# Swansea University

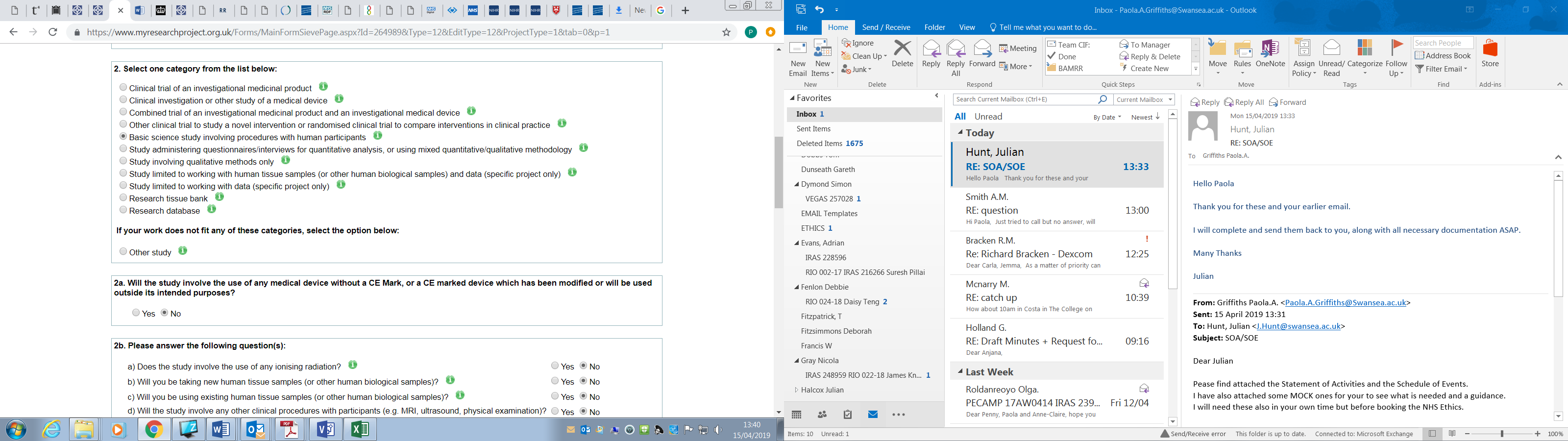
# Integrated Research Applications System (IRAS) **Guidance**

## Below is some guidance on completion of the IRAS dataset

**Please use it to complete your form to save time**

#### **Project Filter Pages**

Please ensure that the correct filter questions are ticked, otherwise the correct pages to complete in IRAS will not be populated. Questions are simultaneously populated on the relevant forms



#### **Project Application Form**

Please ensure that you enter the following information for the appropriate sections of the application form.

More comprehensive information can be found in the [IRAS HELP](https://www.myresearchproject.org.uk/Signin.aspx) menu:

|  |  |  |
| --- | --- | --- |
| **Part A:** | **Section** | **Advice** |
| **Administrative**  **details** | IRAS FORM  project information | Please ensure short title matches that on protocol and on the Patient Information Sheet(PIS) and Consent Form (CF).  Please do not put version and date after the short title. |
|  | A1 | Full title should match that on protocol, PIS/CF and other patient facing documentation. |
|  | A2-2 | Student details and Supervisors details if PhD educational project.  Note the Supervisor will be the CI not the student. |
|  | A3-2 | Please ensure that correct details for CI or PI are entered to this section. |
|  | A4 & A64-1 | The main contact for Swansea University as Sponsor is:  Paola Griffiths  Research Governance Manager  Research Engagement & Innovation Services  Swansea University  Swansea SA2 8PP  Tel: 01792 606060  Email: researchgovernance@swansea.ac.uk |
|  | A5-1 | • **Sponsor’s reference number** given when application is validated for Sponsor review should be added here.  • **Protocol version and date** (matching that on the protocol) should be entered. Care should be taken to update this section once all the documents are finalised.  • Registration number of the **publically accessible database (e.g. clinicaltrials.gov, ISRCTN)** where possible.   * **EudraCT number** should be added. for CTIMPs |
| **Overview of the Research** | A6-1 | Brief lay summary of the research, maximum 300 words |
|  | A6-2 | All main ethical, legal and management issues should be summarised here. Can also be used to highlight specific issues where REC advice would be welcome |
| **Purpose and design of the research** | A10, A11 | In lay words describe ALL objectives of the research project. Please be consistent in the way visits and the project are described (e.g., Day 1, visit 1, baseline visit, trial or study or Phase 1/2/3).  If indicated that posters / leaflets will be used for recruitment purposes, please forward copies of these for review by Sponsor, they will need to be included as part of your REC submission. |
|  | A12 | In lay words describe the scientific justification of the research project. Place the research in context of previous work and demonstrate you are familiar with the area and show how this research project will contribute to knowledge. |
|  | A13 | In lay words give a complete overview of the research project describing why the project design and methodology were chosen and what influenced the choice. All assessments described in the protocol should be summarised in this section. The involvement of potential recruits or with community or patient groups should also be described. |
| **Risks and ethical issues** | A15 | Select the main identifying feature(s) of the participants, data or samples. Where the research project does not involve identification by disease or diagnosis please select ‘Generic Health Relevance’. |
|  | A17-1 & 17-2 c | This should align with inclusion and exclusion criteria in the **Protocol** and details in the **Participant Information Sheet**.  If stated in A33-1 that only patients who can understand written and verbal English will be involved this must be included in your inclusion/exclusion criteria.  If you have stated that, ‘participants must not have been involved in any other research project within the last X weeks/months’, this must also be in the inclusion and exclusion criteria. |
| **Research procedures, risks and benefits** | A18 | Only non-clinical interventions/procedures included in the protocol should be listed. |
|  | A19 | Only clinical interventions/procedures included in the protocol should be listed. |
|  | A20 | The possible consequences of withdrawing or withholding treatment and the justification for doing so should be described. This should be consistent with the **Protocol** and **Participant Information Sheet** |
|  | A22 | Details all risks or inconveniences to the participant along with mitigations, which will be in place.  Where necessary, all drug side effects as listed in the Investigator Brochure should be included.  This should be consistent with the **Protocol** and **Participant Information Sheet.** |
| **Recruitment and informed consent** | A27-1, A27-2 | Any contact prior to consent should only be from the clinical care team and not the research team, (e.g. searches via GP surgeries by practice staff). Sources of identifiable personal information used to identify patients should be detailed. |
|  | A28 | If ‘yes’, you should send to the REC a copy all material designed to recruit participants. Also enclose a copy of the text that you intend to use on websites for recruitment. All should be given a **version number and date**. |
|  | A31 | There are no fixed guidelines for this. It is recommended that patients have at least up to 24h to consider drug or device projects. The date of approach and date of consent should be documented. |
|  | A33-1 | If you have stated that all participants must understand written and verbal English this must be included in your inclusion/exclusion criteria.  For participants in Welsh centres the Welsh Language Act must be considered with participant materials available in both languages and opportunities to participate through either language.  Information on health measures available in Welsh are available via http://www.micym.org/llais/static/index.html |
|  | A37 | **Personal data** falls under the GDPR |
| **Confidentiality** | A40 | Add text to this section to state that  **‘medical notes and research project data, may be accessed by authorised individuals from the Sponsor, regulatory authorities (where applicable) or host NHS site (e.g. ABMU, Hywel Dda) for monitoring and audit purposes’.**  This must also be stated in your **Participant Information Sheet** and **Consent Form** |
|  | A41 | If **personal data** will be leaving the host NHS site, details for data transfer and ensuring confidentiality needs to be detailed. This must also be stated in your **Participant Information Sheet** and **Consent Form**. |
|  | A42 | This would usually be the Chief Investigator of the research project. For a student their Primary Supervisor should be the custodian of the data, unless the project is a CTIMP when it will be a nominated research sponsor archivist |
|  | A44 | This is 25 years for a CTIMP and 10 years minimum for all other research. |
|  | A45 | If identifiable data will be held e.g. consent forms, these should be held separately to research data. |
|  | A46 | Clarify amount/type per participant per visit and whether payment will only be given on production of a valid receipt. All must also be stated in your **Participant Information Sheet** and **Consent Form**. |
|  | A49-1, A49-2 | If ‘yes’, then a GP letter should be submitted for Sponsor review. Notification of GP should also be stated in your **Participant Information Sheet** and **Consent Form** |
| **Publication and dissemination** | A50-1 | If you selected one of the first 4 categories in question 2 of the project filter the research should be registered on a public database. Researchers are encouraged to register **All** research on a public database. |
|  |  | If ISRCTN registration https://www.isrctn.com/ is not an option, researchers should consider using ClinicalTrials.gov https://clinicaltrials.gov/ if they have no other preferred public registry |
| **Scientific and Statistical Review** | A56 | When the project involves statistics the details of who provided the main review should be included. |
|  | A57, A58 | Primary and secondary outcome measures should be as described in the protocol. |
|  | A59, A60 | Details of the sample size and how this was calculated should be included with sufficient information for readers to reproduce the calculation |
| **Management of the research** | A63 | Please ensure all co-grant holders and protocol co-authors name, full address, email address and phone number are included. |
|  | A64-2 | Mr Ceri Jones  Director REIS  Research Engagement & Innovation Services  Swansea University  Swansea SA2 8PP  Tel: 01792 606060  Email: researchgovernance@swansea.ac.uk  This is the SU authorised signatory |
|  | A66 | Please ensure all **vendors/third parties/subcontractors** are listed e.g. use of a Clinical Trials Unit, Laboratories, Manufacturers, Clinical Research Facilities to enable contracts to be valid. |
|  | A68-1 | The lead R&D office should be contacted at the earliest possible stage to advise and support the research through the review and set-up process.  They should be the main NHS collaborator  Please ensure you complete the following fields:  Forenames/Initials  Surname  Organisation  Work email  Telephone  **Any other** lead site, please enter the appropriate details in this section. |
|  | A69-1, A69-2 | Be realistic with planned start and end dates. |
|  | A71-1 – A 72 | Ensure number of sites match each other and match what you insert in **Part C**. |
|  | A74 | Please include the following text, adding your own applicable study procedures at the end.  “*Swansea University* *has a risk adaptive approach will often build in flexibility for monitoring activities*  NOTE: Swansea University currently only has capacity to oversee CTIMP and other high risk interventional projects via involving **Swansea Trials Unit.** . |
|  | A76-1, A76-2 | For Swansea University employees/students/honorary staff members please tick 'other insurance…. apply' and write.’  “*Swansea University has in force a Public Liability Policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage*” |
|  |  | Where NHS staff are named on the protocol and/or research projects are Co-sponsored by Swansea University and an NHS organisation please tick both boxes and write ‘NHS indemnity and Swansea University insurance applies |
|  | A76-3 | Tick both *NHS Indemnity’* and other add “*Swansea University has in force a Public Liability Policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage”* |
|  | A77 | If question available the response is ‘yes’ |
|  | A78 | If *‘yes*’ here, the project should have received advice from a Swansea University IP officer based in REIS |
| **Part B Sections 1 – 10**    Medicinal products,  Medical devices,  Ionising radiation,  Existing samples,  New samples,  Adults unable to consent, | Children,  CAG information,  Information security ,  HMPPS information. | Individual sections will be available as a result of responses in the Project Filter. Sponsor contacts should be as detailed in A4 and A64-1  Where there is the expectation of involvement of a NHS department e.g. radiology, pathology their agreement should be requested in advance of the application being submitted.  Further information and guidance can be sought via researchgovernance@swansea.ac.uk |
| Part C Research sites & Investigators |  | Number of sites should match Section A71 and A72 |