local committee checklist:

committee contact details:

Name of Committee: **St. Vincent’s Healthcare Group Ethics and Medical Research Committee**

Contact Person: **Ms. Justyna Wardell**

Address: **Education Research Centre**

**St. Vincent’s University Hospital**

**Elm Park**

**Dublin 4.**

Tel: **00 353 1 221 4117**

**E-Mail:** [**justyna.wardell@ucd.ie**](mailto:justyna.wardell@ucd.ie) **or svhgethics@ucd.ie**

**Website:** [**Research Ethics - St. Vincent's University Hospital (stvincents.ie)**](https://www.stvincents.ie/research-and-education/research-ethics/)

committee remit:

**St. Vincent’s University Hospital.**

**St. Vincent’s Private Hospital.**

**St. Michael’s Hospital, Dun Laoighaire**

**St. Colmcilles Hospital, Loughlinstown.**

**Our Lady’s Hospice, Harold’s Cross.**

**Blackrock Hospice.**

**Merrion Road Breast Check Centre.**

**Royal Hospital Donnybrook.**

Local requirements (if any):

**It is a requirement to name an employee of St. Vincent’s University Hospital Group as the Principal Investigator in All Cases.**

**For most studies the Principal Investigator will be an authorised healthcare professional employed by St. Vincent’s University Hospital Group – for the purposes of indemnity.**

**For research being undertaken for the purposes of obtaining an academic qualification, the student’s academic supervisor must be named as co-investigator on the Standard Application Form.**

**The St. Vincent’s Healthcare Group template Patient Informed Consent should be used for all research studies.**

**Please ensure the named Principal Investigator will remain in the employment of St. Vincent’s University Hospital Group for the entire duration of the research study.**

**Where a research study involves St. Vincent’s University Hospital Group patients, their family members or informal caregivers and the named Principal Investigator is a St. Vincent’s University Hospital Group healthcare professional, but not a St. Vincent’s University Hospital Group consultant doctor, it is a requirement to list a St. Vincent’s University Hospital Group consultant doctor as a co-investigator in all cases – for the purposes of clinical governance -**

* **The Principal Investigator must sign the Signatory Page**
* **The Academic Supervisor (where applicable) must sign the Signatory Page**

**APPLICATIONS WHICH DO NOT FULFILL THE ABOVE LOCAL REQUIREMENTS WILL BE DEEMED INVALID.**

**Applicants submitting studies to this committee are requested to adapt the Template Information Leaflets and Consent Forms available on** [**Research Ethics - St. Vincent's University Hospital (stvincents.ie)**](https://www.stvincents.ie/research-and-education/research-ethics/) **to their own studies.**

**THESE TEMPLATES ARE COMPULSORY FOR USE – sponsors unable to use these templates are requested to contact the Ethics Office.**

**Applicants conducting studies in St. Vincent’s University Hospital Group are requested to complete and submit the Template Data Protection Impact Assessment Statement available on** [**Research Ethics - St. Vincent's University Hospital (stvincents.ie)**](https://www.stvincents.ie/research-and-education/research-ethics/)

**APPLICATIONS WHICH DO NOT FULFILL THE ABOVE LOCAL REQUIREMENTS WILL BE DEEMED INVALID.**

Local restrictions (if any):

**NB -** 1 electronic copy (all documents) to be submitted to justyna.wardell@ucd.ie

**Please aim to keep the file sizes as small as possible**

fees:

**N/A Unless the research is sponsored by a Pharmaceutical Company.**

documents required:

|  |  |  |  |
| --- | --- | --- | --- |
| **Documents Required:** | **Number of E Copies**  **Required** | **Yes / No / N/A** | **Document Version / Date** |
| **Cover Letter (listing all documents for review, including Version number)** | **1** |  |  |
| **Standard Application Form (RECSAF Version 5.6 last updated Beaumont 16.5.23** | **1** |  |  |
| **Signatory Page** | **1** |  |  |
| **2 page CV of Chief Investigator, signed and dated (for file)** | **1** |  |  |
| **2 page CV of Principal Investigator, signed and dated (for file)** for multi-site studies, this refers to the cv of the Principal Investigator in St. Vincent’s Hospital only | **1** |  |  |
| **Research Study Registration Form** | **1** |  |  |
| **Research Proposal / Study Summary /** **Protocol /** (if one exists) | **1** |  |  |
| **PIL - Combined with Data Confidentiality Agreement** – use new template | **1** |  |  |
| **PIL - Participant Information and Consent Form** – use new template | **1** |  |  |
| **Recruitment Material** | **1** |  |  |
| **Questionnaire / Interview Prompts** | **1** |  |  |
| **Copies of Current GCP**  **Certification for all the Investigators and research team** | **1** |  |  |
| **Draft Agreement / Contract (where applicable)** | **1** |  |  |
| **Draft Data Protection Impact Assessment** – use new template | **1** |  |  |
| **Other Associated Documents** | **1** |  |  |
| **Radiation Declaration Form** | **1** |  |  |
| **Radiological procedure assessment form (for return to Jackie McCavana, Medical Physics)** | **1** |  |  |

**SVUH Compliance Requirements:**

* All Principal Investigators and Research Staff must complete the Statement of Interests for the purposes of Section 18 of Ethics in Public Office Act 1995 (SIPO) document. All Hospital Consultant’s must complete this on an annual basis.
* If a Medical Device is being used as part of a research study, the Principal Investigator must inform the hospital’s Clinical Engineering Department and the Department of Infection Control in advance of the device being used. **Ref: PPG ORG 97**
* If Photography is being used as part of the research, this must be stated clearly in the PIL/Consent outlining how patient confidentiality will be maintained, where the photographs will be stored and how long they will be retained for.
* The Principal Investigator and the Research Team must comply with SVUH Data Protection Policies. **Ref: PPG – ORG -126**
* If Healthy Volunteers are recruited as part of the research study, a separate Informed Consent must be provided and submitted for review and approval by the SVHG EMRC.
* If Staff are recruited as healthy volunteers, staff members are responsible for requesting permission from their line Managers before participating in the research. The needs of the service must take priority and therefore participating may not always be possible. A separate Informed Consent must be provided and submitted for review and approval by the SVHG EMRC.
* If hazardous materials are part of the research, the SVUH policy on Hazardous materials must be adhered to. **Ref: PPG ORG 132**
* Annual Safety reports of all healthcare related research must be forwarded to the ethics committee on at least an annual basis. The EMRC will acknowledge receipt of the annual reports and notify the principal investigator of any requirements or concerns of the committee with respect to the information provided.
* On completion of a healthcare related research project the Principal Investigator must notify the committee by completing a Termination Report Form. The completed form must be submitted to the EMRC within 90 days of the end of the clinical trial or healthcare related research. If the healthcare related research is terminated early the period shall be reduced to 15 days and the reasons clearly stated.
* Any complaints regarding the research study by participants should be directed to the SVUH Quality & Patient Safety **Ref: PPG ORG 114**

**local committee declaration and signatory page:**

Name of Committee: **St. Vincent’s Healthcare Group Ethics & Medical Research Committee**

Title of Study:

**declaration of Principal investigator:**

* The information on this form is accurate to the best of my knowledge

Name of Principal Investigator:

Signature of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Has this study been approved by St. Vincent’s University Hospital Finance Department?**

YES NO

Approval Signature Finance Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_