Research Studies and Clinical Trials Requiring Access to Patient Information/Medical Records

Health Innovation All staff/researchers **Hub Ireland** Research Partners **Application** (send to risk.management@sivuh.ie) Must Include: Research proposal •Clinical Supervisor details •Cork Regional Ethics Committee (CREC) application and approval Reviewed by D.P.O. to check (or equivalent) (if applicable) compliance with DPA Health Data Collection Methodology Research Regs 2018 •If sponsored Clinical Trial, then confirmation of liability insurance •Copy of consent forms (if applicable) •Copy of Information leaflet for patients (if applicable) Subject to Approval by Clinical Indemnity Scheme (as required) •Board Of Directors (as required) **Approval granted** The applicant will receive notification by email from the Quality & Risk The Quality & Risk Management Department, a record of **Management Department** the research will be logged on the will notify the Drugs & Quality Management Sytem. HIPE and **Once Approved** Therapuetics Committee of Medical Records will be made aware of approved Clinical Trials the approval of the research. If conducting audit out · If HIPE data is required, • If conducting research out of If access to medical records of hours, on arrival; submit request allowing is required notify Medical hours notify SIVUH Data adequate time for report Records as soon as possible **Protection Officer and** to be generated Nursing Administration at once approved, in order to Check in at · Email: least 48 hours before coming ascertain timeframe reception. crowley.therese@sivuh.ie required for retrieval of on site to conduct research. Sign visitors book. medical records. · Email dpo@sivuh.ie Alert ADON to your Outline number of files arrival. required. mccarthy.eleanor@sivuh.ie • Email regan.niall@sivuh.ie **Once complete** Notify Quality and Risk Management Department at risk.management@sivuh.ie • A copy of the results of the research must be provided to SIVUH via Quality and Risk Department on completion of the study, failure to do so may influence approval of future research, email findings to risk.management@sivuh.ie SIVUH must be acknowledged in any publications

No medical records are to be removed from SIVUH. No research on SIVUH medical records is to be conducted at any location outside SIVUH.