Project DPIA Form

About the Project		Section
Project name	Arginine Supplementation to improve Cardiovascular and Endothelial function after NSAID Treatment (ASCENT)	About the Project
Date Form Created	07/06/2019	About the Project
Project ID	[redacted]	About the Project
Description of Project	ASCENT is a mechanistic study looking at how COX-2 inhibition by celecoxib affects vascular and platelet function and biomarkers associated with the COX-2/prostacyclin/ADMA axis in healthy male volunteers. In addition we will investigate how this is altered by L-arginine supplementation. Forty Healthy volunteers will undergo 7 days treatment with either placebo or 200mg BD Celecoxib. There will then be a 7 day washout period followed by 7 days treatment with either placebo + Arginine or Celecoxib + arginine. Our primary endpoint will be endothelial function measured using EndoPAT. Secondary endpoints include: sitting blood pressure, cardiovascular biomarkers, platelet function, eicosanoid and methylarginine/amine levels, plasma proteome and blood transcriptome. There will be no additional follow up required.	About the Project
Project Sponsor		About the Project
Details of Sponsor where outside Imperial	TRUE	About the Project
Information Asset Owner	[redacted]	About the Project
Information Asset Administrator		About the Project
Contact Details not recorded elsewhere	NHLI	About the Project
Department	To be transferred	About the Project
Cost Centre	NHLI	About the Project
Project Status	FALSE	About the Project
Please provide details about project status		About the Project
Project Start Date		About the Project
Project End Date		About the Project
Please provide additional details about project start and end dates		About the Project
From which type of funding is the project funded?		About the Project
Please provide the codes used for funding (e.g. P12345, G12345)	No defined start and end date	About the Project
Legal basis for processing		About the Project
Data on roughly how many individuals will be processed as a result of these activities?	Research	About the Project
Do you have a privacy notice for the project?	Don't know	About the Project
Who authorised the privacy notice?:		About the Project
Please provide details of any data protection training that you or your team may have undertaken outside of College mandated courses	Yes - other processing (e.g. scanning of consent forms etc.)	About the Project
If your linked dataset is not in the list below you will be given the opportunity to register additional datasets on completion of this form.		About the Project
Data sharing / outsourcing		
Does this project have collaboration with other organisation(s), e.g. Universities, industry, partners etc., that you share or will share data with?	No	Data sharing / outsourcing
Is data transferred or going to be transferred outside of the European Economic Area (EEA)?		Data sharing / outsourcing
Do you outsource or will you outsource data processing (e.g. use of cloud based apps)?	Yes	Data sharing / outsourcing
High Risk Activities		

About the Project		Section
Evaluating, scoring, profiling or predicting from data	FALSE	High Risk Activities
Evaluating Scoring Mitigation	Data collected will be pseudoanonymised. Original datasets will be stored/analysed on secure/encrypted Imperial College computers/servers. Paper records will be stored in a locked cabinet on Imperial College premises. Access to all data will be restricted to the study team.	High Risk Activities
Making decisions or taking action against individuals in ways which can have a significant impact on them	Yes	High Risk Activities
Significant Impact Against Individuals Mitigation	Data collected will be pseudoanonomised. Original datasets will be stored/analysed on secure/encrypted Imperial College computers/servers. There will be no access to patient identifiable	High Risk Activities
Systematic monitoring or observing of individuals where they may not be aware of it	No	High Risk Activities
Systematic Monitoring Mitigation		High Risk Activities
Contacting individuals in ways which they may find intrusive	No	High Risk Activities
Intrusive Contact Mitigation		High Risk Activities
Automated decision making about individuals with legal or similar effects		High Risk Activities
Automated Decision Making Mitigation	Yes	High Risk Activities
Using new technologies for processing personal data (e.g. AI, data mining algorithms etc.)	No	High Risk Activities
New Technologies Mitigation		High Risk Activities
NHS Patient data processed	20	High Risk Activities
Children and/or Vulnerable persons	1-50	High Risk Activities
Special Category data processed	P72842_WHCS	High Risk Activities
Risk mitigation		
Loss, theft, destruction and alteration of data	Yes	Risk mitigation
Loss Theft Mitigation Arrangements		Risk mitigation
Unauthorised Access Arrangements	Not sure	Risk mitigation
Unauthorised Access Mitigation Arrangements	Data collected will be pseudoanonymised. Original datasets will be stored/analysed on secure/encrypted Imperial College computers/servers. Paper records will be stored in a locked cabinet on Imperial College premises. There will be no access to patient identifiable data during analysis outside the study team.	Risk mitigation
Research communication to external comm		
Do you use individuals' contact details to tell them about research communication, public engagement, outreach etc. This may qualify as marketing	Not sure	Research communication to external comm
Do you have explicit consent from individuals for their details to be used for marketing communications?		Research communication to external comm
Do you have a mechanism for people to opt-out from receiving such communications?		Research communication to external comm
Research governance		
Do you have Ethics for the project?		Research governance
Please provide as much detail as possible about ethics	Yes - obtained via ICREC (Imperial College Research Ethics Committee) - please provide JRCO Ref Number	Research governance
Ethics ID	WHCS- Vascular Biology	Research governance
Do you hold consent forms for the project?	No	Research governance
Please provide as much detail as possible about how consent forms are held	Yes - I keep hard copies and/or electronic copies	Research governance
How are consent forms received?	Patients will be consented by the research team.	Research governance
Do you have HRA approval for the project	The above study was reviewed and approved by the Imperial College Research Ethics Committee on	Research governance
Do you have approval from CAG under section 251?	[redacted]	Research governance
Does your project use human tissue or organs?	Consent form will be collected by the team and physically stored in a secure cabinet on Imperial College premises ([redacted]). No electronic versions will be stored.	Research governance
HTA Details	Yes - other	Research governance
Tissue Bank ID		Research governance
Is the project run as a Clinical Study	We will collect samples as described above and store them locally on Imperial College premises (Sir	Research governance
Clinical Study Details	No	Research governance
InForm Study Name		Research governance
Clinical study ID	18IC4757	Research governance