# **RESEARCH ASSISTANT**



Job Title:	CTU Research Assistant (Trial Manager)
Department:	Non-Communicable Disease Epidemiology
Faculty:	Epidemiology and Population Health
Location:	Keppel St, London
FTE:	1.0 FTE
Grade:	G5
Accountable to:	Richard Evans (Senior Manager of the CTU)
Job Summary:	<ul> <li>To play an active role in the conduct and management of studies conducted by the Clinical Trials Unit.</li> <li>To oversee day to day management of clinical trials, in particular the ARREST and CHIP-BCIS3 trials, and to support a team of data managers and assistant trial managers in liaison with the Senior Manager of the CTU.</li> <li>To represent the Clinical Trials Unit in meetings with collaborators and funders.</li> </ul>

#### **GENERAL INFORMATION**

#### The London School of Hygiene & Tropical Medicine

The London School of Hygiene & Tropical Medicine (LSHTM) is renowned for its research, postgraduate studies and continuing education in public and global health.

Our mission is to improve health and health equity in the UK and worldwide; working in partnership to achieve excellence in public and global health research, education and translation of knowledge into policy and practice.

We embrace and value the diversity of our staff and student population and seek to promote equity, diversity and inclusion as essential elements in contribution to improving health worldwide. We believe that when people feel respected and included, they can be more creative, successful, and happier at work. While we have more work to do, we are committed to building an inclusive workplace, a community that everyone feels a part of, which is safe, respectful, supportive and enables all to reach their full potential.

#### History

Founded in 1899 at the London Docks, LSHTM is now based in Bloomsbury, where it has two main sites at Keppel Street and Tavistock Place, and additional sites in The Gambia and Uganda. Today, our staff, students and alumni work in government, academia, international agencies and health services across the world. Learn more about the history of LSHTM.

#### Research

Research income has grown to more than £180 million per year from national and international funding sources including UK government and research councils, the European Union, the Wellcome Trust, Gates Foundation and other philanthropic sources.

Our diverse research talents, skills and experience underpin our position as a leader in public and global health. These range from the molecular to the global, the theoretical to the applied, the analytical to the political. Our staff are conducting research in more than 100 countries.

#### Staff community

We have 3,300 staff based all around the world with core hubs in London and at the MRC Units in The Gambia and Uganda, which joined LSHTM in February 2018. Our outstanding, diverse and committed staff make an impact where it is most needed - deploying research in real time in

response to crises, developing innovative programmes for major health threats, or training the next generations of public and global health leaders and researchers.

#### **Partnerships**

Working in partnership is central to achieving our mission. Our strategic collaborations in the UK and across high-, middle- and low-income countries deliver health and socioeconomic benefits across the world, especially in the most disadvantaged communities.

LSHTM is also a member of the M8 Alliance of Academic Health Centers, Universities and National Academies, the Association of Schools of Public Health in the European Region, and the Consortium of Universities for Global Health.

#### Education

We deliver research-led educational programmes to future health leaders, managers and researchers across the world. We have more than 1,200 face-to-face Master's and Doctoral students, 3,000 studying by distance learning, and 1,000 each year on short courses and continuous professional development. Our free online courses are studied by more than 270,000 participants globally.

#### Excellence in research and education

We perform strongly in various global university league tables. In the Shanghai Ranking's Global Ranking of Academic Subjects 2020 we placed 3rd in public health (1st in the UK). In the 2020 CWTS Leiden Ranking LSHTM is ranked the UK's top university for the proportion of academic research with women listed as authors, and third in Europe for publishing open access research.

In the US News Best Global Universities Ranking 2021, we ranked 3rd in the world for public, environmental & occupational health, 4th in the world for infectious diseases, 11th in the world for social sciences & public health, and 12th best University in the UK overall. We ranked 27th for medicine in the 2019 QS World University Rankings.

In 2017, the inaugural Center for World University Rankings by Subject placed LSHTM first in the world for tropical medicine research, second for parasitology and seventh for infectious diseases, public, environment and occupational health, and social sciences and biomedical.

LSHTM was named University of the Year 2016 by Times Higher Education and awarded a Queen's Anniversary Prize for Higher and Further Education in 2017 in recognition of our response to the 2014 Ebola epidemic in West Africa. LSHTM does not appear in the Times Higher Education World University Rankings as universities are excluded if they do not teach undergraduates.

We seek to foster and sustain a creative and supportive working environment based upon an ethos of respect and rigorous scientific enquiry. We embrace and value the diversity of our staff and student population and seek to promote equality as an essential element in contribution to improving health worldwide.

LSHTM is one of around 20 specialist institutions that receive institution specific funding from the Office for Students (OfS). This funding recognises the additional costs that LSHTM incurs because of its unique range of teaching, specialist facilities, and the scale of its contributions to national and international agencies.

## FACULTY INFORMATION

The Faculty of Epidemiology & Population Health (EPH) houses a large group of epidemiologists, demographers, statisticians and nutritionists working on issues of major public health importance in the UK and globally. EPH has approximately 400 staff members organised into four research departments.

- Department of Infectious Disease Epidemiology
- Department of Medical Statistics
- Department of Non-communicable Disease Epidemiology
- Department of Population Health

The Faculty has a teaching programme consisting of ten MSc courses: Epidemiology, Demography and Health, Medical Statistics, Public Health in Developing Countries (run jointly with the Faculties of Infectious & Tropical Diseases and Public Health & Policy), Nutrition for Global Health, Reproductive & Sexual Health Research, Veterinary Epidemiology (run jointly with the Royal Veterinary College), Global Mental Health (run jointly with Kings College London -Institute of Psychiatry) and the Distance Learning courses in Epidemiology and Clinical Trials. The Faculty also has approximately 120 research students studying for an MPhil, PhD or DrPH degree.

The Dean of Faculty is Professor Elizabeth Allen.

#### **DEPARTMENT INFORMATION**

The Department of Medical Statistics (MSD) specializes in methodological research in medical statistics, especially in relation to clinical trials, observational epidemiology and disease prevention. A recent development concerns pharmaco-epidemiologic research, both methodological and applied. The Department incorporates a Clinical Trials Research Group (concerned with planning, co-ordination, statistical analysis and reporting of clinical trials), and has a special interest in cardiovascular disease, asthma, HIV and perinatal studies. MSD has established a reputation for being one of the leading innovative centres in Europe for biostatistical methodology relevant to the planning and reporting of medical research.

The Head of MSD is Professor Linda Sharples, and MSD's professors are Neil Pearce, James Carpenter, Elizabeth Allen, Tim Clayton, Stephen Evans, Diana Elbourne, Chris Frost, Nicholas Jewell and Stuart Pocock.

#### **CLINICAL TRIALS UNIT INFORMATION**

The LSHTM Clinical Trials Unit is a world-renowned centre of excellence in the design, conduct, analysis and reporting of clinical trials and a fully registered unit with the UK Clinical Research Collaboration (UKCRC). The CTU is based across both the Department of Public Health (DPH) and the Department of Medical Statistics (MSD). It also has a strong focus on clinical trial methodology, including methods for data monitoring, trial reporting, adaptive designs, non-inferiority trials, surrogate endpoints, multiplicity of data (e.g. subgroup analyses, composite endpoints, repeated measures) and methods for systematic reviews, as well, conducts qualitative research into the views of trial participants. We bring to these processes' extensive knowledge and practical experience of trial co-ordination, gained from holding a respected position within the clinical scientific community. To date this has led to successful collaborations in many clinical fields, including cardiology, emergency care, adult and neonatal respiratory failure, liver disease and reproductive health. The CTU works closely with clinical collaborators at every stage of a trial's design and implementation. This includes the development of the clinical question and trial protocol, preparation of applications for funding and research ethics committee approval, all aspects of data collection and statistical analysis, and submission of results for publication.

The CTU team housed within MSD is strongly established in the field of cardiovascular and renal disease, and in UK-based surgical trials. The CTU has established collaborations with

investigators at King's College London, University College London and Barts Health. It has extensive experience in designing and delivering trials looking at the role of pre-conditioning in various conditions including renal transplantation (REPAIR), patients undergoing cardiac surgery (ERICCA) and patients suffering heart attacks (ERIC-PPCI). There is also a strong research focus on increasing participation in clinical trials, and an extensive programme of randomised trials of public health interventions for example the TXT2STOP smoking cessation trial and the safetxt trial in safer sex behaviour in young adults. The MSD CTU is also building strong collaborations with teams conducting research in Low and Middle-Income Countries (LMIC) in EPH.

The CTU team housed in the Department of Population Health is a specialist in the conduct of large international multi-centre trials. Examples include the MRC CRASH trial (10,000 patients with traumatic brain injury), the CRASH-2 trial (20,000 patients with traumatic bleeding) and the WOMAN trial (20,000 women with post-partum haemorrhage).

Overall, LSHTM currently manages 90+ trials around the world, in a range of interventions such as investigational medicinal products (IMPs), nutritional and macronutrient studies, public health and behavioural interventions, surgery and medical devices.

The portfolio of duties outlined below will vary in accordance with the detailed expectations of the role (attached), which may be varied from time to time, and agreed at your annual Performance and Development Review (PDR).

## JOB DESCRIPTION

## Main Activities and Responsibilities

## KNOWLEDGE GENERATION

- 1. To undertake high quality research as directed by your line manager, including contributing to drafting grant proposals and peer-reviewed and other outputs, and evaluating teaching practice;
- 2. To support the administration of projects linked to your employment, helping ensure compliance with good practice in relation to the conduct of research, the ethics policy, and other relevant School policies;
- 3. To coordinate clinical trials run by the MSD CTU, in particular the BHF PROTECT-TAVI trial.

## EDUCATION

- 1. To participate in some aspects of the School's Education Programme or educational outreach activities;
- 2. To contribute to the MSD Essentials of Clinical Trials Short Course

## INTERNAL CONTRIBUTION

- 1. To undertake activities that support the Department, Faculty, MRC Unit or the School;
- 2. To reflect LSHTM's EDI goals in your work and behaviour;
- 3. To participate in the School's PDR process;

## EXTERNAL CONTRIBUTION

1. To demonstrate good external citizenship by supporting the external academic and practice communities;

## PROFESSIONAL DEVELOPMENT & TRAINING

- 1. To keep up-to-date with the latest research / thinking in your academic field and with changes to pedagogic practice within the School and more generally;
- 2. For lab-based disciplines: where the length and nature of the position permits, to apply for and, if accepted, undertake a doctoral degree (if not already acquired);
- 3. To undertake and successfully complete the mandatory training required by the School as appropriate to the role;
- 4. Maintain a working knowledge of current trial relevant SOPs and ICH GCP guidelines

## GENERAL

All academic staff are free within the law to question and test received wisdom, and put forward new ideas and controversial or unpopular opinions, to enable the School to engage in research and promote learning to the highest possible standards.

All staff at LSHTM are also expected to:

- 1. Act at all times in the School's best interests;
- 2. Treat School staff, students and visitors with courtesy and respect at all times;
- 3. Comply fully with School policies, procedures and administrative processes relevant to the role;
- 4. Uphold and support the School's values (as set out in the School Strategy);
- 5. Act as ambassadors for the School when hosting visitors or attending external events;

The above list of duties is not exclusive or exhaustive and the role holder will be required to undertake such tasks as may reasonably be expected within the scope and grading of the role.

Role descriptions should be regularly reviewed to ensure they are an accurate representation of the role.

# PERSON SPECIFICATION

This form lists the essential and desirable requirements needed by the post holder to be able to perform the job effectively.

Applicants will be shortlisted solely on the extent to which they meet these requirements.

## ESSENTIAL CRITERIA:

- 1. MSc degree either awarded or imminent, or equivalent experience / training.
- 2. Relevant experience in managing a clinical trial.
- 3. Evidence of good organisational skills, including effective time management.
- 4. Proven ability to work independently, as well as collaboratively as part of a research team.
- 5. Evidence of excellent interpersonal skills, including the ability to communicate effectively both orally and in writing
- 6. Relevant computer skills, particularly in Microsoft Office.
- 7. A good understanding of ICH Good Clinical Practice and UK regulatory requirements governing clinical trials.

## DESIRABLE CRITERIA

- 1. Some experience of teaching
- 2. Experience of gaining and managing regulatory approvals in clinical research.
- 3. Experience working as part of a Clinical Trials Unit or similar organisation.

## SALARY AND CONDITIONS OF APPOINTMENT

The post is fixed-term and full-time, funded for 12 months and is available from 1 August 2022 or possibly earlier.

The salary will be on the Academic scale, Grade 5 scale in the range £35,377 - £40,611 per annum (inclusive of London Weighting). The post will be subject to the LSHTM terms and conditions of service. Annual leave entitlement is 30 working days per year, pro rata for part time staff. In addition to this there are discretionary "Wellbeing". Membership of the Pension Scheme is available.

Applications should be made on-line via our website at <u>http://jobs.lshtm.ac.uk</u>. Applications should also include the names and email contacts of 2 referees who can be contacted immediately if shortlisted. Online applications will be accepted by the automated system until 10pm of the closing date. Any queries regarding the application process may be addressed to jobs@lshtm.ac.uk.

The supporting statement section should set out how your qualifications, experience and training meet each of the selection criteria. Please provide one or more paragraphs addressing each criterion. The supporting statement is an essential part of the selection process and thus a failure to provide this information will mean that the application will not be considered. An answer to any of the criteria such as "Please see attached CV" will not be considered acceptable.

Please note that if you are shortlisted and are unable to attend on the interview date it may not be possible to offer you an alternative date.

#### **ASYLUM AND IMMIGRATION STATEMENT**

The School will comply with current UKVI legislation, which requires all employees to provide documentary evidence of their legal right to work in this country prior to commencing employment. Candidates will be required to email a copy of their passport (and visa if applicable) to HR prior to their interview and if appointed will be asked to bring the original documents in to be copied and verified before their start date.

Applications from candidates who require sponsorship to work in the UK will be considered alongside other applications. Applicants who do not currently have the right to work in the UK will have to satisfy UK Visas & Immigration regulations before they can be appointed.

Further information about Sponsorship and eligibility to work in the UK, can be found at: <a href="https://www.gov.uk/guidance/immigration-rules/immigration-rules-appendix-skilled-worker">https://www.gov.uk/guidance/immigration-rules/immigration-rules/immigration-rules-appendix-skilled-worker</a>

Date amended: JUL 2021

## Academic Expectations: Research Assistant

Examples of expected types of activities are listed; the selection of activities will vary from year to year and not all activities in each category would necessarily be done in any one year. The statement in each shaded heading summarises the general expectations for contributions in each category. Research Assistants employed on research projects will be expected to focus on Knowledge Generation, in accordance with their job description, but some activity in other areas is required and will support career progression. Research Assistants predominantly employed to support Education will be expected to have more limited contribution to Knowledge Generation, again as reflected in their job description.

**Knowledge generation:** High quality support for, and contribution to, knowledge generation

Research and scholarship

- Undertaking research, as directed by line manager
- Contributions to funding applications including supporting more senior staff in completing applications
- Contributing to peer-reviewed and other research outputs as expected by the subject area/discipline in terms of types of output
- Poster/oral presentations at conferences
- Social media contributions such as twitter, blogs, web-based media or webinars

Reflective practice and critical enquiry (RPaCE)

- Participating in RPaCE
- Disseminating learning and experiences through presentations to colleagues

Doctoral degree supervision

 None expected though involvement in advisory activities/roles or provision of practical skills training is encouraged where relevant

Research management, leadership and support

- · Effective management of own time and activities
- Supporting the administration of projects he/she is employed on, eg taking meeting minutes

Professional development

- · Appropriate courses and other development activities, referenced to RDF
- Especially for lab-based disciplines: where the length, nature and funding source of the position permit, to apply for and, if accepted, undertake a doctoral degree (if not already acquired).

Education: Participation in educational activities<sup>1</sup>

Teaching and assessment

 Participation in some aspects of the School's Education Programme or education outreach activities e.g. contributions to taught courses, research methods training, mentoring school pupils on outreach programmes

Educational development and innovation

• Contributions to educational innovations or developments, e.g. helping to update the content or delivery of a course or module

Educational leadership and management

None expected

Professional development

• Formal study/training and/or other activities that develop educational knowledge and expertise, referenced to UKPSF; working towards Associate Fellow HEA

Internal contribution: Support to the academic environment in the Department or beyond

Internal citizenship including contributing to supportive academic environment

 Supporting Department/Faculty/Centre/School events or special interest groups; organising seminars/lab meetings/journal clubs; group or departmental social organising; support to EDI activities including Athena Swan; support to external partnerships

General leadership and management roles

None expected

External contribution: Support to the external academic community

External citizenship

- Involvement in journal or book reviews, if opportunities arise
- Sharing examples of good practice (e.g. contributing to discipline-specific interest group or professional bodies)

Knowledge translation and enterprise: not expected but options include

- Collection of evidence of research impact for impact case studies (e.g. policy records, correspondence with policy makers, media highlights)
- Engagement with policy/practice/industry/NGO communities and with the general public

<sup>&</sup>lt;sup>1</sup> it is accepted that some RA roles and/or funding make it difficult to give time to Educational activities, but some degree of engagement is encouraged