noclor

NHS

How we Sponsor: Perspectives from Mental Health and the Community

Nick Portman

Housekeeping

- Zoom Etiquette

Agenda

- What is Noclor?
- Building a Sponsorship Service
- How we Sponsor
- Challenges in our Setting

- Contact Details
- Questions & Discussions

What is Noclor?

- Specialist NHS service supporting research
- A joint R&D office to multiple Community, Mental Health and Acute NHS Trusts
- Support Local Clinical Research Networks
- We specialise in Community, Mental Health & Primary Care
- Hosted by Central and North West London NHS Foundation Trust

What is Noclor?

NHS Partner Trusts

- Camden and Islington NHS Foundation Trust
- Barnet, Enfield and Haringey Mental Health Trust
- Whittington Health NHS Trust
- Tavistock and Portman NHS Foundation Trust
- East London NHS Foundation Trust
- West London NHS Trust

What is Noclor?

Primary Care

What is Noclor?

Academic Affiliations

- Queen Mary University of London
- University College London
- Imperial College London
- City University of London

What is Noclor?

What services do we provide?

- Study Management & Support
- Study Delivery
- Sponsorship
- Costing & Contracting
- Strategic Advice & Support
- Communications

What is Noclor?

Other Support We Provide to Our Researchers

- Training
- Support with recruitment (HR)
- General research advice and support
- Small bursaries and starter grants

Building a Sponsorship Service

Areas for Development

- No assessment of validity / appropriateness
- No formal mode of Researcher making application
- Minimal volume of sponsored studies
- No consistent process of review or signatory
- Ongoing oversight lacking
- Multiple internal teams involved in same study

Building a Sponsorship Service

Encouraging award of grants to Trusts

- Push for HTA, RFPB and other NIHR grants to be awarded to Trusts
- Generates RCF £
- Generally will Sponsor if awarded grant
- Full control of grant
- Encourage researchers to budget for Trial manager where appropriate
- Ensures study activities are costed appropriately

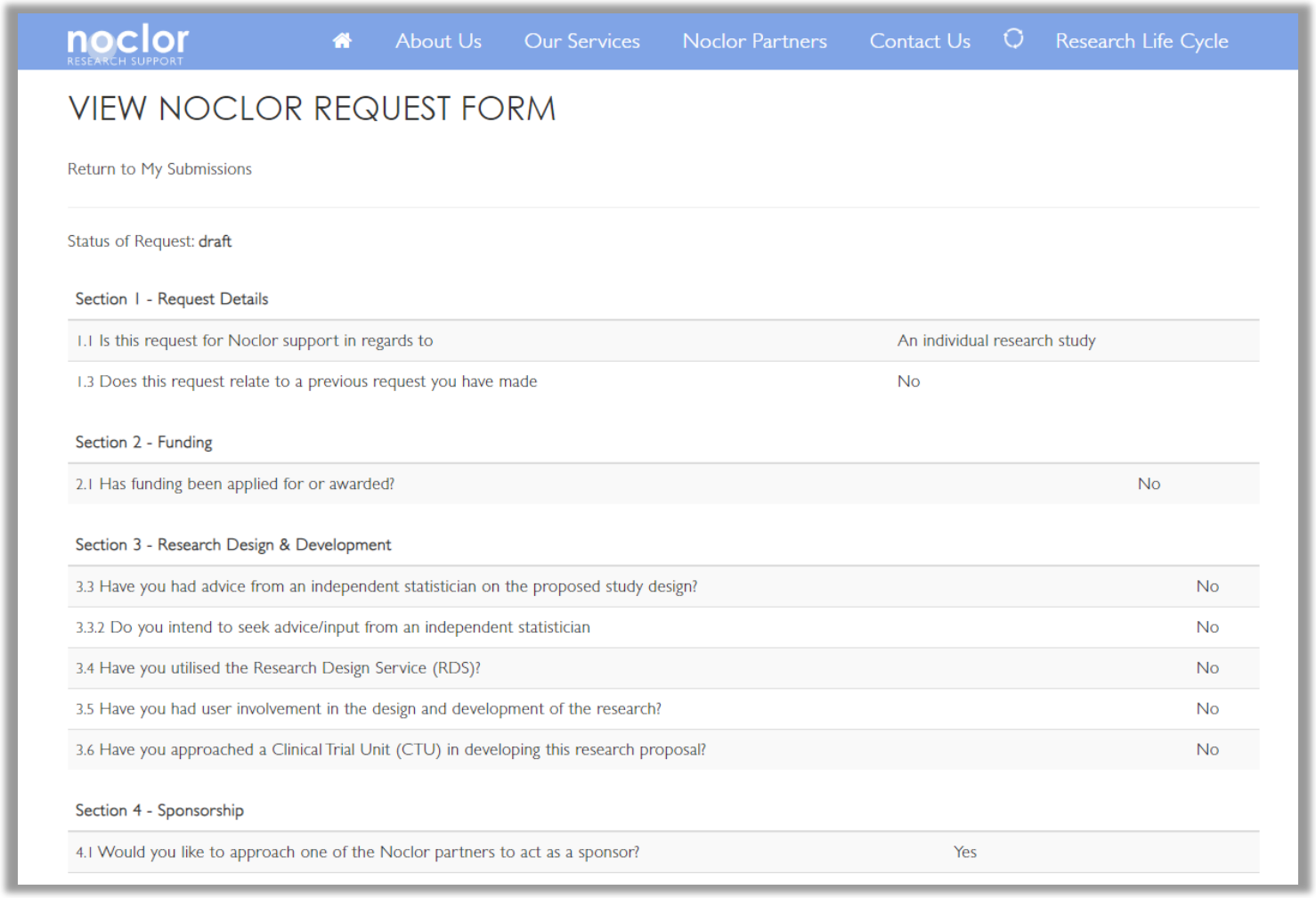
How We Sponsor

- Website with application portal
- Systematic peer review
- Business intelligence
- High level of support for Investigators
- Risk Management
- Ongoing oversight and transparency agenda

How We Sponsor

The Sponsorship Process, making an application

- E-interview via website
- Sponsor reference
- Linked to ongoing grant application
- 5 day validation process
- Assigned Team Member
- Multiple reviews culminating in HRA readiness review


noclor
RESEARCH SUPPORT
About Us
Our Services
Noclor Partners
Contact Us
Research Life Cycle
VIEW NOCLOR REQUEST FORM
Return to My Submissions
Status of Request: draft
Section 1 - Request Details
1.1 Is this request for Noclor support in regards to
An individual research study
1.3 Does this request relate to a previous request you have made
No
Section 2 - Funding
2.1 Has funding been applied for or awarded?
No
Section 3 - Research Design & Development
3.3 Have you had advice from an independent statistician on the proposed study design?
No
3.3.2 Do you intend to seek advice/input from an independent statistician
No
3.4 Have you utilised the Research Design Service (RDS)?
No
3.5 Have you had user involvement in the design and development of the research?
No
3.6 Have you approached a Clinical Trial Unit (CTU) in developing this research proposal?
No
Section 4 - Sponsorship
4.1 Would you like to approach one of the Noclor partners to act as a sponsor?
Yes

How We Sponsor

Peer review

- Defined criteria for peer review
- Access to subject matter experts to arrange peer review
- Pragmatic approach
- Parallel initial regulatory review

How We Sponsor
Relationships

- LCRN
- Contracts and Costings
- Service and Clinical Directors
- Primary care team
- NIHR Funded study delivery teams
- Researchers

How We Sponsor
Business Intelligence

- Bespoke Information Management System – Quick-base platform
- Virtual interview and sponsorship application system
- Performance metrics and reporting
- EDGE and comparing systems
- Alerts and notifications for study milestones

SIV Date	Project site date initiation visit - imported from EDGE	EDGE Error status - SIV Date	Date Site Ready to Start	Project site date open to recruitment - imported from EDGE	EDGE Error status - Date ready to start	Date of First Patient Recruitment	First site patient recruited (any) - imported from EDGE	EDGE Error status - Date first participant recruited	Predicted recruitment end date	Project site planned recruitment end date - imported from EDGE	EDGE Error status - Predicted Recruitment end date
		OK	26-JUN-2019	16-MAY-2019	NO	23-JUL-2019	23-JUL-2019	OK	31-MAR-2020	31-MAR-2020	OK
18-SEP-2019	20-DEC-2019	NO	04-DEC-2019	04-DEC-2019	OK			OK	31-MAR-2021	31-MAR-2021	OK
		OK			OK			OK	28-FEB-2019	14-AUG-2020	NO
		OK	27-JUN-2017	27-JUN-2017	OK			OK			OK
		OK	21-JAN-2020	21-JAN-2020	OK			OK			OK

How We Sponsor
Managing Risk

- Formal structured risk assessment
- Mitigating actions built into protocol
- Quality checks within review process
- Documenting processes in real time in our Information Management System
- Ongoing oversight

How We Sponsor

Supporting Investigators and Managing Expectations

- Early engagement during grant process
- Explaining process at application stage
- Regular updates and feedback
- Goal is a fast HRA /ethics review
- A source of advice and support not a regulatory hurdle

How We Sponsor

Roles and responsibilities

- Chief Investigator delegation of responsibilities
- Collaboration agreements
- Working with Clinical Trials Unit
- Contracts and agreements for services (transcription, randomisation etc)

How We Sponsor
Ongoing Studies

- RTT and performance metrics
- Amendments
- Legacy studies
- Audits
- Monitoring

How We Sponsor

End of study and transparency

- End study approach date
- In Close-down status
- Transparency and study registries
- Archiving
- Publishing

Challenges in our Setting

Consent

- No consent study design for populations difficult to consent
- Mental Health Act, applicable to clinical care not research
- Mental Capacity Act, a presumption of capacity
- Sexual Health Services, underage participants
- Prisons and detention settings
- COVID, remote consent

Challenges in our Setting

Sensitive Data

- Mental Health and Sexual health both particularly sensitive
- Community settings often involve travelling
- Seeing study participants in their homes
- Linking and multi setting: prison/NHS/social care etc.

Contact Details

- Sponsorhip: **sponsor.noclor@nhs.net**
- General: **contact.noclor@nhs.net**
- Phone: **020 3317 3045**
- First Floor, Bloomsbury Building, St Pancras Hospital, 4 St Pancras Way, NW1 0PE

Thanks for Listening

- Questions & Discussion