**Imperial Investigators (College or Trust) should complete this form if they are carrying out any health-related research project and are requesting sponsorship from the Imperial College Research Governance and Integrity Team (Trust or College).**

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| **Sponsorship or Insurance** |
| If Imperial College London is designated the sponsor of your study the project will automatically be registered for Imperial College negligent and non-negligent harm insurance cover.  If Imperial College Healthcare NHS Trust is designated the sponsor of your study **only** the normal NHS indemnity will apply. |
| **Project Details - Please note if this information is incorrect then we will not be able to sponsor the project. The form must be signed by the Chief Investigator to confirm content.** |
| **Faculty:** Choose an item.  **Imperial College London Division/Department (if applicable):** Choose an item.  **Imperial College Healthcare NHS Trust Division (if applicable):** Choose an item.  **Project Title:** Click here to enter text.  **Start date:** Click here to enter a date. **End date:** Click here to enter a date.  **Funding:**  **External Funding Source**:Yes  No  If yes:   * Specify grant holder: Click here to enter text. * Was funding awarded via open competition across England Yes  No * Does study meet [Eligibility for Clinical Research Network](https://www.nihr.ac.uk/documents/eligibility-for-nihr-clinical-research-network-support/23746) Yes  No   **Internal Funding Source:** Yes  No  If yes specify Click here to enter text.  **InfoEd/WorkTribe Reference Number (for funds coming into College) :** Click here to enter text.  (i.e. P00000 (for externally funded projects). Internally funded studies should have a cost code provided)  **College dept. cost codes** **(i.e. WPAR G00000) (for funds coming into College) :** Click here to enter text.  **Trust/Departmental cost code (for funds coming into ICHT):** Click here to enter text.  **Please give name and email of person responsible for signing off the grant budget:**  **Is ICHT a site in this study?** Yes  No  **If Yes, please provide documas number:**  *All studies involving ICHT should have been costed via the Trust JRO and provided a documas reference number.*  **Type of project:**  Medical device study  Investigational Medicinal Product study    Other  Please specify: Click here to enter text.     * **Is this project part of an Imperial College educational qualification: PhD  MSc  No**   **Clinical Trials Unit:**  **Is the Imperial College Clinical Trials Unit (ICTU) being used:** Yes  No  **Is any other Clinical Trials Unit (CTU) being used:** Yes  No Please specify: Click here to enter text.  -        CTU use must be discussed between the study team and the CTU and an appropriate delegation of responsibilities (DoR) must be in place  -        DoR for all CTUs (other than ICTU) should be discussed with the appropriate person from [Imperial JRO Contracts Team](https://www.imperial.ac.uk/research-and-innovation/support-for-staff/joint-research-office/people/)   * For ICTU (CTIMP studies only) – please discuss whether any DoR is needed with [RGIT CTIMP team](mailto:RGIT%20CTIMP%20Team%20%3crgit.ctimp.team@imperial.ac.uk%3e) (not required for Imperial sponsored non CTIMPS)   **Study Equipment:**  **Is any study specific equipment being loaned or gifted to a research site Yes  No**  **If yes provide details here:** Click here to enter text.  **Is the device/equipment being loaned with a contract? Yes  No**  **Are any devices/equipment being purchased for the study without a contract in place Yes  No**  Please specify: Click here to enter text.  **Does the device manufacturer have product liability insurance in place for the medical device/equipment?:**Click here to enter text.  **Guidance notes for equipment for Imperial sponsored studies:**  **For Imperial College London sponsored studies:** If a device is loaned and accompanied with contracts, the College policy would respond if there were any bodily injury resulting from the equipment being defective, but ultimately the manufacturers should be responsible for any defects in the product. This should be stipulated in the contract and coupled with a requirement for the manufacturers to carry products liability insurance, to prevent the College’s insurers being left with liability and no means of recovering the loss from the manufacturer’s insurers.  **For Imperial College London sponsored studies** - In the absence of any contracts, the master policy would initially respond to claims for bodily injury resulting from participation in the study. If it is determined that the bodily injury was due to a defect in the product, insurers would be able to subrogate against the manufacturer’s insurers for the value of the loss.  **For Imperial College Healthcare NHS Trust (ICHT) sponsored studies** where there is harm as a result of fault in equipment, liability would lie with the manufacturer and NHS indemnity would not apply. However, NHS indemnity may apply if the investigator continued to use equipment they knew to be faulty. NHS liability may apply if the equipment was manufactured by ICHT as part of the research.  Any device/equipment that is publicly available and purchased should be covered by product liability. If the equipment is not the subject of the research then the MIA may cover the equipment use. Please find details here: <https://www.hra.nhs.uk/about-us/news-updates/use-master-indemnity-agreement-research-updated-dh-guidance/> |
| **Chief Investigator Contact Details**  **This is key information on who sponsors the study and must be confirmed directly with CI/PI** |
| Name: Click here to enter text.  Work Address: Click here to enter text.  Email: Click here to enter text. Telephone:Click here to enter text.  Substantive Employer: Choose an item. Specify if other: Click here to enter text.  Honorary Contract Employer (if applicable): Choose an item. Specify if other: Click here to enter text. |
| **Principal Investigator at ICHT Contact Details (if different from CI)** |
| Name: Click here to enter text.  Work Address: Click here to enter text.  Email: Click here to enter text. Telephone: Click here to enter text. |
| **Location of Research** |
| **Imperial College Healthcare NHS Trust Site:**  *Click boxes as appropriate:*  St Mary’s Hospital  Hammersmith Hospital  Charing Cross Hospital  Queen Charlotte’s Hospital  Western Eye Hospital  **Imperial College London Campus:**  *Click boxes as appropriate:*  St Mary’s Campus  Hammersmith Campus  White City  Charing Cross Campus  NW London Campus  Royal Brompton Campus  Chelsea and Westminster Campus  **Specify ALL other sites (UK and abroad):**  Click here to enter text.  **Participant Identification Centres (see** [IRAS](https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#PIC) guidance) for definition of PIC**:**  Click here to enter text. |
| **Brief Summary of Study – attach separate sheet if necessary**  (**Must** include details of any clinical procedures human subjects will undergo, including any imaging).  Click here to enter text. |
| **Participant Information** |
| **Participant Type:** Choose an item. **Anticipated Number of Participants:** Click here to enter text.  **Will your research involve:**  *Click boxes as appropriate:*  Pregnant women  Children under five  Genetic engineering  Contraceptives  Administration or use of medicinal substances, devices or equipment manufactured  by Imperial College  Overseas sites  More than 5000 participants (Interventional study only)  **Will any of the research participants have the following conditions\*:**  *Click boxes as appropriate:*  HIV  Hepatitis  CJD  **\***Imperial College London policy does not exclude trials with participants enrolled with these conditions, but  excludes participants from contracting these conditions as a result of participation in the programme, e.g. through unintentional needle sharing. For Imperial College London sponsored studies [specific insurance wording](https://www.imperial.ac.uk/research-and-innovation/support-for-staff/research-governance-and-integrity-team/project-planning/insurance/) needs to be included on the participant information sheet.    **PLEASE NOTE**: If you check any boxes above please provide full details of the proposed involvement on a separate page as approval may be required from the College’s Insurers before ‘no fault’ cover can be provided |
| **Additional Details** |
| Are there any other factors that should be brought to the Insurer’s attention? If so, please specify.  Click here to enter text. |
| **Signed by Chief Investigator:**  **…………………………………………………. Date ………………………………………..** |
| **To be completed by RGIT only**  Designated Sponsor organisation:  Imperial College London  Imperial College Healthcare Trust  Other (please specify) Click here to enter text.  Referral to Insurance Manager: Yes  No  If Yes please specify date: Click here to enter a date.  RGIT Staff member: |

This declaration of information is required to streamline information flows between College and Trust units. It is important to ensure the study is sponsored by the correct legal organisation and is required by the College’s Insurers to confirm insurance for the study.