**The Operating Room Global (TORG) Institutional Review Board (IRB) Study Assessment Template**

Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (D/M/Y): \_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator (s): **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 License No. \_\_\_\_\_\_\_\_\_\_\_\_\_

Institution Contact No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Co-investigator (s)

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Contact Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Contact Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Contact Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Contact Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Contact Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Contact Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total No. of Participants: \_\_\_\_\_\_\_\_\_\_\_\_No. of Study Sites: \_\_\_\_\_\_\_\_\_\_\_\_

Funding Agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Contact No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Types of the Study Intervention Epidemiology Observation

 Document based Individual Based Genetic

 Social Survey Others, Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Review Status: Regular Expedited Exempted Emergency

Description of the study in brief: Mark whatever applied to the study

Randomized  Stratified Randomized Open Labelled

Double Blind Placebo Controlled Treatment Controlled

Cross over Parallel Interim Analysis

Use of Tissue Samples Use of Blood Samples Use of Genetic Materials

Multicentre Study Screening Descriptive

**Methodological Description**

* Brief the study design\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Study Objectives:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Hypothesis of the study\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Study Area\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* The statistics used\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Mark and comment on whatever items applicable to the study.**

1, Objectives of the Study

 Clear  unclear What should be improved?

2, Need for Human Participants

 Yes  No Comment:

3, Methodology:

 Clear  unclear What should be improved?

4,Background Information and Data

 Sufficient  insufficient Comment:

5, Risks and Benefits Assessment

 Acceptable  unacceptable

6, Inclusion Criteria

 Appropriate  inappropriate Comment:

7, Exclusion Criteria

 Appropriate  inappropriate Comment:

8, Withdrawal Criteria

 Appropriate  inappropriate Comment:

9, Involvement of Vulnerable Participants

 Yes  No Comment:

10, Voluntary, Non-Coercive Recruitment of Participants

 Yes  No Comment: NA

11, Sufficient number of participants?

 Yes  No Comment:

12, Control Arms (placebo, if any)

 Yes  No Comment: NA

13, is the research design and methods are scientifically valid and capable of achieving the objectives?

 Yes  No Comment:

14, Are Qualification and experience of the Participating Investigators appropriate?

 Yes  No Comment:

15, Disclosure or Declaration of Potential Conflicts of Interest

 Yes  No Comment:

16, Facilities and infrastructure of Participating Sites

 Appropriate  Inappropriate Comment:

17, Community Consultation

 Yes  No Comment: NA

18, Involvement of Local Researchers and Institution in the Protocol Design, Analysis and

Publication of Results

 Yes  No

Comment:

19, Contribution to Development of Local Capacity for Research and Treatment

 Yes  No Comment:

20, Benefit to Local Communities

 Yes  No Comment:

21, Availability of similar Study / Results

 Yes  No Comment:

22, Are blood/tissue samples sent abroad?

 Yes  No Comment: NA

23, Are procedures for obtaining Informed Consent appropriate?

 Yes  No Comment:

24, Contents of the Informed Consent Document

 Clear  unclear Comment:

25, Language of the Informed Consent Document

 Clear  unclear Comment:

26, Contact Persons for Participants

 Yes  No Comment:

27, Privacy & Confidentiality

 Yes  No Comment: NA

28, Inducements for Participation

 Unlikely  Likely Comment: NA

29, Provision for Medical / Psychosocial Support

 Appropriate  inappropriate Comment: NA

30, Provision for Treatment of Study-Related Injuries

 Appropriate  inappropriate Comment: NA

31, Provision for Compensation

 appropriate  inappropriate Comment: NA

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|  |

32, provide adequate provision for monitoring data to ensure subjects safety

 Yes  No Comment: NA

33, is the study alter standard of producers or normal activities

 Yes  No Comment: NA

34, is the research complies with applicable laws, regulations, and institutional policies

 Yes  No Comment: NA

**Review status**

 Approved  Rejected  Pending

 **Reviewers**

 **Name**  **position**  **sign**

1,

2,

3,

4,

5,