PROTOCOL TEMPLATE: CReDO 1

1**. Title Page**

a) Full title of the clinical study- Survey of ‘Enhanced Recovery After Surgery’ practice in gynecologic oncology

b) Protocol / Study number, and protocol version number with date – CReDO protocol 1.0, Jan 2020, 20th Jan 2020

c) The IND name/number of the investigational drug – ERAS Survey

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h) Financial support- None

2. **Background and Introduction**

Enhanced recovery pathways are a set of peri-operative practices that aim to hasten patient’s recovery after a surgery. Increasing number of studies are suggesting improved surgical outcomes and healthcare savings when patients are managed as per ‘Enhanced Recovery After Surgery’ (ERAS) protocols. These results have been shown in several surgical specialties including colo-rectal, urology and gynecology. [1-4]The ERAS Society undertook a systematic review of literature that led to the publication of ERAS guidelines in gynecologic oncology in 2016. [5,6] In March 2019, these were further revised and updated ERAS guidelines were published for gynecologic oncology. [7] Since the release of these guidelines, adoption of ERAS practices has been studied in a US study recently published. [8] This survey aims to assess ERAs practice across several nations, to get a global perspective.

2. **Information about Treatment/Device and/or Investigational Product**

The cross-sectional survey was adopted from Ore et al study [8] to make it inclusive for general gynecologists and surgical oncologists, who manage gynecologic cancer patients in almost all countries. Survey primarily comprises of questions related to pre-, intra- and postoperative practices as per ERAS guidelines. The survey is attached as appendix to this protocol.

3. **Summary of Risks and Benefits**-

There are no ‘risks’ envisaged by conducting this study.

5. **Study Rationale** – ERAS survey will provide a global insight into enhanced recovery practice among various practitioners caring for gynecologic cancer patients as well as geographic differences, if any.

5.1 Study Objective - To assess ERAS practices among various specialists caring for gynecologic cancer patients.

6. **Study Design** – Cross-sectional survey

7. **Study Population**: Around 2000 Gynecologists/Gynecologic-oncologists/surgeons/Surgical-oncologists will be contacted by electronic mail and social media platforms like Whatsapp, Twitter, Facebook, Social Link. Survey will be sent through online survey development cloud-based software ‘Survey Monkey’ as electronic mail and various social media platforms.

8. **Endpoints**-

Survey will be open for a duration of 2 months.

9. **Study Conduct**

9.1 Schedule of events- Survey link will be sent to various surgical specialists involved in gynecologic cancer patient care, as soon as such link is created.

9.2 Follow up procedures- Fortnightly reminders will be sent till a period of 2 months post sending survey first time.

9.3. Study participant drop-out/ Lost-to-follow up – Participants will have the option of dropping out of survey or not answering the survey at all.

9.4 Adverse Events – None envisaged since it’s a non-interventional study

10. **Data Analysis**

10.1 Sample size calculation- Not required since this is a cross-sectional survey.

10.2 Statistical analysis- Relevant statistical tests would be applied to study survey inputs like Fisher’s exact test. P values <0.05 will be considered statistically significant.

11. **Ethical considerations**: Institutional ethical clearance will be taken

12. **References**

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2. Kisielewski M, Rubinkiewicz M, Pędziwiatr M, *et al*. Are we ready for the ERAS protocol in colorectal surgery? *Wideochir Inne Tech Maloinwazyjne* 2017;12:7–12.

3. Lemanu DP, Singh PP, Stowers MDJ, *et al*. A systematic review to assess cost effectiveness of enhanced recovery after surgery programmes in colorectal surgery. *Colorectal Dis* 2014;16:338–46.

4. Pache B , Joliat G, Hübner M, Grass F, Demartines N, Mathevet P, Achtariet C. Gynecologic Oncology 154 (2019) 388–393.

5.Nelson G, Altman AD, Nick A, *et al*. Guidelines for pre- and intra-operative

care in gynecologic/oncology surgery: Enhanced Recovery After Surgery (ERASR) Society recommendations--Part I. *Gynecol Oncol* 2016;140:313–22.

6. Nelson G, Altman AD, Nick A, *et al*. Guidelines for postoperative

care in gynecologic/oncology surgery: Enhanced Recovery After Surgery (ERASR) Society recommendations--Part II. *Gynecol Oncol* 2016;140:323–32.

7. Nelson G, Bakkum-Gamez J, Kalogera E, *et al*. Guidelines for perioperative care in gynecologic/oncology: enhanced recovery after Survery (ERASR) Society recommendations – 2019 update. *Gynecol Oncol* 2019

8. Ore AS, Shear MA, Liu FW, *et al*. *Int J Gynecol Cancer* 2020;30:122–127.