**Self-assessment form: ethics (SAFE)**

All staff and students carrying out **audit, service evaluation and research** involving **human participants**, **human tissue** and/or **human participant data** must complete the **Self-Assessment Form Ethics: SAFE** before recruitment or data collection begins.

Please check **that your project does not require NHS REC:**

[**http://www.hra-decisiontools.org.uk/ethics/index.html**](http://www.hra-decisiontools.org.uk/ethics/index.html)

Please complete, version control the form and sign (wet/electronic signature) the declaration below, and email to [sgulREC@sgul.ac.uk](mailto:sgulREC@sgul.ac.uk) **with your study proposal and all participant facing documents**. Once assessed and verified by the Research Ethics and Integrity Officer you will be informed if you need to provide additional information or you will be assigned a JRES Reference number.

**Student studies: The form must be signed by the supervisor and the student.**

**Project Title:**

**Student/Researcher:**

**IMBE  PH  I&I  MCS  SGHFT**

**IMBE – Institute of Medical and Biomedical Education, PH – Population Health, I&I – Infection and Immunity, MCS – Molecular and Clinical Science, SGHFT – St George’s NHS Trust**

**Supervisor:**

**Start and End Date of the project (DD/MM/YYYY):**

**Staff  BSc  MSc  PhD  Other**

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| **1. Are you investigating existing working or professional practices among participants whom you (the researcher) might be able to identify at your own place of work (this may be St George’s University and Hospital or another organisation where you, your supervisor or co-investigator work)?** |  |  |
| **2.** **Does the study recruit participants outside of St George`s, University of London?**  e.g. universities UK wide, public, other NHS Trust |  |  |
| **3. Does the study aim to recruit more than 500 participants?** |  |  |
| **4. Does the study involve questions which can cause MORE than minimal stress to the participant?**  e. g. questions on identifiable sensitive data, i.e. race, ethnicity, political views, religion, sexual life/orientation |  |  |
| 5. **Do you plan to offer incentives which may unduly influence participants’ decision to participate?**  e. g. involves financial payment more than £100 |  |  |
| **6. Do you plan to use any device in the UK that is CE/UKCA marked but is being used outside its authorisation? Or are you using any non-CE/non-UKCA marked product(s)?** |  |  |
| **7. Are there any procedures involving any risk to a participant's health or well-being?**  e.g. information that relates to illegal, sexual or deviant behaviour |  |  |
| **8. Does the study involve the new collection or donation of human tissue, as defined by the Human Tissue Act, from a living person or the recently deceased according to the Human Tissue Authority?** |  |  |
| **9. Does the study require participants to take part in the study without their knowledge and/or consent at the time?**  e. g. covert observation of people, emergency research |  |  |
| **10. Does the study involve activities where the safety/wellbeing of the researcher may be in question?**  e. g. potential risk of physical threats, compromising situation, working overseas |  |  |
| **11. Does the study involve: Children under 16 years**  **Vulnerable groups** |  |  |
|  |  |
| **12. Could the behavioural/physiological intervention possibly lead to discovery of ill health or concerns about wellbeing in a participant incidentally even if the intervention in itself causes no more than minimal stress is to the research participant?** |  |  |
| **13. Are you linking or sharing personal data or confidential information beyond the initial consent given?**  e.g. sharing data with local or overseas collaborators where patient or participant consent has not been sought; linking participant-provided data with electronic health record data beyond the participant’s initial consent |  |  |

We will publish a summary of your research (taken from your application) in our annual report and in other reports that summarise the work of the SGREC. Please speak with us if you need further clarification on [sgulREC@sgul.ac.uk](mailto:sgulREC@sgul.ac.uk)

Student and Staff: I declare that I have completed the above to the best of my knowledge and in line with the SAFE guidance provided.

**Student/Staff Name:**

**Course/Job title:**

**Signature:**

**Date:**

Supervisor (for student studies only): I declare that I have reviewed the completed SAFE questions to the best of my knowledge and in line with the SAFE guidance provided and study protocol.

**Supervisor Name:**

**Job title:**

**Signature:**

**Date:**