SLTL/ FlexyRap DES-1

Application form for requesting wavier of consent

1. **Name of the Study Coordinator:**

2. **Designation** : Head- Clinical Research

3. **Study Tittle:** A retrospective, single-arm, multi-centre, observational, post-market clinical follow-up study to evaluate the safety and performance of FlexyRap Cobalt Chromium Rapamycin Eluting Coronary Stent System in patients with de novo coronary artery disease under real-world settings.

4. **Protocol Number:** SLTL/ FlexyRap DES-1, version 1.0.0 dated15-Feb-2022

5. Request for wavier of Informed Consent :

   Please tick the reason(s) for requesting wavier (in box provided)

   i. Research involves 'less than minimal risk' : ☒
   ii. There is no direct contact between the researcher and participant : ☒
   iii. Retrospective studies, where the participants are de-identified or cannot be contacted. : ☒
   iv. Certain types of public health studies / surveillance programme / programme evaluation studies. ☐
   v. Research on anonymised biological samples/data. ☐
   vi. Research on using data available in the public domain. ☐
   vii. Any other (please specify) PI/Study coordinator provide justification for the wavier of consent.

6. Statement assuring that the rights of the participants are not violated.
   As, this is retrospective study only patient data will be collected and used for study. In the entire process, participants identify will not be published throughout the study including presentation or publication. We will ensure throughout the study that participant's rights are being violated.

7. State the measure described in the protocol for protecting confidentiality of data and privacy of research participants
   Patients will be identified by the study number and no information related to patients will be released in public. The patients identify (name, case number) will be de-identified and will not be published throughout the study, including presentation or publication. This will ensure subject confidentiality maintained.

Principal Investigator/ Study Coordinator signature with date