

**School of Health & Life Sciences**

|  |
| --- |
| **Step-by-step guide for research ethics and access permissions involving the NHS** |
| This step-by-step guide will explain the process of seeking ethical approval and access permissions for studies involving human participants. There are several stages involved with the process, depending whether the project involves the NHS and/or is classified as research. All studies will have to complete step 1, but other steps will also need to be completed depending on whether the study involves the NHS and/or is research. Make sure you complete all the necessary steps (and all the bullet points required at each step) before commencing the study. Only commence the study when you have secured ethical approval and access permissions for the study. It is the responsibility of the chief investigator to ensure they have all the necessary approvals and permissions before starting a study. |
| **Step 1**  **All studies** |
| * Review guidance and templates provided online [www.gcu.ac.uk/hls/ethics/](http://www.gcu.ac.uk/hls/ethics/) * The chief investigator is responsible for completeness and quality of the ethics applications (academic supervisors are chief investigators for student projects). * Incomplete or low quality applications will be returned without being reviewed. * Consider whether the project involves the NHS (e.g. patients, premises, data, resources, or staff)?   Go to step 2 if study does not involve the NHS  Go to step 3 if the study does involve the NHS |
| **Step 2**  **Study does NOT involve the NHS** |
| * Submit completed EC1 (or EC3) and accompanying GCU documents via email to appropriate ethics committee * Wait for GCU ethical approval * Commence study once ethical approval has been given |
| **Step 3**  **Study DOES involve the NHS** |
| * Complete ‘*is my study research*?’ tool to decide if project is research [www.hra-decisiontools.org.uk/research/](http://www.hra-decisiontools.org.uk/research/) N.B. ‘service evaluation’ involving NHS staff may use qualitative data collection methods, but may not be categorised as qualitative research if it involves only staff opinion about existing services   Go to step 4 if the study involves the NHS, but is NOT research  Go to step 5 if the study involves the NHS and is research |
| **Stet 4**  **Study involves the NHS, but is NOT research** |
| * Submit completed EC1 (or EC3) and accompanying GCU documents via email to GCU ethics committee * Make sure all documents use the term ‘project’ or ‘study’ rather than research * Wait for GCU ethical approval * Speak to NHS ethics and explain the study is NOT research, is for educational purposes (if relevant), and has GCU ethical approval * Request NHS ethics and R&D waiver (email confirmation) * IRAS form will not normally need to be completed because this project is not research * Project may need registered with NHS clinical effectiveness or obtain Management Access Permission * Email waivers and management approval to the ethics committee and Lyndsay McDade (Senior Research Governance Manager) [Lyndsay.McDade@gcu.ac.uk](mailto:Lyndsay.McDade@gcu.ac.uk) * Commence study once all approvals have been given |
| **Step 5**  **Study involves the NHS and is research** |
| * Complete ‘*do I need NHS REC approval*?’ [www.hra-decisiontools.org.uk/ethics/](http://www.hra-decisiontools.org.uk/ethics/). The outcome will determine whether you use GCU documentation (i.e. NHS REC approval not required) or IRAS documentation (i.e. NHS REC approval required) for GCU internal approval. * Submit completed EC1 (or EC3) and accompanying GCU or IRAS documents via email to GCU ethics committee * Wait for GCU ethical approval before moving to the next step * Access latest information about applying for NHS approval (https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx)   Go to step 6 if study involves NHS, is research, but does not need NHS REC approval  Go to step 7 if study involves NHS, is research, and requires NHS REC approval |
| **Step 6**  **Study involves the NHS, is research, but does not need NHS REC approval** |
| * The application will use GCU research ethics documentation * Email NHS research ethics co-ordinator to explain: the study is for educational purposes (if relevant) and the study is research * The study may not need NHS REC approval (request REC waiver) * Request R&D approval (email confirmation) * Some R&D departments may request an IRAS form be completed * If necessary, complete IRAS form with supervisor [www.myresearchproject.org.uk/](http://www.myresearchproject.org.uk/) * If completing the IRAS form, use HRA validation criteria to check the application in completed correctly (<https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/fast-track-research-ethics-review-pilot/#validation>) * If completing IRAS form for R&D, then the supervisor will have to email SHLS IRAS sponsor (Kay Currie [k.currie@gcu.ac.uk](mailto:k.currie@gcu.ac.uk)) with brief summary of study, confirmation of SHLS Ethics approval, Information Security Training, Data Protection and Privacy Training, GCP training, and to alert them about pending authorisation request * Use ‘Request Authorisation’ tab to request sponsor approval from: Kay Currie [k.currie@gcu.ac.uk](mailto:k.currie@gcu.ac.uk) N.B. Do not ‘transfer form’ as this prevents sign off * Forward approval to the ethics committee and Lyndsay McDade (Senior Research Governance Manager) [Lyndsay.McDade@gcu.ac.uk](mailto:Lyndsay.McDade@gcu.ac.uk) * Commence study once all approvals are secured |
| **Step 7**  **Study involves the NHS, is research, and requires NHS REC approval** |
| * The application can be completed using IRAS and HRA documentation (i.e. no need to use GCU protocol) * Speak to NHS Ethics and R&D to explain: the study is research and for educational purposes (if relevant) * The study is likely to need NHS REC approval and IRAS form * Complete IRAS form with supervisor [www.myresearchproject.org.uk/](http://www.myresearchproject.org.uk/) * Use HRA validation criteria to check the application in completed correctly (<https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/fast-track-research-ethics-review-pilot/#validation>) * Supervisor to email SHLS IRAS sponsor (Kay Currie [k.currie@gcu.ac.uk](mailto:k.currie@gcu.ac.uk)) with brief summary of study, confirmation of SHLS Ethics approval, Information Security Training, Data Protection and Privacy Training, GCP training, and to alert them about pending authorisation request * Use ‘Request Authorisation’ tab to request sponsor approval from: Kay Currie [k.currie@gcu.ac.uk](mailto:k.currie@gcu.ac.uk) N.B. Do not ‘transfer form’, as this prevents sign off * Submit to NHS REC and await outcome * Forward approval ethics committee and Lyndsay McDade (Senior Research Governance Manager) [Lyndsay.McDade@gcu.ac.uk](mailto:Lyndsay.McDade@gcu.ac.uk) * Commence study once all approvals have been secured |