

NHS and Imperial College working principles underlying research contract negotiation and execution

AIM: To outline the sharing of responsibility for ensuring standards of excellence of research and clinical studies: in support of this aim the parties shall work together to create an efficient process underpinning the negotiation and execution of research and clinical trial contracts undertaken by staff of Imperial College or NHS.

- The parties agree that bi-partite contracts with the research funder/commercial sponsor shall be completed in the majority of occasions by either the NHS or College. It shall be the right of the contract holder to negotiate the contract with the funder or commercial sponsor.
- It is the duty of the contract holder to ensure they can fulfil the legal obligations placed upon that party by the contract. Where the contracting party is required by the sponsor or funder to place legally binding obligations on or access to rights or property belonging to the other party the parties agree to discuss such obligations in advance of executing the contract. The NHS and College shall use reasonable endeavours to work in a collaborative manner to ensure the contract holder can fulfil the legal and regulatory obligations of the contract, for example executing an assignment of intellectual property rights to the other party provided there are no conflicts of interest or third party rights.
- It is in the interest of all parties to have a fast and efficient contracting process, a nominated person for each College site or NHS Trust shall be the designated administrative contact for each contract (such contact shall not be the PI). The contract holder shall be the primary contact for negotiating the contract with the relevant third party.
- The College agrees to use reasonable endeavours to notify the NHS of any changes to the PI/CI's employment status and the NHS agrees to use reasonable endeavours to notify the College regarding any serious issues occurring which involves a College staff member or NHS staff with College honorary employment status.
- It is the duty of the contract holder to distribute any agreed financial compensation to the NHS or College as appropriate.
- The NHS and College agree to report every [6]/[12] months on contracts undertaken by the College or NHS on behalf of the other party's member of staff. The NHS or College agree to share details of such contracts under suitable confidentiality arrangements if requested. The terms of contracts, unless expressly stated otherwise, are confidential and as such shall not be subject to the Freedom of Information Act.

(1) Non-Commercial Contracts and Research Funding

For all non-commercial contracts (excluding clinical trials) and charitable funders where the CI/PI is a College employee or a College honorary contract holder, the College shall be the contract holder, such contracts may be for clinical studies using NHS facilities or laboratory based studies where work is predominantly performed using College facilities.

The College shall consult with the relevant NHS site if such contract involves access to patients. NHS shall have the right to suggest changes to the contract that effect duty of care to patients.

(2) Commercial Clinical Trial Contracts Sponsored by College

For all commercial contracts which are 'Sponsored' by the College where the CI/PI is a College employee or College honorary contract holder the College shall be the contract holder. For the avoidance of doubt, Sponsored by College includes all investigator led studies or trials as these are normally performed for a subsidised price.

The College shall consult with the relevant NHS site if such contract involves access to patients. NHS shall have the right to suggest changes to the contract that effect its duty of care to patients.

(3) Commercial Clinical Trial Contracts Sponsored by a commercial entity

For all commercial contracts which are 'Sponsored' by the commercial partner where the CI/PI is a College employee or College honorary contract holder the NHS shall be the contract holder.

The NHS parties agree to consult the College regarding any questions of contract costing and recovery of College's costs, contracts terms and conditions varying from the agreed templates, and conflict of interests presented by the proposed contract.

(4) In the event a non-commercial entity is acting as Sponsor for an investigator led clinical trial or a non-commercial clinical trial, the NHS and College agree to meet to discuss which party is best placed to be the contract holder on a case-by-case basis. For example, the NHS may be the best placed as contract holder for later stage trials phase II, III and IV, whilst the College may be best placed to be the contract holder on early stage phase I and II trials.