Ollscoil na Gaillimhe
University of Galway

# Validation Officer, Grade 5

## College of Medicine, 1 FTE, SPC

## Ref #: 010278

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| **Unit** | College of Medicine |
| **Post Title & Subject Area** | Validation Officer, College of Medicine |
| **Post Duration** | Specific Purpose Contract |
| **Level** | Grade 5 |
| **Reports to** | Head of Programmes, Institute for Clinical Trials |

1. **Job Advertisement**

Applications are invited for an appointment as Validation Officer (1 FTE, Grade 5) at CORRIB Research Centre for Advanced Imaging and Core Laboratory and HRB-Clinical Research Facility Galway [HRB-CRFG] at University of Galway.

This post is being offered as a specific purpose contract and will terminate by reason of the expiry of its specific purpose. It is anticipated that the duration of this assignment will be circa 1 year.

The purpose of this role is to lead the validation processes required to verify that the rights and well-being of research participants are protected and that the integrity of the trial data is upheld. The role will be working within a highly qualified team to support the running of Clinical Research, providing Computer System Validation (CSV) and process validation expertise to the CORRIB Research Centre for Advanced Imaging and Core laboratory and the HRB-Clinical Research Facility. This will be achieved by establishing and maintaining key Computer System Validation Processes aligned to a quality management system, reviewing existing electronic systems, advising on the implementation of new systems and effecting CSV and process validation procedures for the units.

The post-holder will report directly to the Head of Programmes, Institute for Clinical Trials, working closely with the Quality Manager(s), Programme Manager(s), Data Management team and Clinical Operations Lead(s).

This is a full time role. Flexible working hours to fulfil the contract hours and the option for hybrid working, in line with University policies, will be considered for this role.

For informal enquiries, please contact CorribCLABfinance@universityofgalway.ie.

Additional information on the CORRIB Research Centre & Core Lab is available at: Corrib Core Lab - University of Galway

Additional information on HRB-CRFG is available at: https://www.universityofgalway.ie/hrbcrfg/services/clinicalresearch/

Information on the University's Strategic Plan is available at: Strategy | Straitéis 2020-2025 - University of Galway

**Salary: €57,931 to €78,536 p.a. pro rata if part time** (applicable to new entrants effective from January, 2011) and in accordance with the terms and conditions of the University's Remuneration policy.

This appointment will be made on the Grade 5 scale in line with current Government pay policy.

**Closing date for receipt of applications is 17:00 (Irish Time) on Thursday, 18th April 2024. It will not be possible to consider applications received after the closing date.**

Garda vetting may apply.

Appointments will be conditional on work authorisation validation. Further details are available at www.dbei.ie

For more information and Application Form please see Jobs - University of Galway
Applications should be submitted online.

Please note that appointment to posts advertised will be dependent upon University approval, together with the terms of the Employment Control Framework for the higher education sector.

University of Galway is an equal opportunities employer.

## 2. Role Relationships

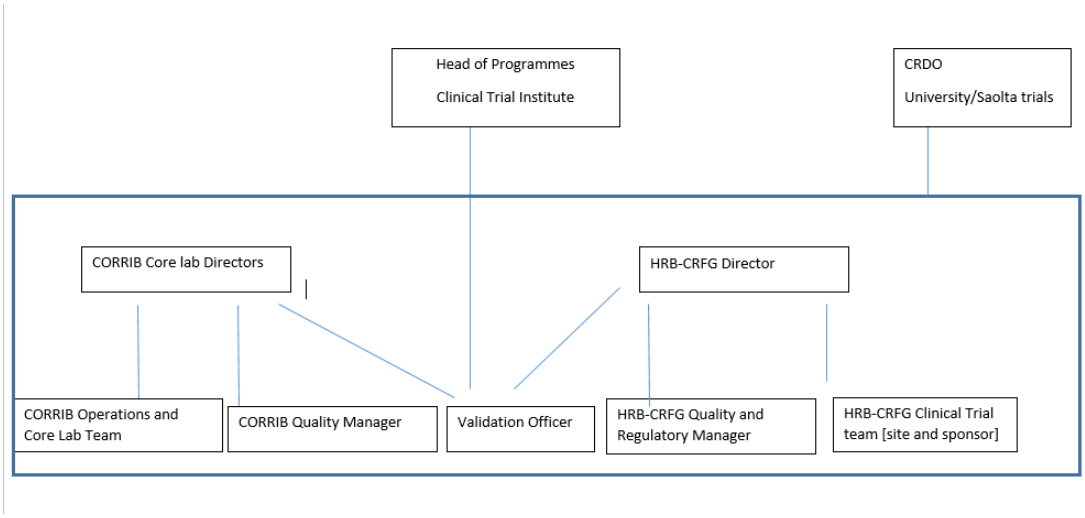
The holder has specific job contact with:

- Quality Managers CORRIB Research Centre and HRB-CRFG
- Director(s) of CORRIB Research Centre and HRB-CRFG
- Senior Members of CORRIB Research Centre and HRB-CRFG (Clinical Trials Programme Manager, Clinical Research Operations Lead, Biometrics Unit Lead)
- Statisticians at HRB-CRFG and CORRIB Research Centre & Core Lab
- CORRIB Research Centre and HRB-CRFG Trial Coordination team members (e.g. senior trial coordinators/project managers, data management/development team, IT officer etc.)
- CORRIB Research Centre & Core Lab Academic Team, students (post graduate) and research fellows
- Clinical Research and Development Office (CRDO)
- Professional Services staff at University of Galway and/or Saolta Health Care Group

S/He has general contact with:

- Director of Strategic Development, College of Medicine, Nursing and Health Sciences
- Director of Risk and Internal Audit, University of Galway
- HR and Finance Business Partners, College of Medicine, Nursing and Health Sciences
- Other University Offices including but not limited to the Office of the Registrar and Deputy President, Buildings Office, Research Office, Research Accounts, Procurement, Information Systems and Solutions, Human Resources, International Affairs.

Organisation chart



## 3. Main Purpose of Job

The purpose of this role is to lead the Computer System Validation (CSV) and process validation processes required to conduct clinical research in the CORRIB Research Centre for Advanced Imaging and Core laboratory and the HRB-CRFG in a regulatory compliant manner.

The role will support both the CORRIB Core Lab and Research Centre and HRB-CRFG and the role will work with both teams under the appropriate directorship to support the CSV needs within the units. The role is overseen by the Clinical Trials Institute and Head of Programmes.

Flexible working hours to fulfil the contract hours and the option for hybrid working will be considered for this role in line with appropriate policy requirements.

## 4. Main Duties and Responsibilities

- The role will support both the CORRIB Core Lab and Research Centre and HRB-CRFG and the role will work with both teams under the appropriate directorship to support the Computer System Validation (CSV) needs within the respective units, to support quality assurance of our clinical research programmes.
- Deliver expertise and lead on all validation processes for the units including CSV processes and process validation as required. This includes validation of imaging and analysis software, image transfer systems, Electronic Data Capture (EDC) systems and software, randomisation software, electronic document management systems, study management systems, and aspects of data validation., , as they apply to the processes, software, electronic systems and equipment in the associated research programme.
- Lead and coordinate multiple validation and qualification activities with various research units and external vendors taking a risk based approach to validation.
- Lead creation of user requirements specifications, technical specifications and validation reports in accordance with regulatory requirements.
- Maintain validation processes within the quality system in collaboration with QA personnel to ensure that studies carried out in the CORRIB Research Centre and HRB-CRFG are conducted in accordance with Good Clinical Practice (GCP) standards, national and international legislation and meet the quality needs of unit personnel.
- Adherence to the requirements of GCP, ISO 14155, GDPR and all associated regulatory, ethical and legislative requirements in the execution of the research programme.
- Coordinate and deliver mandatory Computer System validation training for unit staff, including CSV training as required.
- Monitoring the validated state of all systems that require validation and working with the Quality Manager to ensure that they are validated, and maintained in a validated state, according to the SOPs
- Manage the CSV change control process and controlled software installation and updates relating to clinical research in associated units.
- Managing the validation of the functional aspects of the system such as installation, database connection etc.

- Contribute to the implementation and oversight of security protection for associated systems.
- Develop, review and approve computer system policies and procedures ensuring compliance with cGMP's, lab policies and procedures and regulatory requirements (21 CFR Part 11, Annex 11)
- Implement continuous improvement to associated processes as required.
- Contribute to associated procurement activities as required.
- Support regulatory inspections and internal audits.
- Contribute to the investigation of associated non-conformances and implementation of corrective and preventative actions.
- Undertake additional team tasks as agreed, to support effective running of the CORRIB Research Centre and HRB-CRFG.
- Any other duties that arise within the ambit of the post.

## 5. Requirements for the role:

The successful candidate will demonstrate the eligibility requirements below in terms of qualification, skills and experience:

**Clinical Trial Activity:**

CORRIB and HRB-CRFG specialise in clinical trial activities. These clinical trials frequently require delivery of the role of the legal Sponsor per ICH-GCP. Appropriate oversight of regulated clinical trials is mandated per applicable legislation, in accordance with ICH-GCP, ISO14155 (Clinical investigations of medical devices for human subjects – Good Clinical Practice), Clinical Trials Regulation (CTR) and Medical Device Regulation (MDR). Knowledge of these standards and regulations is desirable.

The role requires a competency for validation processes and in particular CSV. The role requires a candidate who can consistently deliver high quality activities with meticulous attention to detail, using standardised and efficient processes under a regulatory and legislative framework. The role requires a candidate who can lead and work autonomously on process development, implementation and management and also someone who is a strong team player.

**Essential Requirements**

- Bachelor's degree in a scientific, engineering or health care field, or equivalent experience
- Minimum of 4 years' experience of working within a regulated quality management system in a similar or related role(s) working under a quality system framework and ideally with computer systems validation associated activities. (e.g. medtech, biomedical, pharmaceutical industry.)
- Extensive knowledge of validation deliverables associated with each step of the computer system life cycle including FDA and European compliance regulations and GAMP guidelines applicable to computer system validation.
- The role requires a candidate who can lead and work autonomously on process development and implementation and management and also someone who is a strong team player.
- Experience in the delivery of training
- Excellent oral and written communication skills
- Excellent organizational and interpersonal skills

- **Desirable Requirements**
- Experience working in quality assurance, risk management, audit and/or regulatory inspection
- Knowledge of Clinical Data Management systems [CDMS] and related software eg. idatafax,RedCap, CASTOR
- Project Management skills
- Knowledge of clinical research practices and standards
- ICH-GCP and/or ISO 14155 Training

## 6. Application

**Existing University of Galway employees**

If you are an existing University of Galway employee, please use the University of Galway Core Portal to apply for this post. The following is a link to the Core Portal http://ess.universityofgalway.ie

Core Portal user guides can be found at https://www.universityofgalway.ie/human-resources/employeeselfservice/

Please ensure that you read the attached guide prior to applying for this post and allow sufficient time to make your online submission in advance of closing date.

Please note that closing dates/ times cannot be extended for user error. Unfortunately, late applications cannot be accepted.

Agency Workers who meet the eligibility criteria for support posts should contact recruit@universityofgalway.ie for access.

Employment permit restrictions apply for this category of post.

The completed application document must be submitted online to reach the Human Resources Office no later than Thursday, **18th April 2024**.

**B. All applicants will receive an acknowledgement of application.**

If you do not receive an acknowledgement of receipt of your application or if you have any other queries regarding the application process please contact recruit@universityofgalway.ie or telephone 091-492151.

**C. Incentivised Scheme for Early Retirement (ISER):**

It is a condition of the Incentivised Scheme for Early Retirement (ISER) as set out in Department of Finance Circular 12/09 that retirees, under that scheme, are debarred from applying for another position in the same employment or the same sector. Therefore, such retirees are ineligible to apply for this position.

**D. Pension Entitlements:**

This is a pensionable position. Details of the applicable Pension Scheme will be provided to the successful candidate. The Pension element of this appointment is subject to the terms and conditions of the Pension scheme currently in force within the University. This Scheme may be amended or revised by the Irish Government or its agents at any time.

The Public Service Superannuation (Miscellaneous Provisions) Act 2004 set a minimum retirement age of 65 and removed the upper compulsory retirement age for certain New Entrants to the Public Sector on or after 1 April 2004. Effective from 1st January 2013, The Single Public Service Scheme applies to all first-time new entrants to the public service, as well as to former public servants returning to the public service after a break of more than 26 weeks.

Retirement age set, initially, at 66 years; this will rise in step with statutory changes in the State Pension Contributory (SPC) age to 67 years in 2021 and 68 years in 2028.

Compulsory retirement age will be 70.

**E. Declaration:**

Applicants will be required to declare whether they have previously availed of a public service scheme of incentivised early retirement. Applicants will also be required to declare any entitlements to a Public Service pension benefit (in payment or preserved) from any other Public Service employment and/or where they have received a payment-in-lieu in respect of service in any Public Service employment.

**F. Collective Agreement: Redundancy Payments to Public Servants:**

The Department of Public Expenditure and Reform letter dated 28th June 2012 to Personnel Officers introduced, with effect from 1st June 2012, a Collective Agreement which had been reached between the Department of Public Expenditure and Reform and the Public Services Committee of the ICTU in relation to ex-gratia Redundancy Payments to Public Servants. It is a condition of the Collective Agreement that persons availing of the agreement will not be eligible for re-employment in the public service by any public service body (as defined by the Financial Emergency Measures in the Public Interest Acts 2009 – 2011) for a period of 2 years from termination of the employment. Thereafter the consent of the Minister for Public Expenditure and Reform will be required prior to re-employment. People who availed of this scheme and who may be successful in this competition will have to prove their eligibility (expiry of period of non-eligibility) and the Minister's consent will have to be secured prior to employment by any public service body.

Please refer to Revenue circular (www.revenue.ie/en/about/foi/s16/income-tax-capital-gains-tax.../05-05-19.pdf) for information on revised tax arrangements which may apply on rehire if you have previously received a redundancy payment from University of Galway.

**G. Department of Health and Children Circular (7/2010):**

The Department of Health Circular 7/2010 dated 1 November 2010 introduced a Targeted Voluntary Early Retirement (VER) Scheme and Voluntary Redundancy Schemes (VRS). It is a condition of the VER scheme that persons availing of the scheme will not be eligible for re-employment in the public health sector or in the wider public service or in a body wholly or

mainly funded from public moneys. The same prohibition on re-employment applies under the VRS, except that the prohibition is for a period of 7 years, after which time any re-employment will require the approval of the Minister for Public Expenditure and Reform. People who availed of either of these schemes are not eligible to compete in this competition.

**H. Declaration:**

Applicants will be required to confirm whether they have previously availed of a public service scheme of incentivised early retirement and/or the collective agreement outlined above. The above represents the main schemes and agreements restricting a candidate's right to be re-employed in the public service. However it is not intended to be an exhaustive list and candidates should declare details of any other exit mechanism they have availed of which restricts their right to be re-employed in the public service. Applicants will also be required to declare any entitlements to a Public Service pension benefit (in payment or preserved) from any other Public Service employment and/or where they have received a payment-in-lieu in respect of service in any Public Service employment.

**I. Annual Leave**

For those existing employees who at any time in the future lose annual leave days on promotion then the standard compensation formula of time off calculated at 1.5 times the annual loss will apply on a once-off basis at the time of promotion.

**J. Work Permits:**

Work permits are permits which are granted to non-EU/EEA Citizens to allow them to work in Ireland legally. It's an illegal offense to work in Ireland without a work permit and both the employer and the employee are held responsible.

For more information on work permits and for future updates, visit the Enterprise, Trade and Employment website www.djei.ie. Please see list of ineligible categories for work permits at https://dbei.gov.ie/en/What-We-Do/Workplace-and-Skills/Employment-Permits/Employment-Permit-Eligibility//

**Assessment Procedure**

**A. Board of Assessors**

Applications will be considered by a Board of Assessors, who will shortlist and interview candidates. All applications and other materials submitted by applicants will be treated in strict confidence by all panel members and others involved in the administration of the recruitment. No information about the identity of applicants, or details of their applications, will be released to others, except where it is necessary as part of the selection process.

## B. Interview Dates

Candidates will be advised of arrangements in due course. We endeavour to give as much prior notice as possible for interview dates etc. Candidates should make themselves available for interview and presentation on the date(s) specified by the University.

Candidates who do not attend for interview or other test when and where required by the University or who do not, when requested, furnish such evidence as the University requires in regard to any matter relevant to their candidature, will have no further claim to consideration.

## C. Referees

Referees listed on the application form of the successful candidate will be contacted following interview, with the exception of academic posts.

## D. Offer

All candidates will in due course be notified of the outcome of their application. The Human Resources Office will offer the post to the candidate appointed once the appointment has been made by the University Appointing Authority.

The successful candidate will be required to submit evidence of age, original qualifications and may be required to complete a medical examination.

Once a conditional job offer has been made, the candidate will be asked to complete a confidential pre-employment health questionnaire that the University's Occupational Health Service will use in order to assess medical fitness to undertake the duties of the post.

The information provided on the questionnaire will be used (i) to assess the candidates medical capability to do the job applied for; (ii) to determine whether any reasonable adjustments may be required to accommodate any disability or impairment which the candidate may have; and (iii) to ensure that none of the requirements of the job for which the candidate applied would adversely affect any pre-existing health conditions the candidate may have.

Human Resources Office