Research Investigators Guide to completing the IRAS Full Project Dataset (version 5.21) for Clinical Research (non-CTIMPs) Requiring UCL or UCLH Sponsorship under the Department of Health Research Governance Framework for Health and Social Care (April 2005)

Introduction	Project filter questions	How to use this guide
This guide is devised to assist investigators to complete their online IRAS full set of project data (known as "integrated data set"). The online form is in two forms the project filer questions and the full set of project data which has 4 sections A, B, C and D. This guide is designed to help you complete the full data set for **Part A (Core Study documentation), Part C (location details) and Part D (Declarations/authorisations).**	Having opened your project in IRAS you will first complete the **11 questions that comprise the "project filter questions"** as they set the forthcoming questions and sections you will have to complete relevant to the type of research you are conducting. **Filter Question 2** is perhaps the most important of the filter questions, it is crucial that the correct responses are selected as they will either open or collapse other sections/and questions. Where free text allows and the question is not applicable, state "*not applicable*" rather than leave it blank. We have provided **standard responses** for some of the questions for you to copy and paste into your online IRAS form.	Look at the online IRAS form and then find the corresponding question in this guide. There are four columns: • **First column** displays the IRAS question number (*based on current version 3.5*) • **Second column** – subject question • **Third column** - response to questions where there is blue font, copy and paste this into your online form as these responses are standard and must appear in your online form. Where an i icon is shown in the online form, please click this icon for specific question guidance. The investigator/research team must respond to these study-specific questions where they appear. • **The fourth column** in additional guidance points where you may find examples, websites and other information to help you complete the online IRAS form.

Completing the Integrated Research Application System (IRAS) Integrated Dataset (version 3.5)

PART A - Core study information

ADMINISTRATIVE DETAILS

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information
Filter Q4	Research Review bodies	The review bodies as listed on IRAS include: • IRAS Form • Administration of Radioactive Substances Advisory Committee (ARSAC) • Confidentiality Advisory Group (CAG) • Gene Therapy Advisory Committee (GTAC) • Health Research Authority (HRA) for projects seeking HRA Approval • Medicines and Healthcare products Regulatory Agency (MHRA) • NHS / HSC R&D offices • NHS / HSC Research Ethics Committees • National Offender Management Service (NOMS) • Social Care Research Ethics Committee	IMPORTANT: If your project is taking place in the NHS and is led from England select **'IRAS Form'**. When you select this option you should ensure that the options for "NHS R&D" and the "NHS REC" (including options for GTAC and Social Care REC) are not selected. If you need to apply for other reviews, such as MHRA or NOMS, then these should be selected at this point. **HRA Approval** HRA Approval is the process for the NHS in England that comprises a review by a NHS Research Ethics Committee (REC), where required, as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA staff. It replaces the need for NHS permission by each participating organisation in England. From 31 March 2016, HRA Approval is the process for applying for approvals for all project-based research in the NHS led from England. You can read more about the development and implementation of HRA Approval by clicking here.

			You should apply for HRA Approval if: • The lead NHS R&D Office for your project is in England; and • Your research is described by any of the IRAS filter question 2 categories (except those for "Research Tissue Bank" and "Research Database"). Select the **icon** i for further guidance.
A1	Title of research	i	
A2-1	Student(s) project details and Contact details of Academic supervisor(s)	i	If two or more registered UCL students are collaborating on the same research then only one IRAS application need be made
A2-2	Chief Investigator (CI) for student project		UCL policy is that students **cannot** be CI's. This is because the CI must hold a UCL substantive employment contract, so that the organisation (UCL) can take overall responsibility for that individual.
A3-1	CI details	i	For UCL sponsored studies, if the CI is external (i.e. not UCL substantively employed) then evidence of an honorary contract with UCL is required.
A4	Sponsor contact details i	Name of JRO Portfolio Co-ordinator (PC) who has been allocated the research study to co-ordinate. This will NOT be the UCL or UCLH Sponsor Representative.	This needs to contain the details of the study coordinator i.e. the person who actually drives the permission process on behalf of the sponsor, rather than the sponsor representative named in

		Please use the following email address randd@uclh.nhs.uk	A64-1 who provides oversight. This is for both for NIHR CSP adopted studies and non-CSP processed NHS research.
A5-1	Research reference numbers	Enter the registered Project R&D Number (format of 00/0000) you have been given by the Joint Research Office for your project, against: **"Applicant's/organisation's own reference number"** Enter your UCL Data Protection Registration Number (format, Z6364106/0000/00/00) under: **"Additional reference number(s)"**	If the study is externally funded, enter reference number from the funding awarding body, if known, under **"Funder's reference number"**. Email data-protection@ucl.ac.uk for all data protection registration and enquiries. To download the DP related "Application for Inclusion of a Research Project (Form 9)" click: http://www.ucl.ac.uk/finance/legal_services/data_protection/documents/Joint_UCL_UCLH_and_RF_BRU.doc NOTE: projects which are using completely anonymised data that cannot be processed into identifiable data, does NOT need to be registered with UCL Records Office.
A5-2	Other linked studies or applications		
A5-3	US DHHS grant applications		Only relevant if funding has been awarded by a US Federal Authority e.g. National Institutes of Health (part of the US Department of Health & Human Services (DHHS).

OVERVIEW OF THE RESEARCH

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information
A6-1	Lay summary of study	i	
A6-2	Study purpose & design	i	
A6-3	Proportionate ethical review	i	To find out if your study may be suitable for proportionate review click: http://www.nres.npsa.nhs.uk/applications/proportionate-review/

PURPOSE AND DESIGN OF THE RESEARCH

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information
A7	Methodology description	i	
A10	Principal research question	i	
A11	Secondary research question	i	
A12	Scientific justification	i	
A13	Summary of design & methodology	i	
A14-1	Patient & public involvement (PPI)	i	PPI refers to the involvement of public/patient in the actual design of the research and not to the patient being a participant in the study. More information and advice on PPI is available from Dr Ros Yu (PPI Manager, Joint Research Office). Email: rosamund.yu@ucl.ac.uk
A14-2	Consulting patients/public on use of data without consent	i	

A14-3	Service user involvement	i	

RISKS AND ETHICAL ISSUES

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information
A15	Sample group or cohort	i	
A17-1	Inclusion criteria		This should include the age range and gender of the participants
A17-2	Exclusion criteria		

RESEARCH PROCEDURES, RISKS AND BENEFITS

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information
A18	Details of non-clinical interventions or procedures	i	
A19	Details of clinical interventions or procedures	i	Persons listed here should also appear in question A63-1
A20	Withholding of clinical interventions or procedures	i	
A21	Length of time of participation	i	
A22	Potential risks and burdens	i	
A23	Potential for distress in	i	

	interviews, questionnaires, or group discussions		
A24	Potential benefits to participants	i	
A25	Arrangements for continued provision of intervention after research finished	i	
A26	Potential risks for researchers	i	

RECRUITMENT AND INFORMED CONSENT

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information
A27-1	Identification of potential participants, records or samples	i	
A27-2	Screening personal data	i	
A27-3	Methods and resources	i	
A27-4	Access to personal data outside the care team	i	
A27-5	Consent to access identifiable data	i	
A28	Details of recruitment	i	
A29	How and by whom potential participants will be approached	i	

A30-1	Obtaining informed consent	i	
A30-2	Recording consent	i	
A30-3	Practicalities of seeking consent	i	
A30-4	Record of individual dissent	i	
A30-5	Use of data without consent	i	
A31	Time to decide on participation	i	
A32	Participants involvement in other research	i	
A33-1	Participants with inadequate English language skills or special communication needs	i	
A33-2	Provision of information in the Welsh language (compliance with Welsh Language Act)		This question only appears if you have ticked "Wales" in filter question 3. CI/PI maybe able to use the NISCHR PCU translation service which is currently available free of charge to non-commercial studies originating outside Wales. AllWales.R&D@wales.nhs.uk for advice
A34	Providing information to participants during the research	i	
A35	Loss of capacity to consent during the study	i	

CONFIDENTIALITY

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information

A36	Checklist of data processing activities	i	
A37	Physical security of data storage	i	This applies to both records in hard copy format and to the physical security of computers and other electronic devices.
A38	Confidentiality of data	i	The UCL Information Security Policy is available at: http://www.ucl.ac.uk/isd/common/cst/swg/policy The UCL Data Protection Policy is available at: http://www.ucl.ac.uk/isd/common/cst/swg/policy/public-policy/Data_protection_policy_ISC_20110215 Further guidance on research and data protection, is available from the Legal Services web pages at https://www.ucl.ac.uk/finance/legal/dp-foi-overview
A39	Separation/encryption of identifiers	i	
A40	Access to identifiable data during the study	i	Please ensure that this statement is reconciled with the PIS and protocol
A41	Analysis of data and location	i	
A42	Data custodian for data generation	i	Your UCL data custodian will be your Departmental IT representative. You may be able to find this information by visiting the following link https://www.ucl.ac.uk/isd-extra/community/reps/list/.
A43	Retention of identifiable data at	i	

	end of the study		
A44	Period of data storage	Enter 20 years	In accordance with the UCL Records Retention Policy, research data are retained by UCL in their capacity as sponsor for 20 years after the research study has ended. Data is then securely destroyed. At the time of archiving a research study, visit http://www.ucl.ac.uk/library/about/records-office to arrange secure storage of research records. Student studies are not subject to these requirements and retention is at the discretion of the student.
A45	Long term arrangements for data storage	Enter the statement: UCLH sponsored: UCLH and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The study master file will be archived at UCL in accordance with the UCLH Standard Operating Procedure 10 Archiving of Investigator Site File (ISF) and Pharmacy Site File (PSF). It will be archived for a minimum of 5 years from the study end, and no longer than 30 years from study end. UCL sponsored: UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such	Further information on the UCL Records Office and UCL's off-site archiving facility is available at: http://www.ucl.ac.uk/library/about/records-office Local arrangements for data storage can also be included.

		end is defined within this protocol). The Chief Investigator confirms that he/she will archive the study master file at [insert site name] for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents for [insert duration] and in line with all relevant legal and statutory requirements.	

INCENTIVES AND PAYMENTS

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information
A46	Financial payments/incentives (participants)	i	
A47	Financial payments/incentives (researchers)	i	
A48	Conflicts of interest	i	

NOTIFYING OTHER PROFESSIONALS

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information
A49-1	Notifying GP or health professional	i	

A49-2	Permission to notify	i	

PUBLICATION AND DISSEMINATION

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information
A50-1	Study registration on public database	i	Public registration of research studies is encouraged wherever possible. If the study is a randomised controlled trial, registration via www.controlled-trials.com/ https://clinicaltrials.gov/ is required. Studies that are eligible for NIHR adoption, is included in the NIHR CRN clinical research studies database. From 30 September 2013, registration of clinical trials (first 4 categories in the IRAS filter) in a publicly accessible register will be a condition of the favourable ethical opinion. Further information is available by accessing the following link http://www.hra.nhs.uk/news/2013/09/10/trial-registration-to-be-condition-of-the-favourable-rec-opinion-from-30-september/
A51	Dissemination of study results	i	
A52	Ensuring anonymity of published data	i	
A53	Informing participants of	i	

	results		

SCIENTIFIC AND STATISTICAL REVIEW

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information
A54-1	Peer review	i	Peer review is required for all studies please refer to the guidance at http://www.ucl.ac.uk/jro/
A56	Statistical critique	i	
A57	Primary outcome measure	i	
A58	Secondary outcome measures	i	
A59	Sample size	i	
A60	Sample size determination		
A61-1	Randomisation	i	
A62	Methods of analysis	i	

MANAGEMENT OF THE RESEARCH

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information
A63	Key investigators/ collaborators	i	
A64-1	Lead Sponsor i Name of organisation Contact person / details Is sponsor based outside UK?	**Tick "Academic" or "NHS"** (under "Status") and **"Non-commercial"** (under "Commercial status" from the drop down menu) University College London or University College London Hospital Trust Tabitha Kavoi, Joint Research Office, UCL, Gower Street. London. WC1E 6BT Tel: 020 3447 5199 Fax: 020 7380 9937 Email: randd@uclh.nhs.uk **Tick "No"**	The sponsor is the organization that accepts responsibility for the initiation, regulatory management and monitoring of a study. **UCL does not offer co-sponsorship.** It only offers sole sponsorship
A65	External funding	i	Enter details of the funder(s) of your research if you have ticked either: **"Funding secured from one or more funders"** or **"External funding application to one or more funders in progress"**
A66	Delegation of activity to a subcontractor	i	
A67	Previous rejection by a REC	i	
A68	Lead R&D contact i	**UCLH NHS Foundation Trust** Enter the name of your Portfolio Coordinator Joint Research Office, UCL, Gower Street. London.	* If the Lead Site is **not** UCLH or the Royal Free or Whittington Health, then details of other R&D contacts can be obtained from the NHS R&D Forum at:

		WC1E 6BT. Tel: 020 7380 9833 Fax: 020 7380 9937 Email: RandD@uclh.nhs.uk	http://www.rdforum.nhs.uk/044.asp and Click **Trusts and Acute organisations** under "Contacting NHS R&D Offices"
A69-1	Duration of study		Indicative study start/end dates are required
A70	Definition of end of trial		
A71-1	Single / Multicentre		
A71-2	Location of research in the UK / EU/ Outside of EEA		Countries within the EU and EEA are listed at: http://www.conformance.co.uk/info/eea.php Enter the total number of UK sites participating in the study
A72	UK hosting organisations	i	The number of organisations (research participatory sites) put here in response to this question, must also be named in **Section C** (see below) of the full data set. For e.g. if it is stated that there are 4 NHS Trusts as host organisations, then those 4 Trusts must be named under **Section C** .
A73-1	Identification of participants by other organisations	i	If your response to this question is "yes" then you will be required to complete question A73-2 relating to PICs. A Participant Identification Centre (PIC) is any organisation responsible for identifying and informing potential participants about a study taking place in another organisation. The other organisation is responsible for the subsequent

			assessment of potential participants and their possible recruitment and informed consent into the study.
A73-2	Participant Identification Centres (PICs)		If the response to this question is "yes" then you will need to provide details of the PIC(s) at **Section C – Overview of research sites**
A73-3	Resources for PICs		
A74	Monitoring and auditing the conduct of the research i	Enter the statement: The Chief Investigator will be responsible for the day to day monitoring and management of the study. The UCLH/UCL/ Joint Research Office, on behalf of UCL or UCLH as Sponsor, will monitor and conduct random audits on a selection of studies in its clinical research portfolio. Monitoring and auditing will be conducted in accordance with the Department of Health Research Governance Framework for Health & Social Care (April, 2005), and in accordance with the Sponsor's monitoring and audit policies and procedures.	You can also add your own local audit and monitoring arrangements here if they are established within your department.
A75-1	DMC and stopping rules	i	
A75-2	Criteria for stopping trial prematurely		
A76-1	Insurance and indemnity - *management* of study i	**If UCL sponsored Tick "Other insurance or indemnity arrangements will apply"** & add the response: The management of the research will be covered by UCL insurance for negligent harm If UCLH sponsored tick NHS indemnity scheme applies	**What does UCL cover as sponsor?** UCL's insurance policy provides for negligent and non-negligent harm for all studies BUT in line with current sponsor's arrangements, non-negligent harm insurance is only covered for all CTIMP's and other non-CTIMP interventional studies. All other studies will be covered for negligent harm cover only.

A76-2	Insurance and indemnity - *design* of study i	**If UCL sponsored Tick "Other insurance or indemnity arrangements will apply"** & add the response: UCL insurance provides cover for negligent harm arising from the design of the research. If UCLH sponsored tick NHS indemnity scheme applies	
A76-3	Insurance and indemnity - *conduct* of study i	**There is one of two responses to this question:** **1.** If your study involves NHS participation only, then: **Tick " NHS indemnity scheme will apply (protocol authors with NHS contracts only)"** & do not add any response **OR** **2.** If your study is taking place at both NHS & non-NHS sites then: **Tick "NHS indemnity scheme or professional indemnity will apply"** and **"Research includes non-NHS sites"** & add the response: UCL insurance provides cover for negligent harm arising from the conduct of the research.	
A76-4	Insurance and indemnity – *any aspect* of the study i	**Add the statement:** UCL hold an insurance policy to provide for the payment of compensation to research participants where legal liability arises. The policy in place at the time of this NRES submission states that the level of	This question only appears when the selection of "Social Care Research Ethics Committee" is ticked against filter question A4 (Which review bodies are you applying to?)

		compensation payable would be £10,000,000 in the aggregate any one trial to an annual aggregate limit of £12,500,000 in respect of all claims covered by the policy. UCL's arrangements with individual trial sites require the sites to hold NHS indemnity, or to be part of another insurance scheme, to meet their own legal liabilities.	
A77	No fault compensation	**Tick "**No**"** However, for high risk studies there may be provision for "non-negligent" harm insurance. In these cases, **Tick** "yes" and **add the statement:** UCL hold an insurance policy to provide for the payment of compensation to research participants where no legal liability arises. The policy in place at the time of this NRES submission states that the level of compensation payable would be £10,000,000 in the aggregate any one trial to an annual aggregate limit of £12,500,000 in respect of all claims covered by the policy.	The response to this question is determined by the level risk of the particular research study.
A78	Intellectual property	i	
A79	Commercial participation		
A80	Area of research		

PART C - Overview of research sites

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information

C1	List of research site and NHS participant identification centres (PICs)		List the name of research sites (including PICs if applicable). The number of sites you include in this section, must reconcile against response given to question A72. Please name the overarching NHS Trust organisation for each site e.g. if a site is the National Hospital, then the Trust will be UCL Hospitals NHS Foundation Trust.

PART D – Declarations (electronic signatures)

IRAS question number	Subject	Standard response to question or refer to information icon i in IRAS for guidance	Further JRO guidance / information
D1	Chief Investigator (CI)		The electronic authorisation of the CI **must be obtained first** before requesting the authorisation of the SR for UCL
D2	Sponsor's representative (SR)		Request the electronic authorisation of the UCL or UCLH sponsor representative: via your IRAS account you will be advised of the email address when you are ready to collect e authorisations
D3	Academic supervisor(s) (AS) – *for UCL student projects*		The electronic authorisation of the AS **must be obtained first** before requesting the authorisation of the SR for UCL
D4	Information Guardian (NIGB only)		The electronic authorisation of the Information Guardian **must be obtained first** before requesting the authorisation of the SR for UCL or UCLH

Key	Explanation

IRAS Icon	Comprehensive guidance on responding to questions is available whenever this icon is shown against a question in the full data set within IRAS
Text in blue	Responses to cut and paste into IRAS full data set