Research Ethics Committee
Dev Sanskriti Vishwavidyalaya, Haridwar

Revised as per 49th Academic Council meeting

Dev Sanskriti Vishwavidyalaya (DSVV) is a non-conventional center of teaching and research, which has been born out of a unique vision of the groundbreaking scholar and visionary, Pt. Shriram Sharma Acharya, who was also a renowned social reformer and a celebrated freedom fighter. He had a vision to establish a University devoted to the preservation and propagation of the Indian Culture, which to him was Dev Sanskriti, that could combine the percepts of practical knowledge (shiksha) and spiritual education (vidya) to create truly enlightened individuals. As a result, DSVV was established in the year 2002, with the primary focus of providing a confluence of modern education with instillation of human values in the students.

Besides offering undergraduate, post-graduate and doctoral programs in a wide array of subjects, DSVV conducts research in various areas including Yoga and Health, Psychology, Indian History and Culture, Tourism Management, Journalism and Mass Communication, Environmental Science, Computer Science, Sanskrit, Indian Classical Music, Oriental Studies (Ayurveda, Philosophy, Hindi), etc. DSVV is committed to maintaining high standards of ethics and quality in its research activities.

A number of studies pursued in DSVV involve participation of human subjects. As a result, a Research Ethics Committee (REC-DSVV) was constituted to review all research proposals involving human subjects, submitted by faculty members and research students. In view of the current Indian Council of Medical Research (ICMR) guidelines, and other similar guidelines, the constitution of Research Ethics Committee (REC-DSVV) for human subjects is being modified.

Constitution of REC

Research Ethics Committee for research on human subjects was constituted on 5th December 2013. In view of the current Indian Council of Medical Research (ICMR) guidelines, and other similar guidelines, the constitution of Research Ethics Committee (REC-DSVV) for human subjects is being modified. The REC-DSVV is supposed to review all research proposals submitted by the faculty members, as well as Ph.D. work involving human participants.

The tenure of the Chairperson and the Member Secretary is five years, while that for the members on the panel is three years from the date of appointment.

A. Proposed Constitution of REC-DSVV is as follows:

1. Chairperson
2. Chancellor's Nominee
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
10. Legal Advisor (External)

11. Legal Advisor (Internal, DSVV)
12. Lay Persons (one or two)
13. Member Secretary (DSVV)

A suggested panel of names in each one of these categories is given below. The panel includes the names of some of the earlier members for another term. Every category has a panel of names so that at least one from each category may be included while constituting a committee for a specific project review meeting.

Tenure

Every member in the panel will have a tenure of three years, after which a fresh panel of three names in the same category may be nominated by the DSVV Administration. For the sake of continuity the Chairperson and the Member Secretary will have a term of five years.

Terms of Appointment

As per ICMR guidelines, the 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.

Process

The REC will meet at least once every semester, to review all the applications including proposals for Ph.D. research involving human subjects, as well as research proposals submitted by the faculty involving human subjects for any kind of data. The internal members of the committee will screen the proposals before they are circulated to the external members. The presence of minimum five persons, including the Chairperson and Member Secretary will be mandatory to conduct a meeting.

Certificate

Once the REC is satisfied that the study is in no way harmful to the subjects under study, the committee will issue an Ethical Clearance Certificate, valid for the period of the study specified.

The committee will also advise the researcher about the "Informed Consent" to be obtained from the subjects, and "confidentiality" to be maintained vis-a-vis the subjects.

The Standard Operating Procedure (SOP)

The Standard Operating Procedure (SOP) of REC is to outline the development, approval, organization, implementation and management of all Human Research protocols to be conducted in Dev Sanskriti Vishwavidyalaya, Haridwar. 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 she/he must observe while dealing with human participants and / or materials.

The SOP for REC of DSVV is given in the attached document - 'sop.doc'

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, Haridwar (DSVV). 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 she/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- https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzM5NQ== - accessed on 17th January 2025) (CDSCO-Good-Clinical-Practice-guidelines.pdf)
- CDSCO- Central Drugs Standard Control Organization - "The Drugs and Cosmetics Act (1940) and Rules (1945) (As amended up to the 31st December, 2016)" (Available from - https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf - accessed on

17th January 2025) (2016DrugsandCosmeticsAct1940Rules1945.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 - https://publicationethics.org/guidance/endorsed-guidance/international-standards-editors-and-authors-wcri-2010 - Accessed on 17th January 2025) (international-standards-authors.pdf)
- ICMR - Indian Council of Medical Research - "Ethical Guidelines for Biomedical Research on Human Participants" - (Available from - https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf - Accessed on 17th January 2025) (ICMR_National_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 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, etc., 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
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 current version of the Drugs & Cosmetics Act, 1940, 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 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 nominated by

the DSVV Administration. 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

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.

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. 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

Appendix A

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

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 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:

(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.

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)

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

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

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 [ ] क्षतिपूर्ति	....

7. Confidentiality [ ] .....
गोपनीयता .....

8. Rights of Participant [ ] .....
प्रतिभागी के अधिकार .....

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

10. Any Other [ ] .....
कोई अन्य सूचना .....

Name of the Subject/Participant/ प्रतिभागी का नाम:

Signature of Participant/Parent/Guardian/ प्रतिभागी/माता/पिता/संरक्षक के हस्ताक्षर:

Relationship to Subject/ प्रतिभागी से संबंध:

Date/ दिनांक:

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/ शोधकर्त्ता/शोधार्थी के हस्ताक्षर: Date/
दिनांक:

Name of the Investigator/ शोधकर्त्ता/शोधार्थी का नाम:

Signature of the Witness/ गवाह के हस्ताक्षर: Date/
दिनांक:

Name of the Witness/ गवाह का नाम:

PART-II Informed Consent Form (ICF)

CONSENT FORM

(from experimental group participant/subject/patient)

The advantages and disadvantages of the research in which I am expected to participate, for which I have to do _____ , fill _____ , undergo _____ investigations, have been explained to me.

I willingly, under no pressure from the researcher-

1. agree to take part in this research, and agree to participate in all the measurements / investigations, which will help acquire knowledge for the benefit of mankind,
2. agree to do _____ , fill _____

My consent is explicitly not for disclosing any personal information. Further consent should be obtained for disclosing any such personal information obtained from the investigations conducted on me.

I have been informed that _____ (Name of Institution) and the researcher(s) (Principal Investigator (PI) - _____, and his/her Research Supervisor - _____) will take my prior consent before they draw benefits from research based on me and my data. I give my consent that without revealing my personal information, this data can be used for research purposes, and the data/conclusions drawn from it can be presented, as well as published in research journals and conferences.

Signatures

| --- | --- | --- |
| Subject | Witness | Principal Investigator |

सहमति पत्र

(प्रायोगिक समूह के रोगी/प्रतिभागी हेतु)

मुझे शोधकर्त्ता द्वारा, जिस उद्देश्य के लिए मुझे शोधकार्य में भाग लेना है, उसके फायदे व नुकसान बता दिए गए हैं। मुझे ज्ञात है कि इस शोधकार्य के अंतर्गत मुझे _____ करवाया जाएगा, _____ का माप मुझ पर किया जाएगा, और _____ प्रश्नावली भरवाई जाएगी |

मैं बिना किसी दबाव के, अपनी इच्छानुसार:

(1) इस शोधकार्य में भाग लेने के लिए सहमत हूँ। इस शोधकार्य के लिए सभी प्रकार के परीक्षण, जो मानव जाति के कल्याण के लिए ज्ञान प्रदान करते हैं, के लिए सहमत हूँ।

(2) इस शोधकार्य के लिए मैं _____ करने के लिए सहमत हूँ। इस शोधकार्य के लिए _____ का माप जो मुझ पर किया जाएगा,और _____ प्रश्नावली जो मुझे भरनी है, उसके लिए मैं सहमत हूँ।

मेरी सहमति प्रत्यक्ष रूप से किसी भी व्यक्तिगत जानकारी के खुलासे के लिए नहीं है। मेरे आंकड़ों से प्राप्त व्यक्तिगत जानकारी के खुलासे के लिए मेरी अगली अनुमति अनिवार्य है। मुझ पर की गई जाँच से प्राप्त ऐसी किसी भी व्यक्तिगत जानकारी को प्रकट करने के लिए आगे सहमति ली जानी चाहिए।

मुझे सूचित किया जा चुका है कि _____ (संस्थान का नाम) एवं शोधकर्ता (मुख्य शोधकर्ता - _____, एवं उनके/उनकी शोध निर्देशक - _____), मेरे ऊपर की जाने वाली शोध एवं उससे प्राप्त आंकड़ों से किसी भी प्रकार का लाभ लेने से पूर्व, इस हेतु मेरी सहमति अवश्य लेंगे। मैं इस बात से सहमत हूँ कि बिना मेरी व्यक्तिगत जानकारी का खुलासा किए, इस जानकारी (आंकड़ों, आदि) को शोधकार्य हेतु प्रयुक्त किया जा सकता है, एवं इस जानकारी (आंकड़ों, आदि) और इससे प्राप्त निष्कर्षों को शोध सम्मेलनों में प्रस्तुत किया जा सकता हैं, एवं शोध पत्रिकाओं में प्रकाशित किया जा सकता है।

.....	.....	.....
प्रतिभागी के हस्ताक्षर	गवाह के हस्ताक्षर	प्रधान अन्वेषक के हस्ताक्षर

CONSENT FORM

(for the control group participant/subject/patient)

The advantages and disadvantages of the research in which I am expected to participate, for which I have to do _____ , fill _____ , undergo _____ investigations, have been explained to me.

I willingly, under no pressure from the researcher-

1. agree to take part in this research, and agree to participate in all the measurements / investigations, which will help acquire knowledge for the benefit of mankind,
2. agree to do _____ , fill _____

My consent is explicitly not for disclosing any personal information. Further consent should be obtained for disclosing any such personal information obtained from the investigations conducted on me.

I have been informed that _____ (Name of Institution) and the researcher(s) (Principal Investigator (PI) - _____, and his/her Research Supervisor - _____) will take my prior consent before they draw benefits from research based on me and my data. I give my consent that without revealing my personal information, this data can be used for research purposes, and the data/conclusions drawn from it can be presented, as well as published in research journals and conferences.

Signatures

| --- | --- | --- |
| Subject | Witness | Principal Investigator |

सहमति पत्र

(नियंत्रित समूह के रोगी/प्रतिभागी हेतु)

मुझे शोधकर्ता द्वारा, जिस उद्देश्य के लिए मुझे शोधकार्य में भाग लेना है, उसके फायदे व नुकसान बता दिए गए हैं। मुझे ज्ञात है कि इस शोधकार्य के अंतर्गत मुझे _____ करवाया जाएगा, _____ का माप मुझ पर किया जाएगा, और _____ प्रश्नावली भरवाई जाएगी |

मैं बिना किसी दबाव के, अपनी इच्छानुसार:

(1) इस शोधकार्य में भाग लेने के लिए सहमत हूँ। इस शोधकार्य के लिए सभी प्रकार के परीक्षण, जो मानव जाति के कल्याण के लिए ज्ञान प्रदान करते हैं, के लिए सहमत हूँ।

(2) इस शोधकार्य के लिए मैं _____ करने के लिए सहमत हूँ। इस शोधकार्य के लिए _____ का माप जो मुझ पर किया जाएगा,और _____ प्रश्नावली जो मुझे भरनी है, उसके लिए मैं सहमत हूँ।

मेरी सहमति प्रत्यक्ष रूप से किसी भी व्यक्तिगत जानकारी के खुलासे के लिए नहीं है। मेरे आंकड़ों से प्राप्त व्यक्तिगत जानकारी के खुलासे के लिए मेरी अगली अनुमति अनिवार्य है। मुझ पर की गई जाँच से प्राप्त ऐसी किसी भी व्यक्तिगत जानकारी को प्रकट करने के लिए आगे सहमति ली जानी चाहिए।

मुझे सूचित किया जा चुका है कि _____ (संस्थान का नाम) एवं शोधकर्ता (मुख्य शोधकर्ता - _____, एवं उनके/उनकी शोध निर्देशक - _____), मेरे ऊपर की जाने वाली शोध एवं उससे प्राप्त आंकड़ों से किसी भी प्रकार का लाभ लेने से पूर्व, इस हेतु मेरी सहमति अवश्य लेंगे। मैं इस बात से सहमत हूँ कि बिना मेरी व्यक्तिगत जानकारी का खुलासा किए, इस जानकारी (आंकड़ों, आदि) को शोधकार्य हेतु प्रयुक्त किया जा सकता है, एवं इस जानकारी (आंकड़ों, आदि) और इससे प्राप्त निष्कर्षों को शोध सम्मेलनों में प्रस्तुत किया जा सकता हैं, एवं शोध पत्रिकाओं में प्रकाशित किया जा सकता है।

.....	.....	.....
प्रतिभागी के हस्ताक्षर	गवाह के हस्ताक्षर	प्रधान अन्वेषक के हस्ताक्षर

PARTICIPANT INFORMATION SHEET

संस्थान का नाम / पता

_____ विभाग

<u>प्रतिभागी सूचना पत्रक</u>

"शोध का विषय"

शोध निर्देशक: **शोधकर्ता:**

शोध कार्य का परिचय -

आपको क्या करना है ?

शोध कार्य से मिलने वाले सम्भावित फायदे -

इस कार्य से सम्बन्धित खतरे -

अभिलेखों की गोपनीयता -

दुर्घटना द्वारा असमय मृत्यु हो जाने पर मिलने वाला मुआवजा -

कार्य को छोड़ कर जाने की स्वतंत्रता -

प्रतिभागी का नाम:_____

प्रतिभागी/माता/पिता/संरक्षक के हस्ताक्षर:_____ दिनांक:_____

प्रतिभागी से संबंध:_____

<u>शोधकर्ता का कथन -</u>

मैंने प्रतिभागी/ संरक्षक/ अभिभावक (जिन्होंने हस्ताक्षर किए हैं) को उनके समझने योग्य भाषा में शोध कार्य की पूरी विधि, फायदे व खतरों के बारे में अवगत करा दिया है।

शोधकर्त्ता के हस्ताक्षर:_____ दिनांक:_____

शोधकर्त्ता का नाम:_____

गवाह के हस्ताक्षर:_____ दिनांक:_____

गवाह का नाम:_____

NAME / ADDRESS OF INSTITUTION

DEPARTMENT _____

PARTICIPANT INFORMATION SHEET

"Research Topic"

Research Supervisor: **Research Scholar:**

What is the study about?

What will you have to do?

The benefits that might be expected from the outcome of the research to the subject -

Any risk to the subject associated with the study -

Maintenance of the confidentiality of records -

Compensation of subjects for disability or death resulting from injury -

Freedom of individual to participate and to withdraw from research at anytime without penalty or loss of benefits to which the subject would otherwise be entitled -

Name of the Subject/Participant: _____

Signature of Subject/Participant/Parent/Guardian: _____

Relationship to Subject: _____

Date: _____

Investigator's Statement:

I, the undersigned, have explained to the subject/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: _____ Date: _____

Name of the Investigator: _____

Signature of the Witness: _____ Date: _____

Name of the Witness: _____

(To be translated into regional language)

Sample I

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 under-nutrition.

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 analyzing 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.

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

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 international 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 - https://publicationethics.org/guidance/endorsed-guidance/international-standards-editors-and-authors-wcri-2010 - Accessed on 17th January 2025) (international-standards-authors.pdf)

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) (Few pages available at - https://ccras.nic.in/clinical-research-protocols-for-traditional-health-sciences-e/ - Accessed on 18th January 2025)

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.

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

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.

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.

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.

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