

**APPLICATION FORM FOR A LETTER OF SPONSORSHIP**

|  |  |  |  |
| --- | --- | --- | --- |
| **Rev** | **Date** | **Purpose of Issue/Description of Change** | **Equality Impact Assessment Undertaken** |
| 1. | 23rd January 2023 | Initial Issue |  |
| 2. | 27th March 2023 | Review and approval by the University Ethics Committee |  |
| 3. | 29th March 2023 | Minor edits (RR) |  |
| 4. |  |  |  |
| 5. |  |  |  |
| 6. |  |  |  |
| 7. |  |  |  |
| 8. |  |  |  |
| 9 |  |  |  |
| 10. |  |  |  |
| 11. |  |  |  |
| 12. |  |  |  |
| 13. |  |  |  |
| 14. |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Policy Officer** | **Senior Responsible Officer** | **Approved By** | **Date** |
| Deputy Secretary / Head of Governance Service | Senior Research Governance & Policy Officer | University Research Governance and Ethics Committee | 27th March 2023? |

The pro forma and the process is presented here as a paper-based (while we pilot it) but it should really be web-based as a facility on the university’s Research Governance pages .

**1. Background: What is university research sponsorship and why do we need it?**

Under UK legislation, medical or health-related studies involving NHS patients or their families, NHS staff, premises, resources, NHS data or human tissue are required to go before an NHS or Social Care Research (SCR) Ethics Committee under [Health and Care Research Wales/Health Research Authority](https://www.hra.nhs.uk/) (HRA) [approval processes](https://www.hra.nhs.uk/approvals-amendments/). The same is true for certain other types of study involving adult social care services across England and Wales, individuals under the probation or prison services, the use of medical devices, ionising radiation or certain genetic interventions. Clinical trials must also be approved by the HRA (see below). Under this system, submitting a study to an NHS or Social Care Research Ethics Committee through the [Integrated Research Application System (IRAS)](https://www.myresearchproject.org.uk/) first requires the university to undertake the role of study 'sponsor'. Study sponsors take responsibility for the appropriate conduct and completion of a study in accordance with legal requirements and standards of good practice (including any measures specified by research ethics review).

**2. What does university sponsorship involve?**

The [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) lists 9 [responsibilities](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/#sponsors) of an organisation or university undertaking the role of sponsor.

Summarising, these include:

(a) the scientific quality of the study;

(b) the availability of sufficient funding/resources to complete of study;

(c) the suitability, expertise and capacity of the investigators and team;

(d) compliance with all necessary regulatory frameworks and permissions obtained;

(e) review of the study by an appropriate research ethics committee;

(f) ensuring arrangements for findings of the research to be made published appropriately;

(g) appropriate indemnities for the institution, researchers and study participants;

(h) monitoring of study conduct and reporting of any adverse events; and

(i) appropriate data management, sharing and publication arrangements.

Sponsorship of clinical trials involving drugs ('Clinical Trial of an Investigational Medicinal Product'; CTIMPs) or other kinds of health interventions ('complex interventions') brings extra responsibilities (e.g. identifying a clinical trials unit (CTU) to help design and support the trial and ensuring registration with an appropriate clinical trials database and appointing a sponsor representative to act on behalf of the sponsor as the trial progresses). CTIMPs falling under the Medicines for Human Use (Clinical Trials) Regulations 2004/No.1031) and the Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019) must also meet requirements around [Good Clinical Practice (GCP) and legal representation](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/#ctimps). Investigational Medicinal Products require registration with the [Medicines and Healthcare products Regulatory Agency](https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency) (MHRA) as can other studies involving [medical devices](https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety).

Mostly, the non-commercial sponsor (such as the NHS or universities) will be the employer of the study’s Chief Investigator (CI). Sponsorship is not automatic – the employer must explicitly accept the responsibilities of being the sponsor. Funding bodies can be sponsors although not necessarily (e.g. in the more usual situations where UKRI fund a study sponsored and conducted by a university). Two or more organisations can be co- or joint sponsors of a study. Co-sponsors allocate specific responsibilities between them whilst joint sponsors each accept liability for all of the responsibilities. Research agreements/contracts with external partners – any of governmental, UKRI, industrial or commercial, or charity/3rd sector – should indicate which organisations of those involved are the sponsors.

Therefore, some of Bangor University’s (BU) medical, health and social care studies require the university, as sponsor, to take responsibility for steps 2(a) through (i) above before submission to an NHS/SCR Research Ethics Committee. Importantly, university sponsorship is implicit in its governance arrangements for research studies funded internally and for studies that are reviewed by other external ethics committees (e.g. Ministry of Defence).

This document introduces a new system for obtaining a Letter of Sponsorship for the submissions to NHS/Social Care Research Ethics Committees, for HRA approval processes, and (where appropriate) for funding applications.

**3. Why do we need a new system for study sponsorship?**

Arranging university sponsorship and NHS/SCR research ethics review are two separate processes. Previously, university sign-off of sponsorship of a study falling under the UK Policy Framework is completed by a college manager (usually in the College of Human Sciences) at the point when he/she approves the submission of an application (via IRAS) for review by an NHS/Social Care Research Ethics Committee. Previously, this could not happen until the study had first been given a favourable opinion by one of BU’s Academic Research Ethics Committees (ARECs). This reflects a long-standing practice whereby the university uses AREC ‘approval’ as a proxy indicator that the university is happy to sponsor a study (i.e. an indication that the university can meet its sponsorship responsibilities).

However, this procedure has several weaknesses. First, the remit of an AREC (i.e. specifying those arrangements needed to ensure that a study is both ethical and is safe) is not the same as deciding that the university can or even wants to sponsor a study (e.g. on the basis of being satisfied that those arrangements are in fact in place and that a study can proceed safely). Second, serial review first by an AREC and then by an NHS/Social Care Research Ethics Committee could introduce inconsistencies in the conditions of approval for the same study, potentially complicating the resolution of complaints or legal processes. Third, the current process is inefficient for university staff, both in terms of the significant effort expended in preparing and getting two ethics applications approved and in terms of the aggregated time spent waiting for two review processes to be completed.

Therefore, the intention here is to offer a procedure that removes the need for review of medical and health-relevant studies by an AREC (and its work burdens) where a submission to NHS/Social Care Research Ethics Committee will be made and replaces it with a process, led by school Directors of Research to decide whether the university can act as study sponsor. The process is intended to be risk-based but proportionate; and its output will be, if an approval, a 'Letter of Sponsorship' that can be attached to applications for review by an NHS/Social Care Research Ethics Committee (for IRAS), other HRA approval processes (e.g. involving NHS R&D offices in new study sites), or funding applications.

**4. For researchers: How do I get a sponsorship statement for my study?**

There are 3 essential steps, but the process depends on the type of study. Organising sponsorship for clinical trials (CTIMPs or complex interventions) begins at an earlier stage of developing a study than for other types of health research studies falling under the UK Policy Framework and requires the support of a clinical trials unit (CTU). The CTU could be BU’s [North Wales Organisation for Randomised Trials in Health](https://nworth-ctu.bangor.ac.uk/) (NWORTH) or a CTU at another university, NHS Health Board or Trust (in England) or health provider and should be [UKCRC](https://ukcrc-ctu.org.uk/) registered. In general, securing a Letter of Sponsorship for clinical trials involves significantly more extensive documentation and a broader review process by the university (see below).

For all studies there are 3 steps:

Step 1. You – the Chief Investigator - start by completing Section A of the pro forma below. Each of the sections relates to the sponsorship responsibilities listed (a) through (i) above. For the most part, these sections should be straightforward since most, if not all, of the information needed will be available in your study protocol, the materials of any funding application (e.g. peer reviews) or other sections of your IRAS application form. However, if you have any particular queries, please contact your School or College Director of Research or the [Senior Research Governance & Policy Officer](https://www.bangor.ac.uk/the-governance-services/contacts) or the governance team.

Step 2. Send (a) the pro forma (with Section A completed); (b) your study protocol, (c) peer reviews and (d) evidence of external funding (where appropriate) to your school Director of Research. He/she should have a good enough understanding of your research and research partners and environment to make a risk-based but proportionate assessment of your study against sponsorship elements 2(a) through (i) above. Possibly, your Director of Research will ask for advice from other staff working on similar studies (where there are no significant conflicts of interest) or the governance team. So, please be sure to allow sufficient time for he/she to complete this process against IRAS submission deadlines.

Step 3. Finally, once your school Director of Research has approved sponsorship of your study and signed Section C below, you will need to send the completed proforma to your college manager. Following a final check, he/she will generate and sign a Letter of Sponsorship to attach to your application for review by an NHS/Social care Research Ethics Committee (via IRAS) and to be passed back to you for your records and other uses.

For clinical trials (CTIMPs and complex interventions):

The process of organising sponsorship for clinical trials usually begins before applying for funding. This is because funders (e.g. the [National Institute of Health Research](https://www.nihr.ac.uk/researchers/apply-for-funding/)) require evidence of sponsorship and CTU support with applications for trial grants. Therefore, if you are at the early point of just having formulated a proposal for a clinical trial, you will need to select a CTU to help with (i) preparing a formal study protocol; (ii) specifying independent statistical and data management processes; (iii) understanding the necessary MHRA registrations (for CTIMPs or studies involving medical devices); (iv) securing agreements with collaborators, sites and clinical partners; (e.g. for secure data sharing); (v) preparing a financial costing for a funding application and (vi) completing an initial risk assessment.

Once you have a CTU in place and completed these steps for a funding application, or if you have done so already and have secured funding, you can apply for university sponsorship.

The steps are similar to those for non-clinical trial studies but with 3 differences:

Step 1. You will need to complete Sections A and Section B of the pro forma, signing both.

Step 2. You will need to send the following documents to your school Director of Research:

(a) the pro forma (with Section A and B completed);

(b) a study protocol;

(c) a scientific evaluation of the protocol;

(d) any necessary MHRA registrations or correspondence with the MHRA;

(e) letter of support by your CTU (signed by the director or CTU manager);

(f) collaboration agreements;

(g) data sharing agreements (if applicable);

(h) a financial costing (or evidence of secured funding);

(i) a Certificate of Insurance

(j) a study risk assessment

Step 3. Your Director of Research will chair a small group also involving the college/Research Institute Director, the Senior Research Governance Officer and, for those trials supported by external CTUs, the NWORTH Director or CTU Manager) and complete a risk-based assessment against sponsorship elements 2(a) through (i) above. Where appropriate, the group will appoint a [sponsor representative](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/#legal) to monitor compliances as the trial progresses.

Please be aware that your CTU (NWORTH or any other) cannot be involved in signing off on the sponsorship of your trial. Your CTU needs to remain independent of the sponsorship process but can provide advice and support to you as a CI.

Finally, if the group approves sponsorship for your trial and your school Director of Research has signed Section C below, you will need to send the completed proforma to your college manager. Following a final check, he/she will generate and sign a Letter of Sponsorship to attach for your use and records etc.

**5. For school Directors of Research: What do I need to do?**

Applications for Letter of Sponsorship are allowable for submissions to NHS/Social Care Research Ethics Committees, for HRA approval processes, and (where appropriate) for funding applications. You should read the completed Section A (and Section B as appropriate) of the pro forma below and the supporting documentation to complete a risk-based assessment of whether the university and research team can complete the study successfully against the sponsor responsibilities listed in Section 2(a) through (i) above.

Section C includes a set of criteria derived from the sponsor responsibilities listed in Section 2(a)-(i). You can use this to record your or your group’s assessment. For the majority of applications that are not clinical trials, you should have the information you need from your own knowledge of your school/college and staff’s research profiles. However, for more complicated studies where the risks are more consequential in terms of the personal safety of individual, finance and university reputation, you can consult with staff working in relevant research areas (if they are not involved in the study and have no significant conflict of interest), your college research institute director and the governance team as required. For clinical trials, you should have a small group also involving the college/Research Institute Director, the Senior Research Governance Officer and, for those trials supported by external CTUs only, the NWORTH Director or CTU Manager). You will need to consult with the governance team to identify a sponsor representative for your trial.

Your assessment should be proportionate and pragmatic (e.g. the weighting given to concerns about any individual items such as the importance of the scientific question might be moderated in a non-intrusive questionnaire-based student project compared with a clinical trial). Provision of adequate peer review is mandatory for ethics applications through IRAS. Studies supported by external competitive funding will normally have independent peer reviews made available to funding committees. However, studies funded by industry or funded internally may have only review by other BU staff or by colleagues of the staff member/investigator at other institutions. So, weighting against the risks of the project, you may need to judge whether these reviews are adequate.

If you are satisfied that the risks are managed appropriately, you (and the Sponsor Representative if the application involves a clinical trial) should sign Section C and return it as ‘Approved’ to the staff member/CI. If not, you can mark it as ‘Referred’ and ask for clarifications in a revision; or you can seek advice from the governance team. If you have serious concerns, you can reject the application outright. You should retain the signed form as part of your school or college research recording.

**6. For College Managers: What do I need to do?**

You should read a staff member/investigator’s sponsorship pro forma and check that it has been completed properly and been signed off appropriately by school Director of Research (and working group) or Sponsor Representative (if the study is a clinical trial), then generate and sign a Letter of Sponsorship before passing it back to the staff/investigator for their use. You should retain the pro forma and Letter of Sponsorship for your own records. It is important that you do not generate and sign a Letter of Sponsorship without an appropriately completed pro forma.

**7. For researchers: How can I check that my study falls under the UK Policy Framework and that I need HRA/REC approval and university sponsorship?**

There are several online resources supported by the HRA for checking whether your study proposal needs to be submitted to an NHS/SCR Research Ethics Committee and therefore will need a university sponsorship statement.

First, you can assess whether or not your study counts as research in a way that would require being seen by an NHS/Social Care Research Ethics Committee using the HRA [Research Decision Tool](https://www.hra-decisiontools.org.uk/research/question1.html). Guidance for using the IRAS system to apply for review by an NHS/Social Care Research Ethics Committee is available [here](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/applying-research-ethics-committee/). Guidance for the preparation of Social Care Research studies can be found [here](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/social-care-research/). There are particular arrangements in place for undergraduate and post-graduate student projects involving the NHS/Social Care services [here](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/student-research-toolkit/) along with a [Student Research Toolkit](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/student-research-toolkit/). The HRA’s [Clinical Trial of a Medicinal Product Algorithm](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949145/Algorithm_Clean__1_.pdf) can be useful in determining whether studies involving medicinal products, food supplements, medical devices or other interventions qualify as CTIMPs and for information about which MHRA authorisations are needed.

**8. For researchers, Director of Research or College Managers: Where can I get advice?**

For further guidance, you can contact your School Director of Research, the [Senior Research Governance & Policy Officer](https://www.bangor.ac.uk/governance-and-compliance/ethicsandresearchethics.php.en) or the Associate ProVC for Research Governance. If your study is a clinical trial, or if you are in the process of developing a clinical trial (either a CTIMP or involving a complex intervention) or if your study involves a food supplement, medical device, we advise you to seek the advice of the Director or the CTU Manager at [NWORTH](https://nworth-ctu.bangor.ac.uk/staff.php).

The pro forma below should really be web-based as a facility on the university’s Research Governance pages.

| **Section A** | (for all studies) |
| --- | --- |
| Principal Investigator/e-mail: |  |
| Co-investigators/e-mails: |  |
| Study Title |  |
| Study Acronym |  |
| Study Start Date |  |
| Study End Date |  |
| School/College |  |

|  |
| --- |
| 1. Please indicate why you need a Letter of Sponsorship |
| Tick (as applicable) |
|  | NHS/Social Care Research Ethics review |
|  | Funding application |

|  |
| --- |
| 2.Please provide a brief summary of your study and its objectives (max.50 words) |
|  |

|  |
| --- |
| 3. Please provide details of the study funding and dates of award. |
| Tick | Source | Value (£) | Dates of Grant application Submission/Award |
|  | Internally Funded. |  |  |
|  | NIHR. |  |  |
|  | MRC |  |  |
|  | ESRC |  |  |
|  | NERC |  |  |
|  | EPSRC |  |  |
|  | AHRC |  |  |
|  | WELLCOME |  |  |
|  | HCRW |  |  |
|  | Charity - please state: |  |  |
|  | Other - please state: |  |  |

|  |
| --- |
| 4. Please summarise any research governance policies, guidelines or regulations relevant to the safe completion of the study (e.g. UK Policy Framework for Health and Social Care Research, Good Clinical Practice, MHRA Medicines for Human Use (Clinical Trials) Regulations 2004 No.1031/ MHRA Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019) and provide details of any external approvals not yet in place (e.g. NHS R&D , ethical review by an NHS/Social Care Research Ethics Committee).(Sponsorship is only provided on the strict condition that neither participant recruitment nor data collection begin before all necessary permissions and approvals are in place.) |
|  |

|  |
| --- |
| 5. Which NHS/Social Care Research Ethics Committee (if it has been already allocated) will you be submitting to? (Provide the administrator name and contact details.) |
|  |

| 6. Have you consulted the Bangor University’s insurers, UMAL, in relation to any indemnity issues raised by your study? | Yes | No |
| --- | --- | --- |

| 7. Please outline the data management and security arrangements (e.g. in relation to GDPR) for your study (max. 50 words). Please attach any data sharing agreements. If the application involves a clinical trial, please also attach the data management plan  |
| --- |
|  |

| 8. Please outline any potential issues or risks to the university as sponsor (max. 50 words) |
| --- |
|  |

| Applicant/Chief Investigator |
| --- |
| Name:  |
| School/College: |
| Signature:…………………………………………………… |
|  Date:  |

| **Section B (for clinical trials)** |
| --- |
| If your trial is a Clinical Trial of an Investigational Medicinal Product (CTIMP), a clinical trial of a medical device or complex intervention, please complete the following: |
|  | Yes | No | N/A |
| 1. Is your study being supported by Bangor University’s North Wales Organisation for Randomised Trials in Health (NWORTH)? |  |  |  |
| 2. If not NWORTH, provide the name and registration number of the CTU |  |
| Name:  |
| Name of Director: |
| Address and contact details: |
| CTU website: |  |  |  |
| 3. Is the CTU accredited by the [UK Clinical Research Collaboration](https://www.ukcrc.org/about-the-ukcrc/what-is-the-ukcrc/)? |  |  |  |
| 4. Please indicates which accreditations/services your CTU is supporting? (e.g. statistics, IT, data management, randomisation, trial management, pharmacovigilance, quality assurance etc). |  |  |  |
| 5. Will your trial be supported by NIHR’s [Clinical Research Network](https://www.nihr.ac.uk/explore-nihr/support/clinical-research-network.htm)? |  |  |  |
| 6. Which publicly accessible database will your clinical trial be registered with? (e.g. ISRCTN, ClinicalTrials.gov or the EU Clinical Trials Register) |  |
| 7. Who has been appointed the sponsor representative at BU? |
| Name: |  |  |  |
| Position:  |  |  |  |
| Contact details |  |  |  |
| 8. If your trial is a CTIMP, will you use the HRA's [Combined Review](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-ways-working-pilot/) facility? |  |  |  |
| 9. If your trial is a CTIMP, please provide the Eudract No. ISRCTN number: |  |
| 10. If your trial involves a medical device, is it registered with the [MHRA](https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device)? |  |  |  |
| 11. Please confirm you have provided the following |  |  |  |
| (a) a trial protocol |  |  |  |
| (b) a scientific evaluation of the protocol |  |  |  |
| (c) letter of support by your CTU, signed by director/ CTU manager |  |  |  |
| (d) any necessary MHRA registrations or correspondence with MHRA |  |  |  |
| (e) collaboration agreements |  |  |  |
| (f) data sharing agreements  |  |  |  |
| (g) a financial costing (or evidence of secured funding) |  |  |  |
| (h) a Certificate of Insurance |  |  |  |
| (i) a risk assessment |  |  |  |

| Applicant/Chief Investigator |
| --- |
| Name:  |
| School/College: |
| Signature:…………………………………………………… |
|  Date:  |

| **Section C (for directors of research)** |
| --- |
| Risk-based assessment for sponsorship. Assess the application for sponsorship against the sponsorship roles listed above as 2(a) through (i). Please keep in mind that the assessment should reflect (a) the likelihood that the study can be successfully completed as proposed and (b) that the assessment should be proportionate against the seriousness of any safety, time or cost concerns. |

| Research Question. Does the study/trial address an answerable and important question? Does it address a clear gap in the evidence base? Will its outcome have a significant impact in scientific, clinical or terms? (If the application involves a PGT MSc student project, it is legitimate to include the positive (or negative) educational/training benefits.)  |
| --- |
|  |

| Team: Has an appropriate research team been assembled? Does it have the appropriate expertise, mix of skills and capacity to complete the study/trial as planned? If the application involves a clinical trial, has a sponsor representative been appointed? |
| --- |
|  |

| Feasibility. How feasible is the study/trial? Is the methodology, number of sites (if a clinical trial), timeframe, and recruitment plan appropriate? Has any pilot work already been undertaken? Is there a need to complete any pilot work? |
| --- |
|  |

| Funding/finances – is there adequate funding to complete the study? If the application involves a clinical trial prior to a funding application, how well does the proposal fit with the intended funding scheme? Is there an identified source of funding and what are the chances of success? Is there evidence that the CTU (NWORTH or external) has the resources to support the study?  |
| --- |
|  |

| Permissions/agreements etc. Are the necessary permissions in place? Is there sufficient evidence of compliance with relevant regulatory policies, guidelines or regulations? If the application involves a clinical trial, are the agreements with collaborators, services or manufacturers appropriate? Are there IPR issues? |
| --- |
|  |

| Ethics. Are the plans for ethical review appropriate? Are there any reasons to suppose that the application might not be given a favourable opinion (e.g. by an NHS/Social Care Research Ethics Committee)? Are there any significant risks of serious harm to participants or staff? If a clinical trial, is a Certificate of Insurance available? |
| --- |
|  |

| Data management. Are the arrangements for data confidentiality and data management appropriate? If the study involves access to NHS data, does the study use the DSP toolkit? If the application involves data sharing (e.g. in the context of a clinical trial), are the data-sharing agreement agreements in place with collaborators or external partners appropriate? Has the data sharing agreement been agreed with the governance team? |
| --- |
|  |

| Risks. Are you sufficiently confident that the study can be safely completed as proposed? Have the identified risks been adequately addressed? Have you identified any new ones that need addressing? Is there a risk of significant reputational damage to the university if the study/trial fails or is substantially delayed? Finally, are there any dual-use/security concerns? If the application involves a clinical trial, is the risk-assessment adequate?  |
| --- |
|  |

| School Director of ResearchApprove (Bangor University will act as sponsor)/Reject (delete as appropriate) |
| --- |
| Name:  |
| School/College: |
| Signature:…………………………………………………… Date: |
| For clinical trials, Sponsor representative: |
| Name:  |
| School/College: |
| Signature:…………………………………………………… Date: |
|  |

Robert Rogers, Colin Ridyard, Zoe Hoare, Kirstie Pye

20th March 2023