**SReDA CRIB SHEET for all study types**

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| **NEW PROJECT FIELDS** | **SOURCE** | **✓ or N/A** |
| License/Location | Select location where study will take place - info from **SSI Q3** |  |
| Project ID  *Co-ordinator Assistants will generate this ID.* | Follow SOP 50.009,Project Numbering |  |
| R&D Officer | Nameof R&D Co-ordinator managing the study. |  |
| Study Type | Select category – info can be found in **IRAS** **project filter** **Q2.** |  |
| Project Type | **IRAS R&D QA65** or **SSI** **Q21** |  |
| REC No. | Reference No. from Ethics correspondence |  |

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| **INFORMATION TAB** | **SOURCE** | **✓ or N/A** |
| R&D Officer | Nameof R&D Co-ordinator |  |
| Lead Reviewer | This is the name of the Lead Generic reviewer for a multi-centre study, NRSPCC will complete this field | N/A |
| Archive Project | No data to be entered until further notice | N/A |
| Archive Reference | Number from archive box that paperwork is filed in |  |
| Archive Date | Datewhen paperwork is archived in box |  |
| Project ID | As above - follow SOP 50.009,Project Numbering |  |
| System Generated Project ID | Automatically populated | N/A |
| LREC No. | No data to be entered | N/A |
| REC No. | Reference No. from Ethics correspondence |  |
| IRAS Project Code: | First five numbers found at the bottom right-hand corner of the IRAS R&D or SSI form |  |
| Eudract | **IRAS R&D** **QA5** or Ethics correspondence |  |
| CTA No. (MHRA Ref.) | The first 12 numbers from the reference of the MHRA letter |  |
| UKCRN ID | ThisReference No. can be obtained from UKCRN Website if applicable |  |
| UKCRN Project | Tick this checkbox if study information has been added to the UKCRN Website. |  |
| Contract Type: | Pick from drop down – ask Coordinator for this information. |  |
| UKCRN Date Initialised | No data to be entered | N/A |
| UKCRN Minimum Dataset Entered | No data to be entered | N/A |
| ISRCTN | **IRAS R&D** **QA5**, UKCRN or NIH Websites |  |
| Protocol | Enterthe most currentProtocol ID if available, Version No. and Date, info can be found on front page of the Protocol. |  |
| Protocol | Tick box when in receipt of Protocol |  |
| Short Title | Acronymof study title, if applicable can be found on the front page of the Protocol |  |
| Research Title | IRAS R&D Form QA1 |  |
| Comments | Add date and description of status of study. *Example*: 10/10/08 – have requested peer review. |  |
| HB Comments | This comments box is only visible by our own Health Board. This could be used to add description of status of study if preferred. |  |
| Website | Enter website for Study if applicable, this can be found in the Protocol, **IRAS R&D QA5** or on UKCRN. |  |
| Ethics Notes | Can be used to record any relevant information regarding submission to Ethics |  |
| **MANAGEMENT TAB** | **SOURCE** | **✓ or N/A** |
| IRAS Form Start Date | **IRAS R&D** **QA69** |  |
| Multi Centre | Tick if study is Multi Centre, info from **IRAS R&D QA72** |  |
| IRAS Form End Date | Date from **IRAS R&D QA69** if 2 dates are given then use the later date |  |
| Main REC Ethics Approval Date | Date from Main REC letter issuing favourable opinion |  |
| Study Type | **IRAS project filter Q2** |  |
| National Priorities | Select appropriate button – info can be found in **IRAS R&D QA15** or ask Coordinator Assistant |  |
| Education Qualification Aim | This info can be found in **IRAS project filter Q9,** enterNo Aimif not a student project |  |
| Main REC Ethics Status | This info can be found in most recent Main REC letter |  |
| Involves IMP | **IRAS project filter** **Q2** |  |
| Involves Tissue Collection | **IRAS project filter** **Q2** |  |
| Involves Medical Device | **IRAS project filter** **Q2** |  |
| Confidentiality Issues | Leave as N/K until further notice | N/A |
| MHRA Authorisation Required | **IRAS project filter** **Q2** |  |
| UKCRC Health Category | **IRAS R&D QA15** |  |
| **LICENCE LEVEL DATA** | | |
| Actual Start Date | Date when Management Approval letter issued |  |
| NHS Programmes | No data to be entered | N/A |
| Actual End Date | Dateof Management Approval letter – plus -duration of study which can be found in the **IRAS SSI Q7** if 2 dates are given then use the latter date |  |
| Patient | This field is being discussed, leave blank until further notice | N/A |
| Is Lead Centre | Select Yes if CI is employed by NHS Greater Glasgow or any affiliated University, if CI is external to any of above then tick No **-** info from **IRAS R&D QA3** |  |
| Study | This field is being discussed, leave blank until further notice | N/A |
| Activity Area | This field is being discussed, leave blank until further notice | N/A |
| Lead Centre Name | If the CI is not employed by NHS Greater Glasgow or any affiliated University enter the Name of the Health Board or University the CI is employed by - info from **IRAS R&D QA3** |  |
| Organisation | This field is being discussed, leave blank until further notice | N/A |
| Project Status | Status should be set to **Proposed** and changed to **Active** once Management Approval has been issued |  |
| **LOCAL LEVEL DATA**  **It is important to check the right location has been picked on the project status bar before updating the local fields** | | |
| Local Start Date | Date of Management Approval. This area is site specific. *Example*: 2 sites within GG&C which receive Management Approval on different dates, this pink area will change to site specific info when you select the GG&C location from the Quick bar |  |
| Ethics Approval Date | No data to be entered | N/A |
| Recruitment Target | **SSI** **Q10** |  |
| Local End Date | Dateof Management Approval plus duration which can be found in the **SSI Q7** if 2 dates are given then use the latter date |  |
| Ethical Status | No data to be entered | N/A |
| Recruitment Actual | When study is active a progress report will be submitted to R&D with current recruitment numbers. |  |
| Status | Status should be set to **Proposed** and changed to **Active** once Management Approval has been issued |  |
| Actual Recruitment Recorded Date | No data to be entered | N/A |
| **RECRUITMENT TAB** | **SOURCE** | **✓ or N/A** |
| Recruitment Data | Coordinator together with Co-ordinator Assistants will complete this section. |  |
| **STAKEHOLDERS TAB**  All Investigator details must be checked to match current information | **SOURCE** | **✓ or N/A** |
| Personnel:  Chief Investigator | AddName of C.I, info from **SSI** **Q1.** |  |
| Personnel:  Investigator name | Add all Names of Investigators named on SSI, this should include the CI. Check all Investigator Details are correct |  |
| P.I | Tick this box for the Principal Investigator |  |
| **Click on Investigator Name to check and update Investigator Details:** | | |
| Honorary Contract | If GG&C have issued an Honorary Contract then tick Yes |  |
| Enhanced Disclosure Required | Tick this box if a disclosure has been requested by us, or received from Investigator |  |
| Letter of Access | Tick this box if a letter of access has been issued by GG&C |  |
| Research Passport | Tick this box if a Research Passport has been requested by R&D, or received from the Investigator |  |
| Research Passport Number | Use the reference number from the Disclosure form until further notice |  |
| Documents | Import the Honorary Research Contract once issued by GG&C. |  |
| Honorary Contract and Courses Tab | This information can be found on the Honorary Contract issued by GG&C |  |
| WTE and Employment Tab | This is being discussed, leave blank until further notice | N/A |
| Funder Name | **IRAS R&D QA65** or Funder Award letter |  |
| Funder Ref | **IRAS R&D** **QA5** or Funder Award letter |  |
| Start Date | **IRAS R&D QA65** or Funder Award letter |  |
| End Date | **IRAS** **R&D QA65** or Funder Award letter |  |
| Total | **IRAS R&D QA65** or Funder Award letter |  |
| Sponsor Name | **IRAS R&D QA64** or Sponsor letter |  |
| Sponsor Ref | Sponsor letter |  |
| **RESEARCH TAB** | **SOURCE** | **✓ or N/A** |
| Primary Research Question | **IRAS R&D QA10** |  |
| Secondary Research Question | **IRAS R&D QA11** |  |
| Outcome Measure | No data input is required for this field | N/A |
| Methodology | **IRAS R&D QA13** |  |
| Randomised Controlled Trial | Tick box if this is a Randomised Controlled Trial this will be mentioned within the Titleor **IRAS R&D QA7** |  |
| Sample Group | Infocan be found in Protocol or **IRAS R&D** **QA15** select all that apply. |  |
| Trial Phase | **IRAS R&D QA9.** Select n/a if no trial phase |  |
| Trial Type | **IRAS project filter Q2** |  |
| Project Type | **IRAS R&D QA65** |  |
| **COSTINGS TAB** | **SOURCE** | **✓ or N/A** |
| Support Department | SSI form |  |
| Support Type | SSI form – if unsure please check with Coordinator |  |
| Sign off received | Signature or email from Head of Support Department |  |
| All Finance Fields | Leave blank until further notice | N/A |
| **INDEMNITY TAB** | **SOURCE** | **✓ or N/A** |
| Negligence Cover for Non-NHS staff | Keep this at N/K until further notice | N/A |
| Compensation Route for participants | Enter *Sponsor (insurance backed*) if there is evidence of valid Insurance. |  |
| Valid Insurance Certificate provided by Sponsor | Select appropriate button |  |
| Insurance provider | Info from Insurance certificate |  |
| Amount | Enter amount stated on Insurance certificate and pick correct currency from drop-down |  |
| Insurance Valid from | Date from Insurance certificate |  |
| Insurance Valid to | Date from Insurance certificate |  |
| Insurance notes | Can be used to record any relevant information regarding Insurance |  |
| **POST APPROVAL TAB** | **SOURCE** | **✓ or N/A** |
| Type | Select from drop-down Info can be found in *Notification of Amendment Form* |  |
| Reference | Enter amendment reference and the Health Board entering these details i.e: AM01 (GGHB), info found in Notification of Amendment Form E1 |  |
| Title | S/A until further notice |  |
| Date of Amendment | Enter Date from the *Notification of Amendment Form* part E1 if this is missing then the date the form was signed off if this is missing then use the dated noted by REC |  |
| Date of R&D Approval | Date of R&D Management Acknowledgement of Amendment |  |
| MHRA Approval Date | Date MHRA approved Amendment |  |
| Ethics Approval Date | Date Ethics approved Amendment |  |
| Summary of Amendment | List of amended documents this info will be on the *Amendment Checklist* |  |
| ADVERSE EVENTS | Leave blank until further notice | N/A |
| SAEs |
| SUSARs |
| **CHECKLIST TAB** | **SOURCE** | **✓ or N/A** |
| Clocks Overview | Coordinator together with Co-ordinator Assistants will complete | N/A |
| **DOCUMENT TAB** | **SOURCE** | **✓or N/A** |
| Document Store | Upload Management approval and Amendment acknowledgement emails from project e-file |  |
| **LOCATIONS TAB** | **SOURCE** | **✓ or N/A** |
| Add Location(s) | Select Locationfor all sites named on the **SSI Q3** this field must not be set as GG&C |  |
| **IMPORT TAB** | **SOURCE** | **✓or N/A** |
| Imported Files:  *When importing from xml please ensure the database details on GGHB if Sponsor are the correct format of NHS Greater Glasgow & Clyde Health Board – no address.* | Upload the IRAS R&D and SSI in xml format to SReDA |  |
| **PROJECT REMINDERS TAB** | **SOURCE** | **✓or N/A** |
| Project Notes | Set up any project reminders if needed |  |
| **MONITOR TAB** | **SOURCE** | **✓or N/A** |
| Create Email Alert (if needed) | Any email alert to be sent to Coordinator Assistant and Database Assistant enter subject, study reference and message |  |
| **IMAGING TAB** | **SOURCE** | **✓or N/A** |
| **Imaging Tab Data** | Coordinator together with Co-ordinator Assistants will complete this section. This section is completed at the point where there study goes to the finance department. |  |
| **PHARMACY/CUSTOM TAB** | **SOURCE** | **✓or N/A** |
| NRS Project | Tick if the study has NRSPCC involvement |  |
| MHRA Approval Date | Enter Date MHRA approved the study |  |
| Portfolio | Enter which Portfolio Team is managing the study |  |
| Risk Assessment | Coordinator together with Co-ordinator Assistants will complete |  |
| ARSAC No. | Reference No. will be on the ARSAC Licence if applicable |  |
| Gov Site Visit Status | Coordinator together with Co-ordinator Assistants will complete this section if it is required. This section is completed at the point where there study goes to the finance department. |  |
| Gov Site Visit Folders |  |
| Gov Site Visit Contact |  |