**TITLE: Agarwal Prabhu Supe Surgical innovations and ethics**

**Reviewer 1**

1. The authors must be congratulated on tackling an important issue.
2. The article as a whole needs to be more comprehensively referenced as there are many unsupported assertions in the article. Each sentence of the first paragraph is an example of this. The entire IDEAL statement and framework should be referenced as this is not the authors’ original thought.
3. The term oversight is open to misinterpretation – supervision is perhaps a better word. I would like to disagree with the authors statement that in phase 1 of the development of a truly novel procedure, the IRB need not be involved.
4. Is reference 3 the most appropriate for the innovations committee?
5. Practical aspects of oversight in the Indian context should be discussed on the basis of the personal experience of the authors.
6. The issue of cost merits more attention especially in a resource poor country- Who pays for the innovation. How far are we justified in charging patients?
7. The paragraph on informed consent needs referencing. Issues on obtaining informed consent in Indian patients should be discussed including blind faith in doctors, lack of education, poverty and lack of a redressal method in case they are wronged.
8. The learning curve too needs more discussion. What is the status of animal models for training under the current laws in India? ‘As a common sense group wisdom is better than individual’ needs explanation. The issue of credentialing and monitoring in India is not discussed.
9. ‘However, in India, IRB procedures are long.’ needs referencing. Why is this an Indian problem? This has neither been explained or referenced.

10. ‘In some countries, innovative procedures in children require informed consent not only from their parents, but also from the patients themselves if they are above 10 years‘ is an ill-informed statement- the issues of assent should be appropriately discussed.

11. The article may be significantly improved if specific Indian examples are provided, which are abundant.

12. Further regulations such as *The* *Medical Devices Rules* 2017 should be discussed in detail.

**Reviewer 2:**

The authors have written on an aspect of surgery that has always remained below the radar of Ethics. That surgical innovations have been rapidly making their way into India is well known – some of them have originated in India. Laparoscopy, Lasers, Robotics, newer energy sources and alternate surgical procedures lead the pack. There are some aspects of surgical innovations in India that are disturbing, even alarming:

1. The complete absence of peer, institutional and regulatory oversight
2. An unreliable “Informed consent” process;
3. Indiscriminate resort to surrogate consent from relatives or whoever is accompanying the patient instead of from the patient himself/herself;
4. The scramble for “Surgical workshops” and “Surgical CME” programmes at which procedures are often “demonstrated” to an audience seated elsewhere, with little opportunity for questioning
5. Absence of follow-up data of the patients who underwent such “innovative” procedures; and
6. Absence of a registry of such innovations, be they small or major ones.

This was highlighted quite some time ago in a symposium published in the *Indian Journal of Urology* (See: Ethics and contemporary urology practice: Setting out principles.*Indian J Urol* 2009;25:340-2). It is a matter of deep regret that things continue to be as they were then. I wish that a formal scheme of review as outlined by the authors comes into effect – it will not only protect patients’ rights, it will also validate the innovations before a large number of surgical specialists jump onto the bandwagon just to be seen as “leaders” in their specialties.

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