



Contents lists available at ScienceDirect

Journal of Ayurveda and Integrative Medicine

journal homepage: <http://elsevier.com/locate/jaim>

Discussion Kernel

Making ASU ethics committees more productive: Responsible research needs more than developing the guidelines

Sanjeev Rastogi

State Ayurvedic College and Hospital, Lucknow University, Tulsi Das Marg, Lucknow, 226003, India

ARTICLE INFO

Article history:

Received 6 January 2020

Received in revised form

19 September 2020

Accepted 5 October 2020

Available online 24 October 2020

Keywords:

Human Resource Management

Ayurveda education

Health care

Higher education

ABSTRACT

Ethics has been an integral component of health care research. Various guidelines have been developed globally to ensure ethical conduct of research. Ethics committees (EC) at research organizations have been instituted and empowered to oversee the research conduction in an ethical context. Traditional Indian health care research involving AYUSH systems (particularly drug based systems including Ayurveda, Siddha and Unani – ASU), also come under the broad ethics purview since it involves human or animal participation. Although assigned with a greater responsibility of ensuring and promoting responsible research in the campus, ECs at ASU institutions are yet to be positioned as the promoters of ethics and integrity in research. There had been anomalies in EC structure and function and there had not been the observance of SOPs about considering ethics in research. Poor understanding about their role and function in EC by individual members and poor appreciation of their role in building a responsible research culture across the institution holds much behind suboptimal EC performance. Central Council of Indian Medicine's (CCIM) recent note of the situation and initiation to make a separate guideline for EC functioning in ASU is a welcome step in this regard. However, it may not be the most appropriate step for its possibility of diluting the research standards in favor of ASU. What seems more appropriate is to empower the ASU ECs with knowledge about global standards of ethics and integrity in research to optimize their role in building a responsible research culture in ASU. Naturally, they may need initial help to get evolved subsequently as accountable stakeholders able to care for their own research needs while making attempts to make their benchmarks similar to the global standards.

© 2020 The Authors. Published by Elsevier B.V. on behalf of Institute of Transdisciplinary Health Sciences and Technology and World Ayurveda Foundation. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

1. Background

The Journal of Ayurveda and Integrative Medicine (J-AIM) in 2018 published a thought provoking article raising the issue of malfunctioning ethics committees at Ayurveda institutions of higher learning [1]. The article 'Ethics Committees in Ayurvedic PG institutions: Losing opportunities of making an impact' categorically narrated the failure of Ayurveda ECs in becoming the true custodian of responsible research. The issue was received well by Ayurveda academia across the country and was expected to be responded through initiation of appropriate steps in the right direction. The ultimate argument was to make EC more empowered, dynamic and accountable. ECs have also been foreseen as an opportunity to give Ayurveda research a cutting edge through a

multidisciplinary representation in the ECs. This is highly gratifying to see that some momentum is made in this direction and as a result, CCIM has initiated developing the guidelines for structure and function of ASU-ECs as is evident by its circular directed to Principals/Deans/Directors of all ASU colleges 'regarding the making of guidelines for Ethics Committee in Ayurveda PG regulations' [2].

While appreciating the step taken by CCIM as the probable first of a long process of actions aiming at a single objective of improving the ASU-EC functioning and impact, we need to reiterate that developing fresh guidelines for ASU-EC functioning may not be the most appropriate step to standardize the ASU research. In the presence of many existing and evolving ethics guidelines including those of Indian Council of Medical Research (ICMR) [3] and Good Clinical Practices for Ayurveda, Siddha and Unani drugs (GCP-ASU) [4], the very need of evolving a fresh guideline for ASU-EC functioning may raise more cautions than comforts. Understanding the purpose of ethical considerations of research, seeing how this step

E-mail: rastogisanjeev@rediffmail.com

Peer review under responsibility of Transdisciplinary University, Bangalore.

can be utilized to bring qualitative improvements in ASU research and connecting it with research methods and outcomes across the disciplines is extremely necessary. The ultimate objective of any such step is to bring ASU research at par with research conducted in any other discipline of study anywhere in the world.

2. Moving alone: The advantages and disadvantages

ASU in India is still a small community comprising of few thousand faculties and less than a million practitioners. The existing standard of education, practice and research in ASU is largely known for its poor quality and impact on overall health care delivery. Most ASU educational institutions in the country struggle continuously to meet the minimum standards required (MSR) to run their academic activities [5]. In the absence of enough resources and expertise in concerned subject areas, and absence of learning opportunities through cross-disciplinary approaches, moving alone with the embedded limitations has inbuilt possibilities of dilution of benchmarks suiting to its currently limited capacity but not reaching to the universal standards.

For domains like research and ethics having uniform global standards, building the restrictive boundaries will eventually be unhealthy for disallowing the need of getting inspired by the standards set by others in similar or dissimilar knowledge areas.

Researching *in silo* as one segregated community also restricts the process of knowledge evolution through constructive criticism offered by peers from other disciplines, had it been an open community [6]. For the areas like research and ethics no such disciplinary boundaries actually exist since their essence lies in the global common good irrespective of knowledge areas. Research in a pluralistic health care scenario seems more apt to this proposition since here the means and methods of research are essentially the same. Naturally, the research methods and its guiding principles adopted in such cases ought to be of same standard. Although the drug formulations to be studied in clinical studies from ASU systems may be different from those studied in modern medicine, the participants are similar. They have the same concerns, risks and benefits. Hence, the guidelines in protecting them need not be different.

There can be advantages in moving alone if we belong to a completely distinct category not matching to any other stream of knowledge and if our needs and methods are entirely different than others. ASU do have some of these situations where its traditional wisdom is being revalidated for effective translational use and where the conventional methods of research do not appropriately fit into fundamental research questions of Ayurveda [7]. Some buffer is also required to be provided in situations where the traditional formulations are planned to be re-evaluated for newer indications or for their extent of action. An Ayurvedic formulation based research need not to be discouraged for want of pre-clinical safety studies, if the formulation is found to be in use by the traditional practitioners without any noticeable adversity. Such situations, not matching to the ethics framework of conventional health care research may warrant for a separate understanding of ethics related to research needs in ASU. The best could have been the middle way adopting the stringent methods of research designed by conventional health care research but at the same time having the dynamicity to accommodate the peculiar needs of ASU research.

3. Optimizing the performances: Building the team and building its capacity

It is important to understand that merely developing the guidelines may not deliver its real benefits unless the people

complying with it are empowered with the knowledge required to perform optimally. ECs in ASU institutions so far have been set up casually without looking at the competence of the people in the area of ethics and research. Moreover, the team often lacks the diverse representations from various disciplines defeating the purpose of getting benefitted through the diversity of opinions. There are no mechanisms of encouraging the real contributors and revisions in EC structures are rarely attempted in ASU colleges. There are no mechanisms of sensitizing the EC team members about what is expected from them during reviews and how their active participation can become a game changer in terms of qualitative improvements in ASU research. Adopting the similar policies and guidelines as adopted by global researchers, ASU–EC team members can easily get inducted for their responsibilities and accountability by national organizations like ICMR and Forum for Ethics Review Committees in India (FERCI) and international organizations like Forum for Ethics Review Committees in Asia Pacific (FERCAP) and Committee of Publication Ethics (COPE). COPE may have a special significance here seeing that study protocols after the approval from ECs are now accepted by many research journals as fully citable, independent, open access articles. It is presumed that publishing study protocols will help to improve the standard of health care research [8]. There are many other agencies working in the area of bioethics across the globe and these are regularly offering courses and workshops for extending awareness among EC members. ASU–EC members can get an easy access to the knowledge provided by such institutions by merely adhering to their principles. Building a diverse yet responsible team with a common objective of making ASU research more responsible and at the same time improving their skills to work optimally in the area could be the most feasible strategy. The emphasis on training of EC members in scientific review techniques should be given a high priority. On the lines of Continuing Medical Education (CME) and Re-orientation Training Programs (ROTP) organized by Ministry of AYUSH, there can be regular training programs across the country for EC members in research methodology, scientific review and review of ethics related issues.

4. Empowering the ECs: Ensuring their independence

Independence is the core strength of an EC to ensure its unbiased functioning. Although institutional ECs by and large are situated within the premise of an ASU institution and comprise of a member secretary from the same institution, their function should essentially remain independent of institutional influences. For this reason, ECs are proposed to have their independent office and working staff and should be allocated with a small budget to ensure their smooth functioning. To ensure their financial autonomy, some ECs have started incurring charges for the review of proposals. The funds generated through the review process may come as a great help to ensure ECs financial independence and also as a help to arrange capacity building programs for EC members. This model may be adopted by ASU-ECs as well. The decisions like expedited review, re-review, revision, rejection or acceptance should solely lie upon the merit and should not be influenced by the reasons other than merit. Such decisions should always be taken consensually in the presence of the quorum. To make it further transparent, every EC member should also declare Conflict of Interest (COI) while becoming the member. Individual COI declarations may also be required in reference to the proposals being discussed in a particular meeting. If declared, such member should not be allowed to participate in the discussion related to the particular research proposal. Actually, every EC is needed to develop its own standard operating procedure (SOP) based upon its priorities, structure and

area of concern. We however see that most of ASU-ECs are yet to develop their SOPs to ensure their functioning as per rules.

5. Accountability in ECs: Bringing it down to the level of natural practice

Accountability comes as a natural instinct by attaching responsibility with the worth of actions and their impacts. Making every EC member aware about how their individual commitments and actions are supportive to a big cause of promoting value in research and its outcome, and how their opinion matters to reach at a collective goal for whole EC is the easiest way to inculcate accountability in the whole team. Since whole EC activity is a voluntary act involving a group of self motivated people, the accountability in EC cannot be piped in by adopting monitoring methods alone. There should be an appeal and re-reviewing mechanism for all decisions taken by an EC when the researcher is not satisfied with the decision. Such re-reviews should also be taken as a learning opportunity to all involved in earlier review. Such re-reviews may either be conducted at the same EC in another meeting with a bigger representation of members including external experts or there can be an appellate authority who can review the decisions made by the EC.

6. Strengthening other filters to ensure responsible research in ASU

Ensuring and pursuing responsible research is not the responsibility of EC alone. There are many filters and checks already existing before a research proposal actually reaches EC. The checks like Departmental Review Board (DRB) may actually add much value to the proposal if such reviews are conducted seriously at initial level. Such review may add much value to the proposal if it also involves the people from other concerned departments or disciplines and the people having an expertise in research ethics. DRB usually acts as the primary filter and once thoroughly reviewed and cleared by DRB, there remains much less for EC or any other filtering agency to do.

7. CCIM initiative to ensure effective functioning of ECs

CCIM functions as the statutory body to regulate ASU education and practice in India. It is not directly linked with research planning and conduction in ASU but since research is an integral part of PG and PhD education, CCIM has its say to regulate research associated with these educational programs. The recent initiative of CCIM to develop guidelines for effective functioning of ECs in ASU although a welcome move, is not free from concerns and cautions. Two important concerns in this regard are 1. The proposition of final approval of a research proposal by University Board of Studies (UBS), and 2. CCIM proposal of framing its own Central Ethics Committee (CEC) as a monitoring agency and asking every EC to submit their annual report to CCIM. The first concern is about independence of EC on ethics related issues and its authority to reach at a decision. Naturally, if EC is not visualized as an independent authority, its strength will be diluted to no gain. The time taken for final approval of a work in such case and for research being taken-up in a time bound manner as a component of the PG or PhD curricula is also a matter of concern [9]. Shifting the ultimate decision-making to the UBS also has a risk of making the earlier steps less valued and irrelevant. This will eventually dilute the very existence of the EC and will not truly help the idea of giving more freedom and autonomy to ECs and ensuring their accountability. We need to understand that independence and autonomy are envisaged as the hallmarks of EC functioning. Delegating its

decisive powers to board of studies is neither practical nor has any precedence in the history. Current practice of Ayurveda research in the country is the submission of research synopsis having an EC approval to the University authorities for its final approval during any upcoming faculty meeting. Continuing this practice has no harm if the EC functions responsibly while reviewing the research proposals.

The statement 'It should be mandatory for all Ayurveda institutions to send the annual IEC report to the Ethics Committee of CCIM, New Delhi' reflects the CCIM proposition of making its own Central Ethics Committee (CEC) fraught with problems since CCIM has no direct liability of conducting research in ASU neither it has any expertise; therefore, its taking the charge of monitoring the ASU research in India seems completely unwarranted. Again such steps are overambitious and alarming. In contemporary health care research, we do not have any precedence of ECs being monitored by councils like Medical Council of India (MCI), Dental Council of India (DCI) or Indian Nursing Council (INC). EC monitoring for ASU research by a central monitoring agency could have been a good step to keep EC abide by the set Standard Operating Procedures (SOP) conducting reviews provided they should not have any big brother's role to play and independence of EC remains unaffected. Such regulatory monitoring can be done by some ASU agency related to the drug research and regulation at par with Central Drugs Standard Control Organization (CDSCO) [10]. The office of Central Drug Controller for ASU&H drugs which has been contemplated by Ministry of AYUSH since long can be a highly pragmatic alternative to CDSCO for ASU systems [11]. The drug development, regulatory section/division of Ministry of AYUSH has recently been vertically shifted to CDSCO office, so the long pending demand has started rolling out. We are expecting more clarity in this regard in the coming time [12,13].

There is EC registration process with Department of Health Research (DHR) which is mandatory as per NDCT Rules, 2019 and which takes care of the functional integrity of the ECs. The CCIM-CEC may get a note of actual idea of EC registration which means adherence to some minimum standards of functioning. Later on, accreditation of ECs by some appropriate ASU research regulatory agency may also be attempted.

Let us be very clear about CEC role as monitoring or registering body. Equivalent to CDSCO and DHR, CCIM can create a portal for registering of EC of AYUSH institutions. NDCT Rules allows their inclusion since it comes under biomedical and health research although there had been some initial confusion in categorizing Ayurveda formulations and fundamental based research with in the context of health research. The registration, if envisaged can take care of structure and function of EC on paper like SOPs and training certificates with CV of members may be needed for registration. This will rectify many structural gaps. If CEC is envisaged as a central body for ethics then the task would be huge to monitor all AYUSH ECs. Instead it can reserve its mandate for certain purposes like Central Ethics Committee for Human Research (CECHR) as ICMR does. The latter sees proposals of national significance and policy matters where national sensitivity is concerned. We suggest that a deeper thought process and brainstorming may be initiated to give this issue a shape assuring its effective utilization in streamlining the quality of research in Ayurveda.

Many other proposals suggested in the CCIM circular as special points to be included in the proposed EC guidelines have similar concerns. Suggestion of a plagiarism check for synopsis and thesis (it reads as 'Plagiarism will be implemented in all theses. Relaxation of 20% may be given to drug and literature review') seems to be ideal but is impossible to implement since there are no such repositories available on web which are storing the PG synopsis and thesis in ASU and are allowing their retrieval for a plagiarism

check. UGC Shodha Ganga repository currently is available for the PhD dissertations only and it does not store MD dissertations [14]. There is nothing like a synopsis repository in ASU which may store the research proposals before they are actually executed. To enable any plagiarism check in research synopsis and thesis, CCIM may need to come with its own searchable repository for ASU-PG synopsis and dissertations to imply such ambitious objectives. This can be a mega task storing over 4000 ASU MD synopsis and dissertations submitted every year in the country and making them available for the online plagiarism check. If done, it however would possibly be one big leap towards the qualitative improvisation of the current ASU research in the country by allowing all the previous ASU PG research searchable on the internet. A plagiarism check in ASU PG research can only be made possible once this repository is formed.

8. Conclusion

Developing guidelines do not end the miseries especially when these are overarching beyond the ground realities. Guidelines are helpful as the referral advisory documents intending to help reach at certain pre-conceived standards of operations. The objective of developing the guidelines is to encourage the people to adhere to such standards which are needed to give uniform and optimal results through a known course of action. Guidelines are therefore different from acts and are never mandatory. In order to make the people abide by the guidelines essentially, requires an evidence-based approach showing the clear benefits of doing so. Thus, developing the guidelines does not mark the end of the job but rather its beginning. Tougher job is to make the people adhere to the guidelines for their own reasons and not because it is made mandatory. We are aware of the net outcomes of such mandatory provisions existing in ASU education and research. While taking this task of revising the role of EC in ASU research, CCIM or any other regulatory agency in ASU may wish to get ready for the bigger challenges of playing a facilitator in the field rather than becoming a watchman. This is a multistep and multilevel task and can be accomplished only by stakeholders working in tandem towards a unified goal. Adhering to the existing guidelines within the purview of ICMR and GCP-ASU may make a way to find more time to address the challenges like developing a repository of ASU-PG research and erecting an independent central institution to monitor ASU drug research. Eventually the ultimate objective of any such activity is to bring ASU research at par with the global standards.

Source(s) of funding

None.

Conflict of interest

None.

Acknowledgement

Author is highly thankful to the anonymous reviewers who helped extensively to improve the manuscript through their suggestions.

References

- [1] Rastogi Sanjeev. Ethics Committees in Ayurvedic PG institutions: Losing opportunities of making an impact. *J Ayurveda Integr Med* 2018;9(2):151–4.
- [2] CCIM circular ref No 3-1-2018 (Ay. Committee). To Principles/Deans/Directors of all ASU Colleges on Subject – To make guidelines for ethics committees in Ayurved PG regulations- regarding. 2019.
- [3] National ethical guidelines for biomedical and health research involving human participants. 2017. Available at: https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx.
- [4] Good clinical practice guidelines for clinical trials in Ayurveda, Siddha and Unani medicine (GCP-ASU). 2013. Available at: <https://main.ayush.gov.in/acts-rules-and-notifications/good-clinical-practice-guidelines-clinical-trials-asu-medicine>
- [5] Rastogi S. Ayurveda education in India: Addressing the human resource barriers to optimize the delivery. *J Ayurveda Integr Med*. <https://doi.org/10.1016/j.jaim.2020.04.003>.
- [6] Lakhotia SC, Patwardhan Kishor, Rastogi Sanjeev. AYUSH advisory presents ominous outlook for research in traditional Indian healthcare systems. *Curr Sci* 2019;116(9):1459.
- [7] Rastogi Sanjeev, Bhattacharya Arindam, Singh RH. Evidence building in Ayurveda: generating the New and optimizing the old could Be strategic, in 'Ayurveda in the New millennium emerging roles and future challenges' eds. D Suresh Kumar, .CRC Press, NW (in print ISBN: 978-0-367-27954-7 (hbk)).
- [8] Study Protocol, Available at: <https://bmcpublihealth.biomedcentral.com/submission-guidelines/preparing-your-manuscript/study-protocol>.
- [9] Indian medicine central council (post graduate Ayurveda education) regulation. 2016. Available at: <https://ccimindia.org/pdf/rul-reg-mse-ay-2016-9.pdf>.
- [10] Ethics committee. Available at: <https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/>, . [Accessed 29 August 2020].
- [11] Central drug controller for ASU and H. Available at: <https://main.ayush.gov.in/drugs-and-pharmaceuticals/quality-assurance-campaign>. [Accessed 29 August 2020].
- [12] Singh Amritpal. Central Ayush drug controller in Ministry of Ayush. 2019. Available at: <http://www.pharmabiz.com/ArticleDetails.aspx?aid=118905&sid=9>.
- [13] Aayush in CDSco, Available at: <https://cdsco.gov.in/opencms/opencms/en/Aayush/>.
- [14] Shodhganga, A reservoir of Indian thesis@INFLIBNET, available at: <https://shodhganga.inflibnet.ac.in/browse?type=title>.