Guideline Number	**51.014A**	Version	**1.0**
Title	**IRAS Form Completion Guidance for Non-Regulated Studies**		

1. IRAS Form Completion Guidance for Non-Regulated Studies

This guide provides step-by-step support for completing the IRAS form for all non-commercial research studies excluding CTIMPs and CIMDs where NHSGGC are Sponsor. For more guidance there is also e-learning available on the IRAS website:
https://www.myresearchproject.org.uk/ELearning/index.html

IRAS Project Filter Questions

1. Select "Yes"
2. Select the most appropriate category, as selected on R&I Strategic plan (Form 51.010E) and costing sheet (Form 51.010A)
2a. Answer "No" for non-device studies.
2b. Confirm if applicable and ensure consistency with supporting documents regarding ionising radiation and the use of biological samples
3. Select which countries of the UK the research sites be located which have been costed for
3a. Select "Scotland"
4. Select "IRAS Form"
5. Select "yes" if there are NHS sites involved
5c. If sites are in England, confirm whether you wish to apply for NIHR Clinical Research Network support. Guidance on which studies are eligible for this support can be found here:
https://www.nihr.ac.uk/eligibility-nihr-research-delivery-network-support
6. Confirm if the study will involve children and describe consent/assent processes (see SOP 51.002)
7. Confirm if study will involve adults lacking capacity and ensure legal safeguards are described
8. Confirm if study will involve prisoners and describe ethical safeguards.
9. Indicate if the study is part of an academic qualification, please note if the qualification is with UoG, they should be Sponsor (see SOP 51.007)
10. Indicate if the study will be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs
11. Confirm if identifiable patient data will be accessed outside the care team without prior consent.

Short Title: A concise version of the full title or acronym

PART A: Core study information

A1–A5: Administrative Details

- A1: Use the full, descriptive title as it appears in the protocol
- A2: Use a short, recognisable title (≤70 characters).
- A3–1: Include CI's full name, qualifications, employer, and contact details.
- A4: Provide R&I Sponsor Co-ordinator or Facilitator's name, role, and contact details.
- A5–1: Sponsor/applicant's reference number are both the R&I reference number e.g. GN25AA001. Include protocol version/date, registry numbers if you have them (e.g. ISRCTN, NCT), and funder references.
- A5–2: Describe links to previous/current studies, if applicable include IRAS/R&I reference of linked study

A6–A13: Study Overview

- A6–1: Write a lay summary explaining purpose, methods, and impact. Ensure language is not too technical as REC will publish this description on their website and require simple language for readers and for lay members of the REC
- A6–2: List ethical, legal, and management issues and how they're addressed.
- A7: Tick all applicable methodologies and justify each.
- A10: State the main research question in lay terms.
- A11: List secondary objectives and hypotheses.
- A12: Provide scientific rationale, referencing relevant literature.
- A13: Describe study design, participant flow, and timeline.

A14–A20: PPI and Risks

- A14–1: Describe how patients/public were involved in design, delivery, or dissemination. Include how this has been incorporated and at which stages of your study PPI involvement will be sought.
- A15: Tick relevant health areas and demographics.
- A17–1: List inclusion criteria clearly and concisely.
- A17–2: List exclusion criteria clearly and concisely.
- A18: Describe non-clinical procedures (e.g. interviews, questionnaires) with duration and personnel.
- A19: Describe clinical procedures (e.g. assessments, interventions) with duration and personnel.
- A20: Explain if any routine care is withheld and justify.

A21–A35: Consent and Recruitment

- A21: State total duration of participant involvement.
- A22: Describe risks and burdens, and how they'll be minimised.
- A23: List sensitive topics and describe handling procedures.
- A24: Describe direct and indirect benefits. If there are no direct benefits to participants, indicate that. Other wider benefits e.g. advancing scientific knowledge, improved healthcare of future patients, can then be described.
- A25: Explain post-study care or continued access to interventions.
- A26: Describe any risks to researchers and mitigation plans. Include details of any safety requirements of the Sponsor e.g. lab safety policies, lone study/working policies and procedures etc.
- A27–1 to A27–4: Describe recruitment methods, confidentiality safeguards, and access to records. Screening of medical records to identify eligible participants should be carried out by the clinical care team; researchers should not have access without express permission from the patient unless researcher is part of the routine clinical care team.
- A27-5: Confirm if consent is being sought to access data such as medical records, NHS numbers, or other personal identifiers, provide details on how consent will be obtained. If consent is not being sought, you must justify this and explain the legal basis for accessing the data (e.g. public health).
- A28: Describe publicity materials and channels.

- A29: State who will first approach participants and how. There should not be any unsolicited contact with patients by the research team. The initial approach should come from the clinical team or self-referral e.g. from posters etc. Pt may then give verbal consent to be contacted by researchers (this should be documented in medical records), be provided with contact information of researchers or be introduced to researchers.
- A30–1: Describe consent process, including materials and timing.
- A30–2: Confirm written consent and describe how it's recorded.
- A31: Specify how long participants have to decide.
- A32: Describe inclusion of participants in other studies and justify.
- A33: Describe arrangements for non-English speakers or those with communication needs. If participant facing documents in languages other than English will be used, REC will expect to review these versions too. If proposing the use of interpreters, ensure funding is available for this research cost. If not feasible to include non-English speakers, please justify e.g. patient population or risk
- A34: Describe how new information will be communicated.
- A35: Tick and justify approach to loss of capacity. If retaining identifiable data/tissue after loss of capacity, mention this in the PIS.

A36–A45: Data Confidentiality

- A36: Tick all applicable data handling activities and describe.
- A37: Describe physical security of data (e.g. locked cabinets, password protection). Note, no identifiable patient data can be stored on UoG computer systems (other than cloud with approved CSSP or a certified CTU; data should be pseudonymised, with the code linking to identifiable information held separately.
- A38: Describe anonymisation/pseudonymisation procedures.
- A40: List who will access personal data and justify. Include that sponsor representatives and regulatory bodies may require access for monitoring or audit purposes
- A41: State where data will be analysed and by whom.
- A42: Name the data custodian and their role.
- A43: State how long personal data will be stored and justify. Minimum 5 years required for non-CTIMPs, (see SOP 51.025).
- A44: State how long research data will be stored. Minimum 5 years required for non-CTIMPs, (see SOP 51.025). Note UoG requires research data of long-term value, such as those supporting a thesis or publication, to be retained for at least 10 years after completion of the research study.
- A45: Describe long-term storage arrangements and access controls in line with UK GDPR. Include details of data custodian (normally the CI), physical and electronic storage, and anonymisation.

A46–A48: Incentives and Conflicts

- A46: Describe participant payments, reimbursement, or incentives.
- A47: Confirm if researchers receive additional payments.
- A48: Declare any conflicts of interest.

A49–A53: GP Notification and Dissemination

- A49–1: Confirm if GPs will be informed and include template letters.
- A49–2: Confirm if participant permission will be sought.
- A50–1: Confirm registration and list registry. For the first four categories in the project filter, registration is required. If registering, mention where you intend to register e.g. clinicaltrials.gov (free) or ISRCTN (incurs charge). SRA can send clinicalTrials.gov details (see SOP 51.017). If not required, state "Registration is not required for this type of research."
- A51: Tick dissemination methods and describe.
- A52: Describe how anonymity will be maintained.
- A53: Describe how and when participants will be informed of results.

A54–A60: Scientific and Statistical Review

- A54–1: Tick and describe scientific review process. Confirm that study has undergone peer review, if eligible funder this will have been done as part of the application, if not then internal peer review process should have taken place (see SOP 51.003)REC may request written reviewer comments.
- A56: Tick and describe statistical review process.
- A57: Define primary outcome measure.
- A58: List and describe secondary outcomes.
- A59: State sample size and breakdown.
- A60: Justify sample size with references or calculations.

A61–A63: Randomisation and Collaborators

- A61–1: Describe randomisation method and rationale.
- A62: Describe analysis methods (statistical and qualitative).
- A63: Ensure all collaborators with roles and affiliations named in the protocol are listed here.

A64–A67: Sponsor and Funding

- A64–1: Provide sponsor details and status. Sponsor is NHS GGC or NHS GGC and UoG for Co-Sponsored studies, add NHS GGC R&I Co-ordinator as Sponsor Contact.
- A64-2: State "the relative responsibilities of the co-sponsors will be described in a co-sponsorship agreement, executed before the study commences".
- A65: Describe funding source, amount, and duration. Ensure that details are provided for funding already secured, as well as funding applied for. Award letters should be included in the submission.
- A66: List subcontractors and responsibilities e.g. external laboratories, transcription companies etc. Appropriate contracts will be required.
- A67: Describe any previous ethics rejection and resolution.

A68–A75: R&D and Monitoring

- A68–1: Provide R&I Senior Research Assistant (SRA) details as R&D contact details.
- A69–1: State study start/end dates and total duration.
- A70: Define what constitutes the end of the trial as detailed in the protocol (e.g. last visit of last participant).
- A71–1 to A71–2: Describe centre type and locations.
- A72: Tick host organisations and list them.
- A73–1: Any organisations involved only in identification of potential participants are described as participant identification centres (PIC) sites. E.g. GP practice whereby the GP identifies patients only. Include details of all PIC sites and activities as applicable. If "Yes" selected, secondary PIC questions will appear in Part C. Enter contact details and activities in Part C where applicable.
- A74: If monitoring has not been costed for, state "The sponsor has implemented an audit programme, based on risk, for its non-CTIMP studies. This study may be subject to audit."
- A75–1 to A75–2: Describe safety monitoring and stopping criteria.

A76–A78: Insurance and IP

- A76–1: This relates to who the study Sponsor is. Select "NHS" if NHSGGC is the Sponsor and detail CNORIS will apply. Select both if the study is co-sponsored. If UoG insurance applies, the relevant insurance document and free text will be provided for inclusion in the submission.
- A76-2: This relates to the protocol authors (the design of the research): Select NHS if any of the protocol authors are substantively employed by an NHS organisation. Select "Other" if any of the protocol authors are substantively employed by UoG or are UoG students. Select both if applicable.
- A76–3: This relates to where the research sites for the study are and the conduct of the research. The answer must be consistent with the sites listed in Part C of the IRAS application. Select "NHS" if NHS sites will be used. Select "Research includes non-NHS sites" if non-NHS sites (e.g. University or community sites) will be used. Select both if applicable.
- A77: Confirm compensation arrangements.
- A78–1: Confirm whether the research may generate IP.
- A78–2: Describe the nature of potential IP (e.g. new product, process).
- A78–3: Outline ownership and management of IP if applicable.

Optional Part B sections

Part B: Section 2 – Medical Device Manufacturer Details

- **B2–1:** Provide the name, address, and contact details of the manufacturer.
- **B2–2:** Include device identification name and number.
- **B2–3:** Describe the intended use of the device and how your study use differs.
- **B2–4:** Confirm CE/UKCA marking status and any modifications.

Part B: Section 3 – Exposure to Ionising Radiation

Please note, this must be completed prior to IRAS submission (timeline of approx. 4 weeks). For more information see SOP 51.014 or visit the IRAS website:
https://www.myresearchproject.org.uk/help/hlpradiation.aspx

- **B1: Details of other ionising radiation:** List each procedure (e.g. chest X-ray), number of procedures, and estimated dose.
- **C1: Dose and risk assessment:** Must be completed by a Medical Physics Expert (MPE). Includes total dose and cancer risk.
- **C2: Declaration by MPE:** Signed statement confirming the assessment is accurate.
- **D1: Clinical assessment:** Completed by a Clinical Radiation Expert (CRE) to confirm exposures are justified.
- **D3–D4: Declaration and details of CRE:** Includes professional registration and contact details.

Part B Section 4: Existing Samples

- **B4–1:** Type of human tissue or biological material.
- **B4–2:** Describe anonymisation procedures.
- **B4–3 to B4–5:** Describe consent arrangements.
- **B4–6 to B4–7:** Licensing for human application.
- **B4–8 to B4–9:** Types of analysis and genetic testing.
- **B4–10 to B4–11:** Handling of clinically significant findings.
- **B4–12 to B4–15:** Storage, importation, and disposal plans.

Part B: Section 5 – Use of Newly Obtained Human Tissue

- **1–2: Types and collection of tissue:** Describe sample types (e.g. blood), volumes, and who collects them.
- **3–4: Donor status and consent:** Confirm samples are from living donors and that consent is obtained.
- **6: Human application testing:** Confirm if samples will be used for human application.
- **8. Storage format:** Tick whether samples are anonymised, linked anonymised, or identifiable.
- **9–10. Types of analysis and DNA use:** Describe planned analyses (e.g. proteomics, transcriptomics) and DNA testing.
- **11–12. Clinical significance and notification:** Confirm if findings may be clinically relevant and how donors will be informed.
- **13–14. Storage and custodianship:** Describe where samples will be stored, who has access, and long-term plans (e.g. transfer to biorepository).

PART B: Section 6 - Adults Unable to Consent

- B2: Justify why the study cannot be done without including adults who lack capacity.
- B3: Who assesses capacity and what training they have.
- B7–B8: Consultation arrangements in England and Wales.
- B7–1: Consent arrangements in Scotland.
- B10–B14: How participants' wishes, objections, and advance decisions will be respected.

Part B: Section 7 – Children

- B7–1: Specify the age range of children and justify inclusion.
- B7–2: Confirm if children will be recruited as controls and explain.
- B7–3: Describe how consent will be obtained from parents or guardians.
- B7–4: Outline how assent or agreement will be sought from children, if applicable.
- B7–5: Describe arrangements for non-English speakers or those with communication needs.

PART C: Overview of research sites

- Site Identification: List all UK sites responsible for research delivery (e.g. NHS sites, universities etc.). This should be consistent with A72.
- Investigator Details: Provide name, qualifications, and contact details of the site Principal Investigator.
- Site Type: Indicate whether each site is NHS/HSC or non-NHS.
- Site Address: Include full postal address and postcode.
- Site Capacity and Capability: Confirm that each site has the resources and staff to conduct the study.
- Site-Specific Information: Ensure consistency with the Organisation Information Document (OID).
- PICs: If you have indicated at A73 that Participant Identification Centres (PICs) will be used, details of PIC sites should be included here.

PART D: Declaration

- Chief Investigator Declaration: Confirm that the CI has reviewed and approved the application.
- Sponsor Declaration: Confirm that the sponsor agrees to the responsibilities outlined.
- Authorised Signatory: Provide name and contact details of your R&I Co-ordinator or Facilitator to sign on behalf of NHSGGC as Sponsor.
- Date of Declaration: Ensure the date is current and matches submission timing.
- Electronic Signature: Confirm that electronic submission is valid and accepted by the sponsor.

Helpful Tips:

- Ensure consistency across all submitted documents (e.g. protocol, IRAS form, PIS, consent forms).
- Any blank boxes on your IRAS form will prevent e-submission. If a section is not applicable, please enter 'N/A'. Use the IRAS validation tool to identify missing fields.
- Answer all IRAS filter questions accurately, these determine which sections and forms are generated.
- Check that all required signatures and authorisations are completed before submission. Note that if there are any changes made after signature / authorisations have been completed they will be voided and must be requested from the relevant people again.
- Include all supporting documents such as insurance certificates, CVs of key personnel, and ethical approvals.
- Use clear and concise language throughout the form to avoid ambiguity.
- If unsure about any section, visit https://www.hra.nhs.uk or contact your R&I Sponsor Co-ordinator or Facilitator for guidance.
- Schedule of Activities or Schedule of Events Cost Attribution Tool (SoA/SoECAT) required for studies involving NHS resources.
- Organisation Information Document (OID) required for multi-site studies
- For any technical issues, contact IRAS Help Desk.

Guideline signatories

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Document history

Version	Date	Description	Retrospective Implementation
1.0	04/12/2025	First Release	No