Curriculam: Ph.D Course Work

The basic purpose of any education is to enable a person to widen his horizon of knowledge and develop skills necessary to comprehend and handle his life situation better and make his life and that of his fellow beings more meaningful happy. It is a well known fact that life situations change every day and every moment so it demand continuous updating of knowledge, exploration of new dimensions and search of new solutions to make necessary adjustment. Obviously it is the area of research methods which provide us guidance to explore new knowledge and find out solutions of problems. We already have been relied on it for long to fill the gap in knowledge and extension of knowledge. There are many areas (education, culture, health etc) in which academic and immediate solutions of problems are required. In this regard various PhD programs have been conducted by different universities all over the world as well as in India for a long. To Strengthen and improve the quality of research in various fields and corresponding subjects the University grant commission of India has instructed the universities of India to conduct a six month PhD Program (must include research methodology, statistics and knowledge of computer applications and publication ethics) for the PhD students selected through entrance examination.

Keeping all these points in mind the course content of the PhD program for the students of Psychology, Yoga Science, Indian Culture & Tourism etc. have been developed with the following objectives.

1- To impart the accumulated and the most recent knowledge with a view to develop proficiency to such level that the student should be capable of independent and critical thinking in regard to research problems and issues.

2- To develop a deeper understanding of research methods, research designs and their application in testing hypotheses.

3- To give students the fundamental as well as advance knowledge of statistical methods which help them in analyzing research data with proper understanding.

4- To increase the awareness about the publication ethics and publication misconducts.

5- To provide knowledge of computer application

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Ph.D. Course Work Program: Credit Structure

Sr. no.	Course	L+T+P	Credit
01	Research Methodology & Statistics	06+2+0	08
02	Computer Fundamental, Research & Publication Ethics	04+0+04	08
03	Subject Specific Course	4+2+00	06
			Total 22

Paper I- Research Methodology & Statistics

Description

(I) This course will be of 100 marks, out of which 60 marks will be assigned to external evaluation and 40 marks will be to internal evaluation.

(II) Inernal evaluation will be done by the concered teacher by conducting internal test, assignment or other possible measues.

(III) There shall be two parts - one Statistics (04 Credit) and another Research Methodology (04 Credit). All questions will be carried out of these two parts equally.

(IV) Credit: 08 (04 credits for Statistics + 04 credits for research methodology)

(Part - I)
Research Methodology

Unit -I :

Science & scientific approach, concept, construct and theory; Meaning, objectives and types of research; Paradigms of research: quantitative, qualitative and mixed method approach; Types of variables, research problem, hypotheses, sampling

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UNIT – II: Internet Basics

Internet: what is internet, Use of Internet, Electronic Mail (E-mail), www, Downloading & Uploading, Access of E-Journals, E-Library, SearchEngines, Searching the keywords, Overview of Google Applications (Forms, Drive, Meet, and Classroom).

UNIT – III: Formatting, Data Handling & PresentationTool

MS-Word: Toolbars, Menu, Editing a Document, File handing and various Format of File, Mail Merge, Basics of Latex.

MSExcel: Toolbars, Menu, Creating Worksheet, Charts, Sorting and Filtering, Use of Formulas.
MS-Power Point: Creating Presentations and adding Effects.

Reference Books:
1. Basics of computer by Peter Norton
2. Basics of computers by P.K. Sahani
3. Microsoft office 2000 complete, BPB publication

PART-II

Research and Publication Ethics (RPE)

Description: This course has total 3 units focusing on basics of Philosophy of science and ethics, research integrity, publication ethics. Hands-on sessions are designed to identify research misconduct and predatory publications. Indexing and citation databases, open access publications, research metrics (citations, h-index, Impact Factor, etc.) and plagiarism tools will be introduced in this course.

COURSE LEVEL
2 credit course (30 Hrs.)

Evaluation:
Continuous assessment will be done at two levels. First through tutorials, assignments, quizzes and group discussions and second will be based on life management skills and ethical awareness & practices. Weightage will be given for active participation. Final written examination will be conducted at the end of the course.

Marks Allotment: 50 (30 external + 20 internal)

Course Structure
The course comprises of three modules listed in table below.

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Modules	Unit Title	Teaching Hours
Theory		
RPE 01	Philosophy and Ethics	4
RPE 02	Scientific Conduct and Publication Ethics	11
Practice		
RPE 03	Open Access Publishing, Publication Misconduct, Database and Research Metrics	15
	Total	**30**

SYLLABUS IN DETAIL

Theory:

RPE 01: PHILOSOPHY AND ETHICS (4hrs)

1. Introduction to Philosophy: definition, nature and scope, concept, branches
2. Ethics: Definition, moral philosophy, nature of moral judgements and reactions.

RPE 02: SCIENTIFIC CONDUCT AND PUBLICATION ETHICS (11hrs.)

1. Ethics with respect to science and research
2. Intellectual honesty and research integrity
3. Scientific misconducts: Falsification, Fabrication and Plagiarism (FFP)
4. Redundant publications: duplicate and overlapping publications, salami slicing
5. Selective reporting and misrepresentation of data
6. Publication ethics: definition, introduction and importance
7. Best practices/standards setting initiatives and guidelines: COPE, WAME etc.
8. Conflicts of interest
9. Publication misconduct: Definition, concept, problems that lead to unethical behavior and vice versa, types
10. Violation of publication ethics, authorship and contributorship
11. Identification of publication misconduct, complaints and appeals
12. Predatory publishers and journals

Practice:

RPE 03: OPEN ACCESS PUBLISHING, PUBLICATION MISCONDUCT, DATABASES AND RESEARCH METRICS (15hrs.)

1. Open access publications and initiatives

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RESEARCH ETHICS COMMITTEE
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STANDARD OPERATING PROCEDURE
for Research Ethics Committee for Research on Human participants

(This Standard Operating Procedure (SOP) is to outline the development, approval, organization, implementation and management of all Human Research protocols to be conducted in Dev Sanskriti Vishwavidyalaya. This SOP document is also meant to guide the researcher on how to apply for ethical clearance, what all documents to submit and the points that s/he must observe while dealing with human participants and / or materials.)

1. OBJECTIVES

The Research Ethics Committee (REC) is responsible for reviewing research involving human participants at this institution, to ensure that subjects' safety, rights, and welfare are protected in conformity with applicable regulations and guidelines issued by the ICMR, UNESCO, WHO, Indian state and local laws and regulations where such laws or regulations provide protection for human subjects that exceed the protection afforded under national law. A number of studies pursued in Dev Sanskriti Vishwavidyalaya (DSVV) include biological sample (blood/ tissue/ stored sample) collected from diseased and normal subjects for research purposes, as well as non-invasive studies in cases of neurological damage, dyslexia, developmental disorders, etc. Non-invasive studies also include socio-psychological, socio-cultural studies involving human participants. All such studies on biological samples, stored samples, behavioral data samples and socio-cultural-psychological data samples involving human participants need ethical clearance by REC. All such studies require REC clearance before the commencement of the study.

This Standard Operating Procedure (SOP) is to outline the development, approval, organization, implementation and management of all Human Research protocols to be conducted in Dev Sanskriti Vishwavidyalaya. The REC is entrusted not only with the initial review of the proposed research protocols prior to the initiation of the project, but, in case of adverse effects reported by the Principal Investigator (PI)/ participants, the REC is also mandated to review such cases. All adverse effects/ injury/ damage/ loss/ death must be reported immediately to the REC, death to be reported within 24 hours, as per GOI/ CDSCO norms.

In case of modifications in research tools and procedures during the course of the study, reported by the PI/ participants, the REC is also mandated to review and accept/ reject the modifications proposed as the case may be.

References

- CDSCO- Central Drugs Standard Control Organization - "Good Clinical Practices For Clinical Research In India" (Available from- http://www.cdsco.nic.in/html/GCP1.html - accessed on 9th March 2016) (CDSCO-Good-Clinical-Practice.pdf)
- CDSCO- Central Drugs Standard Control Organization - "The Drugs and Cosmetics Act (1940) and Rules (1945)"
    - (Available from - http://www.cdsco.nic.in/writereaddata/Drugs&Cosmetic Act.pdf - accessed on 9th March 2016) (Drugs&Cosmetics-Act-1940.pdf)
    - (Amendment 2008 - Available from - http://www.cdsco.nic.in/writereaddata/ D&C_ACT_AMENDMENT_2008_file.pdf - accessed on 9th March 2016)

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(Drugs&Cosmetics-Act-Amendment-2008.pdf)

- (Revised Schedule Y - Available from - http://dbtbiosafety.nic.in/act/schedule _y.pdf - accessed on 9th March 2016) (schedule-y-2005-drugs-and-cosmetics-act.pdf)

- COPE - Committee on Publication Ethics (publicationethics.org) - "Guidelines on Good Publication Practice - 1999"

- (Philip Fulford, Michael Doherty, Jane Smith, Richard Smith, Fiona Godlee, Peter Wilmshurst, Richard Horton, Michael Farthing (2000) "Committee on Publication Ethics (COPE): guidelines on good publication practice", BJU International, 85, 2-7.) (Available from- http://onlinelibrary.wiley.com/ doi/10.1046/j.1464-410x.2000.00478.x/epdf - Accessed on 9th March 2016) (COPE-guidelines-1999.pdf)

- COPE website lists - "Responsible research publication: international standards for authors - 2011" (Wager E & Kleinert S (2011) Responsible research publication: international standards for authors. A position statement developed at the 2nd World Conference on Research Integrity, Singapore, July 22-24, 2010. Chapter 50 in: Mayer T & Steneck N (eds) Promoting Research Integrity in a Global Environment. Imperial College Press / World Scientific Publishing, Singapore (pp 309-16). (ISBN 978-981-4340-97-7))

(Available from - http://publicationethics.org/files/International%20standards_authors_for%20website_11_Nov_2011_0.pdf - Accessed on 9th March 2016) (International-standards-authors-2011.pdf)

- ICMR - Indian Council of Medical Research - "Ethical Guidelines for Biomedical Research on Human Participants" - (Available from - http://icmr.nic.in/ethical_guidelines.pdf - Accessed on 9th March 2016) (ICMR-ethical-guidelines.pdf)

2. ROLES AND RESPONSIBILITIES OF THE RESEARCH ETHICS COMMITTEE

The basic responsibility of REC is to ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner. REC shall provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research.

The mandate of the committee will be to review all research projects involving human subjects/ materials to be conducted in different Departments at the University. The REC will review all research proposals involving human subjects, submitted by faculty members and research students (through their respective Supervisors). Each investigator shall be responsible for proving the benefit of placing human subjects at risk, and assure the REC about appropriate Informed Consent Process and Subject Confidentiality before the commencement of the study. Each investigator shall be responsible to provide details of primary data/ secondary data/ stored samples/ cell lines/ buying data to the REC in her/ his presentation.

All studies need to be approved before the study procedures begin. No completed studies or those already being pursued will be reviewed by the REC.

3. OPERATING PROCEDURES

3.1 CONSTITUTION OF REC

As per ICMR guidelines, the REC should be multidisciplinary and multi-sectorial in

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composition. Independence and competence are the two hallmarks of a Research Ethics Committee. The members should be a mix of medical/ non-medical professionals, legal experts, experts from sciences and social sciences and humanities, philosophers and activists, internal and external, also including lay persons from NGO's to represent the civil society. (See Appendix B for relevant directives based on ICMR guidelines)

A panel of names in each one of the categories specified below, approved by the DSVV Management, will serve as the Research Ethics Committee of DSVV.

Constitution of REC

1. Chairperson
2. Chancellor's Nominee (will serve as the Chairperson, if the Chairperson is not present)
3. Scientist from Medical Practice (External)
4. Scientist from Medical Practice (Internal, DSVV)
5. Scientist from Basic Sciences (External)
6. Scientist from Basic Sciences (Internal, DSVV)
7. Social Scientist / Philosopher / Social Activist (External)
8. Social Scientist / Philosopher / Social Activist (Internal, DSVV)
9. Advisor, Member of ethics review board of another Institution (ICMR, AIIMS, etc.)
10. Legal Advisor (External)
11. Legal Advisor (Internal, DSVV)
12. Lay Persons (one or two)
13. Member Secretary (DSVV)

With reference to the revised Schedule Y of Drugs & Cosmetics Act, 1940, amended in 2005 (attached herewith as 'schedule-y-2005-drugs-and-cosmetics-act.pdf' - available from - http://dbtbiosafety.nic.in/act/schedule_y.pdf - accessed on 9th March 2016), the Research Ethics Committee approving drug trials should have in the quorum at least one representative from the following groups:

1. One basic medical scientist (preferably one pharmacologist)
2. One clinician
3. One legal expert or retired judge
4. One social scientist/ representative of non-governmental organization / philosopher / ethicist / theologian or a similar person
5. One lay person from the community

3.2. COMPOSITION OF A REVIEW COMMITTEE.

The number of persons in a Research Ethics Committee should be 8 to 12, drawn from the panel of names approved by the Management, as specified above. The Chairperson, REC will approve the names of the members of a review committee, containing members from as many different categories as possible, depending on the nature of the research proposal to be reviewed. (Appendix A for the current Panel of Experts in the REC-DSVV).

3.2.1. APPOINTMENT, RESIGNATION AND RECONSTITUTION

For appointment to the committee, the candidate should be a well-known scholar of his/her discipline and must hold position of significant responsibility. Professional integrity and commitment to human welfare would be important criteria for inclusion as members. After the initial constitution, subsequent appointment to the committee shall be guided by the quorum requirements and activity of the members involved. As per ICMR guidelines, the

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appointee will be informed of the rights and duties of the committee, and that the external members will receive honorarium for every consultative meeting held on the campus.

All Committee members shall sign a confidentiality agreement at the time of appointment, the terms of which shall be binding on them even after the term expires. Co-opted members are also expected to sign confidentiality agreement. All members, except the Chairperson and Member Secretary, shall serve a maximum of a three-year term on the committee, after which a fresh panel of three names in the same category will be submitted to the Management, DSVV so that one out of the three may be appointed in place of the retiring person. For the sake of continuity, the Chairperson and the Member Secretary will have a term of five years.

Extension of membership may be considered due to non-availability of members of similar stature, qualification and intent to contribute to ethical human testing.

Members may voluntarily resign from the Committee at a month's notice citing appropriate reasons, and in case of internal members, their membership would be considered withdrawn, if they resign from the University.

A member who has direct involvement or self-affirmed conflict of interest with a proposal being considered, shall not form a part of the quorum. If a member is found to have a conflict of interest with the results of decision and fails to declare the same, or is found to have drawn direct benefit arising out of the results of the research, or has involved self-interest with the sponsor(s) or investigators, his/her membership shall be terminated with provision of appropriate legal proceedings.

In case a member breaches the confidentiality, his/her membership shall be terminated and the institution may initiate appropriate legal proceedings.

3.2.2. HONORARIUM

External members of the REC, and experts invited (if any) shall receive appropriate compensation for the time and effort expended for the purpose.

3.3. PROCEDURE FOR SUBMISSION AND REVIEW

The REC will meet at least once every semester or more if required, to review all the applications, including proposals for Ph.D., as well as including research proposals submitted by the faculty, involving human subjects/ materials for any kind of data. All proposals shall be reviewed as per the applicable guidelines given in Appendix C. (see Research Protocol Organization Guidelines in Appendix C) Exact meeting date shall be notified in advance so that all members can make themselves available for the purpose. The Chairperson/ Member Secretary shall be the convener with responsibility of laying out the agenda for the meeting. All material relevant to the agenda shall be made available to REC at least 2 weeks* in advance (*under special circumstances, this requirement may be relaxed with due approval from the Chairperson/ Member Secretary). Before they are circulated to the external members, the Member Secretary of the committee, together with one or two internal members, will screen the proposals, to see if the proposals need (i) exemption from review, or (ii) expedited review or (iii) full review (see Appendix B for relevant directives based on ICMR guidelines).

*Inputs from departments at this stage will be important

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All protocols should be submitted in the format prescribed in Appendix C. The proposals shall be addressed and submitted to the office of the Member Secretary, Research Ethics Committee (REC), Dev Sanskriti Vishwavidyalaya, Gayatrikunj-Shantikunj, Haridwar - 249411 (Uttarakhand). One hard copy and soft copy of the documents should be submitted. An application should be submitted at least two weeks* prior to the next review meeting (*under special circumstances, this requirement may be relaxed with due approval from the Chairperson/ Member Secretary). A unique submission number shall be assigned to proposals submitted for review.

Recommendation of the Committee

After discussion, the committee may make one of the following recommendations:

- Approval - indicating that the proposal is approved as submitted;
- Approval after clarifications - indicating that the proposal is approved if the clarification(s) requested are provided to the satisfaction of designated committee members;
- Approval after amendment(s) - indicating that the proposal is approved subject to the incorporation of the specified amendment(s) verified by designated committee members;
- Deferment - indicating that the proposal is not approved as submitted but it can be reassessed after revision to address the specified reason(s) for deferment;
- Disapproval - indicating that the proposal is not approved for the reasons specified.

Format for the Ethical Clearance Certificate will be as given in the Appendix

3.4. DOCUMENTS FOR SUBMISSION OF THE PROPOSAL

1. Protocol of the proposed research in the prescribed format (see Appendix-C) which includes:
   1.1 Rationale / Background information
   1.2. A description of the ethical considerations involved in the research
   1.3. Case report forms, diary cards, and other questionnaires intended for research participants
   1.4. Summary of safety, pharmacological, pharmaceutical, and toxicological data available on the study product, wherever applicable
   1.5. Statement of agreement to comply with ethical principles
   1.6. Statement of conflict of interest
   1.7. Name and address of the Sponsor/ Funding agency
   1.8. Insurance Statement (Wherever required)
2. Investigator's Brochure Including Report of Prior Investigations
3. Investigator(s)'s curriculum vitae
4. Informed Consent
5. In case of students' proposals, synopsis of the Ph.D. research as approved by the Research Degree Committee of DSVV

3.4.1. Regarding no. 4 above (Informed Consent), a template is given in the Appendix-C, which may be modified depending on the nature of participation expected from the study participants.

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3.5. DOCUMENTATION AND RECORDS

The proceedings of all meetings shall be documented and shall be kept in confidence. The release of the detailed documentation to non-committee members can only be made in case of exceptional circumstances, which shall be verified either by court orders or by affirmative opinions by the Chairperson and the Member Secretary. Minutes of the meeting shall be circulated by Member Secretary for verification by the Chairperson and members present during the discussion. After verification, the Member Secretary shall communicate final decisions regarding protocols to the investigator(s). All documentation samples for different kinds of studies must be retained for at least three years after the completion of the study.

The following records should be maintained by the REC office:
I. The Constitution and composition of the REC
II. Signed and dated copies of the latest curriculum vitae of all REC members with records of training, if any
III. Standard Operating Procedure of the REC and modifications approved from time to time
IV. National and International guidelines
V. Copies of protocols submitted for review
VI. All correspondence with the members of the REC, and investigators regarding application, decision and follow up;
VII. Notice and agenda of all REC meetings;
VIII. Minutes of all REC meetings with signatures of the Member Secretary and the Chairperson.
IX. Copies of decisions communicated to the applicants;
X. Record of all notifications issued for premature termination of a study with a summary of the reasons;
XI. Final report of the study including microfilms, CDs and Video recordings/ samples for different kinds of studies. PI may be asked to report completion of the study.

3.6. NOTIFICATION OF AMENDMENTS

Any revision to an approved research protocol or written consent form if proposed must be brought to the attention of the REC for approval. Amendments to approved protocols and other study related documents should not be initiated until the REC approval has been obtained.

All deviations from the study protocol should be documented in the original records along with the reasons for doing so. In case of any adverse event, the same, along with the remedial measures taken, must be reported by the investigator(s) immediately to the Chairperson and the Member Secretary, besides making a note of it in the study documentation.

3.7 ANNUAL REVIEW AND FINAL REPORTING

The Committee should be updated regarding the progress of the study on an annual basis. The Committee must be notified of the trials completed or terminated (wherever applicable). A copy of the final report should be submitted as soon as it is available.

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Statement of PI regarding conclusion/ completion/ termination/ abandonment of the study must be submitted as soon as the study is terminated.

3.8. RECONSTITUTION OF COMMITTEE

The Committee shall be considered non-functional and reconstitution considered in the following instances:

- No meeting is convened for a continuous period of 1 year
- Meeting attendance is below 5 independent members for four consecutive meetings

3.9 AMENDING THIS DOCUMENT

Any amendments to this document shall be approved under the same procedure as for other proposals under the purview of REC.

4. Appendices

Appendix A: List of Members of REC
Appendix B: Relevant directives regarding Review Procedure based on ICMR Guidelines
Appendix C: Research Protocol Organization Guidelines
Appendix D: Good Publication Practice Guidelines
Appendix E: A Sample Research Protocol

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Appendix A

The panel of names in each category as approved by the Management, DSVV.

1. Chairperson
   External Chairperson – nominated by University Management

2. Chancellor's Nominee (will serve as the Chairperson, if the Chairperson is not present)
   Vice Chancellor, Dev Sanskriti Vishwavidyalaya (DSVV), Haridwar
   Pro-Vice Chancellor, Dev Sanskriti Vishwavidyalaya (DSVV), Haridwar
   Dr. Manas Mandal (PhD), Director General - Life Sciences (LS), Defence Research Development Organization (DRDO), New Delhi

3. Scientist from Medical Practice (external)
   1. Dr. Vinod Updhyay (PhD), Rtd. from Gurukul Kangri Vishwavidyalaya, Haridwar
   2. Dr. Sunil Joshi (MS), HOD Dept. of Surgery, Gurukul Kangri Vishwavidyalaya
   3. Prof. Shridhar Dwivedi (MD, PhD), HOD Dept. of Medicine / Preventive Cardiology, Hamdard Institute of Medical Sciences and Research (HIMSR), New Delhi

4. Scientist from Medical Practice (internal, DSVV)
   1. Dr. A. K. Dutta (MS), Shantikunj, Haridwar
   2. Dr. O. P. Sharma (MD), ASRSS Hospital, Shantikunj, Haridwar
   3. Dr. Vandana Shrivastava (PhD), Centre for Ayurveda Studies, Dept. of Yoga and Health, DSVV

5. Basic Sciences / Researchers (external)
   1. Prof. Ishwar Bhardwaj (PhD), HOD Dept. of Yoga, Gurukul Kangri Vishwavidyalaya
   2. Prof. C. P. Khokhar (PhD), HOD Dept. of Psychology, Gurukul Kangri V.V.
   3. Dr. Sanjeev Sharma (PhD), Computer Science, Meerut

6. Basic Sciences / Researchers (internal, DSVV)
   1. Dr. Karna Singh (PhD), Dept. of Rural Management, DSVV
   2. Prof. Abhay Saxena (PhD), HOD Dept. of Computer Science, DSVV
   3. Dr. Santosh Vishvakarma (PhD), Dept. of Psychology, DSVV
   4. Dr. Saurabh Mishra (PhD), Training and Placement Cell, DSVV

7. Social Scientist /Philosopher/ Activist (ext)
   1. Prof. Mahavir Agrawal (PhD), Sanskrit Vishwavidyalaya, Haridwar
   2. Prof. U. S. Bisht (PhD), (Rtd.) Dept. of Philosophy, Gurukul Kangri Vishwavidyalaya
   3. Dr. Govind Singh (PhD), Director, School of Journalism and Media Studies, Uttarakhand Open University, Haldwani

8. Social Scientist /Philosopher / Activist (int. DSVV)
   1. Prof. Suresh Lal Barnwal (PhD), HOD Dept. of Yoga and Health, DSVV, Haridwar
   2. Prof. Sukhnandan Singh (PhD), HOD Dept. of Communication, DSVV, Haridwar
   3. Dr. Krishna Jhare (PhD), Dept. of Oriental Studies, DSVV, Haridwar

9. Advisor / Members of the Research Ethics Committee of other institutions (ext):
   1. Prof. Pankaj Kumar Sharma, Rishikul Ayurvedic College, Haridwar
   2. Prof. Kalpana Sharma, Rishikul Ayurvedic College, Haridwar

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3. Prof. Gyanendra Shukla, Rishikul Ayurvedic College, Haridwar

10. Legal Advisor (ext)
    1. Advocate Shri P. P. Singh, Ghaziabad

11. Legal Advisor (internal, DSVV)
    1. Advocate Sushree Kiran Kapoor, DSVV, Haridwar

12. Lay persons:

In case the study involves children then a parent, or guardian of a child, teacher in a special school, etc. may be invited. In case the study on the agenda involves adults then the Chairperson, REC may involve any one at his/her discretion (Discretion of the Chairperson of REC).

13. Member Secretary
    Registrar, DSVV, Haridwar

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Appendix B

Relevant directives regarding Review Procedure based on ICMR Guidelines

The REC's member secretary or secretariat shall screen the proposals for their completeness, and depending on the risk involved, categorize them into three types, namely, exemption from review, expedited review and full review (see below for explanation). Minimal risk would be defined as one, which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions, since it would be undertaken as part of current everyday life. An investigator cannot decide that her/ his protocol falls in the exempted category without approval from the REC. All proposals will be scrutinized to decide under which of the following three categories it will be considered:

1. Exemption from review

Proposals which present less than minimal risk fall under this category as may be seen in following situations:

Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exceptions: (i) When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.

(ii) When interviews involve direct approach or access to private papers.

2. Expedited Review

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member Secretary and the Chairperson of the REC or designated member of the Committee of the REC may do expedited review only if the protocols involve-

(1) Minor deviations from originally approved research during the period of approval (usually of one year duration).

(2) Revised proposal previously approved through full review by the REC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.

(3) Research activities that involve only procedures listed in one or more of the following categories:

(a) Clinical studies of drugs and medical devices only when –

i. research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or

ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

(4) Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.

(5) When in emergency situations like serious outbreaks or disasters, a full review of the research is not possible, prior written permission of REC may be taken before use of the test

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intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial. Research involving human participants may be initiated later based on the findings of the pilot study, after due approval from the REC.

(6) Research on interventions in emergency situation when proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND)/ devices/ vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients –

i. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;

ii. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of Drug Controller General (India) (DCGI);

iii. Only if the local REC reviews the protocol, since institutional responsibility is of paramount importance in such instances.

iv. If Data Safety Monitoring Board (DSMB) is constituted to review the data;

(7) Research on disaster management - A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans, and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i. Research planned to be conducted after a disaster should be essential, culturally sensitive and specific in nature, with possible application in future disaster situations.

ii. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.

iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.

iv. Protection must be ensured so that only minimal additional risk is imposed.

v. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster-affected population and a priori agreement should be reached on this, whenever possible, between the community and the researcher.

vi. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.

vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

3. Review

All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review, and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.

While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/ benefit analysis:

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(1) Collection of blood samples by finger prick, heel prick, ear prick, or vein puncture, from adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected is strictly as per WHO norms.

(2) Prospective collection of biological specimens for research purposes by non-invasive means, for instance:

a. Skin appendages like hair and nail clippings in a non-disfiguring manner;

b. Dental procedures – deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;

c. Excreta and external secretions (including sweat);

d. Unanimated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;

e. Placenta removed at delivery;

f. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

g. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

h. Sputum collected after saline mist nebulization and bronchial lavages.

(3) Collection of data through non-invasive procedures routinely employed in clinical practice.

(i) Where medical devices are employed, they must be cleared/ approved for marketing, for instance:

a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; weighing or testing sensory acuity;

b. Magnetic resonance imaging;

c. Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow

(ii) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(iii) Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

(iv) Collection of data from voice, video, digital, or image recordings made for research purposes.

(v) Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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Appendix C

Research Protocol Organization Guidelines

I. Protocol

Following are the section headings and brief guidelines on the protocol contents. Though the format below is not binding, the research protocol must include these points in order to enable speedy review.

1. Title of Project

2. Principal Investigator

3. Co-Investigator and other investigative team member list with identified delegation of responsibility

4. Rationale & background information: The Rationale specifies the reasons for conducting the research in light of current knowledge. It should include a well documented statement of the need/ problem that is the basis of the project, the cause of this problem and its possible solutions. It is equivalent to the introduction in a research paper and it puts the proposal in context. It should answer the question of why and what: why the research needs to be done and what will be its relevance.

5. Objectives: Specific objectives are statements of the research question(s). Objectives should be simple, specific and stated in advance. After statement of the primary objective, secondary objectives may be mentioned.

6. Study Design: The scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology. The design of the study should include information on the type of study, the research population or the sampling frame.

7. Participant Selection Criteria: Patients who can take part in the study (e.g. inclusion and exclusion criteria, withdrawal criteria, etc.), and the expected duration of the study with follow-up periods.

8. Methodology: It should include detailed information on the procedures to be used, measurements to be taken, observations to be made, laboratory investigations to be done etc. along with a tabular form study schedule of procedures, for both qualitative and quantitative studies

9. Evaluation of Safety: The adverse event and serious adverse event criteria, and the process to record and report to the REC and any applicable regulatory agency.

10. Research Questionnaire: The protocol should provide research questionnaire containing all parameters under study and also provide information on how the data will be collected including data handling and coding for computer analysis, monitoring and verification.

11. Statistical Analysis: The statistical methods proposed to be used for the analysis of data should be clearly outlined, including reasons for the sample size selected, power of the study,

level of significance to be used in quantitative study. For qualitative studies, as in psychology & cognitive science, the tools and instruments may be clearly explained.

12. Informed Consent Forms: A description of the informed consent process is required accompanied by copies of informed consent forms, both in English and the local language in which they are going to be administered as per ICMR/ WHO requirement. (DCGI/ CDSCO requirement for Drug trials)

13. Budget: The budget section should contain a detailed item-wise breakdown of the funds requested for, along with a justification for each item as applicable.

14. Other support for the Project: This section should provide information about the funding received or anticipated for this project from other funding organizations.

15. Collaboration with other scientists or research institutions, if any. A copy of ethical clearance obtained from the other institution already, must be submitted.

16. References: Brief description of the most relevant studies published, a minimum of 5 on the subject also be listed.

17. Publication policy: Publication policy should be clearly discussed regarding the authorships, who will take the lead in publication and who will be acknowledged in publications. Good Publication Practice guidelines are prescribed in Appendix D.

18. Statement of agreement to comply with ethical principles.

19. Signature of PI and Supervisor or Research Scholar, Co-investigators, Coordinator/ Head of the Centre/ Department.

A Sample Research Protocol is given in Appendix - E

II. Format for Research Ethics Committee Decision Letter / Ethical Clearance Certificate

III. Format for Participant Information Sheet (PIS) and Informed Consent Form (ICF)

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Research Ethics Committee for Research involving Human Participants
Dev Sanskriti Vishwavidyalaya
Gayatrikunj-Shantikunj, Haridwar - 249411

Research Ethics Committee Decision Letter / Ethical Clearance Certificate

Name of the Ethics Committee: REC-DSVV REC Ref. No. ....

Title of the Project Proposal:

Principal Investigator: Sponsor:

Telephone: Email: Fax:

Collaborators' Name, Address, Tel. No., Fax & Email:

FOR OFFICIAL USE

The proposal was reviewed in a meeting held on (date: ....) at (time:...............). The following members were present:

1. Chairperson
2. Member
3.
4.
5.
6.
7.
8. Member Secretary

The committee resolved to
[ ] Approve - indicating that the proposal is approved as submitted;
[ ] Approve - after clarifications - indicating that the proposal is approved if the clarifications requested are provided to the satisfaction of designated committee members;
[ ] Approve after amendment/s - indicating that the proposal is approved subject to the incorporation of the specified amendments verified by designated committee members;
[ ] Defer - indicating that the proposal is not approved as submitted but it can be re-assessed after revision to address the specified reason/s for deferment;
[ ] Disapprove - indicating that the proposal is not approved for the reasons specified*.

*Comments:

Date of Decision:

Member Secretary, REC
Research Ethics Committee

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INSTITUTIONAL ETHICS COMMITEEE
Dev Sanskriti Vishwavidyalaya
Haridwar-249411

Name of the Ethics Committee: **REC-DSVV** REC Ref. No. .....

Title of the Project Proposal:

Principal Investigator: Sponsor:

Telephone: Email: Fax:

Collaborators' Name, Address, Tel.No. Fax & Email:

FOR OFFICIAL USE

The following item [√] have been received and reviewed in connection with the above study to be conducted by the above investigator.

[√] Patient Information Sheet
[ ] Study Protocol / Synopsis
[ ] Summary of Change Document (in case of a revision)
[ ] Patient Information Consent Form
[ ] Investigators' CVs

And have been [√]

[ ] Approved
[ ] Conditionally approved (identify item and specify modification below or in accompanying letter)
[ ] Rejected (identify item and specify reasons below or in accompanying letter)

Comments:

Date of Approval:

Member Secretary
Ethics Committee

Chairperson
Ethics Committee

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8. Rights of Participant [ ] .....
प्रततभागी के अधधकाि .....

9. Alternatives to Participation in the Study [ ] .....
शोध में भागीदाि◌ी के विकल्प .....

10. Any Other [ ] .....
कोई अन्यय सच्चू नना .....

Name of the Subject/Participant/ प्रततभागी का नाम:

Signature of Participant/Parent/Guardian/ प्रततभागी/माता/वपता/संि◌क्षक के हस्ताक्षि:

Relationship to Subject/ प्रततभागी से संबंध:

Date/ टदनांक:

Investigator's Statement:

I, the undersigned have explained to the participant/parent/guardian, in a language she/he understands, the procedures to be followed in the study, and risks and benefits.

Signature of the Investigator/ शोधकर्त्◌ाि◌/शोधार्थी के हस्ताक्षि: Date/
टदनांक:

Name of the Investigator/ शोधकर्त्◌ाि◌/शोधार्थी का नाम:

Signature of the Witness/ गिाह के हस्ताक्षि: Date/
टदनांक:

Name of the Witness/ गिाह का नाम:

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Sample II

Community Responses to Nutritional Rehabilitation in Madhya Pradesh and Jharkhand

INFORMED CONSENT OF RESPONDENTS IN IN-DEPTH INTERVIEWS

Introduction: My name is_____, I am working for Dev Sanskriti Vishwavidyalaya, Haridwar. We are interviewing people here _____(name of the city/ region/ site) in order to understand your responses to the issues and the problems that you face on account of severely under-nourished children and your perceptions on availability and accessibility of services at the nutritional rehabilitation centre. We are also trying to understand the reasons for the delay in reaching the facilities. (Describe the purpose of the study). These issues are being studied in another state as well.

(Name of the other state_____)

CONFIDENTIALITY AND CONSENT

The government has started nutritional rehabilitation centres in your state to take care of malnourished children. In this context, it is important to understand the perceptions of mothers, community leaders and the providers about the availability and access to these services. The goal of this study is to understand the social dimensions, perceptions and likely determinants that facilitate and act as barriers to home-based and institutional care of severe undernutrition.

It is with this main purpose that we wish to talk to you. Your honest answers to the questions will help us understand all the involved issues better. We would highly appreciate your co-operation to provide the information on the issues by your honest and frank responses to all the questions. Your identity and information provided by you shall be completely confidential and the information so gathered from different people shall be used only for research purposes. After analysing the information we are gathering from you, we shall destroy the schedules. However, if you feel strongly not to answer one or some of the question, you feel free not to answer such questions. During the interview process, if you feel not to go ahead with the interview, you can withdraw from the interview at any time you want. You can ask any question/ clarify any doubt pertaining to the issues under study, its purpose or any other related matter. The interview will take about half an hour - one hour to ask the questions. If you are willing to participate, we can begin with the interview by your consent.

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DECLARATION BY THE PARTICIPANT

I have read/ I have been communicated the purpose and other details of the ICMR study "**Community Responses to Nutritional Rehabilitation in Madhya Pradesh and Jharkhand**" and about my voluntary participation in the study. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have also been given the right not to answer any question or withdraw from the study if I so desire.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBED.

Name and Signature of Participant

Date _____

DECLARATION BY THE INVESTIGATOR

I have explained the research to the participant and answered all of his/ her questions. I believe that he/ she understands the information described in this document and freely consent to participate.

_____ _____

Name and Signature of the Investigator Date of the Interview

Status of the interview:

Completed Successfully	1
Respondent became uncomfortable and stopped answering	2
Some interruption due to which interview stopped	3
Did not agree to complete interview	4

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Appendix D

Good Publication Practice Guidelines

1. COPE's guidelines on good publication practice - 1999

The Committee on Publication Ethics (COPE) (http://publicationethics.org/) was established in 1997 by a small group of medical journal editors in the UK, but now has over 10000 members worldwide from all academic fields. Membership is open to editors of academic journals and others interested in publication ethics.

COPE provides advice to editors and publishers on all aspects of publication ethics and, in particular, how to handle cases of research and publication misconduct. It also provides a forum for its members to discuss individual cases.

COPE's guidelines on good publication practice - 1999 are attached herewith as 'COPE-guidelines-1999.pdf'

(Philip Fulford, Michael Doherty, Jane Smith, Richard Smith, Fiona Godlee, Peter Wilmshurst, Richard Horton, Michael Farthing (2000) "Committee on Publication Ethics (COPE): guidelines on good publication practice", BJU International, 85, 2-7.)
(Available from - http://onlinelibrary.wiley.com/doi/10.1046/j.1464-410x.2000.00478.x/epdf - Accessed on 9th March 2016)

2. Responsible research publication: international standards for authors - 2011

During the 2nd World Conference on Research Integrity in Singapore in 2010, COPE helped develop two position statements setting out international standards for responsible research publication for editors and authors.

The internatioal standards for authors - 2011 are attached herewith as 'International-standards-authors-2011.pdf'

(Wager E & Kleinert S (2011) Responsible research publication: international standards for authors. A position statement developed at the 2nd World Conference on Research Integrity, Singapore, July 22-24, 2010. Chapter 50 in: Mayer T & Steneck N (eds) Promoting Research Integrity in a Global Environment. Imperial College Press / World Scientific Publishing, Singapore (pp 309-16). (ISBN 978-981-4340-97-7))
(Available from http://publicationethics.org/files/International%20standards_authors_for%20website_11_Nov_2011_0.pdf - Accessed on 9th March 2016)

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Appendix E

Sample Research Protocol

CLINICAL EVALUATION OF HERBAL PREPARATIONS
IN THE MANAGEMENT OF MANODVEGA
(ANXIETY NEUROSIS)

Drug :

Study Code:

PROTOCOL & CASE REPORT FORMS (CRF)

Source: Lavekar G. S., Padhi M. M. (Editors) (2009) "Clinical Research Protocols for Traditional Health Sciences (Ayurveda, Siddha, Unani, Sowa Rigpa and Others)", Central Council for Research in Ayurveda and Siddha, Department of AYUSH, Ministry of Health and Family Welfare, Government of India, New Delhi (www.ccras.nic.in) (Available at - http://herbalnet.healthrepository.org/bitstream/123456789/2493/1/Research%20protocol%20for%20traditional%20health%20science.pdf - Accessed on 5th March 2016) (research-protocol-for-traditional-health-science.pdf)

CENTRAL COUNCIL FOR RESEARCH IN AYURVEDA AND SIDDHA

CLINICAL EVALUATION OF HERBAL PREPARATIONS IN THE MANAGEMENT OF MANODVEGA (ANXIETY NEUROSIS)

I. BACKGROUND

Life is a conglomerate of body (Shareera), faculties (Indriya), mind (Satva), and soul (Aatma). Any of these cannot be isolated and studied separately. So seers of Ayurveda express that the term Shareera refers body including five senses and mind.

As mind is a dual faculty (Ubhayendriya) or sensory-motor faculty (Jnana-Karmendriya), it perceives and responds. Even the physical well being is reflected in mind, so is the illness. This made the terms happiness (Sukha), and misery (Dukha), synonyms of health and illness. The influence of mind cannot be ruled out in origin, existence or cure of any condition of any disease.

When allowed to persist for long time the psychic and somatic disorders get combined with each other.

Chittodwega/ Manodwega is one of the Manasika Vikara mentioned in Ayurvedic literature. The symptoms of this disease can be assumed mostly similar with the generalized anxiety disorder (GAD). GAD is a disorder requires the presence of unrealistic or excessive anxiety and worry, accompanied by symptoms from three of four categories: (1) motor tension, (2) autonomic hyperactivity, (3) vigilance and scanning, and (4) apprehensive expectation. The anxious mood must continue for at least a month.

The Ayurvedic principle of synthesis of mind, body and soul to consider man as integrated whole one, would help to treat mental disorders effectively. Medhya rasayanas and Satvavajaya chikitsa are such a measures, which can be utilized for the treatment of Chittodwega/ Manodwega.

[1] In Chittodwega/ Manodwega [2], when the mind is afflicted with anxiety, fear, agitation etc.; this leads to worry, apprehension, depression, psychological arousal as anger, irritability and ultimately lead to disturbance in personal, familial and social harmony.

References

1. Charaka Samhita with Ayurveda Dipika commentary of Chakrapanidatta, Chaukhambha Sanskrit Sansthan, 5th edition, Varanasi, 2001
2. Sushruta Samhita with Nibandha Sangraha commentary of Dalhana and Nyayachandrika commentary of Gayadasa, Chaukhambha Orientalia Varanasi, 6th edition, 1997.
3. Harrison: Principals of Internal Medicine Vol. II, 13th edition (International edition).

Anxiety disorders [3] are among the most prevalent psychiatric condition in the world. Further, studies have persistently shown that they produce inordinate morbidity, utilization of health care services, and functional impairment. Recent studies also suggest that chronic anxiety disorder may increase the rate of cardiovascular-related mortality. Hence, clinicians in psychiatry and other specialties must make the proper anxiety disorder diagnosis rapidly and initiate treatment.

Ayurveda provides rational means for the treatment of many disorders, which are considered to be obstinate and incurable in other systems of medicine.

II. OBJECTIVES

To evaluate the anti-anxiety effect of an ayurvedic compound drug in patients suffering with manodwega.

The efficacy of ayurvedic compound drug for six weeks have been studied on manodwega in terms of relieving from the symptoms pridictable through ayurvedic clinical parameters & hamilton's rating scale for anxiety neurosis.

III. CENTRES

CCRAS identified centers

IV. SAMPLE SIZE AND METHODS

Sample Size :	24 patients in each group (2 groups)
Trial period :	45 Days
Design of the study :	Sequential crossover design and double blind method are adopted.
Drug & dosage :	The Ayurvedic compound consists of Mandukaparni (Centella asiatica), Yasti (Glycyrrhiza glabra), Jatamamsi (Nardostachys jatamansi) in the ratio of suspended in the Kshirabala Thaila. The daily dose of Ayurvedic drug is 3 g/day in 3 divided doses. Each capsule contains 500mgs of drug i.e. Mandukaparni (120mg), Yasti (120mg.), Jatamamsi (240mg.) and ksheerabala taila (3 drops). The daily dosage of diazepam is 15mg. /day also in three divided doses. The placebo is plain starch powder.
Duration of the study :	45 days drug therapy with a follow up for 7 days.
Study period :	1 year to complete study.
Follow-Up :	The follow-up will be carried out after 7 days of treatment.

V. CRITERIA FOR INCLUSION

1. Age between 16-45 years of either sex
2. Presence of cardinal features of manodwega
3. Onset between 8weeks to 2 years
4. Ambulatory and co-operative

VI. CRITERIA FOR EXCLUSION

1. Age below 16 yrs. and above 45 yrs.
2. Duration of the disease - below 8weeks and above 2years.
3. Exhibiting psychotic symptoms
4. Factors interfering with concentration and communication
5. Hypertension
6. Diabetes
7. Any other systemic diseases

VII. CRITERIA FOR WITHDRAWAL

1. If patient does not follows the instructions.
2. Any complication developed during the course of trial.

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VIII. ROUTINE EXAMINATION AND ASSESSMENT

A detailed clinical and social history is taken. The patients assessed on the basis of clinical parameters and Hamilton's anxiety rating scales.

IX. METHOD OF ASSESSMENT OF TREATMENT

1. Clinical Symptomatic Relief
2. Psychological parameters
3. Hamilton's anxiety rating scale

X. STATISTICAL ANALYSIS:

Data on clinical symptoms and objective tests before and after the treatment will be tabulated and analyzed using appropriate statistical tools. However, the data of each case will have to be communicated on completion of trial therapy to the Statistical Officer of CCRAS through e-mail.

XI. TRIAL MONITORING AND DATA ANALYSIS

CCRAS, Hqrs, New Delhi will undertake the monitoring of progress of the trial and data analysis.

XII. ETHICAL REVIEW

A. Ethical Committee (REC): The proposal will be placed before Ethical Committee (REC) of trial center for getting clearance certificate before the project is initiated. Patient's information sheet and informed consent form will be submitted along with project proposal for approval by EC. Both will be maintained in duplicate with one copy given to the patient at the time of entry to the trial.

B. Data and safety monitoring board: A Data and safety monitoring board (DSMB) at Hqrs. will carefully monitor the data and side effects during the period of study and put in a place where by prompt reporting of adverse events occur. The data will be reviewed as every 20 participants entered the study and administered the trial drugs. The research team will report immediately to the PI and Data Monitoring Board if, any life threatening conditions whether they are perceived to be study related or not. The Board decides whether the adverse effects warrant discontinuation of the study protocol. Protocols will be written and approved for the treatment of study related adverse events.

XIII. TRAVELING EXPENSES FOR RESEARCH SUBJECTS

A consolidated amount of Rs.100/- per visit i.e., on the 1st day of recruitment after screening, 8th day, 15th day and so on upto 45th day (weekly once).

XIV. TRAINING TO INVESTIGATORS AND PERSONS INVOLVED

Short-term two-day training will be provided to the Investigators and Laboratory personnel involved in the multi-centric trial at CCRAS Hqrs. and Central Research Institute (Ay.), New Delhi. The investigators and technicians will be detailed about the clinical trial

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conduct and laboratory procedures in order to maintain the uniformity.

XV. LABORATORY INVESTIGATIONS

The Laboratory Investigations (Pathological/Biochemical, etc.), which are not available at research Institutes should be conducted at identified reputed labs /Government Institutes under intimation to this Council following codal formalities.

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CENTRAL COUNCIL FOR RESEARCH IN AYURVEDA AND SIDDHA

CLINICAL EVALUATION OF HERBAL PREPARATIONS IN THE MANAGEMENT OF MANODVEGA (ANXIETY NEUROSIS)

WRITTEN INFORMED CONSENT FORM

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all details about the study in the terms easily understood by the patient.

Date:_____ Signature of the Investigator: _____

Name: _____

CONSENT BY SUBJECT

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial and the nature of drug treatment and follow-up, including the laboratory investigations to be performed to monitor and safeguard my body functions.

I am also aware of my right to opt out of the trial at any time during the course of the trial without having to give the reasons for doing so. I am willing to undergo any risk for inclusion in this study.

I, exercising my free power of choice, hereby give my consent to be included as a subject in the clinical trial on "Clinical evaluation of herbal preparations in the management of Manodvega (Anxiety Neurosis)".

Date:_____ Name of the Subject:_____

Signature or Thumb Impression : _____

Date:_____ Name of Witness: _____

Signature or Thumb Impression: _____

Relationship _____

To be translated into regional language.

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CENTRAL COUNCIL FOR RESEARCH IN AYURVEDA AND SIDDHA

CLINICAL EVALUATION OF HERBAL PREPARATIONS IN THE MANAGEMENT OF MANODVEGA (ANXIETY NEUROSIS)

PATIENT INFORMATION SHEET

What is the study about?

Chittodwega/ Manodwega is one of the Manasika Vikara mentioned in Ayurvedic literature. The symptoms of this disease can be assumed mostly similar with the generalized anxiety disorder (GAD). GAD is a disorder requires the presence of unrealistic or excessive anxiety and worry, accompanied by symptoms from three of four categories: (1) motor tension, (2) autonomic hyperactivity, (3) vigilance and scanning, and (4) apprehensive expectation. The anxious mood must continue for at least a month.

The Ayurvedic principle of synthesis of mind, body and soul to consider man as integrated whole one, would help to treat mental disorders effectively. Medhya rasayanas and Satvavajaya chikitsa are such a measures, which can be utilized for the treatment of Chittodwega/Manodwega.

In Chittodwega/ Manodwega, when the mind is afflicted with anxiety, fear, agitation etc. this leads to worry, apprehension, depression, psychological arousal as anger, irritability and ultimately lead to disturbance in personal, familial and social harmony.

Anxiety disorders are among the most prevalent psychiatric condition in the world. Further, studies have persistently shown that they produce inordinate morbidity, utilization of health care services, and functional impairment. Recent studies also suggest that chronic anxiety disorder may increase the rate of cardiovascular-related mortality. Hence, clinicians in psychiatry and other specialties must make the proper anxiety disorder diagnosis rapidly and initiate treatment.

Ayurveda provides rational means for the treatment of many disorders, which are considered to be obstinate and incurable in other systems of medicine.

What will you have to do?

Your doctor will explain clearly what you have to do. It is important that you follow the instructions scrupulously. The study will take approximately 45 days.

Before you start treatment, during the first visit to the clinic, you will undergo a complete physical examination, required objective tests and laboratory investigations will also be done.

If you are found eligible, you would be put on trial treatment for 45 days.

At each visit, you will be supplied with sufficient quantities of drugs to last until your next visit. If any adverse reactions like skin allergy, nausea, vomiting and palpitation/tremor etc., noticed during the treatment period, this should be noticed to the Principle Investigator.

To be translated into regional language.

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CENTRAL COUNCIL FOR RESEARCH IN AYURVEDA AND SIDDHA

CLINICAL EVALUATION OF HERBAL PREPARATIONS IN THE MANAGEMENT OF MANODVEGA (ANXIETY NEUROSIS)

The following forms are given in the document - 'sample-research-protocol.pdf'

CASE REPORT FORM - I - SCREENING - BEFORE TREATMENT

CASE REPORT FORM - II - ADMISSION

CASE REPORT FORM - III - INVESTIGATIONS

CASE REPORT FORM - IV - PERIODICAL OBSERVATION & ASSESSMENT

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Gmail

Viral kumar Patel <viral.patel@dsvv.ac.in>

Fwd: Faculty & Research Scholars' data submitted by (PDS-I-2019-450_Dev_Sanskriti_Vishwavidyalaya,_Gayatrikunj)

PhD Cell DSVV <phdcell@dsvv.ac.in>
To: Viral kumar Patel <viral.patel@dsvv.ac.in>

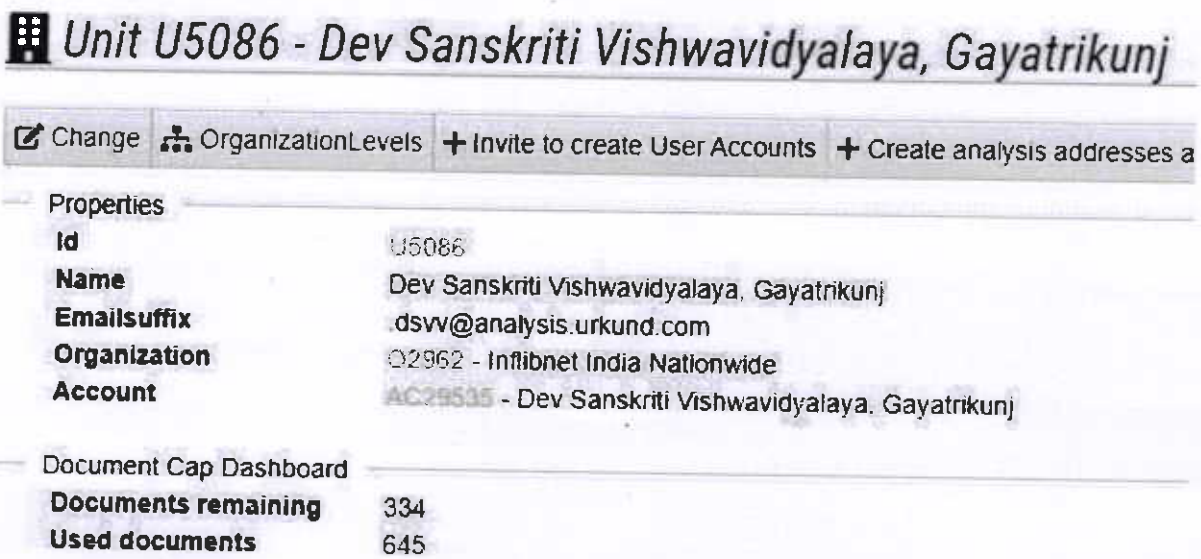
Sat, Feb 11, 2023 at 3:42 PM

---------- Forwarded message ---------
From: **PDS Tech** <pds.tech@inflibnet.ac.in>
Date: Wed, Jun 15, 2022 at 11:08 AM
Subject: Re: Faculty & Research Scholars' data submitted by (PDS-I-2019-450_Dev_Sanskriti_Vishwavidyalaya,_Gayatrikunj)
To: PhD Cell DSVV <phdcell@dsvv.ac.in>
Cc: Manoj Kumar K, Scientist-D(CS) <manoj@inflibnet.ac.in>, Suboohi <surbhi@inflibnet.ac.in>, PDS Survey <pds.help@inflibnet.ac.in>

Dear Sir/Madam,

As per records, there are still **334** documents remaining. We will increase once it crosses **98%** or is close to exhausting. Kindly disregard the system-generated email stating it reached **80%-90%** of your document cap if you've received any.

Screenshot for your reference:



In case of any further assistance please feel free to write or contact the undersigned.

Thanks & Regards,
Mahima Panchal.

Team PDS
INFLIBNET Centre (An IUC of UGC)
Infocity, Gandhinagar - 382007
Gujarat, INDIA.

Registrar
Dev Sanskriti Vishwavidyalaya
Gayatrikunj- Shantikunj, Haridwar- 249411

Phone: +91-79-23268231
Email: pds.tech@inflibnet.ac.in

On Tue, Jun 14, 2022 at 5:13 PM PhD Cell DSVV <phdcell@dsvv.ac.in> wrote:

dear Sir/Madam

Kindly Inform when would be the document cap increase as it is showing nil.

On Tue, Jun 7, 2022 at 4:48 PM ShodhShuddhi <pds.tech@inflibnet.ac.in> wrote:

Dear University Coordinator,

*Thank you for submitting the **Faculty & Research Scholars'** data for **PDS(ShodhShuddhi)' 2021***

*Submitted by: **Dr. Smita Vashishta (phdcell@dsvv.ac.in)***

*(I) Total No. of Faculty (Regular/Adhoc/Contractual): **110***
*(II) Total No. of Research Scholars' pursuing Full Time & Part Time (e.g. PhD/Doctoral, Post-Doctoral, JRF & SRF): **113***
*(III) Other Users (e.g. Research Projects, Conference Proceedings, Publications): **0***
*i.e. Total Number of Users (I + II + III) : **223***

*Feedback to PDS-ShodhShuddhi (Ouriginal) Team : **team is very cooperative***

In case of any further assistance please feel free to write or contact the undersigned.

Team PDS
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Infocity, Gandhinagar -
382007 Gujarat, INDIA.
Phone: +91-79-23268233/31/32/20
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PhD-CELL,
Dev Sanskriti Vishwavidyalaya,
Gayatrikunj-Shantikunj, Haridwar (U.K.)-249411
Web.- www.dsvv.ac.in

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URKUND

J	**Dog-Assisted Therapy in the Treatment of Chronic Schizophrenia Inpatients** URL: aa8195b5-e3c7-4864-97a5-09efedf1f981 Fetched: 3/13/2019 3:13:37 AM	4
W	URL: http://docshare01.docshare.tips/files/24295/242957384.pdf Fetched: 1/25/2021 4:35:00 PM	4
W	URL: https://www.hindawi.com/journals/schizort/2013/705631/ Fetched: 1/25/2021 4:35:00 PM	2
W	URL: https://core.ac.uk/download/pdf/161440484.pdf Fetched: 1/25/2021 4:35:00 PM	8
W	URL: https://www.cambridge.org/core/journals/psychological-medicine/article/what-accoun... Fetched: 1/25/2021 4:35:00 PM	6
J	**Bridging Psychiatric Rehabilitation and Recovery in Schizophrenia: A Life's Work** URL: 6b9addad-1faf-4370-97a9-c5e340855c06 Fetched: 3/13/2019 9:24:35 AM	4
J	**A quick scoping review of psychosocial treatment recommendations for African Americans with schizophrenia spectrum disorders** URL: f0df84e2-a3a6-430d-a5cb-0cb6e5375afe Fetched: 12/11/2019 5:20:18 PM	4
J	**Training in Illness Self-Management for People with Mental Illness in the Criminal Justice System** URL: 47708bd4-f343-4d50-bee8-b8142a3c4692 Fetched: 3/13/2019 9:24:32 AM	2

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ument Information

Analyzed document	Integrted thesis Jitendra yadav.docx (D143994036)
Submitted	9/13/2022 12:01:00 PM
Submitted by	
Submitter email	jyoti.malvi@dsvv.ac.in
Similarity	3%
Analysis address	jyoti.malvi.dsvv@analysis.urkund.com

urces included in the report

SA **University of Delhi, New Delhi / Ph.D. thesis for plagiarism final.pdf** 13
Document Ph.D. thesis for plagiarism final.pdf (D110798557)
Submitted by: saburisahni@yahoo.co.in
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SA **Gurukul Kangri University / Potentiality of Yoga in Overcoming Inferiority Feelings.docx** 11
Document Potentiality of Yoga in Overcoming Inferiority Feelings.docx (D131879797)
Submitted by: 9927884477sk@gmail.com
Receiver: 9927884477sk.gkv@analysis.urkund.com

SA **Bharathiar University, Coimbatore / Naveya. Y.N.pdf** 2
Document Naveya. Y.N.pdf (D110659608)
Submitted by: rspani1967@gmail.com
Receiver: rspani1967.bhauni@analysis.urkund.com

SA **Dev Sanskriti Vishwavidyalaya, Gayatrikunj / submit phd.docx** 2
Document submit phd.docx (D105703179)
Submitted by: kamta.sahu@dsvv.ac.in
Receiver: kamta.sahu.dsvv@analysis.urkund.com

SA **Annamalai University, Chidambaram / 1943160002_S.docx** 1
Document 1943160002_S.docx (D117958599)
Submitted by: au_nagarajan@yahoo.co.in
Receiver: au_nagarajan.annuni@analysis.urkund.com

SA **University of Lucknow, Lucknow, UP / EFFECT OF YOGAON PHYSIOLOGICAL VARIABLE.doc** 2
Document EFFECT OF YOGAON PHYSIOLOGICAL VARIABLE.doc (D27932891)
Submitted by: ganeshpandey284@gmail.com
Receiver: ganeshpandey284.uniucx@analysis.urkund.com

SA **Dev Sanskriti Vishwavidyalaya, Gayatrikunj / all-converted.pdf** 5
Document all-converted.pdf (D76600798)
Submitted by: jyoti.malvi@dsvv.ac.in
Receiver: jyoti.malvi.dsvv@analysis.urkund.com

Sewangy
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Mahapurusha Srimanta Sankaradeva Viswavidyalaya / Thesis final(AutoRecovered) (AutoRecovered) (AutoRecovered).docx
Document Thesis final(AutoRecovered) (AutoRecovered) (AutoRecovered).docx (D137715551)
Submitted by: ujjwalmaske@mssv.ac.in
Receiver: ujjwalmaske.mssv@analysis.urkund.com

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CT OF SELECTED YOGIC PRACTICES ON SELF CONCEPT, INFERIORITY AND INSECURITY FEELINGS OF
OLESCENTS"
SIS SUBMITTED TO
rtment of Yoga and human consciousness Dev sanskriti Vishwavidyalaya Shantikunj Haridwar (Uttarakhand)
R THE DEGREE OF
OCTOR OF PHILOSOPHY
IN
OGIC SCIENCE
MITTED BY
endra Kumar yadav 2022
DER THE SUPERVISION OF
r. Asim Kulshrestha (ASSISTANT PROFESSOR)
EPARTMENT OF YOGA AND HUMAN CONSCIOUSNESS DEV SANSKRITI UNIVERSITY, HARIDWAR, UTTRAKHAND
hapter 1 INTRODUCTION
1. Background of the study

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DEV SANSKRITI VISHWAVIDYALAYA

Gyatrikunj, Shantikunj, Haridwar, Uttarakhand, 249411

Time Table (PhD Course Work - April 2024) Part Time

	Time	Days	
Library/ Library: Reference Section	11:00(AM)-2:00 (PM)	Monday - Saturday	
Courses			Faculty
Research Methodology	3:00-3:50(PM)	Monday - Wednesday	Dr. Santosh Vishvakarma
Statistics	3:00-3:50(PM)	Thursday - Friday	Dr. Santosh Vishvakarma
Subject Specific Course	3:50-4:40(PM)	Monday - Friday	Concerned Department Faculty
Computer Fundamental	4:40-5:30(PM)	Monday - Wednesday	Dr. Rajeshwari Trivedi
Research & Publication Ethics	4:40-5:30(PM)	Thursday - Friday	Prof. Sourabh Mishra
Life-Management	5:30-6:00(PM)	Friday	Dr. Chinmay Pandya
Journal Club/ Assignment	4:40-5:30(PM)	Saturday	Prof. Sourabh Mishra

Note: Classes would be conducted in- Smart Class Vallabhabhi Patel Bhawan

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Curriculam: Ph.D Course Work

The basic purpose of any education is to enable a person to widen his horizon of knowledge and develop skills necessary to comprehend and handle his life situation better and make his life and that of his fellow beings more meaningful happy. It is a well known fact that life situations change every day and every moment so it demand continuous updating of knowledge, exploration of new dimensions and search of new solutions to make necessary adjustment. Obviously it is the area of research methods which provide us guidance to explore new knowledge and find out solutions of problems. We already have been relied on it for long to fill the gap in knowledge and extension of knowledge. There are many areas (education, culture, health etc) in which academic and immediate solutions of problems are required. In this regard various PhD programs have been conducted by different universities all over the world as well as in India for a long. To Strengthen and improve the quality of research in various fields and corresponding subjects the University grant commission of India has instructed the universities of India to conduct a six month PhD Program (must include research methodology, statistics and knowledge of computer applications and publication ethics) for the PhD students selected through entrance examination.

Keeping all these points in mind the course content of the PhD program for the students of Psychology, Yoga Science, Indian Culture & Tourism etc. have been developed with the following objectives.

1- To impart the accumulated and the most recent knowledge with a view to develop proficiency to such level that the student should be capable of independent and critical thinking in regard to research problems and issues.

2- To develop a deeper understanding of research methods, research designs and their application in testing hypotheses.

3- To give students the fundamental as well as advance knowledge of statistical methods which help them in analyzing research data with proper understanding.

4- To increase the awareness about the publication ethics and publication misconducts.

5- To provide knowledge of computer application

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Ph.D. Course Work Program: Credit Structure

Sr. no.	Course	L+T+P	Credit
01	Research Methodology & Statistics	06+2+0	08
02	Computer Fundamental, Research & Publication Ethics	04+0+04	08
03	Subject Specific Course	4+2+00	06
			Total 22

Paper I- Research Methodology & Statistics

Description

(I) This course will be of 100 marks, out of which 60 marks will be assigned to external evaluation and 40 marks will be to internal evaluation.

(II) Inernal evaluation will be done by the concered teacher by conducting internal test, assignment or other possible measues.

(III) There shall be two parts - one Statistics (04 Credit) and another Research Methodology (04 Credit). All questions will be carried out of these two parts equally.

(IV) Credit: 08 (04 credits for Statistics + 04 credits for research methodology)

(Part - I)
Research Methodology

Unit -I :

Science & scientific approach, concept, construct and theory; Meaning, objectives and types of research; Paradigms of research: quantitative, qualitative and mixed method approach; Types of variables, research problem, hypotheses, sampling

UNIT – II: Internet Basics

Internet: what is internet, Use of Internet, Electronic Mail (E-mail), www, Downloading & Uploading, Access of E-Journals, E-Library, SearchEngines, Searching the keywords, Overview of Google Applications (Forms, Drive, Meet, and Classroom).

UNIT – III: Formatting, Data Handling & PresentationTool

MS-Word: Toolbars, Menu, Editing a Document, File handing and various Format of File, Mail Merge, Basics of Latex.

MSExcel: Toolbars, Menu, Creating Worksheet, Charts, Sorting and Filtering, Use of Formulas.
MS-Power Point: Creating Presentations and adding Effects.

Reference Books:
1. Basics of computer by Peter Norton
2. Basics of computers by P.K. Sahani
3. Microsoft office 2000 complete, BPB publication

PART-II
Research and Publication Ethics (RPE)

Description: This course has total 3 units focusing on basics of Philosophy of science and ethics, research integrity, publication ethics. Hands-on sessions are designed to identify research misconduct and predatory publications. Indexing and citation databases, open access publications, research metrics (citations, h-index, Impact Factor, etc.) and plagiarism tools will be introduced in this course.

COURSE LEVEL
2 credit course (30 Hrs.)

Evaluation:
Continuous assessment will be done at two levels. First through tutorials, assignments, quizzes and group discussions and second will be based on life management skills and ethical awareness & practices. Weightage will be given for active participation. Final written examination will be conducted at the end of the course.

Marks Allotment: 50 (30 external + 20 internal)

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Course Structure
The course comprises of three modules listed in table below.

Modules	Unit Title	Teaching Hours
Theory		
RPE 01	Philosophy and Ethics	4
RPE 02	Scientific Conduct and Publication Ethics	11
Practice		
RPE 03	Open Access Publishing, Publication Misconduct, Database and Research Metrics	15
	Total	**30**

SYLLABUS IN DETAIL

Theory:

RPE 01: PHILOSOPHY AND ETHICS (4hrs)

1. Introduction to Philosophy: definition, nature and scope, concept, branches
2. Ethics: Definition, moral philosophy, nature of moral judgements and reactions.

RPE 02: SCIENTIFIC CONDUCT AND PUBLICATION ETHICS (11hrs.)

1. Ethics with respect to science and research
2. Intellectual honesty and research integrity
3. Scientific misconducts: Falsification, Fabrication and Plagiarism (FFP)
4. Redundant publications: duplicate and overlapping publications, salami slicing
5. Selective reporting and misrepresentation of data
6. Publication ethics: definition, introduction and importance
7. Best practices/standards setting initiatives and guidelines: COPE, WAME etc.
8. Conflicts of interest
9. Publication misconduct: Definition, concept, problems that lead to unethical behavior and vice versa, types
10. Violation of publication ethics, authorship and contributorship
11. Identification of publication misconduct, complaints and appeals
12. Predatory publishers and journals

Practice:

RPE 03: OPEN ACCESS PUBLISHING, PUBLICATION MISCONDUCT, DATABASES AND RESEARCH METRICS (15hrs.)

1. Open access publications and initiatives

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2. Online resource like SHERPA/RoMEO to check publisher copyright & self-archiving policies
3. Software tool to identify predatory publications developed by SPPU
4. Journal finder/journal suggestion tools viz. JANE, Elsevier Journal Finder, Springer Journal Suggester, etc.
5. Subject specific ethical issues, FFP, authorship
6. Conflicts of interest
7. Complaints and appeals: examples and fraud from India and abroad
8. Use of plagiarism software like Turnitin, Urkund and other open source software tools
9. Indexing databases
10. Citation databases: Web of Science, Scopus etc.
11. Research Metrics - Impact factor of journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score
12. Research Metrics: h-index, g index,i10 index, altmetrics

Paper – III
Subject Specific Course

Duration : six months **Marks assigned : 100**
(60 external and 40 internal)

Credit: Six (06)

Description:

This course pertains to the awareness about the updation and advancement of the subject in which candidate is about to persue his/her research work for the award of doctoral degree. This course will be taught with the objective to equipped the students with the knowledge of subjcet specific research methodology, scope of research in the field and any essentail skills. Concerned Department will run this course and do the evaluation itself.

(I) This course will be of 100 marks, out of which 60 marks will be assigned to external evaluation and 40 marks will be to internal evaluation.
(II) Internal evaluation will be done by the concered teacher by conducting internal test, assignment or other possible measures.
(III) Credit: 06

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RESEARCH ETHICS COMMITTEE
DEV SANSKRITI VISHWAVIDYALAYA, HARIDWAR

STANDARD OPERATING PROCEDURE
for Research Ethics Committee for Research on Human participants

(This Standard Operating Procedure (SOP) is to outline the development, approval, organization, implementation and management of all Human Research protocols to be conducted in Dev Sanskriti Vishwavidyalaya. This SOP document is also meant to guide the researcher on how to apply for ethical clearance, what all documents to submit and the points that s/he must observe while dealing with human participants and / or materials.)

1. OBJECTIVES

The Research Ethics Committee (REC) is responsible for reviewing research involving human participants at this institution, to ensure that subjects' safety, rights, and welfare are protected in conformity with applicable regulations and guidelines issued by the ICMR, UNESCO, WHO, Indian state and local laws and regulations where such laws or regulations provide protection for human subjects that exceed the protection afforded under national law. A number of studies pursued in Dev Sanskriti Vishwavidyalaya (DSVV) include biological sample (blood/ tissue/ stored sample) collected from diseased and normal subjects for research purposes, as well as non-invasive studies in cases of neurological damage, dyslexia, developmental disorders, etc. Non-invasive studies also include socio-psychological, socio-cultural studies involving human participants. All such studies on biological samples, stored samples, behavioral data samples and socio-cultural-psychological data samples involving human participants need ethical clearance by REC. All such studies require REC clearance before the commencement of the study.

This Standard Operating Procedure (SOP) is to outline the development, approval, organization, implementation and management of all Human Research protocols to be conducted in Dev Sanskriti Vishwavidyalaya. The REC is entrusted not only with the initial review of the proposed research protocols prior to the initiation of the project, but, in case of adverse effects reported by the Principal Investigator (PI)/ participants, the REC is also mandated to review such cases. All adverse effects/ injury/ damage/ loss/ death must be reported immediately to the REC, death to be reported within 24 hours, as per GOI/ CDSCO norms.

In case of modifications in research tools and procedures during the course of the study, reported by the PI/ participants, the REC is also mandated to review and accept/ reject the modifications proposed as the case may be.

References

- CDSCO- Central Drugs Standard Control Organization - "Good Clinical Practices For Clinical Research In India" (Available from- http://www.cdsco.nic.in/html/GCP1.html - accessed on 9th March 2016) (CDSCO-Good-Clinical-Practice.pdf)
- CDSCO- Central Drugs Standard Control Organization - "The Drugs and Cosmetics Act (1940) and Rules (1945)"
    - (Available from - http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf - accessed on 9th March 2016) (Drugs&Cosmetics-Act-1940.pdf)
    - (Amendment 2008 - Available from - http://www.cdsco.nic.in/writereaddata/D&C_ACT_AMENDMENT_2008_file.pdf - accessed on 9th March 2016)

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(Drugs&Cosmetics-Act-Amendment-2008.pdf)

- (Revised Schedule Y - Available from - http://dbtbiosafety.nic.in/act/schedule _y.pdf - accessed on 9th March 2016) (schedule-y-2005-drugs-and-cosmetics-act.pdf)

- COPE - Committee on Publication Ethics (publicationethics.org) - "Guidelines on Good Publication Practice - 1999"

- (Philip Fulford, Michael Doherty, Jane Smith, Richard Smith, Fiona Godlee, Peter Wilmshurst, Richard Horton, Michael Farthing (2000) "Committee on Publication Ethics (COPE): guidelines on good publication practice", BJU International, 85, 2-7.) (Available from- http://onlinelibrary.wiley.com/ doi/10.1046/j.1464-410x.2000.00478.x/epdf - Accessed on 9th March 2016) (COPE-guidelines-1999.pdf)

- COPE website lists - "Responsible research publication: international standards for authors - 2011" (Wager E & Kleinert S (2011) Responsible research publication: international standards for authors. A position statement developed at the 2nd World Conference on Research Integrity, Singapore, July 22-24, 2010. Chapter 50 in: Mayer T & Steneck N (eds) Promoting Research Integrity in a Global Environment. Imperial College Press / World Scientific Publishing, Singapore (pp 309-16). (ISBN 978-981-4340-97-7))

(Available from - http://publicationethics.org/files/International%20standards_authors_for%20website_11_Nov_2011_0.pdf - Accessed on 9th March 2016) (International-standards-authors-2011.pdf)

- ICMR - Indian Council of Medical Research - "Ethical Guidelines for Biomedical Research on Human Participants" - (Available from - http://icmr.nic.in/ethical_guidelines.pdf - Accessed on 9th March 2016) (ICMR-ethical-guidelines.pdf)

2. ROLES AND RESPONSIBILITIES OF THE RESEARCH ETHICS COMMITTEE

The basic responsibility of REC is to ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner. REC shall provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research.

The mandate of the committee will be to review all research projects involving human subjects/ materials to be conducted in different Departments at the University. The REC will review all research proposals involving human subjects, submitted by faculty members and research students (through their respective Supervisors). Each investigator shall be responsible for proving the benefit of placing human subjects at risk, and assure the REC about appropriate Informed Consent Process and Subject Confidentiality before the commencement of the study. Each investigator shall be responsible to provide details of primary data/ secondary data/ stored samples/ cell lines/ buying data to the REC in her/ his presentation.

All studies need to be approved before the study procedures begin. No completed studies or those already being pursued will be reviewed by the REC.

3. OPERATING PROCEDURES

3.1 CONSTITUTION OF REC

As per ICMR guidelines, the REC should be multidisciplinary and multi-sectorial in

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composition. Independence and competence are the two hallmarks of a Research Ethics Committee. The members should be a mix of medical/ non-medical professionals, legal experts, experts from sciences and social sciences and humanities, philosophers and activists, internal and external, also including lay persons from NGO's to represent the civil society. (See Appendix B for relevant directives based on ICMR guidelines)

A panel of names in each one of the categories specified below, approved by the DSVV Management, will serve as the Research Ethics Committee of DSVV.

Constitution of REC

1. Chairperson
2. Chancellor's Nominee (will serve as the Chairperson, if the Chairperson is not present)
3. Scientist from Medical Practice (External)
4. Scientist from Medical Practice (Internal, DSVV)
5. Scientist from Basic Sciences (External)
6. Scientist from Basic Sciences (Internal, DSVV)
7. Social Scientist / Philosopher / Social Activist (External)
8. Social Scientist / Philosopher / Social Activist (Internal, DSVV)
9. Advisor, Member of ethics review board of another Institution (ICMR, AIIMS, etc.)
10. Legal Advisor (External)
11. Legal Advisor (Internal, DSVV)
12. Lay Persons (one or two)
13. Member Secretary (DSVV)

With reference to the revised Schedule Y of Drugs & Cosmetics Act, 1940, amended in 2005 (attached herewith as 'schedule-y-2005-drugs-and-cosmetics-act.pdf' - available from - http://dbtbiosafety.nic.in/act/schedule_y.pdf - accessed on 9th March 2016), the Research Ethics Committee approving drug trials should have in the quorum at least one representative from the following groups:

1. One basic medical scientist (preferably one pharmacologist)
2. One clinician
3. One legal expert or retired judge
4. One social scientist/ representative of non-governmental organization / philosopher / ethicist / theologian or a similar person
5. One lay person from the community

3.2. COMPOSITION OF A REVIEW COMMITTEE.

The number of persons in a Research Ethics Committee should be 8 to 12, drawn from the panel of names approved by the Management, as specified above. The Chairperson, REC will approve the names of the members of a review committee, containing members from as many different categories as possible, depending on the nature of the research proposal to be reviewed. (Appendix A for the current Panel of Experts in the REC-DSVV).

3.2.1. APPOINTMENT, RESIGNATION AND RECONSTITUTION

For appointment to the committee, the candidate should be a well-known scholar of his/her discipline and must hold position of significant responsibility. Professional integrity and commitment to human welfare would be important criteria for inclusion as members. After the initial constitution, subsequent appointment to the committee shall be guided by the quorum requirements and activity of the members involved. As per ICMR guidelines, the

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appointee will be informed of the rights and duties of the committee, and that the external members will receive honorarium for every consultative meeting held on the campus.

All Committee members shall sign a confidentiality agreement at the time of appointment, the terms of which shall be binding on them even after the term expires. Co-opted members are also expected to sign confidentiality agreement. All members, except the Chairperson and Member Secretary, shall serve a maximum of a three-year term on the committee, after which a fresh panel of three names in the same category will be submitted to the Management, DSVV so that one out of the three may be appointed in place of the retiring person. For the sake of continuity, the Chairperson and the Member Secretary will have a term of five years.

Extension of membership may be considered due to non-availability of members of similar stature, qualification and intent to contribute to ethical human testing.

Members may voluntarily resign from the Committee at a month's notice citing appropriate reasons, and in case of internal members, their membership would be considered withdrawn, if they resign from the University.

A member who has direct involvement or self-affirmed conflict of interest with a proposal being considered, shall not form a part of the quorum. If a member is found to have a conflict of interest with the results of decision and fails to declare the same, or is found to have drawn direct benefit arising out of the results of the research, or has involved self-interest with the sponsor(s) or investigators, his/her membership shall be terminated with provision of appropriate legal proceedings.

In case a member breaches the confidentiality, his/her membership shall be terminated and the institution may initiate appropriate legal proceedings.

3.2.2. HONORARIUM

External members of the REC, and experts invited (if any) shall receive appropriate compensation for the time and effort expended for the purpose.

3.3. PROCEDURE FOR SUBMISSION AND REVIEW

The REC will meet at least once every semester or more if required, to review all the applications, including proposals for Ph.D., as well as including research proposals submitted by the faculty, involving human subjects/ materials for any kind of data. All proposals shall be reviewed as per the applicable guidelines given in Appendix C. (see Research Protocol Organization Guidelines in Appendix C) Exact meeting date shall be notified in advance so that all members can make themselves available for the purpose. The Chairperson/ Member Secretary shall be the convener with responsibility of laying out the agenda for the meeting. All material relevant to the agenda shall be made available to REC at least 2 weeks* in advance (*under special circumstances, this requirement may be relaxed with due approval from the Chairperson/ Member Secretary). Before they are circulated to the external members, the Member Secretary of the committee, together with one or two internal members, will screen the proposals, to see if the proposals need (i) exemption from review, or (ii) expedited review or (iii) full review (see Appendix B for relevant directives based on ICMR guidelines).

*Inputs from departments at this stage will be important

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All protocols should be submitted in the format prescribed in Appendix C. The proposals shall be addressed and submitted to the office of the Member Secretary, Research Ethics Committee (REC), Dev Sanskriti Vishwavidyalaya, Gayatrikunj-Shantikunj, Haridwar - 249411 (Uttarakhand). One hard copy and soft copy of the documents should be submitted. An application should be submitted at least two weeks* prior to the next review meeting (*under special circumstances, this requirement may be relaxed with due approval from the Chairperson/ Member Secretary). A unique submission number shall be assigned to proposals submitted for review.

Recommendation of the Committee

After discussion, the committee may make one of the following recommendations:

- Approval - indicating that the proposal is approved as submitted;
- Approval after clarifications - indicating that the proposal is approved if the clarification(s) requested are provided to the satisfaction of designated committee members;
- Approval after amendment(s) - indicating that the proposal is approved subject to the incorporation of the specified amendment(s) verified by designated committee members;
- Deferment - indicating that the proposal is not approved as submitted but it can be reassessed after revision to address the specified reason(s) for deferment;
- Disapproval - indicating that the proposal is not approved for the reasons specified.

Format for the Ethical Clearance Certificate will be as given in the Appendix

3.4. DOCUMENTS FOR SUBMISSION OF THE PROPOSAL

1. Protocol of the proposed research in the prescribed format (see Appendix-C) which includes:
   - 1.1 Rationale / Background information
   - 1.2. A description of the ethical considerations involved in the research
   - 1.3. Case report forms, diary cards, and other questionnaires intended for research participants
   - 1.4. Summary of safety, pharmacological, pharmaceutical, and toxicological data available on the study product, wherever applicable
   - 1.5. Statement of agreement to comply with ethical principles
   - 1.6. Statement of conflict of interest
   - 1.7. Name and address of the Sponsor/ Funding agency
   - 1.8. Insurance Statement (Wherever required)
2. Investigator's Brochure Including Report of Prior Investigations
3. Investigator(s)'s curriculum vitae
4. Informed Consent
5. In case of students' proposals, synopsis of the Ph.D. research as approved by the Research Degree Committee of DSVV

3.4.1. Regarding no. 4 above (Informed Consent), a template is given in the Appendix-C, which may be modified depending on the nature of participation expected from the study participants.

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3.5. DOCUMENTATION AND RECORDS

The proceedings of all meetings shall be documented and shall be kept in confidence. The release of the detailed documentation to non-committee members can only be made in case of exceptional circumstances, which shall be verified either by court orders or by affirmative opinions by the Chairperson and the Member Secretary. Minutes of the meeting shall be circulated by Member Secretary for verification by the Chairperson and members present during the discussion. After verification, the Member Secretary shall communicate final decisions regarding protocols to the investigator(s). All documentation samples for different kinds of studies must be retained for at least three years after the completion of the study.

The following records should be maintained by the REC office:
I. The Constitution and composition of the REC
II. Signed and dated copies of the latest curriculum vitae of all REC members with records of training, if any
III. Standard Operating Procedure of the REC and modifications approved from time to time
IV. National and International guidelines
V. Copies of protocols submitted for review
VI. All correspondence with the members of the REC, and investigators regarding application, decision and follow up;
VII. Notice and agenda of all REC meetings;
VIII. Minutes of all REC meetings with signatures of the Member Secretary and the Chairperson.
IX. Copies of decisions communicated to the applicants;
X. Record of all notifications issued for premature termination of a study with a summary of the reasons;
XI. Final report of the study including microfilms, CDs and Video recordings/ samples for different kinds of studies. PI may be asked to report completion of the study.

3.6. NOTIFICATION OF AMENDMENTS

Any revision to an approved research protocol or written consent form if proposed must be brought to the attention of the REC for approval. Amendments to approved protocols and other study related documents should not be initiated until the REC approval has been obtained.

All deviations from the study protocol should be documented in the original records along with the reasons for doing so. In case of any adverse event, the same, along with the remedial measures taken, must be reported by the investigator(s) immediately to the Chairperson and the Member Secretary, besides making a note of it in the study documentation.

3.7 ANNUAL REVIEW AND FINAL REPORTING

The Committee should be updated regarding the progress of the study on an annual basis. The Committee must be notified of the trials completed or terminated (wherever applicable). A copy of the final report should be submitted as soon as it is available.

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Statement of PI regarding conclusion/ completion/ termination/ abandonment of the study must be submitted as soon as the study is terminated.

3.8. RECONSTITUTION OF COMMITTEE

The Committee shall be considered non-functional and reconstitution considered in the following instances:

- No meeting is convened for a continuous period of 1 year
- Meeting attendance is below 5 independent members for four consecutive meetings

3.9 AMENDING THIS DOCUMENT

Any amendments to this document shall be approved under the same procedure as for other proposals under the purview of REC.

4. Appendices

Appendix A: List of Members of REC
Appendix B: Relevant directives regarding Review Procedure based on ICMR Guidelines
Appendix C: Research Protocol Organization Guidelines
Appendix D: Good Publication Practice Guidelines
Appendix E: A Sample Research Protocol

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Appendix A

The panel of names in each category as approved by the Management, DSVV.

1. Chairperson
   External Chairperson – nominated by University Management

2. Chancellor's Nominee (will serve as the Chairperson, if the Chairperson is not present)
   Vice Chancellor, Dev Sanskriti Vishwavidyalaya (DSVV), Haridwar
   Pro-Vice Chancellor, Dev Sanskriti Vishwavidyalaya (DSVV), Haridwar
   Dr. Manas Mandal (PhD), Director General - Life Sciences (LS), Defence Research Development Organization (DRDO), New Delhi

3. Scientist from Medical Practice (external)
   1. Dr. Vinod Updhyay (PhD), Rtd. from Gurukul Kangri Vishwavidyalaya, Haridwar
   2. Dr. Sunil Joshi (MS), HOD Dept. of Surgery, Gurukul Kangri Vishwavidyalaya
   3. Prof. Shridhar Dwivedi (MD, PhD), HOD Dept. of Medicine / Preventive Cardiology, Hamdard Institute of Medical Sciences and Research (HIMSR), New Delhi

4. Scientist from Medical Practice (internal, DSVV)
   1. Dr. A. K. Dutta (MS), Shantikunj, Haridwar
   2. Dr. O. P. Sharma (MD), ASRSS Hospital, Shantikunj, Haridwar
   3. Dr. Vandana Shrivastava (PhD), Centre for Ayurveda Studies, Dept. of Yoga and Health, DSVV

5. Basic Sciences / Researchers (external)
   1. Prof. Ishwar Bhardwaj (PhD), HOD Dept. of Yoga, Gurukul Kangri Vishwavidyalaya
   2. Prof. C. P. Khokhar (PhD), HOD Dept. of Psychology, Gurukul Kangri V.V.
   3. Dr. Sanjeev Sharma (PhD), Computer Science, Meerut

6. Basic Sciences / Researchers (internal, DSVV)
   1. Dr. Karna Singh (PhD), Dept. of Rural Management, DSVV
   2. Prof. Abhay Saxena (PhD), HOD Dept. of Computer Science, DSVV
   3. Dr. Santosh Vishvakarma (PhD), Dept. of Psychology, DSVV
   4. Dr. Saurabh Mishra (PhD), Training and Placement Cell, DSVV

7. Social Scientist /Philosopher/ Activist (ext)
   1. Prof. Mahavir Agrawal (PhD), Sanskrit Vishwavidyalaya, Haridwar
   2. Prof. U. S. Bisht (PhD), (Rtd.) Dept. of Philosophy, Gurukul Kangri Vishwavidyalaya
   3. Dr. Govind Singh (PhD), Director, School of Journalism and Media Studies, Uttarakhand Open University, Haldwani

8. Social Scientist /Philosopher / Activist (int. DSVV)
   1. Prof. Suresh Lal Barnwal (PhD), HOD Dept. of Yoga and Health, DSVV, Haridwar
   2. Prof. Sukhnandan Singh (PhD), HOD Dept. of Communication, DSVV, Haridwar
   3. Dr. Krishna Jhare (PhD), Dept. of Oriental Studies, DSVV, Haridwar

9. Advisor / Members of the Research Ethics Committee of other institutions (ext):
   1. Prof. Pankaj Kumar Sharma, Rishikul Ayurvedic College, Haridwar
   2. Prof. Kalpana Sharma, Rishikul Ayurvedic College, Haridwar

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3. Prof. Gyanendra Shukla, Rishikul Ayurvedic College, Haridwar

10. Legal Advisor (ext)
    1. Advocate Shri P. P. Singh, Ghaziabad

11. Legal Advisor (internal, DSVV)
    1. Advocate Sushree Kiran Kapoor, DSVV, Haridwar

12. Lay persons:

In case the study involves children then a parent, or guardian of a child, teacher in a special school, etc. may be invited. In case the study on the agenda involves adults then the Chairperson, REC may involve any one at his/her discretion (Discretion of the Chairperson of REC).

13. Member Secretary
    Registrar, DSVV, Haridwar

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Appendix B

Relevant directives regarding Review Procedure based on ICMR Guidelines

The REC's member secretary or secretariat shall screen the proposals for their completeness, and depending on the risk involved, categorize them into three types, namely, exemption from review, expedited review and full review (see below for explanation). Minimal risk would be defined as one, which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions, since it would be undertaken as part of current everyday life. An investigator cannot decide that her/ his protocol falls in the exempted category without approval from the REC. All proposals will be scrutinized to decide under which of the following three categories it will be considered:

1. Exemption from review

Proposals which present less than minimal risk fall under this category as may be seen in following situations:

Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exceptions: (i) When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.

(ii) When interviews involve direct approach or access to private papers.

2. Expedited Review

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member Secretary and the Chairperson of the REC or designated member of the Committee of the REC may do expedited review only if the protocols involve-

(1) Minor deviations from originally approved research during the period of approval (usually of one year duration).

(2) Revised proposal previously approved through full review by the REC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.

(3) Research activities that involve only procedures listed in one or more of the following categories:

(a) Clinical studies of drugs and medical devices only when –

i. research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or

ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

(4) Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.

(5) When in emergency situations like serious outbreaks or disasters, a full review of the research is not possible, prior written permission of REC may be taken before use of the test

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(1) Collection of blood samples by finger prick, heel prick, ear prick, or vein puncture, from adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected is strictly as per WHO norms.

(2) Prospective collection of biological specimens for research purposes by non-invasive means, for instance:

a. Skin appendages like hair and nail clippings in a non-disfiguring manner;

b. Dental procedures – deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;

c. Excreta and external secretions (including sweat);

d. Unanimated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;

e. Placenta removed at delivery;

f. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

g. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

h. Sputum collected after saline mist nebulization and bronchial lavages.

(3) Collection of data through non-invasive procedures routinely employed in clinical practice.

(i) Where medical devices are employed, they must be cleared/ approved for marketing, for instance:

a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; weighing or testing sensory acuity;

b. Magnetic resonance imaging;

c. Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow

(ii) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(iii) Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

(iv) Collection of data from voice, video, digital, or image recordings made for research purposes.

(v) Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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Appendix C

Research Protocol Organization Guidelines

I. Protocol

Following are the section headings and brief guidelines on the protocol contents. Though the format below is not binding, the research protocol must include these points in order to enable speedy review.

1. Title of Project

2. Principal Investigator

3. Co-Investigator and other investigative team member list with identified delegation of responsibility

4. Rationale & background information: The Rationale specifies the reasons for conducting the research in light of current knowledge. It should include a well documented statement of the need/ problem that is the basis of the project, the cause of this problem and its possible solutions. It is equivalent to the introduction in a research paper and it puts the proposal in context. It should answer the question of why and what: why the research needs to be done and what will be its relevance.

5. Objectives: Specific objectives are statements of the research question(s). Objectives should be simple, specific and stated in advance. After statement of the primary objective, secondary objectives may be mentioned.

6. Study Design: The scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology. The design of the study should include information on the type of study, the research population or the sampling frame.

7. Participant Selection Criteria: Patients who can take part in the study (e.g. inclusion and exclusion criteria, withdrawal criteria, etc.), and the expected duration of the study with follow-up periods.

8. Methodology: It should include detailed information on the procedures to be used, measurements to be taken, observations to be made, laboratory investigations to be done etc. along with a tabular form study schedule of procedures, for both qualitative and quantitative studies

9. Evaluation of Safety: The adverse event and serious adverse event criteria, and the process to record and report to the REC and any applicable regulatory agency.

10. Research Questionnaire: The protocol should provide research questionnaire containing all parameters under study and also provide information on how the data will be collected including data handling and coding for computer analysis, monitoring and verification.

11. Statistical Analysis: The statistical methods proposed to be used for the analysis of data should be clearly outlined, including reasons for the sample size selected, power of the study,

level of significance to be used in quantitative study. For qualitative studies, as in psychology & cognitive science, the tools and instruments may be clearly explained.

12. Informed Consent Forms: A description of the informed consent process is required accompanied by copies of informed consent forms, both in English and the local language in which they are going to be administered as per ICMR/ WHO requirement. (DCGI/ CDSCO requirement for Drug trials)

13. Budget: The budget section should contain a detailed item-wise breakdown of the funds requested for, along with a justification for each item as applicable.

14. Other support for the Project: This section should provide information about the funding received or anticipated for this project from other funding organizations.

15. Collaboration with other scientists or research institutions, if any. A copy of ethical clearance obtained from the other institution already, must be submitted.

16. References: Brief description of the most relevant studies published, a minimum of 5 on the subject also be listed.

17. Publication policy: Publication policy should be clearly discussed regarding the authorships, who will take the lead in publication and who will be acknowledged in publications. Good Publication Practice guidelines are prescribed in Appendix D.

18. Statement of agreement to comply with ethical principles.

19. Signature of PI and Supervisor or Research Scholar, Co-investigators, Coordinator/ Head of the Centre/ Department.

A Sample Research Protocol is given in Appendix - E

II. Format for Research Ethics Committee Decision Letter / Ethical Clearance Certificate

III. Format for Participant Information Sheet (PIS) and Informed Consent Form (ICF)

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Research Ethics Committee for Research involving Human Participants
Dev Sanskriti Vishwavidyalaya
Gayatrikunj-Shantikunj, Haridwar - 249411

Research Ethics Committee Decision Letter / Ethical Clearance Certificate

Name of the Ethics Committee: REC-DSVV REC Ref. No. .....

Title of the Project Proposal:

Principal Investigator: Sponsor:

Telephone: Email: Fax:

Collaborators' Name, Address, Tel. No., Fax & Email:

- -

FOR OFFICIAL USE

The proposal was reviewed in a meeting held on (date: .....) at (time:.....).
The following members were present:

1. Chairperson
2. Member
3.
4.
5.
6.
7.
8. Member Secretary

The committee resolved to
[ ] Approve - indicating that the proposal is approved as submitted;
[ ] Approve - after clarifications - indicating that the proposal is approved if the clarifications requested are provided to the satisfaction of designated committee members;
[ ] Approve after amendment/s - indicating that the proposal is approved subject to the incorporation of the specified amendments verified by designated committee members;
[ ] Defer - indicating that the proposal is not approved as submitted but it can be re-assessed after revision to address the specified reason/s for deferment;
[ ] Disapprove - indicating that the proposal is not approved for the reasons specified*.

*Comments:

Date of Decision:

Member Secretary, REC
Research Ethics Committee

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INSTITUTIONAL ETHICS COMMITEEE
Dev Sanskriti Vishwavidyalaya
Haridwar-249411

Name of the Ethics Committee: **REC-DSVV** REC Ref. No. .....

Title of the Project Proposal:

Principal Investigator: Sponsor:

Telephone: Email: Fax:

Collaborators' Name, Address, Tel.No. Fax & Email:

FOR OFFICIAL USE

The following item [√] have been received and reviewed in connection with the above study to be conducted by the above investigator.

[√] Patient Information Sheet
[ ] Study Protocol / Synopsis
[ ] Summary of Change Document (in case of a revision)
[ ] Patient Information Consent Form
[ ] Investigators' CVs

And have been [√]

[ ] Approved
[ ] Conditionally approved (identify item and specify modification below or in accompanying letter)
[ ] Rejected (identify item and specify reasons below or in accompanying letter)

Comments:

Date of Approval:

Member Secretary
Ethics Committee

Chairperson
Ethics Committee

Registrar
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Gayatrikunj- Shantikunj, Haridwar- 249411

Consent Form
(in English and in local language of the region)

(To be filled in by PI and presented at the time of Review (Periodic, Continuing, and Interim))

Part I - PIS, Part II - ICF

Title of the Project:

Investigators:

Collaborators:

Potential Funding Agency:

PART - I Participant Information Sheet (PIS)
भाग-1

A brief description of the study objectives in simple language .....

.....

Section - A. The following have been explained to me

	Explained in Detail
1. Purpose of the Study [ ] परियोजना का उद्देश्य	....
2. Study Procedures [ ] शोध प्रणाली	....
3. Risk of the Study [ ] शोध के जोखिम	....
4. Benefits from the Study [ ] शोध के लाभ	....
5. Complications [ ] जटिलताएँ	....
6. Compensations [ ] क्षतपूर्ति	....
7. Confidentiality [ ] गोपनीयता	....

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8. Rights of Participant [ ] .....
प्रततभागी के अधधकाि .....

9. Alternatives to Participation in the Study [ ] .....
शोध में भागीदाि◌ी के विकल्प .....

10. Any Other [ ] .....
कोई अन्यप्य सचू ना .....

Name of the Subject/Participant/ प्रततभागी का नाम:

Signature of Participant/Parent/Guardian/ प्रततभागी/माता/वपता/संि◌क्षक के हस्ताक्षि:

Relationship to Subject/ प्रततभागी से संबंध:

Date/ टदनांक:

Investigator's Statement:

I, the undersigned have explained to the participant/parent/guardian, in a language she/he understands, the procedures to be followed in the study, and risks and benefits.

Signature of the Investigator/ शोधकर्त्◌ाि◌/शोधार्थी के हस्ताक्षि: Date/
टदनांक:

Name of the Investigator/ शोधकर्त्◌ाि◌/शोधार्थी का नाम:

Signature of the Witness/ गिाह के हस्ताक्षि: Date/
टदनांक:

Name of the Witness/ गिाह का नाम:

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Sample II

Community Responses to Nutritional Rehabilitation in Madhya Pradesh and Jharkhand

INFORMED CONSENT OF RESPONDENTS IN IN-DEPTH INTERVIEWS

Introduction: My name is_____, I am working for Dev Sanskriti Vishwavidyalaya, Haridwar. We are interviewing people here _____(name of the city/ region/ site) in order to understand your responses to the issues and the problems that you face on account of severely under-nourished children and your perceptions on availability and accessibility of services at the nutritional rehabilitation centre. We are also trying to understand the reasons for the delay in reaching the facilities. (Describe the purpose of the study). These issues are being studied in another state as well.

(Name of the other state_____)

CONFIDENTIALITY AND CONSENT

The government has started nutritional rehabilitation centres in your state to take care of malnourished children. In this context, it is important to understand the perceptions of mothers, community leaders and the providers about the availability and access to these services. The goal of this study is to understand the social dimensions, perceptions and likely determinants that facilitate and act as barriers to home-based and institutional care of severe undernutrition.

It is with this main purpose that we wish to talk to you. Your honest answers to the questions will help us understand all the involved issues better. We would highly appreciate your co-operation to provide the information on the issues by your honest and frank responses to all the questions. Your identity and information provided by you shall be completely confidential and the information so gathered from different people shall be used only for research purposes. After analysing the information we are gathering from you, we shall destroy the schedules. However, if you feel strongly not to answer one or some of the question, you feel free not to answer such questions. During the interview process, if you feel not to go ahead with the interview, you can withdraw from the interview at any time you want. You can ask any question/ clarify any doubt pertaining to the issues under study, its purpose or any other related matter. The interview will take about half an hour - one hour to ask the questions. If you are willing to participate, we can begin with the interview by your consent.

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DECLARATION BY THE PARTICIPANT

I have read/ I have been communicated the purpose and other details of the ICMR study **"Community Responses to Nutritional Rehabilitation in Madhya Pradesh and Jharkhand"** and about my voluntary participation in the study. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have also been given the right not to answer any question or withdraw from the study if I so desire.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBED.

Name and Signature of Participant Date _____

DECLARATION BY THE INVESTIGATOR

I have explained the research to the participant and answered all of his/ her questions. I believe that he/ she understands the information described in this document and freely consent to participate.

_____ _____

Name and Signature of the Investigator Date of the Interview

Status of the interview:

Completed Successfully	1
Respondent became uncomfortable and stopped answering	2
Some interruption due to which interview stopped	3
Did not agree to complete interview	4

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Appendix D

Good Publication Practice Guidelines

1. COPE's guidelines on good publication practice - 1999

The Committee on Publication Ethics (COPE) (http://publicationethics.org/) was established in 1997 by a small group of medical journal editors in the UK, but now has over 10000 members worldwide from all academic fields. Membership is open to editors of academic journals and others interested in publication ethics.

COPE provides advice to editors and publishers on all aspects of publication ethics and, in particular, how to handle cases of research and publication misconduct. It also provides a forum for its members to discuss individual cases.

COPE's guidelines on good publication practice - 1999 are attached herewith as 'COPE-guidelines-1999.pdf'

(Philip Fulford, Michael Doherty, Jane Smith, Richard Smith, Fiona Godlee, Peter Wilmshurst, Richard Horton, Michael Farthing (2000) "Committee on Publication Ethics (COPE): guidelines on good publication practice", BJU International, 85, 2-7.)
(Available from - http://onlinelibrary.wiley.com/doi/10.1046/j.1464-410x.2000.00478.x/epdf - Accessed on 9th March 2016)

2. Responsible research publication: international standards for authors - 2011

During the 2nd World Conference on Research Integrity in Singapore in 2010, COPE helped develop two position statements setting out international standards for responsible research publication for editors and authors.

The internatioal standards for authors - 2011 are attached herewith as 'International-standards-authors-2011.pdf'

(Wager E & Kleinert S (2011) Responsible research publication: international standards for authors. A position statement developed at the 2nd World Conference on Research Integrity, Singapore, July 22-24, 2010. Chapter 50 in: Mayer T & Steneck N (eds) Promoting Research Integrity in a Global Environment. Imperial College Press / World Scientific Publishing, Singapore (pp 309-16). (ISBN 978-981-4340-97-7))
(Available from - http://publicationethics.org/files/International%20standards_authors_for%20website_11_Nov_2011_0.pdf - Accessed on 9th March 2016)

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Appendix E

Sample Research Protocol

CLINICAL EVALUATION OF HERBAL PREPARATIONS IN THE MANAGEMENT OF MANODVEGA (ANXIETY NEUROSIS)

Drug :

Study Code:

PROTOCOL & CASE REPORT FORMS (CRF)

Source: Lavekar G. S., Padhi M. M. (Editors) (2009) "Clinical Research Protocols for Traditional Health Sciences (Ayurveda, Siddha, Unani, Sowa Rigpa and Others)", Central Council for Research in Ayurveda and Siddha, Department of AYUSH, Ministry of Health and Family Welfare, Government of India, New Delhi (www.ccras.nic.in) (Available at - http://herbalnet.healthrepository.org/bitstream/123456789/2493/1/Research%20protocol%20for%20traditional%20health%20science.pdf - Accessed on 5th March 2016) (research-protocol-for-traditional-health-science.pdf)

CENTRAL COUNCIL FOR RESEARCH IN AYURVEDA AND SIDDHA

CLINICAL EVALUATION OF HERBAL PREPARATIONS IN THE MANAGEMENT OF MANODVEGA (ANXIETY NEUROSIS)

I. BACKGROUND

Life is a conglomerate of body (Shareera), faculties (Indriya), mind (Satva), and soul (Aatma). Any of these cannot be isolated and studied separately. So seers of Ayurveda express that the term Shareera refers body including five senses and mind.

As mind is a dual faculty (Ubhayendriya) or sensory-motor faculty (Jnana-Karmendriya), it perceives and responds. Even the physical well being is reflected in mind, so is the illness. This made the terms happiness (Sukha), and misery (Dukha), synonyms of health and illness. The influence of mind cannot be ruled out in origin, existence or cure of any condition of any disease.

When allowed to persist for long time the psychic and somatic disorders get combined with each other.

Chittodwega/ Manodwega is one of the Manasika Vikara mentioned in Ayurvedic literature. The symptoms of this disease can be assumed mostly similar with the generalized anxiety disorder (GAD). GAD is a disorder requires the presence of unrealistic or excessive anxiety and worry, accompanied by symptoms from three of four categories: (1) motor tension, (2) autonomic hyperactivity, (3) vigilance and scanning, and (4) apprehensive expectation. The anxious mood must continue for at least a month.

The Ayurvedic principle of synthesis of mind, body and soul to consider man as integrated whole one, would help to treat mental disorders effectively. Medhya rasayanas and Satvavajaya chikitsa are such a measures, which can be utilized for the treatment of Chittodwega/ Manodwega.

[1] In Chittodwega/ Manodwega [2], when the mind is afflicted with anxiety, fear, agitation etc.; this leads to worry, apprehension, depression, psychological arousal as anger, irritability and ultimately lead to disturbance in personal, familial and social harmony.

References

1. Charaka Samhita with Ayurveda Dipika commentary of Chakrapanidatta, Chaukhambha Sanskrit Sansthan, 5th edition, Varanasi, 2001
2. Sushruta Samhita with Nibandha Sangraha commentary of Dalhana and Nyayachandrika commentary of Gayadasa, Chaukhambha Orientalia Varanasi, 6th edition, 1997.
3. Harrison: Principals of Internal Medicine Vol. II, 13th edition (International edition).

Anxiety disorders [3] are among the most prevalent psychiatric condition in the world. Further, studies have persistently shown that they produce inordinate morbidity, utilization of health care services, and functional impairment. Recent studies also suggest that chronic anxiety disorder may increase the rate of cardiovascular-related mortality. Hence, clinicians in psychiatry and other specialties must make the proper anxiety disorder diagnosis rapidly and initiate treatment.

Ayurveda provides rational means for the treatment of many disorders, which are considered to be obstinate and incurable in other systems of medicine.

II. OBJECTIVES

To evaluate the anti-anxiety effect of an ayurvedic compound drug in patients suffering with manodwega.

The efficacy of ayurvedic compound drug for six weeks have been studied on manodwega in terms of relieving from the symptoms pridictable through ayurvedic clinical parameters & hamilton's rating scale for anxiety neurosis.

III. CENTRES

CCRAS identified centers

IV. SAMPLE SIZE AND METHODS

Sample Size :	24 patients in each group (2 groups)
Trial period :	45 Days
Design of the study :	Sequential crossover design and double blind method are adopted.
Drug & dosage :	The Ayurvedic compound consists of Mandukaparni (Centella asiatica), Yasti (Glycyrrhiza glabra), Jatamamsi (Nardostachys jatamansi) in the ratio of suspended in the Kshirabala Thaila. The daily dose of Ayurvedic drug is 3 g/day in 3 divided doses. Each capsule contains 500mgs of drug i.e. Mandukaparni (120mg), Yasti (120mg.), Jatamamsi (240mg.) and ksheerabala taila (3 drops). The daily dosage of diazepam is 15mg. /day also in three divided doses. The placebo is plain starch powder.
Duration of the study :	45 days drug therapy with a follow up for 7 days.
Study period :	1 year to complete study.
Follow-Up :	The follow-up will be carried out after 7 days of treatment.

V. CRITERIA FOR INCLUSION

1. Age between 16-45 years of either sex
2. Presence of cardinal features of manodwega
3. Onset between 8weeks to 2 years
4. Ambulatory and co-operative

VI. CRITERIA FOR EXCLUSION

1. Age below 16 yrs. and above 45 yrs.
2. Duration of the disease - below 8weeks and above 2years.
3. Exhibiting psychotic symptoms
4. Factors interfering with concentration and communication
5. Hypertension
6. Diabetes
7. Any other systemic diseases

VII. CRITERIA FOR WITHDRAWAL

1. If patient does not follows the instructions.
2. Any complication developed during the course of trial.

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VIII. ROUTINE EXAMINATION AND ASSESSMENT

A detailed clinical and social history is taken. The patients assessed on the basis of clinical parameters and Hamilton's anxiety rating scales.

IX. METHOD OF ASSESSMENT OF TREATMENT

1. Clinical Symptomatic Relief
2. Psychological parameters
3. Hamilton's anxiety rating scale

X. STATISTICAL ANALYSIS:

Data on clinical symptoms and objective tests before and after the treatment will be tabulated and analyzed using appropriate statistical tools. However, the data of each case will have to be communicated on completion of trial therapy to the Statistical Officer of CCRAS through e-mail.

XI. TRIAL MONITORING AND DATA ANALYSIS

CCRAS, Hqrs, New Delhi will undertake the monitoring of progress of the trial and data analysis.

XII. ETHICAL REVIEW

A. Ethical Committee (REC): The proposal will be placed before Ethical Committee (REC) of trial center for getting clearance certificate before the project is initiated. Patient's information sheet and informed consent form will be submitted along with project proposal for approval by EC. Both will be maintained in duplicate with one copy given to the patient at the time of entry to the trial.

B. Data and safety monitoring board: A Data and safety monitoring board (DSMB) at Hqrs. will carefully monitor the data and side effects during the period of study and put in a place where by prompt reporting of adverse events occur. The data will be reviewed as every 20 participants entered the study and administered the trial drugs. The research team will report immediately to the PI and Data Monitoring Board if, any life threatening conditions whether they are perceived to be study related or not. The Board decides whether the adverse effects warrant discontinuation of the study protocol. Protocols will be written and approved for the treatment of study related adverse events.

XIII. TRAVELING EXPENSES FOR RESEARCH SUBJECTS

A consolidated amount of Rs.100/- per visit i.e., on the 1st day of recruitment after screening, 8th day, 15th day and so on upto 45th day (weekly once).

XIV. TRAINING TO INVESTIGATORS AND PERSONS INVOLVED

Short-term two-day training will be provided to the Investigators and Laboratory personnel involved in the multi-centric trial at CCRAS Hqrs. and Central Research Institute (Ay.), New Delhi. The investigators and technicians will be detailed about the clinical trial

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conduct and laboratory procedures in order to maintain the uniformity.

XV. LABORATORY INVESTIGATIONS

The Laboratory Investigations (Pathological/Biochemical, etc.), which are not available at research Institutes should be conducted at identified reputed labs /Government Institutes under intimation to this Council following codal formalities.

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CENTRAL COUNCIL FOR RESEARCH IN AYURVEDA AND SIDDHA

CLINICAL EVALUATION OF HERBAL PREPARATIONS IN THE MANAGEMENT OF MANODVEGA (ANXIETY NEUROSIS)

WRITTEN INFORMED CONSENT FORM

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all details about the study in the terms easily understood by the patient.

Date:_____ Signature of the Investigator: _____

Name: _____

CONSENT BY SUBJECT

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial and the nature of drug treatment and follow-up, including the laboratory investigations to be performed to monitor and safeguard my body functions.

I am also aware of my right to opt out of the trial at any time during the course of the trial without having to give the reasons for doing so. I am willing to undergo any risk for inclusion in this study.

I, exercising my free power of choice, hereby give my consent to be included as a subject in the clinical trial on "Clinical evaluation of herbal preparations in the management of Manodvega (Anxiety Neurosis)".

Date:_____ Name of the Subject:_____

Signature or Thumb Impression : _____

Date:_____ Name of Witness: _____

Signature or Thumb Impression: _____

Relationship _____

To be translated into regional language.

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CENTRAL COUNCIL FOR RESEARCH IN AYURVEDA AND SIDDHA

CLINICAL EVALUATION OF HERBAL PREPARATIONS IN THE MANAGEMENT OF MANODVEGA (ANXIETY NEUROSIS)

PATIENT INFORMATION SHEET

What is the study about?

Chittodwega/ Manodwega is one of the Manasika Vikara mentioned in Ayurvedic literature. The symptoms of this disease can be assumed mostly similar with the generalized anxiety disorder (GAD). GAD is a disorder requires the presence of unrealistic or excessive anxiety and worry, accompanied by symptoms from three of four categories: (1) motor tension, (2) autonomic hyperactivity, (3) vigilance and scanning, and (4) apprehensive expectation. The anxious mood must continue for at least a month.

The Ayurvedic principle of synthesis of mind, body and soul to consider man as integrated whole one, would help to treat mental disorders effectively. Medhya rasayanas and Satvavajaya chikitsa are such a measures, which can be utilized for the treatment of Chittodwega/Manodwega.

In Chittodwega/ Manodwega, when the mind is afflicted with anxiety, fear, agitation etc. this leads to worry, apprehension, depression, psychological arousal as anger, irritability and ultimately lead to disturbance in personal, familial and social harmony.

Anxiety disorders are among the most prevalent psychiatric condition in the world. Further, studies have persistently shown that they produce inordinate morbidity, utilization of health care services, and functional impairment. Recent studies also suggest that chronic anxiety disorder may increase the rate of cardiovascular-related mortality. Hence, clinicians in psychiatry and other specialties must make the proper anxiety disorder diagnosis rapidly and initiate treatment.

Ayurveda provides rational means for the treatment of many disorders, which are considered to be obstinate and incurable in other systems of medicine.

What will you have to do?

Your doctor will explain clearly what you have to do. It is important that you follow the instructions scrupulously. The study will take approximately 45 days.

Before you start treatment, during the first visit to the clinic, you will undergo a complete physical examination, required objective tests and laboratory investigations will also be done.

If you are found eligible, you would be put on trial treatment for 45 days.

At each visit, you will be supplied with sufficient quantities of drugs to last until your next visit. If any adverse reactions like skin allergy, nausea, vomiting and palpitation/tremor etc., noticed during the treatment period, this should be noticed to the Principle Investigator.

To be translated into regional language.

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CENTRAL COUNCIL FOR RESEARCH IN AYURVEDA AND SIDDHA

CLINICAL EVALUATION OF HERBAL PREPARATIONS IN THE MANAGEMENT OF MANODVEGA (ANXIETY NEUROSIS)

The following forms are given in the document - 'sample-research-protocol.pdf'

CASE REPORT FORM - I - SCREENING - BEFORE TREATMENT

CASE REPORT FORM - II - ADMISSION

CASE REPORT FORM - III - INVESTIGATIONS

CASE REPORT FORM - IV - PERIODICAL OBSERVATION & ASSESSMENT

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Research Ethics Committee for Research involving Human Participants
Dev Sanskriti Vishwavidyalaya, Gayatrikunj-Shantikunj, Haridwar - 249411

Ethical Clearance Certificate

Name of the Ethics Committee: REC-DSVV REC Ref. No.: DSVV/PSY/13191/2024

Title of the Project Proposal: "Effect of Naad Yog Sadhana and Swadhyay on Emotional Competence and Happiness"

Ph.D. Research Scholar: Shivani Saini

Supervisor- Dr. Pragya Rana
Associate Professor
Dept. of Psychology

Sponsor: Not Applicable

FOR OFFICIAL USE

The proposal was reviewed in a meeting of the Research Ethics Committee held on (date: 18 Jan 2024) at (time: 4:00 P.M.).

The committee resolved to

[√] Approve - indicating that the proposal is approved as submitted;
[ ] Approve - after clarifications - indicating that the proposal is approved if the clarifications requested are provided to the satisfaction of designated committee members;
[ ] Approve after amendment/s - indicating that the proposal is approved subject to the incorporation of the specified amendments verified by designated committee members;
[ ] Defer - indicating that the proposal is not approved as submitted but it can be re-assessed after revision to address the specified reason/s for deferment;
[ ] Disapprove - indicating that the proposal is not approved for the reasons specified*.

* Comments of committee:
No Ethical Issues.

Date of Decision: 19 January 2024

Member Secretary (Research Ethics Committee)

Research Ethics Committee for Research involving Human Participants
Dev Sanskriti Vishwavidyalaya, Gayatrikunj-Shantikunj, Haridwar - 249411

Ethical Clearance Certificate

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Supervisor- Dr. Pragya Rana
Associate Professor
Dept. of Psychology

Sponsor: Not Applicable

FOR OFFICIAL USE

The following item [√] have been received and reviewed in connection with the above study to be conducted by the above investigator.

[√] Participant Information Sheet
[√] Study Information Sheet
[√] Synopsis
[√] Participant Information Consent Form
[√] Experimental group subject Consent Form
[√] Investigators' CVs

And have been [√]

[√] Approved
[ ] Conditionally approved (identify item and specify modification below or in accompanying letter)
[ ] Rejected (identify item and specify reasons below or in accompanying letter)

Comments of committee:
No Ethical Issues.

Date of Approval: 16 March 2024

Member Secretary
Research Ethics Committee

Chairperson
Research Ethics Committee

Registrar
Dev Sanskriti Vishwavidyalaya
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AP

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