see note 1]
YES
NO
YES
NO
Sponsorship should be undertaken by the Academic institution awarding the degree [see note 2]
Is your study a **drug trial** or a **device trial** falling under MHRA regulations [see note 3]
Y&STHFT *may* consider co-sponsorship of your study if Y&STHFT is the lead NHS site and has a significant interest in the study with funds being administered through Y&STHFT. In other cases Sponsorship requests should be referred to the substantive employer [see note 4]
Unfortunately Y&STHFT cannot sponsor your project. Please refer your enquiry to your employer [see note 5]
YES [device]
YES [drug trial (CTIMP)]
NO
Y&S NHSFT is unable to Sponsor a clinical investigation undertaken to obtain a UKCA mark unless the device has been designed by a substantive employee and/or IP will reside with the Trust [see note 6]
Y&SNHSFT is able to Sponsor drug trials in some circumstances. Where a CI has an *honorary* contract with the Trust the substantive employer must be willing to enter a co-sponsorship arrangement for CTIMPs [see note 7)
You may request Y&S NHSFT to Sponsor your study [see note 8]
Follow R&D/S02
Follow R&D/S82

Note 1:

Y&STHFT cannot sponsor studies where the applicant does not hold, as a minimum, an honorary appointment with the Trust for the duration of the entire study. It is not considered possible to legally uphold the requirements of study sponsorship without an active employment contract.

Note 2:

The UK Policy Framework for Health and Social Care stipulates that universities and colleges are expected to accept the role of sponsor for all educational research conducted by their own students, unless the student is employed by a health or social care provider that prefers to do this. Sponsors of educational research should ensure that their supervisors can and do carry out the activities involved in fulfilling this role. It is expected that the sponsor will provide any advice and support to students using this process.

Universities and colleges should accept the role of sponsor for all educational research conducted by their own students, unless the student is employed by a health or social care provider that prefers to take on this role. For clarity Y&STHFT does not prefer to take this role.

Sponsors of educational research should ensure that supervisors can and do carry out the activities involved in fulfilling this role. Where the academic supervisor cannot adequately satisfy the sponsor's oversight responsibilities due to location or expertise, the sponsor should agree co-supervision arrangements with a local care practitioner.

Follow Student research toolkit - Health Research Authority (hra.nhs.uk)

In exceptional circumstances the Trust *may* consider co-sponsorship provided the main responsibilities for the study resides with the respective University.

Note 3:

Research studies that fall within the scope of the MHRA's Clinical Trial or Medical Device Regulations have specific legal requirements that mean Sponsorship from Y&STHFT is not guaranteed (note: not all clinical trials will fall under the Regulations). Several factors are taken into consideration when assessing whether the Trust will act as Sponsor for these studies.

- The Chief Investigator (CI) must be substantively employed at Y&STHFT or hold an honorary contract with the substantive employer being willing and able to co-sponsor.
- The CI is at medical consultant level within a speciality relevant to the trial and/or participant group
- The CI has previous experience undertaking clinical trials as a PI
- The CI is currently GMC/BDS registered with no restrictions
- The trial has sufficient funding and central resource to ensure its safe and compliant management
- The grant awarded for the trial is held by Y&STHFT to ensure adequate and continued financial oversight and financial risk control.

Y&STHFT does not recommend that projects that fall within the scope of the Regulations are considered as educational projects. Students cannot act as CI or PI for a CTIMP study (a clinical trial that falls under the scope of the MHRA clinical trial regulations).

Refer to: Medicines, medical devices and blood regulation and safety: Clinical trials and investigations - detailed information - GOV.UK (www.gov.uk)

Note 4:

'Significant interest' would, for example, involve consenting Y&STHFT patients; using Y&STHFT data and/or images and/or samples. The expectation would be that the study would take place on the hospital site and that Y&STHFT staff would be involved in the study design, delivery and resulting publications.

Note 5:

The UK Policy Framework for health and Social Care states that 'The chief investigator's employer is normally the sponsor in the case of non-commercial research.'

Note 6:

The R&D Forum states that 'Institutions are expected to review candidate studies for sponsorship on a case-by-case basis (through a formal application/registration process initiated by the chief investigator) and should only accept the role of sponsor for studies that lie within their range of competence. For example, an organisation that has no experience or infrastructure for the management of clinical trials should avoid acting as a sponsor for such trials unless it can delegate the specific responsibilities to another organisation that has the required expertise. Similarly, an organisation lacking experience managing multi-site studies may be advised to limit itself to sponsoring single centre studies until they have developed the systems (and the competence) to expand their trial portfolio to include multi-site trials.

Y&STHFT does not routinely Sponsor device studies and will not accept this role unless there are exceptional circumstances. Sponsorship for such studies should be sought from alternative institutions.

Note 7:

The R&D Forum states that 'where two or more organisations share a significant interest in a study, for example, one as employer of the chief investigator and another as the principal host institution, they may elect to act as co-sponsors or joint sponsors.

- Co-sponsors agree an allocation of defined sponsor responsibilities. The Clinical Trials Regulations group the sponsor's responsibilities by function (Part 3, 4, 5, 6 and 7). Co-sponsors divide amongst themselves both the responsibilities and the liabilities associated with sponsorship. The clinical trial authorisation (CTA) must clearly define the set of sponsorship responsibilities taken on by each party. The allocation of sponsor responsibilities will be determined by the expertise and capacity of the individual or institution to discharge them in relation to the risk posed by the study.
- Joint sponsors are partner organisations who accept joint liability for all the sponsor's responsibilities. They are jointly and severally responsible for all the duties of the sponsor, such that all are responsible in the event of a failure of any one of the partner organisations to discharge their responsibilities. Both organisations would have to have suitably qualified and trained staff to oversee all the sponsor's activities

Note 8:

It is the expectation of Y&STHFT that all research to be considered for Sponsorship has received appropriate funding to cover all research costs and will be submitted for NIHR CRN Portfolio adoption where applicable.