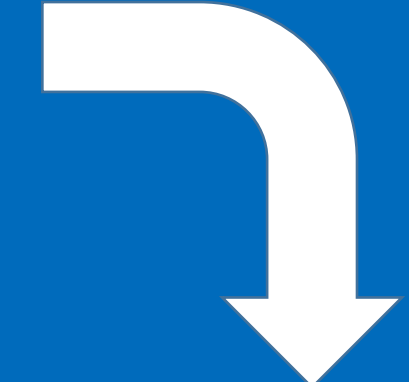
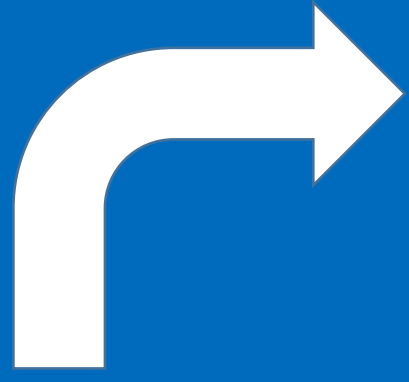


Contractual Lifecycle of Clinical Trial

Mr Charles A Lescott; Dr Amanda C Stewart
Oxford University Hospitals NHS Foundation Trust

Confidentiality Agreement (CDA/NDA)

Can be agreed between Lead Party and Funder / Collaborators to allow discussion of confidential information to establish interest in working together without fear the information could be shared elsewhere or used for any other purpose

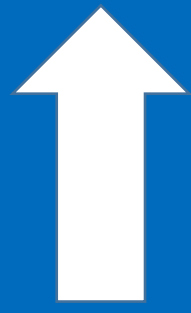


Commercialisation Agreement

Between intellectual property owner and a party wishing to exploit it. Can be a licence or assignment of intellectual property for a defined area of use for commercial return

Funding Agreement

Agreed between Funder and Lead Party to cover financial support of a project. It defines the scope of the money's use; when and how it will be paid and any other conditions e.g. reporting back, acknowledgement on publications



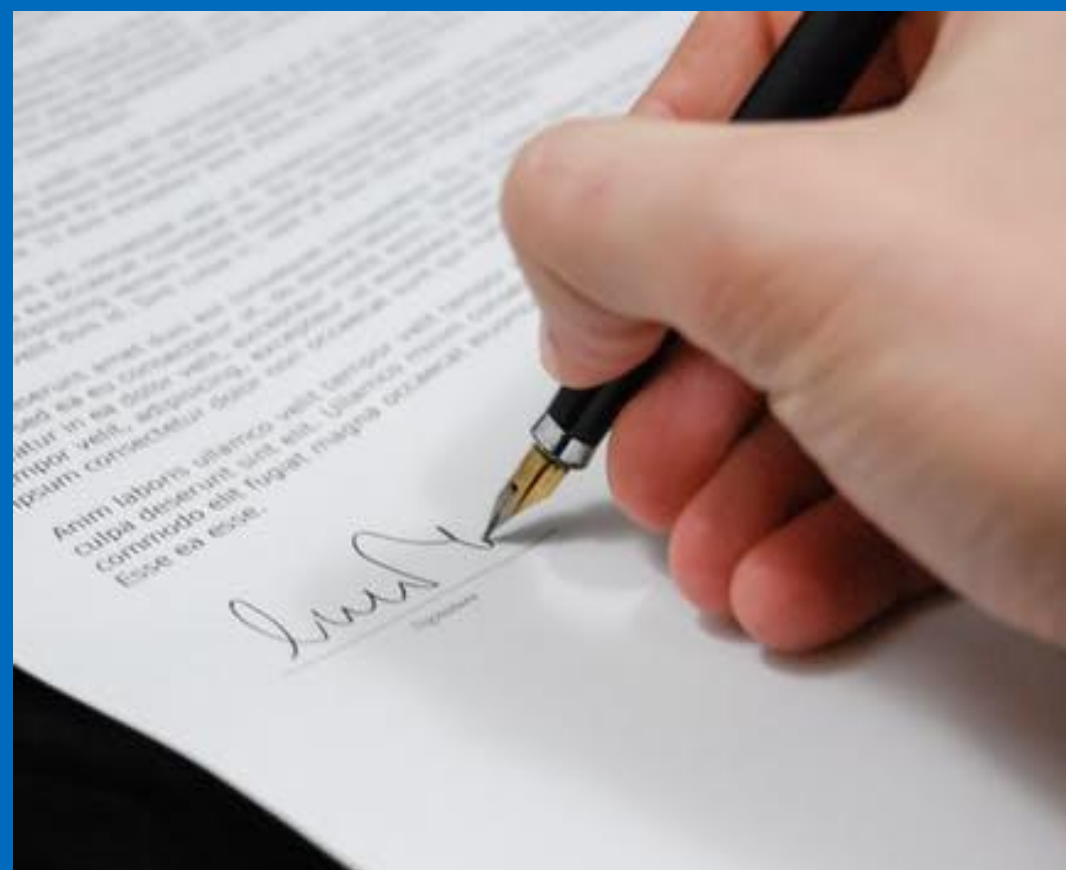
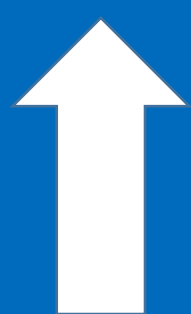
Service Level Agreement (SLA)

Between a Study site and service provider. These cover Fee for service activities e.g. carrying out a protocol procedure for a study site. Typically the service is detailed, along with the payments and timelines e.g. collecting blood samples



Collaboration Agreement

Between Lead Party and Collaborators – sub agreement to funding agreement where the money and tasks are shared amongst collaborators. Any obligations put upon the Lead Party in the funding agreement are also passed on e.g. help in preparing reports



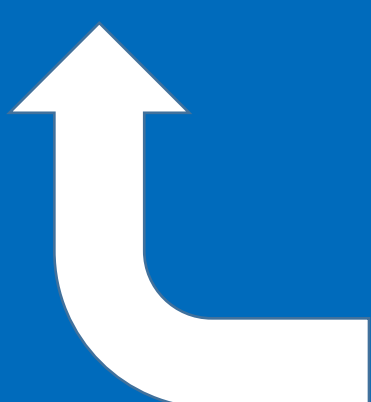
Material Transfer Agreement (MTA)

Between a provider and recipient of defined material. Ensures the parties comply with applicable laws and regulations e.g. the Human Tissue Act 2004. Restricts how the material can be used, who can use it and what must happen to it when the Study is complete. It covers any costs involved in procuring or transferring the material and apportions responsibility for any loss or damage arising from handling of the material



Supply Agreement

Between equipment or Drug suppliers and Study Sponsor. These agreements determine what will be supplied and when as well as defining who is responsible for loss or damage to the equipment or injury to a patient and what benefit a supplier receives in return e.g. access to relevant anonymised data or acknowledgement on publication



Clinical Trial Site Agreement (CTA)

Between Sponsor and the recruiting sites to cover the obligations to perform the Study as per Protocol and accordance with applicable laws and regulations e.g. the Human Tissue Act 2004. It also typically covers what publication rights the site has and who is responsible if a patient was adversely affected by their participation in the study. If there is an invention during the study (new intellectual property is created) a contract typically defines who owns that invention and what if anything they would share with any contributors