INSTITUTIONAL ETHICS COMMITTEE

Maharashtra Arogya Mandal's Sumatibhai Shah Ayurved Mahavidyalaya and

Ayurveda Hospital – Sane Guruji Arogya Kendra Malwadi, Hadapsar, Punc – 411 028.

Phone No.:- +91-20-26998937, +91-20-26999405 Fax:- +91-20-26999467 Email: ssayu@rediffmail.com

Ref: MAM/SSAYU/

Date: 25/01/2018

Minutes

24th Meeting of Institutional Ethics Committee 24th January 2018

Date :- 24/01/2018

Time :- 10.00 AM to 05.30 PM

Venue :- Conference Hall, SGAK, Hadapsar, Pune

Meeting attended by hon'ble members on 24th January 2018:-

 Dr. V.V. Doiphode 	Chairman of IEC
2. Dr. S.M. Sathye	Member of IEC
Dr. Yogini Kulkarni	Member of IEC
 Dr. Satish Puntambekar 	Member of IEC
Dr. Dhananjay Mhasade	Member of IEC
Dr. Rajendra Huprikar	Member of IEC
Dr. Pallavi Jamadagni	Member of IEC
Dr. Sangeeta Sangvikar	Member of IEC
Dr. Vidya Undale	Member Secretary IEC

Following IEC member was absent on 24th January 2018 due to personal reasons.

Mr. Arun Gujar

2. Dr. Pranita Joshi-Deshmukh

Member of IEC

Research Co-ordinator

Welcome Note by Hon, Dr. Vidya Undale, PG Co-ordinator, SSAM, Pune

Principal

M. A. B's. Surnetibhei Shah
Ayervod Mehavidalaya,
Sadaparr, Pass-38.

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Minutes of 24th Institutional Ethics Committee were accepted by Hon, Members.

· Common Suggestions:

 Scientific names of the drugs are to be mentioned correctly along with the name of authority.

2. Part / Parts used of the drug should be mentioned.

3. Do not reveal identity by naming the institute (college, hospital and pharmacy)

PH.D STUDENTS

1. Dr. Bhushan Mhaiskar - Samhita Siddhant

Comparative clinical study of the effect of kaphashamak rasadravya sanyog in the management of Amajivina w.s.r to ras viman addhgohta ras-dosha prabhar.

Title should be reframed w.s.r to be deleted.

2. Research question should be whether ekala & sanyog rasa dravyas are effective.

 Aim should be reframed. As it is Saiddhantik study it should reflect in aim. Evaluation of concept of

 Sample of study is not proper, whether Aamajma or Doshvriddhi symptoms should be studid that should be clarified.

5. Discuss with the guide and present again.

2. Dr. Asmita Sutar - Samhita Siddhant

Critical study of Manuscript Ashtanghridaye sharirstanam chandranandan, Virachit padarth Chandrika teeka.

1. Refer work done by Dr. Gayatri Deshpande TMV, Pune.

Research opinion should be considered. Peculiarities, similarties, dissunitarities of commentary should be taken into consideration.

 Official per mission of concerned authorities should be taken and copy to the same should be attached with their terms & conditions.

Name of Sanskrit expert should be mentioned.

5. Methodology should be mentioned. Number of experts, stastical text etc. should be clarified.

What is the need of transcription as the camera print is clear? It might change original writing format.

Authority letter and comments should be attached (Kolhapur).

8. Establishment of year of manuscripts - Methodology to be mentioned.

9. Reform primary objective i.e. to study critically.

10. Add - To study in comparison with other available texts in secondary objectives.

3. Dr. Bhavana Bhalme - Samhita Siddhant

1. Title be reframed.

2. Marathi consent form and information sheet for patients be added.

3. Exclusion criteria Age be deleted.

- 4. Research question be reframed.
- 5. Spellings and grammar be rechecked.

6. Objectives he rewritten

7. Diacritical mark for Sanskrit words be used.

Principal

A. S's. Succetible: Shell

Against Shell

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4. Dr. Mukund Sonawane - Kriya Sharir

Assessment of effect of Pranava Pranayam on shabda and Roop graham samarthya in school going male children w.s.r. to auditory and visual choice reaction time.

- Slide numbers be given.
- 2. Study type I should be conceptual descriptive be deleted.
- 3. No need to explain different Hypotheses for study types.
- 4. Sample size to be increased.
- 5. Pilot study for perception or preparatory study instead of only pilot study.
- 6. Sample size should be 110 in each group.
- Previous work done to be studied meticulously. No need of control group.
- Randomization method should be precise. Systematic sampling method is used Random no table be used.
- 9. Audio visual testing to be done prior to Randomisation to procure homogenous groups.
- 10. Page No.11 Exclusion Criteria DMX-----
- 11. Page No. 20 CRF Gender instead of sex.
- 12. Page No. 23 Consciousness X Conscious.
- Marathi CRF simple language to be used. Terms to be simplified signs of willness and parents be addedorlocal guardian
- 14. Page No. 21 Socid economic status be deleted.
- 15. Page No. 36 last sentence be deleted.
- 16. Pranav Pranayam be explained in informed consent form and CRF.
- 17. Control group be engaged in other activity.

5. Dr. Varsha Khot - Kayachikitsa

Randomized controlled clinical trial in Amrutadi Yoga in evaluation of HTN.

- Inclusion criteria Stage I HTN ret be mentioned.
- Telmisartan be given to control group instead of Hydroclorthiazide and Record of dose should be maintained.
- 3. Method of B.P. checking be mentioned mean of B.P. be taken. Position.
- 4. Calibrated be deleted from VIII methods of measurement.
- 5. Urine --- be added in screening test,
- 6. Dose, duration & Anupan be mentioned in Research question and Hypotheses.
- 7. Reference of Kalpa be mentioned.
- 8. Informed consent be attached should be prepared using ICMR guidelines.
- 9. Primary objective be reformed, changing
- Secondary objectives, other than x untoward.
- 11. Randomisaltion method should be reformed.
- 12. Exclusion criteria, criterion mentioned in inclusion be deleted.
- Left hand thumb impression of patient be added on consent form.
- 14. Sheet should be prepared for drug consumption and given to patients.
- 15. Toxically study data be mentioned.
- 16. References should be given appropriate numbering.
- 17. CTIR registration is mandatory.

6. Dr. Shachi Desai - Kayachikitsa

Evaluation of Adjuvent effect of Dhatri Nisha Vati in Madhumeha w.r.t. Type II DM.

1. As study with 1 trituration is already done what is the Novelty in this study?

2. Plagiarism is noted. Such data be deleted

CRF be reformed.

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Page no. 11 Mention of sponsors to be deleted.

5. Sample size should be 126 in each group.

Inclusion criteria should be specific i.e. K/C/O DM < 2 years. Control drug should be specified with dose.

Kshuddha vriddhi in CRF- mention quantity to aahar and frequency.

- Instead of 3 Bhavanas, 1 Bhavit drug can be studied with Serum insulin as criterion of assessement.
- Sample size be calculated again and represent again.

10. Informed consent sheet be added.

7. Dr. Geentajali Karale - Rachana Sharir

Randomized controlled trial of Raktamokshana by siravidhi in Bahupitta Kamala w.s.r. to Yakrit.

Why clinical study if your subject is Anotomy.

Correlation of organogenesis with this study is not reffectling in this study. Instead any congenital anatomy can taken into consideration.

3. Relevance of clinical trial not clear.

4. Topic to be changed.

8. Dr. Amit Bairagi - Rachana Sharir

A study of Asthi Dhatu as described in Sushrut Samhita.

- 1. Title should be reframed. Dehadharan to reflect in title.
- 2. Concept of Ashtimala and Upardhatu be taken into consideration.

3. Concept of Dehadharan be clarified.

4. Correlation of AIDS not clarified.

5. Change the Topic.

Discuss with guide & submit the copies.

9. Dr. Deepak Dobade - Rachana Sharir

Comparative study of different embalming thids on his to logical appearance of organ of embalmed Albino Rat Cadaver.

Clearance of animal ethics committee be attached.

NOC from Animal lab where animal trials will be conducted to be attached.

3. Will herbal drugs act as fixative agent?

4. Veterinary expert to be included in the study.

5. Title be reframed.

6. EC will approve this study only after Animal ethics committee approval.

 Comparative study of herbal embalming fluids with convertional embalming fluid appearance of organs of albino Rat Cadaver in Title and Aim.

8. Reference of different herbal formulations be added.

9. Title of Thesis instead of Synopsis.

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REPRESENTATIONS

1. Dr. Bhushan Mhaiskar - Samhita Siddhant

1. Only lakshanas of Kaphavriddhi will be considered irrespective of vyadhi Aamarjna deleted.

2. Information sheet be revised.

- Objectives drop validate.
- 4. Patol is used everywhere instead of Palata.
- 5. Exclusion criteria first 2 be deleted.
- 6. K/C/O instead of having.
- Material & Methods Sampling technique be purposive sampling.
- 8. Method of selection of patients Prayojya anga be mentioned.

2. Dr. Bhavana Bhalmey - Samhita Siddhant

Desciptive study of Pittavriddhi Lakshana and its management with madhur Tikta kashay rasa w.s.r. to Rasdravya Prabhar in Rasviman.

- 1. Title be reframed.
- 2. Marathi consent form and information sheet for patients be added.
- 3. Exclusion criteria Age be deleted.
- 4. Research question be reframed.
- 5. Spellings and grammar be rechecked.
- Objectives be rewritten.
- 7. Diacritical mark for Sanskrit.

3. Dr. Shachi Desai - Kayachikitsa

Trial drug to be changed.

Member Secretary

SSAM, Hadapsar, Pune

Member Secretary , MAM's, S.S.A.M. & Ayurved Hospital

Sane Guruji Arogya Kendra Hadapsar, Pune. Hadapost Purity & swart

Chairman

SSAM, Hadapsar, Pune

Chairman MAN's, S.S.A.M. & Ayurved Hospital Sane Gungi Angya Kendra

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Date: 19/04/2018

Minutes

25th Meeting of Institutional Ethics Committee 17th & 18th April 2018

Date :- 17/04/2018 to 18/04/2018

Time :- 10.00 AM to 05.00 PM

Venue :- Conference Hall, SGAK, Hadapsar, Pune

Meeting attended by hon'ble members on 17th April & 18th April 2018 :-

1. Dr. V.V. Doiphode	Chairman of IEC		
2. Dr. S.M. Sathye	Member of IEC		
3. Dr. Yogini Kulkarni	Member of IEC		
4. Dr. Satish Puntambekar	Member of IEC		
5. Dr. Dhananjay Mhasade	Member of IEC		
6. Mr. Arun Gujar	Member of IEC		
7. Dr. Rajendra Huprikar	Member of IEC		
8. Dr. Pallavi Jamadagni	Member of IEC		
9. Dr. Sangeeta Sangvikar	Member of IEC		
10.Dr. Vidya Undale	Member Secretary IEC		
11. Dr. Pranita Joshi-Deshmukh	Research Coordinator		

Following IEC member was absent on 17th April 2018 due to personal reasons.

Dr. Yogini Kulkarni Member of IEC
 Dr. Satish Puntambekar Member of IEC

Following IEC member was absent on 18th April 2018 due to personal reasons.

1. Dr. Satish Puntambekar

Member of IEC

Principal M's, Sumatibhai Shah

> Welcome Note by Dr. Vidya Undale, PG Co-ordinator, SSAM, Pune

Common Suggestions:

- Scientific names of the drugs are to be mentioned correctly along with the name of authority.
- 2. Part / Parts used of the drug should be mentioned.
- 3. Do not reveal identity by naming the institute (college, hospital and pharmacy)
- Patient information sheet should be prepared as per ICMR guidelines as guided by Hon, Dr. Mhasade.

PRESENTATION OF PG STUDENTS

DAY 1 - Date 17/04/2018

Timings: 10.00 am to 5.00 pm

* AYURVED SAMHITA SIDDHANT

1) Dr. Banashree Patil

- Add 'as hetu' in title, Drop 'of' & modify accordingly.
- Translation of hetus in English to be done (Pg No. 15)
- Patient information sheet to be made more fine.
- Pg No. 16 Left hand thumb impression.
- Secondary objectives to be reframed.
- Pg No. 18 CRF Table of complains to be reframed.
- Inclusion criteria to be changed to 'Patients of Urdhvaga Amlapitta having Kisheera Viruddha annapana & quantity as hetus.
- Frequency, of Viruddhanna to be mentioned.
- Justify 'सेतीकर्तव्यता' of the hetus.
- Authenticate the questionnaire.
- Sample size to be recalculated after discussion with statistician.
- Identify Ksheer viruddha food products and to be mentioned in questionnaire.
- Redesign methodology.

2) Dr. Madhuri Ghogare

- Duration of 'Ratraujagrana' to be mentioned.
- Change title, Drop 'Hetus'.
- Remove 'Healthy volunteers from inclusion criteria.
- Spelling & Grammar to be rechecked.
- Information sheet to be added.
- Specify 'Jagran'.
- Questionnaire to be authenticated.
- Identify specific population for study.
 e.g. Bus drivers, workers or IT Professionals.

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3) Dr. Sneha Ghodake

- Sample Size to be decided by counseling statistician.
- Modify Title.
- Authenticate Questionnaire.
- 'संमतीपत्र' to be corrected.
- Age group to be changed to 20-40.
- Seasons as a variable should be considered.

4) Dr. Aditi Borhade

- Study rationale to be justified.
- Information sheet to be added.
- English consent form to be added.
- Change the topic & represent.

5) Dr. Sayali Bendal

- Title to be changed to.
- 'An observational study to evaluate effects of violation of aahara vidhi vidhan as Grahani Dosh Hetu'.
- Authenticate Questionnaire
- Add information sheet.
- Use word 'Hetu' instead of Nidan.

6) Dr. Rohini Kendre

- Modify title so as to reflect proposed pilot study
- Methodology to be corrected.
- Pathya Apathya aahar vihar to be mentioned.
- Language in patient informed consent to be simplified.
- Page no. 38 Viharaj Apathya to be corrected.

REPRESENTATION

1. Dr. Aditi Borhade

- Drop the raw drugs which are not available.
- Justify the reason behind droping the ingredients.
- Add 'Bahirparimarjan Chikitsa Siddhant' in title.
- Submit 1 Corrected Copy Of Synopsis for IEC Till 21/04/2018.

KRIYA SHARIR

1) Dr. Mahesh Raut

- Study can be made elaborative by changing to experimental study.
- Study rationale to be justified.

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2) Dr. Chivag Chand

- Why only 'Kampa' Lakshana is considered for this study -?
- महयाम from incient texts should be considered.
- Patient information sheet to be added.
- Sample size to be recalculated by consulting statisticians.
- Title can be 'An observational study to assess status of sharir dhatu in diagnosed chronic alcoholic patients.

3) Dr. Mohini Narke

- Concept of 'Sphutit not clear'.
- Change the topic & represent.

REPRESENTATION

1. Dr. Mohini Narke

Term 'Sphutit' should be replaced by Paddari and proceed with the study.

* DRAVYAGUNA

1. Dr. Suraj Rawate

- Inclusion criteria BSL fasting or pp?
- Modify title Patrachurna to be added.
- Duration of study to be increased to 3 months.
- Hb A1C should be criteria for assessment instead of BSL.
- Glucometer should be calibrated.
- Standardization and Authentication of drug to be mentioned as per API.
- References of previous work done to be mentioned.
- Pilot study to be done for deciding dose.
- Explain how your study is different from previous trials.
- Botanical names to be written in italics.
- Identification, Taxonomy, properties, physio chemical parameters of kaidrya to be mentioned.
- Toxicity study data, reference to be added.
- Deposit sample as voucher specimen.

2. Dr. Kajal Shah

- Information sheet to be added.
- 3 groups can be formed as internal, external and both and modify title accordingly.
- Exclusion criteria Pittaj Dushta Kushtha to be added
- Washout period to be mentioned (1 week)
- Standardization of trial drugs to be added
- Severity and duration of symptoms to be mentioned and diagnostic criteria to be quantified.
- SOP of मल्हर कल्पना to be added.
- Exclude patients on steroid therapy.
- Plant part used to be mentioned.

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3. Dr. Prajakta Pasarkar

- Information sheet and consent form to be added.
- Separate consent form to be added for Panchakurma.
- Guardian consent to be added.
- Change the topic if work has already been done.
- Method of administration to be corrected.
- Consider age criteria for ethical issues.

4. Dr. Mitawa Kanade

- Mention whether source of bacteria is clinical or non-clinical.
- NOC of concerned authority to be attached
- Drug authentication to be mentioned.

REPRESENTATION

1. Dr. Prajakta Pasarkar

Work to be done under proper supervision and monitoring.

2. Dr. Mitwa Kanade

Contact the concerned institute where proposed work will be done for permission.

SWASTHAVRITTA

1. Dr. Akshay Khandve

 Parameters as per food science like physiochemical, organoleptic etc. can be added (nutritional value)

2. Dr. Poonam Kale

- Remove 'exam studies' from Group B.
- Duration of study to be increased more than week.
- Define duration of जाग्रण and its frequency.
- Elaborate assessment criteria.
- Get the questionaries' authenticated.
- Study rationale to be justified.
- Remove 'College students' from title and modify title accordingly.

3. Dr. Vijay Deme

- Modify title remove Excessive mental work.
- Patient information sheet and informed consent to be added.
- Mention Dhoomapana <u>vidhi</u> in title
- Alertness assessment scale can be added.
- Page No. 10 change the word 'Interrogation'.
- Assessment of 'Tandra to be added'
- Assessment of verbal and physical responds to be elaborated.

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4. Dr. Surajkumar Bangar

- Aluminum contaîner to be considered instead of plastic.
- Explain how this study is different from previous work done.
- Mention the analytical tests that will be done in laboratory and by the student himself.
- NOC of concerned laboratory to be attached.
- Drop 'optimum essential period' from title.
- Any other water sources can be added for comparison and represent tomorrow.
- Criteria to assess pot ability of water can be added.

5. Dr. Atul Zolekar

- Explain how your study is different from previous study.
- NOC from the laboratory were proposed work will be done to be provided.
- Modify and represent tomorrow.
- Submit 1 Corrected Copy Of Synopsis for IEC Till 21/04/2018.

6. Dr. Saiprasad Rathod

- Modify the title according to Ayurveda.
- Restrict topic to particular hazard described in Ayurveda.
- Remove 'female' from exclusion criteria.
- Drop the word 'interrogation'.
- Change the topic and represent tomorrow.

❖ REPRESENTATION

1. Dr. Saiprasad Rathod

- Get questionnaire authenticated.
- Sample size to be increased.

❖ SHALAKYA TANTRA

1. Dr. Pratibha Chane

- Drop 'w.r.t stomatitis' from title.
- Instead of Ghanavati include Panchavalkal kashay in the study and modify accordingly.
- Information sheet be added.

2. Dr. Anjum Metkari

- Control drug should be mentioned in title itself.
- Drop 'Allergic Rhinitis' from title.
- Information sheet be added.
- Why duration of study is only ten days?
- SOP of Taila Kalpana be mentioned.
- SOP of Swedan to be added.
- Define Bindoo Matra in ml or cc.

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- 3 Dr. Pallavi Vyavbare
- Drop 'ward Migraine' from title.
- Assessment criteria for migraine can be added.
- Mention control drug in title.
- Elaborate similarities of Ardhaybedaka with migraine.
- Add SOP of Taila & Nasya.
- Patient information sheet to be added.
- 4. Dr. Rajnigandha Manwar
- Drop 'w.r.t. senile immature cataract' from title.
- Elaborate similarities of 'Kaphaj Timir' with 'Senile immature cataract'.
- SOP Gutika and Anjana kalpa should be mentioned.
- Patient information sheet to be attached.
- How/Who will monitor application of anjana everyday?
- Sensitivity assessment criteria to be added.
- Feasibility in terms of follow up is not possible.
- Change the topic accordingly and represent tomorrow.

5. Dr. Nirupa Ainlod

- Drop 'w.r.t. simple myopia' from title.
- SOP of Shatavari Ghrita preparation and Netra Tarpana be modified.
- Information sheet be added and mention what do you mean by 'Tarpana' in it.

6. Dr. Varshali Patil

- Drop 'w.r.t. corneal opacity' from title.
- How/Who will monitor application & sensitivity of anjana every day. (Elaborate monitoring technique)
- SOP of varti kalpana and Anjana kalpana.
- Change the topic as monitoring is not possible and represent tomorrow.

* REPRESENTATIONS

- SHALAKYA TANTRA
- 1. Dr. Rajnigandha Manwar
- Title presented today is accepted.
- Patient information sheet to be added.

2. Dr. Varshali Patil

SOP of aschotan to be modified and made more fine.

❖ SHALYA TANTRA

- 1. Dr. Chetan Pawar
- Drop 'w.r.t. Sandhigatvata' & add knee joint in title.
- Page numbers not given.

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- Consent for HIV investigation to be added.
- Sample size to be increased to 20 considering the drop outs
- Add SOP of Jalauka avacharna vidhi.
- Mention reference of X-ray examination for diagnosis of early O.A.
- Differentiate early O.A. with late O.A. with specific symptoms.
- Rewrite and represent again.

2. Dr. Jayashri Karpe

- Numbering of pages not done.
- Bibliography/Referencing need to be corrected.
- Hypothesis to be corrected.
- Secondary objectives to be rewritten.
- Group allocation method to be mentioned in methodology and study design.
- Mention how & where standardization of drug will be done.
- CRF is incomplete.
- O.A. knee joint to be reflected in title.
- Assessment parameters and statistical test not mentioned.
- CRF to be corrected.
- Patient information sheet is not as per ICMR guidelines.
- Duration of study to be increased.
- Rewrite and represent.

3. Dr. Ketan Garje

- Add patient information sheet.
- Sample size should be 30 in each group.
- Modify the procedure of दहनकर्म.

4. Dr. Prajakta Undare

- Explain how your work is different from previous work done.
- Sample size should be 60 in each group.
- SOP of drug preparation to be added.
- Marathi questionaries' to be added.
- Mention part of the drug to be used.
- Reduce dose of Ela.
- Get the questionaries' authenticated.
- Authenticate and standardize the trial drug as per API.
- Submission of voucher specimen.

5. Dr. Rohit Barmukh

- Add patient information sheet.
- Page no. 1, write H2O2 instead of H2SO4.
- Explain how your work is different from previous work done.
- Mention method of Randomization.
- Sample size should be 60 in each group.

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6. Dr. Tejas Dangat

- Sample size should be 60 in each group.
- Authenticate and standardize the trial drugs as per API.

REPRESENTATIONS

1. Chetan Pawar

- Change the topic to avoid ethical issues.
- Submit 1 Corrected Copy Of Synopsis for IEC Till 21/04/2018.

2. Jayashree Karpe

- Necessary corrections not done.

PRESENTATION OF PG STUDENTS

DAY 2 - Date 18/04/2018 Timings: 10.00 am to 6.00 pm

* RASASHASTRA & B.K.

1. Dr. Siddhesh Joshi

- Drop the term 'Reverse Pharmacology' from title and modify accordingly.
- Documented evidence of Lavangankar method to be made available.
- Previous work done should be in descending order.
- Vancouver style to be followed in references.
- Secondary objectives to be rewritten.
- Literary review Review of Literature should be related to somal and its shodhan methods.
- Statistical tests should be changed by consulting statistician.

2. Dr. Akshay Vaidya

- Drop w.r.t and modify title accordingly.
- Secondary objectives should be other than analytical study.
- Methodology for Phytochemical assessment and TLC should be studied thoroughly.
- Title can be 'A Comparative Pharmaceutical and analytical study of Guduchyadi Kashay' churna and Ghanavati mentioned in Ashtang Hruday'.

3. Dr. Richa Agarwal

- Change the drug as 'Raktachandan' is not available (authentic) and represent SOP of lepa Kalpana to be added.
- Information sheet is incomplete.
- Before applying lepa some internal medication should be administered.

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4. Dr. Suvidha Gaikwad

- Mention the type of Pata which will be given.
- Physicochemical assessment should be done after 3rd Puta also.
- Test for elemental assay to be mentioned.

5. Dr. Deepali Bhalerao

As applicable to Suvidha.

6. Dr. Amey Pokale

- Feasibility of diffusion of Ghrita should be confirmed before trial.

* REPRESENTATION

1. Dr. Richa Agarwal

 Use Substitute drug 'Ushir' instead of Raktachandana & Drop 'Kushtha' due to unavailability.

AGADTANTRA

1. Dr. Pallavi Chaudhary

- Animal Ethical Committee clearance and NOC of institute were proposed work will be done should be made available.
- Trial drug should be self prepared instead of using market sample.
- Drop 'LD-50' from title and modify title accordingly.
- Change the trial drug as 'Manahshila' is not available.
- SOP of drug preparation to be added.
- Drop Inclusive exclusive criteria and withdrawal criteria.

2. Dr. Surajsingh Solanki

- FDA clearance letter to be added.
- Drop the word 'Principles' use 'Ingredients' and modify title accordingly.
- Change the topic to avoid ethical issues and represent / Change topic.

3. Dr. Sagar Gorde

- Animal Ethics Committee clearance and NOC of institute were. Proposed work will be done should be made available.
- Change trial drug / Drop 'Chandan' from ingredients.
- Change guidelines for toxicity studies.
- Compare 2 methods of preparation.

REPRESENTATION

1. Dr. Pallavi Chaudhary

- Change the topic.
- Submit 1 Corrected Copy Of Synopsis for IEC Till 21/04/2018.

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2. Dr. Surajsingh Solanki

- Change the topic.
- Submit 1 Corrected Copy Of Synopsis for IEC Till 21/04/2018.

3. Dr. Sagar Gorde

- Drop the ingredient 'Chandan' from the trial drug and proceed with the study.
- The formulation should be self prepared.

❖ ROGNIDAN

1. Dr. Kiran Mangalge

- Questionnaire to be authenticated.
- Use 'Ajeerna' instead of 'Ajirna'.
- Drop Hypothesis.
- Add Patient information sheet.

2. Dr. Pradnya Bharati

- Drop 'Skin related signs and Symptoms' from title and modify accordingly.
- Pg. No. 8 Rewrite study design.
- Get the Questionnaire authenticated.
- Add Patient information sheet.

3. Dr. Madhurani Garud

- Get the Questionaire authenticated.
- Assessment of Volunteers to be done during enrollment itself e.g. Prakruti Parikshan etc.
- Patient information sheet to be added.

4. Dr. Bhingarde Pooja

- Sample size to be increased.
- Patient information sheet to be added.
- Restrict age group from 18 to 70.
- Get questionnaire authenticated.
- Drop hypothesis as this is observational study.

5. Dr. Shweta Badarkhe

- Drop exclusion criteria regarding Blood group systems.
- Patient information sheet and consent form to be added.
- Get the questionnaire authenticated.
- Sample size to be recalculated and increased.

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★ KAYACHIKITSA

1. Dr. Rakesh Hingane

- Attach English Consent form.
- Drop 'Sponsorer' from consent form.
- Drug should be administered twice daily instead of 3 times a day.
- Page No. 4 Add appropriate references for selection of topic.
- Revise objectives.
- Sample size to be recalculated considering error as 5%.
- Patient information sheet to be added.

2. Dr. Amruta More

- Drop the term 'adjuvant' and modify title accordingly.
- Pg. No. 17, drop 3rd point.
- Sample size to be rectified.
- Pg. No. 10, drop sheetajal as anupan.
- Dose of trial drug to be recalculated and administered once a day.
- Pg. No. 10 quantity of drugs should be mentioned in parts instead of mg.

3. Dr. Sneha Hagwane

- Use the term चित्तोद्वेग instead of anxiety in title.
- Calculate the sample size by considering error as 5%.
- Add patient information sheet.
- Modify age group.

4. Dr. Sanket Darawade

- Add patient information sheet.
- Add Marathi consent form
- Pathya apathya should be explained in simple language.

5. Dr. Shweta Lade

- Drop the term 'Adjuvent' use 'Add on' instead in title
- Drop with special reference to type II DM from title.
- Add patient information sheet.
- Range of HbA1C to be taken as 6.5 to 7.5 in inclusion criteria
- Recalculate sample size by considering error as 5%.
- Confirm, procurement of authentic sample of 'Kushtha'.

6. Dr. Poonam Tupe

- Drop w.r.t. osteoarthritis from title
- Page no. 27 drop point no.3
- Add 'Gender' in consent form.

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❖ STREEROG & PRASHTI TANTRA

1. Dr. Bharati Zuniarrao

- Add patient information sheet in both languages (Marathi & English).
- Rewrite materials and methods (Pg. No. 8)
- Explain how your work is different from previous work.
- Give all relevant references.
- Rewrite objectives.
- Sample size should be 60 in each group.
- Mention duration of study.
- Source of drug, authentication, physicochemical assessment should be mentioned voucher specimen to be submitted.

2. Dr. Harsha Gosavi

- Authentication and standardization of ingredients as per API to be done.
- SOP of Bastichikitsa and Taila preparation to be mentioned.
- Separate consent form for Basti Chikitsa should be attached.
- Add patient information sheet.
- Drop 'Paschat karma from mode of drug administration.
- Add Abbreviations
- Part to be used of trial drug should be mentioned.

3. Dr. Shubhangi Kamthe

- Attach patient information sheet.
- Explain how your work is different from previous work done.
- Add 'wound' in title.
- Authentication and standardization of raw material as per API.
- SOP of taila kalpana to be written.

4. Dr. Geetanjali Vaiti

- Mention duration of Dhoopan
- Drop the word 'both' from title and modify title accordingly.
- Mention SOP of Dhoopan Chikitsa.
- Explain how your work is different from previous work done.
- Standardization and authentication of individual ingredients to be mentioned.
- Sample size to be recalculated.

5. Dr. Anita Waghmare

- Change methodology and represent.
- Add patient information sheet.
- Submit 1 Corrected Copy Of Synopsis for IEC Till 21/04/2018.

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6. Dr. Nilakshi Deore

- Authentication and standardization of raw material to be done.
- SOP of Modaka to be added.
- Add patient information sheet.

PROJECTS BY FACULTY MEMBERS.

Dr. Vaishali Deshpande

- Pg. No. 14 Should be 'Prakriti Evaluation' instead of 'Evolution'.
- Indemnity to be attached.
- Scientific names of drugs to be written.
- Part of drug to be used should be mentioned.
- Safety study data if available of relevant extract to be mentioned.

V. CUndale Member Secretary

SSAM, Hadapsar, Pune Member Socretary MAGE, 5.3.A.M. & Ayurved Hospital Sane Gurriji Aragya Kandra Hadapsar, Pune.

Chairman

SSAM, Hadapsar, Pune

AAM o ISAM & Ayuvud Haqqidal Sann Guruji a Egya Kondra

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INSTITUTIONAL ETHICS COMMITTEE

Maharashtra Arogya Mandal's Sumatibhai Shah Ayurved Mahavidyalaya and

Ayurveda Hospital - Sane Guruji Arogya Kendra Malwadi, Hadapsar, Pune - 411 028.

Phone No.:- +91-20-29522503, +91-20-29522504 Email: ssayu@rediffmail.com

Date: 08/03/2019

Minutes

26th Meeting of Institutional Ethics Committee 06th & 07th March 2019

Date :- 06/03/2019 to 07/03/2019

Time :- 10.00 AM to 05.00 PM

Venue :- Conference Hall, SGAK, Hadapsar, Pune

Meeting attended by hon'ble members on 6th March & 7th March 2019:-

1. Dr. V.V. Doiphode Chairman of IEC

Dr. S.M. Sathye Member of IEC

3. Dr. Yogini Kulkarni Member of IEC

4. Dr. Satish Puntambekar Member of IEC

Dr. Dhananjay Mhasade Member of IEC

Mr. Arun Gujar Member of IEC

7. Dr. Rajendra Huprikar Member of IEC

8. Dr. Pallavi Jamadagni Member of IEC

Dr. G.P. Prasad Member of IEC

10.Dr. Vaishali Bhosale(Veer) Member Secretary IEC
11.Dr. Pranita Joshi-Deshmukh Research Coordinator

Research Coordinator

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Following IEC member was absent on 6th March 2019 due to personal reasons.

1. Dr. Pallavi Jamdagni

2. Dr. Vaishali Bhosale(Veer)

Member of IEC Member Secretary IEC

Following IEC member was absent on 7th March 2019 due to personal reasons.

1. Dr. G.P. Prasad

Member of IEC

- Welcome Note by Dr. Pranita Joshi Deshmukh, Research Co-ordinator (PARAS).
- Institutional Ethics committee member (ASU member) Dr. Sangita Sangavikar is transferred to other CCRAS unit, So we requested Assistant Director Of Ayurveda, Regional Ayurveda Institute of Fundamental Research, Kothrud, Pune Dr. G.P. Prasad to be a part of our institutional ethics committee as ASU member. He accepted our request & was present for 26th Institutional Ethics Committee Meeting.
- New member Dr. G.P. Prasad Assistant Director Ayurveda, Regional Ayurveda Institute of Fundamental Research, Kothrud, Pune was introduced to the committee by Dr. Pranita Joshi- Deshmukh.
- Minutes of previous meeting read out by honorable chairman Dr. V.V. Doiphode & unanimously accepted & approved by all the committee members.

• Common Suggestions :

- Botanical names to be written in scientific manner as follows:
 - a. Genus name should start with Capital letter.
 - Species name should start with small letter.
 - Genus & Species name should be in italics & underlined.
 - d. Scientist name should be written at the end & should not be in Italics.
- Vancouver Style of referencing to be followed strictly.
- Questionnaire to be validated.
- Generic names to be used instead of brand names for e.g. 'Povidone iodine' instead of 'Betadine'.

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PRESENTATION OF PG STUDENTS

DAY - 1

DATE: 06/03/2019

Timing: 10.00 am to 5.00 pm

❖ DEPARTMENT OF AYURVED SAMHITA SIDDHANT

1) Dr. Sneha Bedekar:

Study rationale to be reframed as per objectives.

- Hypothesis to be revised as we can not say that Lehan chikitsa siddhant is not
 effective.
- Present knowledge gap to be mentioned.
- Justify why Maricha is selected in Vataj kasa as properties of maricha may aggrevate vata.
- Operational definitions to be mentioned.
- Clinical application to be considered as secondary objectives.
- Change the topic accordingly and represent.

Above suggestion should be followed & represent again 07/03/2019.

After representation on 07/03/2019 revised title & synopsis approved by 1EC.

Revised title 'Literary study of Lehan chikitsa & Kasaghna property of Marichyadi Yoga lehan in Kaphaj kasa'.

2) Dr. Sarika Gavali:

(

- Knowledge gap to be mentioned.
- Referencing style to be revised. (Vancouver 8,9,17).
- Exclusion Criteria no.1 to be deleted.
- Study Rationale Why this study model is used to prove shaman siddhant?
- Operational definitions is not in English.
- Objective '3' not required.
- Literary study of shaman chikitsa siddhant to be elaborated (Primary objective)
- Change the title accordingly.
- Patient information sheet to be revised as per ICMR guidelines ,Informed consent for minor needed.

3) Dr. Barakha Kulkarni :

- Methodology to be elaborated as per ICMR guidelines.
- Give at least one example of similarities and difference, how are you going to proceed.
- Letter /NOC of the institute (Anandashram) to be produced.

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4) Dr. Shaunak Sane:

- Age criteria to be revised to 18-60 years.
- Title to be revised as 'A study of Nasya Karma Siddhant' and 'Shirashoolghna property of Ghrutmanda by Pratimarsha Nasya'.
- Clinical study to be considered as secondary objectives.
- Spelling & grammar to be checked in informed consent.
- Operational definitions of 'bindoo' to be mentioned.
- · Drop 'Profitable' from information sheet.
- 'Left hand thumb impression' to be mentioned in consent form.
- Research question to be reframed.
- SOP of Nasya to be revised.
- Consider specific / diagnosed disease for this study, as screening is difficult for exclusion list.

Above suggestion should be followed & represent again 07/03/2019.

After representation on 07/03/2019 revised title & synopsis approved by IEC.

Revised title 'A study of shirshoolghna property of Ghrutmanda in

Ardhavabhedak by Pratimarsha Nasya with special reference to Nasya karma siddhant.

5) Dr. Payal Sharnagat :

- Title to be revised 'Application of Guna Vishesh Siddhant with efficacy of Sama Shuktaardraka yoga in Mandagni'.
- Questionnaire to be validated. Refer 'Appetite assessment & eating speed 'published in International Journal of obesity(2003).
- References of shukta to be added and SOP revised.
- Research question and hypotheses to be revised. It should reflect duration & dose.

6) Dr. Bhavika Shinde:

- · Knowledge gap to be mentioned.
- Delete 'deposit or fee' from compensation for participation, in Information Sheet.
- · Sample size to be increased.

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* DEPARTMENT OF KRIYA SHARIR

1) Dr. Nimish Bapat:

- Population to be mentioned in title.
- Inclusion criteria –Add more than 5 years continuously.
- Hypotheses to be deleted as study is observational.
- Sample size can be increased.
- Questionnaire to be validated and mentioned in methodology.

2) Dr. Triveni Bisen:

- Hypotheses to be deleted as study is observational.
- Delete 'Cross-sectional' from title as study is observational. Instead of w.s.r. to use 'by using Spirometry' in title.
- Dushti lakshana of Pranvaha strotas to be mentioned in operational definition.

3) Dr. Shraddha Gajare:

- Sample size to be calculated by considering 'Raja guna bahulya'.
- Define, how to identify Raja guna as per classics.
- Title to be revised.

 Revise title is approved by IEC members on 07/03/2019.

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Revised title ' Effect of Dhyana (Sahaja Yoga Meditation) on Raja Guna Predominant School going adolescents.

4) Dr. Rajeshkumar Gore:

Remove 'Cross sectional' from title as study is observational.

5) Dr. Pooja Dubey:

- · Remove no. '2' exclusion criteria.
- Sample size to be increased to 70 in each group.
- · Screening form, Q. No. 1. Delete the word 'Problem'.

6) Dr. Jai Suryawanshi :

- Letter/NOC of concerned authority to be produced otherwise remove "Traffic Police" from title.
- Minimum exposure to be mentioned in individuals.

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❖ DEPARTMENT OF RACHANA SHARIR

1) Dr. Tejas Metkari:

- Modify as per suggestions given by Dr. Sathye on copy.
- Applied anatomy of the study to be mentioned.
- Lady attendant is necessary for female volunteers.

Above suggestion should be followed & represent again 07/03/2019.

After representation on 07/03/2019 revised title & synopsis approved by IEC.

2) Dr. Sachin Narwade:

- Modify as per suggestions given by Dr. Sathye on copy.
- Applied anatomy of the study to be mentioned.
- Lady attendant is necessary for female volunteers.
- Evalution criteria of Atideergha and Atirhasva to be mentioned.

Above suggestion should be followed & represent again 07/03/2019.

After representation on 07/03/2019 revised title & synopsis approved by IEC.

* DEPARTMENT OF AGADTANTRA

1) Dr. Sagar Awhale / Dr. Tejas Bapat / Dr. Shubham Londhe:

- · Add appropriate reference why study model is 100 mg/kg body weight.
- · Mention the bulb of blood collection.
- Animal ethics committee clearance is necessary, before commencing the trial.
- · Title to be changed to 'anti nephrotoxicity'.

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* DEPARTMENT OF PANCHAKARMA

1. Dr. Pradnya Kabra:

- Elaboration of specific karma and when patient should come to hospital other than routine follow up to be mentioned in patient information sheet.
- Information about Temperature of Pradeha to be mentioned.
- Research question to be simplified.
- Add duration of karma in hypotheses.

2. Dr. Manisha Kakade:

- Duration of study to be mentioned in hypotheses.
- Calculated Sample size should be for one group.
- · Mesh size of churna to be mentioned.
- SOP of Lepa/Paste to be added.
- Thickness of lepa to be mentioned in 'mm.'
- · Shloka of Arjun lepa to be added.
- Modern comparative disease condition to be mentioned in introduction.

3. Dr. Milind Kamble:

- Knowledge gap to be mentioned.
- Botanical names of drugs to be added.

4. Dr. Vishakha Patil:

Title to be revised. Remove 'Sandhigat Vaat' and replace with 'Janusandhigat Vaat'.

5. Dr. Riddhima Ranjan:

- 'Khalitya' to be mentioned in lay term in patient information sheet.
- Specific temperature of oil to be mentioned.
- Sample size should be 60 in each group.
- Delete 'Bhrajak Pitta' word from introduction.
- SOP of drug preparation to be mentioned.

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DEPARTMENT OF DRAVYAGUNA

1. Dr. Prajakta Abnave:

Recheck the reference for mention of 'Guda' in processing of seed.

2. Dr. Payal Jain:

- Specific drug and actual avachoornan method to be added in Patient information sheet.
- Patient information sheet in English to be added.
- WHO guidelines to be studied for using traditional medicine in clinical trial.

3. Dr. Shweta More:

 Standard reference of Vrikshaayurved to be followed for preparation of Kunap jal.

4. Dr. Kalyani Sant:

- English information sheet to be added.
- Scales mentioned by Dr.Sathye on synopsis copy to be added.
- Modify the title by mentioning specific karma or trial drug can be changed to 'Aragwadha'.
- WHO guidelines to be studied for using new drug.

5. Dr. Vaibhay Wani:

Instead of Narikel tail use Tila taila.

❖ DEPARTMENT OF STREEROGA & PRASUTI TANTRA

1. Dr. Tanaya Banodkar:

- On page no. 11, Remove the investigations (HIV, HbsAg, VDRL) in last visit.
- On page no. 21, Mention specific disease.
- Rescue medicine to be mentioned in case of corrosive reaction to patients.
- Sensitivity test to be done.
- Instead of single arm, study can be titled as exploratory study.

2. Dr. Swaraj Borade:

- Remove no. '2' exclusion criteria.
- Modify the title, instead of Dhanyak sharkara, it should be Dhanyak and Sharkara.

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3. Dr. Tejaswinee Chavan:

- On page no.22, Explain Nashtartava in lay terms.
- Informed consent form in English and Marathi to be added.
- Age criteria to be revised to 18-35 years.
- · Parent consent to be removed.

4. Dr. Bhakti Kharat:

- · Marathi consent form to be added.
- Instead of Capsule drug can be administered in Ghana Vati form.
- · Instead of 'Wet' use 'Fresh' leaves in SOP.

5. Dr. Varsha Mhaske:

- Abortificent activity of Kankshi Jal to be checked.
- Informed consent form in English and Marathi to be added.
- Purpose & method of study, revise 1st sentence (Page no. 23).

6. Dr. Supriya Patil:

- Avoid technical terms in Patient information sheet.
- Instead of controlled clinical study, comparative study can be done.

PRESENTATION OF PG STUDENTS

DAY - 2

DATE: 07/03/2019

Timing: 10.00 am to 5.00 pm

❖ DEPARTMENT OF RASASHASTRA & BHAISHAJYA KALPANA

1. Dr. Rohit Gujrathi:

- Instead of 'Research gap' use 'Knowledge gap'.(Common for all)
- Letter/NOC of concerned laboratory to be produced.(Common for all)
- Research question to be mentioned.

2. Dr. Vishal Chaudhari:

- · Revise Primary objectives.
- Test for particle size estimation & elemental assay to be mentioned.

3. Dr. Vrushali Ghule:

 Latin name of Vasa to be changed & Latin names of all the drugs to be checked.

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- Specific tests for Avaleha & Kwath to be mentioned.
- Revise all the standardization tests.
- · Remove 'statistical tests.'(Common for all)

4. Dr. Swapnil Mundhe:

- Average diameter of Ghanavati to be mentioned in standardization test.
- · Mention 'Angle of Repose' for churna.
- · How to decide which dosage form is better.
- Mention 'Shabda Parikshan' of churna (Agni) as mentioned in Dravyaguna.

5. Dr. Pranali Patankar:

SOP of Parad shodhan and Gandhak Shodhan to be mentioned.

6. Dr. Ashutosh Todkari:

Add shelf life study /stability study in further scope of study.

❖ DEPARTMENT OF SWASTHA VRITTA

1. Dr. Shruti Badhe:

- Title can be changed to 'A Survey study of school going children as per dincharya vidhi to find awareness of oral hygiene."
- On page no. 33 Replace the word 'Myself' with 'I'.
- Use Non-technical terms in questionnaire.
- Sample size can be increased to 400.

2. Dr. Saurabh Nikhade:

- · Drop 'Retrospective' from title.
- Title can be reframed as 'An observational study of Ahara Viharaj Hetu of Sthaulya in chidhood obesity'.
- Follow suggestion of Dr. Sathye mentioned on copy'.

3. Dr. Pradnya Vibhute:

- Questionnaire to be redesigned by using standard scale for depression.
- Follow suggestions of Dr. Sathaye mentioned on copy.
- Use the word 'Calculate instead of 'Find' in title.

❖ DEPARTMENT OF ROGNIDAN &VIKRUTI VIDNYAN

1. Dr. Leena Dagade:

On page No. 26- Use Non-technical terms.

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2. Dr. Sajjala Jadhav:

- Replace the word 'To establish' with 'To evaluate 'in title.
- Observation table to be prepared for cases and controls.

3. Dr. Bhakti Kale:

· Use non-technical terms in informed consent form.

❖ DEPARTMENT OF SHALAKYA TANTRA

1. Dr. Darshan Dhage:

- Use non technical terms in patient information sheet.
- Instead of controlled, study should be comparative.
- English information sheet to be added.
- Age criteria to be revised to 19 to 50 years.
- · Refraction to be added in CRF.
- Remove 'one eyed person' from exclusion criteria.
- · SOP of parisheka to be revised.
- Rescue treatment to be mentioned.

2. Dr. Shraddha Pandagale:

- On page no. 26- Purpose and nature of study Rewrite line no.4.
- · Study to be considered as comparative instead of controlled.
- Age criteria to be revised to 19 to 50 years.

3. Dr. Vinayak Shirsat:

- On page no. 26 patient code no. to be removed.
- Study to be considered as comparative instead of controlled.
- SOP to be revised.
- Specify severity and duration of shirshoola in inclusion criteria.
- Use K/C/O in exclusion criteria.

4. Dr. Priyanka Bolke:

- · Study should be comparative instead of controlled.
- Use non-technical terms in patient information sheet.
- Mention drug administration and Anupana in patient information sheet.
- Reference of comparison of Timir with Myopia to be added.

5. Dr. Rochan Sharma:

- Study should be comparative instead of controlled.
- · SOP to be revised. Mesh size of churna to be mentioned.
- · SOP of Vati to be mentioned.
- · CTRI registration to be mentioned in Gantt Chart.
- Avoid Generic /trade name in title.

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6. Dr. Suhasini Chaudhari :

- · Use non-technical terms in patient information sheet.
- SOP of drug preparation & drug administration use to be revised.
- Instead of 'Chlorocol-H' use 'chloramphenical with hydrocortisone in title.
- Sampling method to be mentioned.

* DEPARTMENT OF PARAS

Dr. Pranita Joshi -Deshmukh Pl & Research Co-ordinator ,

"A Randomized, multi-center, double blind, interventional, placebo controlled study to evaluate efficacy and safety of ALIMFUS – Air borne low intensity multi-frequency ultrasound, as an Add-on therapy to oral hypoglycemic Agent (OHA) in type II Diabetic patients.

- 1. Calliberation of device after periodic interval will be done or not?
- 2. Insurance copy to be obtained with trial site mentioned on it.
- There should be link document on TIMER letter head mentioning manufacture, sponsor and TIMER.
- Previous preclinical data or publication.

* DEPARTMENT OF KAYACHIKITSA

1. Dr. Karishma Kadam:

- · English Patient information sheet to be added.
- On page no. 23 Left hand thumb impression to be added.
- Remove exclusion criteria no. 1 & 5.
- · Specify type of diabetes I or II.
- Inclusion criteria Define HbA1C in range.
- Page no. 20 objectives criteria instead of 'X' add ' 'wherever applicable.
- Page no.9 Remove 'Accountability'.
- Title to be changed 'Add on effect' of trial drug instead of 'controlled trial'.
- Part used of trial drugs to be mentioned.
- SOP to be revised.
- · Standardization of vati to be mentioned.
- · Modify research question, objectives and hypotheses as per change in title.

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2. Dr. Abhijeet Chavan:

- Spellings to be checked. (Sanskrit & English).
- · Instead of controlled, study should be comparative, modify title accordingly.
- · Modify research question, objectives and hypotheses as per change in title.
- · Setting of Gantt Chart to be checked.
- Guda Nagaradi Yoga to be administered in tablet form instead of capsules.

3. Dr. Milind Upase:

- · Age group to be revised to 19 to 30 years.
- Name of scientist in latin name should not be in Italics.

4. Dr. Ayushi Garge:

- · Trial should be comparative instead of controlled.
- · Age group to be revised to 18 to 60 years.
- · Instead of anxiety, Ayurvedic term to be used in title.

5. Dr. Swati Rathod:

- · Study should be comparative instead of controlled. Modify title accordingly.
- · Page no. 28- Marathi informed consent form omit.
- · Part to be used of Gokshura should be 'Moola' instead of 'Fruit'.
- · Page no. 8, Inclusion criteria, drop the word 'maximum' from no 1.
- Standardization of drug to be mentioned.

6. Dr. Baig Mirza:

- · Study should be comparative instead of controlled.
- Inclusion criteria to be revised.
- Classical reference of trial drugs is not in gutika form. Classical formulation to be used.
- · On page no.15, Omit the shloka.
- Rewrite the synopsis with necessary changes.

❖ DEPARTMENT OF SHALYA TANTRA

1. Dr. Bramhanand Chavhan:

- · Consent form for HIV to be added.
- On page no. 34 Omit profitable from Results of study.
- · Non-technical terms to be used on page no. 35.
- On page no. 38 Drop point no. 4.
- · Patient code To be removed from Page no. 37.

Principal 13
M. A. M's, Sumatibhai Shah
Ayuryed Mahayidyalaya

- · Instead of controlled, study should be comparative.
- · Modify the title by adding 'lower abdomen surgeries'.

2. Dr. Amruta Dandekar:

- On page no.25 & 28 use word spacing.
- On page no. 24 Replace appropriate consent with Informed Consent.
- · Inclusion criteria to be revised.
- · Gangrenous wound can be included in study.

3. Dr. Suhasinee Kolte:

- · 'Drop w.s.r. to acute cystitis from title.
- Mention separate chart for 'Gokshura'.
- · Add 'Guda in the chart.
- On page no. 13- Drop exclusion criteria of age.
- · On page no.32 Remove, Patient code no..
- Mention whether Narikela will be Nava or Purana.

4. Dr. Bhagyashree Patil:

- Page no. 28 Left hand thumb impression to be added.
- Use non-technical terms in patient information sheet.
- · Inclusion criteria to be revised.

5. Dr. Kiran Panditrao:

 If no direct reference of shatadhauta ghrita on vrana /Parikartika is found than study to be done as comparative.

6. Dr. Vishnu Rankhamb:

- On page no. 24 Left hand thumb impression to be added.
- On page no.23- Reframe sentence (purpose & nature of study.)
- English consent form to be added.
- On Page no. 12 Investigation BSL, Remove SOS.

Member secretary

Member Secretary

Same Gurus, Laugya Kendra Hadapsar, Pune. IEC Hadapaar Punel Punel

Chairman

wells

Institutional Ethics Committee SSAM, Hadapsar, Pune

MARY's, 3.S.A.M.

M. A. M's, Sumatibhai Shah da Gurupa angya Kendi Ayurved Mahavidyalaya, Hadapsar, Pune- 411 028

INSTITUTIONAL ETHICS COMMITTEE

Maharashtra Arogya Mandal's Sumatibhai Shah Ayurved Mahavidyalaya and

Ayurveda Hospital - Sane Guruji Arogya Kendra Malwadi, Hadapsar, Pune - 411 028.

Phone No .: +91-20-29522503, +91-20-29522504 Email: ssayu@rediffmail.com

Minutes

31st Meeting of Institutional Ethics Committee

Date :- 18/03/2020 to 18/06/2020

Online meeting of Institutional Ethics Committee.

After departmental presentation of title & synopsis in front of HOD's & guide, corrected copies of Synopsis of all the PG students admitted in 2019-2020 were sent to Honourable IEC members on 18/03/2020.

Due to covid -19 pandemic crisis, meeting of IEC which was scheduled on 07, 08 &09 April was cancelled. Soft copies of all synopsis were sent through Mail to all the honourable IEC members.

IEC members sent their suggestion through mail, on hard copy & also by personally calling to the students. IEC members suggestions were forwarded to the students time to time. Member secretary informed & discussed with IEC chairman about all procedure of synopsis evaluation, suggestions received from IEC members & corrections done by students on 18/06/2020. IEC chairman agree to give approval of title & synopsis of all students. After that students were asked to submit the corrected synopsis, covering letter to IEC chairman regarding corrections according to suggestions of IEC member with permission of HOD & guide.

IEC Chairman scrutinized all the corrected synopsis copies and approved all the title & synopsis of Pre-MD students of 2019-2020 admitted year.

Following Honourable IEC members given suggestions by E-mail, On hard copies & personal calling.

1. Dr. V.V. Doiphode	Chairman of IEC
2. Dr. S.M. Sathye	Member of IEC
Dr. Yogini Kulkarni	Member of IEC
4. Dr. Satish Puntambekar	Member of IEC
5. Dr. Dhananjay Mhasade	Member of IEC
6. Mr. Arun Gujar	Member of IEC
7. Dr. Rajendra Huprikar	Member of IEC
8. Dr. Pallavi Jamadagni	Member of IEC

M. A. M's, Sumatibhai Shah Ayurved Mahavidyalaya, Hadapsar, Pune, 411 000 9. Dr. G.P. Prasad 10.Dr. Vaishali Bhosale(Veer) 11.Dr. Pranita Joshi-Deshmukh

Member of IEC Member Secretary IEC Research Coordinator

- Minutes of previous meeting was accepted & approved by honourable chairman Dr. V.V. Doiphode.
- Suggestions given by Honourable IEC members : Common Suggestion :
 - 1. Botanical names to be written in scientific manner as follows:
 - a. Genus name should start with Capital letter.
 - b. Species name should start with small letter.
 - c. Genus & Species name should be in italics & underlined.
 - d. Scientist name should be written at the end & should not be in Italics.
 - Vancouver Style of referencing to be followed strictly.
 - 3. Questionnaire to be validated.
 - Generic names to be used instead of brand names for e.g. 'Povidone iodine' instead of 'Betadine'.
 - 5. Correct spelling mistakes & grammars.
 - 6. Include witness name & sign in patients informed consent form if applicable.

	AGADTANTRA DEPARTMENT		
Sr. No.	Name of the Student	Queries	
Ŀ	DR. VIVEK GOPAL	 Please reformulate the title Please check sankrit quote In exclusion criteria remove 1 & 2 not necessary Reformulate research question and hypothesis Latin names not written in proper format Reference not in vancouver style NOC of animal house should be attached 	
2.	DR. APEKSHA GUND	 Annexure 2 can be revised as per previous suggestions. Operational Definations for Virudhha Aahar and its various categories can be explained in detail (page 6). 	
3.	DR. NEHA MEHER	 Explain knowledge gap in view of Shriram ras. In agadtantra definition vividha in that both vi should be rhaswa. correct sanskrit In second objectives what is the methodology for calculation of fatal dose as it mentioned in page number 13 is this correct Latin names are not written in standard format Genus name first capital species name in small letters both are in italics and scientists name after theses two and not to be written in italics so correct Latin names accordingly NOC of animal house where experiments will be done is required. 	
4.	DR. JAYATI NAYAK	Primary objective and methodology is too vague to implement Goldwise Justify. Virudhha aahar questions can be revised as per previous	

		suggestions.
5,	DR. ALFIYA SHAIKH	 Objectives should be reformulated Exclusion criteria 2 and 3 should be removed not necessary NOC of animal house where experiments will be done is required.
6.	DR. ANJUM SHAIKH	 Operational Definations for Virudhha Aahar and its various categories can be explained in detail

DRAVYAGUNA DEPARTMENT				
Sr. No.	Name of the Student	Queries		
7.	DR. KOMAL G. BELE	 Good study Only useful part, leaf of Saptaparna is to be verified for further rule out on toxicity. When it is other than classical use (part) directly clinical trail can be done or not to be verified. Photographic assessment is not mentioned in the assessment criteria and consent. Elaborate knowledge gap keeping in view title and objectives. Title should be reformulate Patient information sheet should in question answer formation References should be in vancouver style. 		
8.	DR. AKASH PREM CHAVAN	 Good study Artemisia vulgaris L. may be more suitable. Please verify the botanical identity State reference of animal model used in the study. Justify use of Ashwagandha as standard control. If it's used for comparative efficacy purposes, the same is not mentioned in the title or objective. Submit NOC from the animal study work site. 		
9.	DR. TUSHAR BHASKARRAO SHINDE	 Very good study After treatment with Madanaphala, collected rice if washed and dried and studied for HPLC to determine the quantification of Madanaphala traces, it may be supportive, Please see the feasibility. Use english translation for the Samrakshak Effect particularly in the title. Is there any alternative form of Madanaphal to be used as Akhand madanaphal may itself be damaged or with moisture and there will be a risk of fungal growth? Pilot study can be done for testing the same. Sushrutokta reference page no 4 correct sanskrit. Latin not written in proper format Latin names are not written in standard format Genus name first capital species name in small letters both are in italics and scientists name after theses two and not to be written in italics so correct Latin names accordingly RQ and hypothesis should be reformulate Objectives should be reformulated 		
10,	DR. NEHA, N. SHIVDE	References are not in vancouver style Very good study Dose based on Agni, Bala, Pakruti, Dosha, Desha from 2gm		

Principal

M. A. M's, Sumatibhai Shah
Ayurved Mahavidyalaya,
Hadapsar, Pune-#11 028

		 to 6gm is to be re think and justified USG based assessment is required during the md trial period as any silent case can turn symptomatic. Rescue medications need to be mentioned in withdrawla criteria. Title needs to be modified considering all three phases of study.
11.	DR. GAUTAMI M. PHADKE	 Good study Modern Agricultural Practices are not explained in detail. Many Vrukshayurveda Agricultural Practices are used and among them which is used? Is the work of Dr Shweta More completed? If not avoid reference in the knowledge gap. State Animal study model reference. Is the reference 20 mentioned will be used in your study as well. If yes state details. If not, state a detailed model in consensus with the animal house. Submit NOC from the animal study work site.
12.	DR.SHUBHANKAR MUKUND NAIK	 Good study Please re think on Potassium sorbate use. Elaborate knowledge gap keeping in view title and objectives. Title is not clear and short. Primary objective is not being reflected in the title. Reform title accordingly. Add detailed literary references on safety of Potassium Sorbate. Also justify its use. Is there any alternative to preservatives? Age group inclusion criteria is 6 to 40. Justify. Rescue medication is not mentioned in withdrawal criteria.

Sr. No.	Name of the Student	Queries
13.	DR. AMIRHAMJA SALIM ATTAR	 Synopsis can be more specific Amruta Guggulu is indicated in many other diseases also. Body weight or other specific factors related diabetic population more suitable to Amruta guggulu may be considered. In inclusion p 12 washout period? Add on therapy for various contemporary medicines mean how it will be justified. Primary and Secondary research question mentions reduction of blood sugar as well as HbA1C as main outcome but title mentions as add on effect, justify. Quality of life questionnaire needs validation reference.
14.	DR. MRUNAL CHANDRAKANT KHILARE Principal	 Good Study Reference of Bibhitakyadi churna? Whether it is anubhutayoga if so please mention. How the control Deriphylline is an allopathic drug and is there any Allopathi doctor to assess the effect and to monitor the study. Please clarify. Justify how your work is different than previous work. Trial drug has bibhitakyadi churna, Pimpali and Shunthi with anupana of madhu where as title only mentions one churna.

		Rescue medication is not mentioned.
15.	DR. ROHIT SHIVAJIRAO PATIL	 Good Study Justify how your work is different than previous work.
16.	DR. SADHANA SURESH RANGNEKAR	 Good Study Amalaki loha seems to be anubhutayoga. Then how directly clinical study can be done. Please clarify. Justify how your work is different than previous work in reference to Amalaki. Rescue medication is not mentioned.
17.	DR. ARJUN ANNASAHEB SABLE	 Good Study Kwath preparation for five days needs preservation. Dispensing and monitoring SOP are not clear. Justify. As per the formulation details it is more like syrup than kwath Justify or rename accordingly. Is it comparative trial or RCT? Justify or change title accrodingly
18.	DR. ABHINAV RAVINDRA SONTAKKE	 Good Study But as per the reference claimed the useful part of Aragvadhi and Kutaja are the leaves or bark? Please clarify Elaborate knowledge gap a per title of the study considering application forms and route of administration. Washout period for previous skin medicines/ointment is not mentioned. In research question and hypothesis you have to write duration and frequency Keep hypothesis two 1) null 2) declarative Keep only primary objective others are not correct because methodology used in the synopsis not accordingly Study types comparative clinical trial In sample size sample quoted 33 and in methodology 30 why it is so Scientific names not written in proper References not in vancouver style Patient information sheet should be in question answer format

	KRIYA SHARIR DEPARTMENT		
Sr. No.	Name of the Student	Queries	
19.	DR. MEGHANA DARVATKAR	 Define 'Trika Sandharan Karma' in operational definition. In 9th question 'Did you experience sound from your joints after movement? Whether in this question sound after movement or during the movement Please verify. Try to correlate fragmental analysis of certain important questions and the output. 	
20.	DR. AKSHAY LONKAR	The study was not correlated with Ayurvedic concepts. Effect of insomnia on CRP was already proved. Ayurvedic relevance in the study is not highlighted.	

4			Add 'Status of Meda Dhatu' term in operational definition.
	21.	DR. ARCHANA KHILARE	 For certain questions four optional answers seems not matching. Please re think. Try to correlate fragmental analysis of certain important groups like night watchmen, It professionals etc. Your study is observational so hypothesis will not be applicable hypothesis will be generated after study so remove it In objectives primary objectives can be two so keep other objective as primary objective two In inclusion criteria first criteria will be patients with age group irrespective of gender will be selected correct it In exclusion criteria no 3 remove that point because when you decide that so and so age group you are taking then it is obvious that others will be excluded In point number 4 please specify which surgeries In point 5 please mention known cases of so and so Some references are not in vancouver style please correct it Patient information sheet should be in question answer
	22.	DR. BHAGYASHREE KOLHE	format so bilingually correct it. Add 'Status of Rasa Dhatu' term in operational definition. Hypothesis should not formulated is is not applicable for observational study designs How you are going to diagnose stanyadushti by symptoms and stanyapariksha isn't it so send objective is not correct Previous work done should be descending order means 2020-2019-2018-2017 likewise please organize In inclusion criteria you have to select women with stanya dushti stanya dushti References not in vancouver style Patient information sheet should be in question answer format
	23.	DR. VASUNDHARA MAHEWAR	 Page no 30 chart can be refered for operational defination of fast food as well as Ahitaahar. No clarity on specific street foods. Certain street foods are also healthy like idly, pongal, Uppit, sabudana kichidi etc Generalized term fast food as Ahitahara also to be reconsidered. Fast food in India is to be defined and cannot be compared to western world.
	24.	DR. KOMAL THAKKAR	 Add 'Status of Rakta Dhatu' term in operational definition. Systematically prepared synopsis. But how the questionnaire of Dravata, spandana and Laghuta are prepared? what is the basis should also be mentioned in the synopsis.

		patients with menstrual problems only then Nul hypothesis or negative impact to aim cannot be recorded. Please see the inclusion criteria.
33.	DR. ABOLI GIRME	 Study rationale and outcome of project does not mention the need to conduct the survey. Need more clarification on the rachana sharir aspect. Assessment criteria mainly to be aimed on Ayurvedic parameters.
34.	DR. SONIA GEDAM	 Add Sharir Rachanatmak (Anatomical) effects/term in title. Many allopathic studies already established. This was already written in books. In this hypothesis nothing is appearing related to Ayurveda. Please rethink

	R	ASASHASTRA & B. K. DEPARTMENT
Sr. No.	Name of the Student	Queries
35.	DR. SHRADDHA PATIL	 "Why Sharangdhar Samhita is emphasized" needs to be justified in Introduction.
36.	DR. MINAKSHI NARSALE	 Agar well Diffusion Method needs to be elaborately mentioned with protocol for samples as annexures. Also refer Clinical and Laboratory Standards Institute for bacteria and Yeast testing for additional info. Will Antimicrobial activity be assessed on Minimum Inhibitory Concentration if yes mention details if not justify. Title should be reformulate because if your question is on anti-microbial then question should be reformulate
37.	DR. ADITI MUDHOLKAR	 How your study is different from previous research on bhallataka parpati needs to be explained in detail.
38.	DR. AKSHAY KARANDIKAR	 "Why Ashtang Hridaya is emphasized" needs to be justified in Introduction.
39.	DR. RUCHITA DOLAS	 Agar well Diffusion Method needs to be elaborately mentioned with protocol for samples as annexures. Also refer Clinical and Laboratory Standards Institute for bacteria and Yeast testing for additional Info. Will Antimicrobial activity be assessed on Minimum Inhibitory Concentration if yes mention details if not justify. Title can be write as Antimicrobial activity study of Rasaparpati prepared by using samaguna Gandhak kajjali and Shadguna Gandhak Kijali with pharmaceutico- analytical study Check Sanskrit words References should be in Vancouver style
40.	DR. GOURI DESHPANDE	> No comments received from Email of IEC Member.

	ROC	SNIDAN DEPARTMENT
S r, N o	Name of the Student True Copy	Queries
41.	DR. SHIVANI DE A	ssessment criteria for Atisthaulya can be added with fat

	BHAWAREKAR	percentage. > How Questionnaire validation will be done. Justify.
42.	DR. SHRADDHA CHAVARE	 Assessment criteria for Medorog can be added with fat percentage. How Questionnaire validation will be done. Justify.
43.	DR. SHIVANI KOSSAMBE	Standaridse the questionnaire to assess lakshanas of sweat channels vitiation on the basis of frequency, duration and intensity.
44.	DR. NIKITA KULWAL	 Methodology is not clear in relation with title. Justify strotodushti with respect to selected population suffering from abortion.
45.	DR. MAYUR MUKUND	 Justify rationale and knowledge gap of this subject. What outcome is expected in terms of Rognidana.
46.	DR. RUCHIRA VIRKAR	 Kushtha assessment questionnaire and clinical evaluation may need evidences in terms of photographs of lesion. Consent accrodingly need to mention that. Questionnaire validation is needed, considering retrospective assessment.

	SAMHITA SIDDHANT DEPARTMENT		
Sr. No.	Name of the Student	Queries	
47.	DR. TANVI AGALE	 Operational definitions are not mentioned. 	
48.	DR. SAMRUDHHI ARAGE	 Title is too long and not specific to methodology. Operational definitions are not mentioned. 	
49.	DR. PRADNYA GAIKWAD	> Rescue medicines are not mentioned in case of withdrawal	
50.	DR. ADITI KULKARNI	Operational definitions are not mentioned. Rescue medicines are not mentioned in case of withdrawal	
51.	DR. POONAM MARGAJ	Rescue medicines are not mentioned in case of withdrawal	
52.	DR. APARNA FUNDE	➤ How data from Questionnaire will be analysed? Justify.	

	SHALAKYA TANTRA DEPARTMENT		
Sr. No.	Name of the Student	Queries	
53.	DR. SANDIP PATIL	 Why Kwatha form / coute of administration is selected over standard of care with various ghrita / nasya. Justify in rationale or knowledge gap. Rescue medication needs to be mentioned in withdrawal criteria. Group A has BID dosage and Group B H5. Justify in methodology. 	
54.	DR. MAHEJABEEN JIKARE	 Is it RCT or comparative trial? Methodology seems comparative also as per Hypothesis and objectives. Need to change title accordingly. Rescue medication needs to be mentioned in withdrawal criteria. 	

55.	DR. SNEHA AIR	Is it RCT or comparative trial? Methodology seems comparative also as per Hypothesis and objectives. Need to change title accordingly.
56.	DR. SUPRIYA BHANDARE	 Annexure 1.2 is not clearly stating Varti preparation SOP. Elaborate. Concomitant medicine is not used. Justify. Title should not be in capital letters Previous work done should be latest first means first 2020,2019 like wise control group reference should quote and methodology should be accordingly followed as per standard photograph will not be objective criteria Latin names of medicinal plants are not written as per standard format Information sheet should be in question answer format
57.	DR. MANASI BORKAR	 Rescue medication needs to be mentioned in withdrawal criteria. Will Mrudvikadi Vati need stability testings? Elaborate in methodology if not needed. Consent document is not mentioning about oropharyngeal photograph. Observation table needs to include observations related to oropharngeal status.
58.	DR. DHANASHREE GOLE	 Draksha Sidhha Ghrita my need stability studies. Justify or add in methodology. Rescue medication needs to be mentioned in withdrawal criteria. Detail SOP needs to be mentioned for Draksha Sidhha Ghrita Aschotana from stpes of raw materials to packaging in Methodology.

Sr. No.	Name of the Student	Queries
59.	DR. TEJSHREE RAJENDRA CHAVAN	 SOP for Nirgundi Caplet manufacturing and use need to be added in stepwise details. Define Postoperative conditions in operational definations Rescue medication is not mentioned in case of withdrawal Study duration in consent document and main protocol is different please check.
60.	DR. SNEHA DEORAOJI KAPGATE	 Dose was given as 20 ml. Please see the classical kwatha dose. I think it is less than the minimum. As per the method he selected it comes around 2.5 g course powder made to kwatha. (p 11) Is it a comparative study between efficacy of Haridra and Gokshur Kwath? Justify if not there is need to change Hypothesis, objectives, methodology and title. Informed consent Document is not mentioning about sonological investigations. Explain how your project is different from previous studies in knowledge gap.
61.	DR. VISHAL MOHAN PATOLE	 Non classical dosage form. Should be studied for skin sensitivity test. Page 7 Details of Shatadhaut Ghrita mentions reference 14

*		 Explain how your project is different from previous studies in knowledge gap. Study duration in consent document and main protocol is different please check. Is it a comparative tudy between efficacy of Vata Twak Sidhha Ghrita and Shatadhaut ghrita (as per Other objective 5)? Justify if not there is need to change Hypothesis, objectives, methodology and title.
62.	DR. PRATHMESH P RATHOD	 Whether it is as per classics or anubhutayoga. If non classical dosage form. Should be studied for skin sensitivity test. Rescue medication is not mentioned in case of withdrawal.
63.	DR. AMRIN CHAND SHAIKH	 Informed consent document is not complete and it is not mentioning blood tests. Rescue medication is not mentioned in case of withdrawal. Explain how your project is different from previous studies in knowledge gap.

Sr. No.	Name of the Student	Queries
64.	DR. EKTA V. DESHMUKH	 How this study is different from previous research on Kapha Yonivyapad. Justify the knowledge gap. Justify single arm study. Methodology can be changed to RCT or analytical type considering study aim. Objectives need to be modified as per methodology.
65,	DR. SWETA RAJENDRA GADEKAR	 Selecting literary study is good, but there is no clear specification of the study and its output. No novelty, already many studies were done on garbhini paricharya. It is mentioned in the objective revalidation of concepts of garbhini paricharya. With literary review one cannot revalidate the things directly and for that probably the scholar wants to compare with others' works. But i suggest the study should be with specific aim and objective and not in generalized way. The aim and objective should reflect in title. Please think if the study can conceptualized specifically by working on specific goals. Justify conceptual study design. Clinical study will be more effective in testing the hypothesis Objectives need to be modified as per methodology.
56.	DR. ANURADHA BRIKESHCHAND GUPTA	 Lagenaria siceraria (molina) standi. Is the accepted name for tumbi. Please modify accordingly. When using drug other than classical dosage form it should be tried for safety studies. As it is used externally if possible skin safety test should be conducted on limited number. Objectives need to be modified as per methodology. How this study is different from previous research on Episiotomy wound healing. Justify in the knowledge gap. Possible Wound infection Protocol and rescue medicines need to be added in withdrawal criteria.
57.	DR. ANURAG KISAN JADHAV True Cost	 As per the shloka the anupana are also having important role. See the feasibility of including the anupana. In the study dosage form changed. Even then only churna is given in tablet form. Hence can be considered. Methodology can be changed to RCT or analytical type

		 considering study aim. Objectives need to be modified as per methodology. How this study is different from previous research on Chardi Elaborate in the knowledge gap.
68.	DR. KALYANI MITALKUMAR MAHAJAN	 Methodology can be changed to RCT or analytical type considering study aim. Objectives need to be modified as per methodology. Elaborate the knowledge gap.
69.	DR. PRIYANKA SUNIL CHAUDHARI	 See the feasibility of changing the title with snehan to abhyanga and sweda specifically to nadisweda. Specific Snehan and Swedan drugs need to be mentioned in the title. How this study is different from previous research on Snehan Swedan. Justify in the knowledge gap. Objectives need to be modified as per methodology.

SWASTHAVRITTA DEPARTMENT		
Sr. No.	Name of the Student	Queries
70.	DR. SARITA RAMAKANT MURADE	 BMD is costly test and how the cost can be met for pg study State details of standard of care as calcium supplements in methodology (dosage, frequency etc)
71.	DR. ASHWINI MAROTIRAO PARGEWAR	 Reform title, delete word simple. Add 'simple' bhramari in operational definitions. Questionnaire validation needs to be done.
72.	DR. NIKITA NALAWADE	 Add rescue management in withdrawal criteria.
73.	DR. BHAKTI BHAU MEHTA	 Questionnaire validation needs to be done preferably in the deaddiction center.
74.	DR. VRISHALEE SHRIRAM AMTE	 Add ojakshaya operational definition. Inclusion criteria of 30-70 years seems too broad. Justify.

Member secretary

Member Secretary

. MAM's. S.S.A.M. 8. Ayurved Hospital Sand Guruji Arogya Kendra Hadapsar, Pune.



Chairman Institutional Ethics Committee SSAM, Hadapsar, Pune

AAM's, S.3 A.M.
A Ayuryod Hospital
Saos Gungi Arugya Kendra
Hadapsar, Pune.

M. A. M's, Sumatibhai Shah Ayurved Mahavidyalaya, Hadapsar, Pune, 411 000

INSTITUTIONAL ETHICS COMMITTEE

Maharashtra Arogya Mandal's Sumatibhai Shah Ayurved Mahavidyalaya and

Ayurveda Hespital – Sane Guruji Arogya Kendra Malwadi, Hadapsar, Pune – 411 028.

Phone No.:- +91-20-29522503, +91-20-29522504 Email: ssavu@rediffmail.com

Minutes

32nd Meeting of Institutional Ethics Committee

Date :- 07/07/2021 to 20/07/2021

Online meeting of Institutional Ethics Committee.

After departmental presentation of title & synopsis in front of HOD's & Guides, corrected copies of Synopsis of all the PG students admitted in 2020-2021 were sent to Honourable IEC members on 07/07/2021 due to Covid-19 pandemic crisis. Hard copies of all synopsis were sent to all the honourable IEC members.

IEC members sent their suggestions through e-mail & by hard copy. IEC members suggestions were forwarded to the students from time to time. Member secretary informed & discussed with IEC chairman about all the procedures of synopsis evaluation. Suggestions were received from IEC members & corrections were done by the students until 23/07/2021. After that the students were asked to submit the corrected synopsis. A covering letter to IEC chairman was forwarded regarding corrections made according to the suggestions given by IEC members through the respective HOD's & guides.

IEC Chairman scrutinized all the corrected synopsis copies and approved all the title & synopsis of Pre-MD/MS students of 2020-2021 admission batch.

Following Honourable IEC members provided their suggestions via E-mail / hard copies.

1. Dr. V.V. Doiphode	Chairman of IEC
2. Dr. Anand V. Kalaskar	Member Secretary, IEC
3. Dr. S.M. Sathye	Member of IEC
4. Dr. Yogini Kulkarni	Member of IEC
5. Dr. Satish Puntambekar	Member of IEC
6. Dr. Dhananjay Mhasade	Member of IEC
7. Mr. Arun Gujar	Member of IEC
8. Dr. Rajendra Huprikar	Member of IEC
0 p. p. H	16 1 0100

9. Dr. Pallavi Jamadagni Member of IEC 10.Dr. A. M. Gurav Member of IEC

11.Dr. Pranita Joshi-Deshmukh Research Coordinator

M. A. M's, Sumatibhai Shar Ayurved Mahavidyalaya, Hadapsar, Puna

- Minutes of previous meeting was accepted & approved by honourable chairman Dr. V.V. Doiphode.
- Suggestions given by Honourable IEC members : Common Suggestion :
 - Botanical names to be written in scientific manner as follows:
 - Genus name should start with Capital letter.
 - b. Species name should start with small letter.
 - c. Genus & Species name should be in italics & underlined.
 - d. Scientist name should be written at the end & should not be in Italics.
 - 2. Vancouver Style of referencing to be followed strictly.
 - 3. Questionnaire to be validated.
 - Generic names to be used instead of brand names for e.g. 'Povidone iodine' instead of 'Betadine'.
 - 5. Correct spelling mistakes & grammars.
 - 6. Include witness name & sign in patients informed consent form if applicable.

AGADTANTRA DEPARTMENT				
Sr. No.	Name of the Student	Queries		
1.	DR. VIRNODKAR PRATHA	 Title- A single arm clinical efficacy Page No. 8 - Primary objective time bound should be mentioned. Other objectives should be deleted. Page no. 10 sample size consider drop outs? Page no. 12 Scientist name in Latin should not be in Italic. Page no. 18, Reference style - should be in Vancouver style. Page no. 35, Add "left hand" thumb impression of Patient. 		
2.	DR. KURTKOTI KETAN	 Title should be reformulated. Page no. 10 - Primary objective time bound should be mentioned. 6.2.2 secondary objective is not reflecting in the title. Page no. 20, Reference style – should be in Vancouver style. 		
3.	DR. NAKATE AMRUTA	 Title should be reformulated. Primary objective time bound should be mentioned. Reference style – should be in Vancouver style. 		
4.	DR. RANKHAMB SUDHARMA	 Title should be reformulated. Primary objective time bound should be mentioned. Reference style – should be in Vancouver style. 		
5.	DR. JAIN RUCHA	be with authority & correct spellings should be		

	mentioned.
	Plant material collection is not clearly mentioned,
	whether it will be collected from field or procured from
	market.
	Without authentication of drug it should not be included
	in medicine preparation.
8	How drug standardization will be done is not

Sr. No.	Name of the Student	Queries
6.	DR. BHANUSHALI HARSHA	 Permission/NOC of lab where study will be conducted to be added. What is rationale/ contribution to science by doing such studies.
7.	DR. JADHAV TEJASWINI	 Page no. 06, Previous work done should be presented in descending order. Page no. 07, Primary objectives- These are not objectives, they are the mandatory steps of the projects. Secondary objective – this is the primary objectives. Page no. 17, property of Mundi- Write scientist name. Page no. 18, Reference style – should be in Vancouver style. Study rationale is not acceptable.
8.	DR. LAKADE MANALI	 Title -Clinical study to explore the Rasaprayas Siddhant in P.V. with special reference to amlapitta. Page no. 07, Previous work done should be presented in descending order. Page no. 12, Point no. 6.2 - W.S.R. Use longform. Page no. 13, Point no. 6.3.3 & 6.3.4 -? Page no. 16, Sampling technique mentioned number of patients. Page no. 23, Reference style - should be in Vancouver style. Consent form to be added. What is rationale/ contribution to science by doing such studies.

mentioned.

		 Page no. 6 study rationale in Rasa flowchart- Is it conversion of Rasa?
9.	DR. KSHIRSAGAR SUMEDHA	 What is rationale/ contribution to science by doing such studies. Same general instructions as other departmental synopsis. Permission/NOC of lab where study will be conducted to be added.
10.	DR. GAIKWAD JYOTI	 Please search/mentioned reference for dermal toxicity study or skin sensitization studies of the ingredients. Same general instructions as other departmental synopsis. Page no. 28, Add "left hand" thumb impression of Parent (follow this suggestion in Marathi on page no 29).

		KAYACHIKITSA DEPARTMENT
Sr. No.	Name of the Student	Queries
11.	DR. MALIJSARE MADHAVI	 Which drug is previously explored as Standard drug? If so then title should be reformulated. Patient information sheet should be in question answer format. Page no. 13, Previous work done should be presented in descending order. Page no. 34, Reference style – should be in Vancouver style. Scientist name to be mentioned in Latin name. Sample size should be calculated using efficacy compare formula. Page no. 50, Add "left hand" thumb impression of Patient. Add English information sheet. चिंता (Anxiety), उद्धेन (remorse, bitter repentence). There is difference between anxiety symptoms & anxiety disorders. (Chitto dvega, attatvabhinivesha?) You will have to correct inclusion criteria no. 2 & 3
	True Conv	 because many things are repeated in 2 &3. Remove details of exclusion criteria no. 3, write only depression.
	phinn	Concentrate only on the anxiety symptoms i.e. use

		only Hamilton's scale & Remove no. 2 of inclusion criteria. • If you are considering Chitto dvega as synonym of
		 anxiety symptoms. Remove everything on page no. 20 except anxiety symptoms.
		 Remove page 28,29,46 & 47.
12.	DR. GHUMARE RADHIKA	 Patient information sheet should be in question answer format. Page no. 17, Reference style – should be in Vancouver style. Scientist name to be mentioned in Latin name. Sample size should be calculated using efficacy compare formula. Page no. 8, Previous work done should be presented in descending order. Primary objective should be time bound. Delete Aim. Page no. 28, 29 use simplified terms.
		 Page no. 10 remove inclusion criteria no. 4
13.	DR. NAIK JAVERIYA	 Which drug is previously explored as Standard drug? If so then title should be reformulated. Patient information sheet should be in question answer format. Page no. 13, Previous work done should be presented in descending order. Page no. 34, Reference style – should be in Vancouver style. Scientist name to be mentioned in Latin name. Sample size should be calculated using efficacy compare formula. Page no. 25, use simplified terms. Page no. 4 study rationale needs some more information. Page no. 10 if Goghrit is Anupan, write detail separately. Page no. 8 & 13 "Pandu Vyadhi Lakshnas" do not match. MCV & Hb are mentioned on inclusion criteria, Write separately on page no. 14 & 21 under assessment criteria.
14.	DR. PAWAR MUKUL	 Which drug is previously explored as Standard drug? If so then title should be reformulated. Patient information sheet should be in question answer format. Page no. 13, Previous work done should be presented in descending order.
	M. A. M's, Sumatib	

		 Page no. 34, Reference style – should be in Vancouve style. Scientist name to be mentioned in Latin name. Sample size should be calculated using efficacy compare formula. Page no. 27, mention route of drug administration. Page no. 28, Add "left hand" thumb impression of Patient. Add English information sheet. In inclusion criteria no. 2 write minimum 50% i.e. at least 5 symptoms must be present to confirm the diagnosis of Urdhavaga amlapitta & not one or more. Page no. 6 dose of quath should be either 20ml or 15ml in both cases.
15.	DR. BHOJANE ANUJA	 Which drug is previously explored as Standard drug? If so then title should be reformulated. Patient information sheet should be in question answer format. Page no. 13, Previous work done should be presented in descending order. Page no. 34, Reference style – should be in Vancouver style. Scientist name to be mentioned in Latin name. Sample size should be calculated using efficacy compare formula. Page no. 27,28 Why both forms are in English? Page no. 14 – Gokshur not mentioned. Page no. 25 – Why repetition of strotas parikshan?
16.	DR. MANWAR KOMAL	 Which drug is previously explored as Standard drug? If so then title should be reformulated. Patient information sheet should be in question answer format. Page no. 13, Previous work done should be presented in descending order. Page no. 34, Reference style – should be in Vancouver style. Scientist name to be mentioned in Latin name. Sample size should be calculated using efficacy compare formula. Page no. 28, matter is copy pasted. Add Marathi consent form.
		KRIYA SHARIR DEPARTMENT True Gopy

M. A. M's, Sumatibhai Shah Ayurved Mahavidyalaya,

r. No.	Name of the Student	Queries
17.	DR. LIMBANE ASHWINI	 Title - Why only literary study? Add interview with vaidyas or same observational study to find relation of Vrikka & Pakwashaya. This is a literary study so research question? Hypothesis H1 & Null hypothesis NA. Page no. 4, Previous work done should be presented in descending order. Page no. 12, Secondary objective point no. 2 - Methodology not mentioned in the synopsis. Page no. 15, Reference style - should be in Vancouve style. Grammatical & MS Word correction suggested. When all organ names are written in Sanskrit, it becomes difficult to understand the concepts.
18.	DR. WAGHMARE SAI	 Page no. 38, Add "left hand" thumb impression of volunteer. (follow this suggestion in Marathi on page no. 39). Page no. 5, Previous work done should be presented in descending order & should not be in Vancouver style. Page No. 5, Point no. 5 – Hypothesis not applicable. Page no. 11, Point no. 7 – Secondary objectives shoul be formulated again. Page no. 15, Reference style – should be in Vancouve style. Grammatical & MS Word correction suggested. Sample size calculation not given. How 105 sample size? Please use English terms where possible.
19.	DR. CHAVAN POOJA	 Page no. 62 check spellings. No shortforms used in title. Why two designs included in one study please make it simple. Page no. 6 - Correction in shortform w.s.r. Write effects instead of effect. * Page no. 7- Previous work done should be presented in descending order & should not be in Vancouver style. Page no. 17- test to be applied- in which type of data. Page no. 24, Gannt Chart should be prepared after. Title does not explain the study. Please use English terms where possible. Grammatical & MS Word correction suggested.
20.	DR. PHALE DHANASHREE	Costage no. 6- hypothesis not applicable. Previous workdone should be presented in descending order.

		 Page no. 12 you can enquire no. of female police in specific area & then take sample accordingly. Formula for collection of sample size? Page no. 13 - Exclusion criteria - K/C/O - female traffic police. Page no. 17, Reference style - should be in Vancouver style. Page no. 24, Gannt Chart should be prepared after Please verify sample size calculation. Please review inclusion & exclusion criteria. How will you compare if you exclude police not suppressing the urge approval of synopsis 18 months.
21.	DR. WAGHULE 21. SWARALI	 Page no. 31, Add "left hand" thumb impression of volunteer. Page no. 4, Previous work done should be presented in descending order. Page no. 13, Reference style – should be in Vancouver style. Page no. 33 Gantt Chart ? What is rationale of the study? Based on only observation how it can contribute the science.

		PANCHAKARMA DEPARTMENT
Sr. No.	Name of the Student	Queries
22.	DR. BANGA SUNEERA	 Informed consent document should be formulated in question answer format. Sample size should be calculated using efficacy compare formula. Page no. 57, 58 Revise Marathi questionnaire. Page no. 54, Add "left hand" thumb impression of Patient (follow this suggestion in Marathi on page no 56). Page no. 52, Write "द्यावयाचे " instead of "व्यावयाचे".
23.	DR. KATKAR SHWETA	 Informed consent document should be formulated in question answer format. Sample size should be calculated using efficacy compare formula. Page no. 59, Add "left hand" thumb impression of Patient (follow this suggestion in Marathi on page no. 60). Remove Subsequent complications from page no. 59.
	True Copy	 Page no. 57, Reframe sentences of point no. 3. Remove lakshanas mentioned on page no. 36 & 37. Write only "vataj grahani" lakshanas. Vataj grahani lakshanas mentioned on page no. 37 do

		not tally with subjective & objective assessment criteria on page no. 49, 50, 51, 52. Visuchika in Vataj grahani is gastroenteritis.
		Informed consent document should be formulated in question answer format. Sample size should be calculated using efficacy.
24.	DR. POTDAR SONAL	 compare formula. Page no. 54, Add "left hand" thumb impression of Patient (follow this suggestion in Marathi on page no. 55). Page no. 53, use simplified terms.
25.	DR. SONWANE SNEHAL	 Informed consent document should be formulated in question answer format. Sample size should be calculated using efficacy compare formula. Page no. 55, Add "left hand" thumb impression of Patient (follow this suggestion in Marathi on page no. 56). Page no. 51 use simplified terms. Add separate consent form for using Kukkutanda Pinda swed. Page no. 17 check for spellings & grammar.
26.	DR. GITTE RUPALI	 Informed consent document should be formulated in question answer format. Sample size should be calculated using efficacy compare formula. Page no. 59, Add "left hand" thumb impression of Patient (follow this suggestion in Marathi on page no. 60). Page no. 57 & 58 use simplified terms for avbahuka. Page no. 39 repetition of inclusion criteria no. 4&5.

RASASHASTRA & B. K. DEPARTMENT		
Sr. No.	Name of the Student	Queries
27.	DR. JATEGAONKAR ASHUTOSH	 Page no. 6- table no. 2 HPLC? Page no. 7, Reference style – should be in Vancouver style.
28.	DR. MAHAMUNI POOJA	 Page no. 8 – Analytical Study ? Page no. 9, Reference style – should be in Vancouver style
29.	DR. KULKARNI SNEHAL	 Page no. 6, Previous work done should be presented in descending order. Page No. 8, Test - Physico-chemical parameters - Angle of repose.

		 Page no. 9, Bibliography - Reference style – should be in Vancouver style
30.	DR. BHAVSAR HIMANI	 Page no.11, Point no. 7 - Secondary Objective should be deleted. These are steps of research. Page no. 13, Material latin names not in proper format as Scientist name is not mentioned. Page no. 18, Analytical test table - HPLC methodology? Page no. 20, Bibliography - Reference style - should be in Vancouver style
31.	DR. TUPKARI SHUBHAM	 Page no. 6, Previous work done should be presented in descending order. Page no.8, Point no. 6 - Secondary Objective should be deleted. These are mandatory steps of research. Page No. 15, table no. 2 - Physio chemical examination - Viscosity -? Page no. 21, Bibliography - Reference style - should be in Vancouver style.
32.	DR. TAKWALE GEETANJALI	 Same general instructions as other departmental synopsis. Page no. 7, Point no. 6.2 – Secondary Objective should be deleted.

ROGNIDAN DEPARTMENT		
Sr. No.	Name of the Student	Queries
33.	DR. MIRGAL EKTA	 Page no. 3, Point no. 3 Which type of Kushthavyadhi. Page no. 3, Point no. 4 Primary hypothesis not applicable. Page no. 12, Point no. 6.1 Secondary objective no. 1 – Reformulate it should be other than Page no. 22, Reference style – should be in Vancouver style. Page no. 40, check spellings.
34.	DR. PATIL VRUSHALI	 Page no. 2, Point no. 4 Primary hypothesis not applicable. Page no. 11, Reference style - should be in Vancouver style. Page no. 9 specify "excessive". For this need to have gradation & scoring chart with quantity & frequency. (Attached with this). Why are you considering "doshaj lakshanas" when "Samanya lakshanas" are mentioned as per your title. Concentrate on "Sadyojanaka Hetu" & Pratishyaya Vyadhi.
35.	DR. SAVALE MINAL	وه هو المحرود

- Page no. 12, Reference style should be in Vancouver style.
- Title is different on title page & footer.
- Page no. 23, check spellings.

Sr. No.	Name of the Student	Queries
36.	DR. VYAS MONALI	 Include Hetus - Excessive loss of blood, fat, Kapha & Vayu (Ref. to Su.Ut.25/9,10). How much quantity & frequency should be treated as excess, moderate or less? Write it for each hetu. Prepare criteria for clinical assessment, Gradation & scoring for dietary etc. (Ref. to Ph.D. thesis by Dr. Urmila Pitkar "Vikrut Sharir Kriya & Cancer- A Study" available at Dr. Sathye's Residence) till then "Seti kartvyatako Nidanam" not possible. Use upper case "S" instead of "s" in Shiroshool. Cross sectional study to find the correlation in Hetu of Raktadushti in Shiroshool with special reference to Hetu siddhant. Page no. 5, Previous work done should be presented in descending order. Page no. 10, Point no. 7, Objectives - should be formulated primary & Secondary objectives. Objectives no. 1 & 2 can be cancelled. Point no. 4 Primary objective. Page no. 17, XII- X² test.
37.	DR. MULLA SIMRAN	 Change the title starting with "Study of efficacy of "I place of "Use Of". Attach Patient Consent Form. Attach Patient Consent Form. Study design should be mentioned in the title. Page no. 6, Point no. 3 research question – is Eranda Sneha (5 ml) with shunti kwath (50 ml) for 7 days useful in katishool? Page no. 6, Point no. 4, alternative hypothesis H1 – i Eranda Sneha (5 ml) with shunti kwath (50 ml) for 7 days is significantly effective in katishool? Page no. 6, Point no. 5, null hypothesis H0– is Erand Sneha (5 ml) with shunti kwath (50 ml) for 7 days is not significantly effective in katishool? Page no. 7, reference drug – part used? Page no. 8, Shunti – Scientist name? Part used? Page no. 10, Reference style – should be in Vancouve style. Page no. 12, Formulate Primary & Secondary

		 objectives not aims & objectives. Page no. 15, Point no. 3 should be in exclusion. Point no. 5 Patients having age 30-60 irrespective of gender. Latin name of Shunti should be written along with Authority.
38.	DR. DESHMUKH POONAM	 Write vishesh samprapti of "Atichinta Hetu " only. (Page no. 11). Ref. to sutra "एको हेतुर नेकस्य बहुतां बहुदस्तथा". Atichinta leads to Agnidushti(For vishesh samprapti). If interferon is less it leads to chinta (Immunity is less), it is a destructive stress. Attach patient information sheet. Chinta leads to heart disease (Duke University, America, Psychosomatic medicine publication). Can test for anxiety PAT (Phimatic Applac section test) possible? Chintan is chintya for low stress tolerance examination of prakruti, satva, saar essential. Remark by department.
39.	DR. HINGANE PRANJALI	 Minimum three lakshanas of Gridhrasi to confirm diagnosis with or without SLR. Prepare criteria for clinical assessment gradation & scoring for aahar vihar etc. Frame proper questions for বায়, কাল্ম hetus in questionnaire (Low calorie food ?). Page no. 9, Point no. 6, Aim - should be formulated primary & Secondary hypothesis. Page no. 21, Point no. XI - Specific statistical test should be mentioned. Page no. 22, Reference style - should be in Vancouver style.

Sr. No.	Name of the Student	Queries
40.	DR. PHOPALIYA MEGHANA	 Scientific name of all drugs used should be incorporated in the proposal. Please clearly mention the name of Antioxidant Capsuleused in the study. Patient information sheet should be in question answer format.
	True Copy	 Latin names should be written in standard format. Sample size should be calculated using efficacy compare formula. Primary objectives should be time bound.
	Principal M. A. M's, Sumatibhal S Ayurved Mahavidyalay	Dose & duration of study drug to be mentioned in

41.	DR. NAWALE SONAM	research question & hypothesis. Page no. 37, use simplified terms. Page no. 13, Remove exclusion criteria no. 5. Inclusion criteria- write Age 18 years to 80 years/90 years/100years etc. Madhu mentioned on page no. 18 is not mentioned on page no. 34, Why? Yavakashar- botanical name should be written correctly. Authority of plant should not be in Italic. Patient information sheet should be in question answer format. Latin names should be written in standard format. Sample size should be calculated using efficacy compare formula. Primary objectives should be time bound. Dose & duration of study drug to be mentioned in research question & hypothesis. Page no. 15, Remove exclusion criteria no. 5. Add Parent consent form. Page no. 7 Gilayu samprapti – It should be "Amalaki Asthimatra". If it is a controlled study you need not write "Yashti Madhu Ghan Vati" in the title. If this is in Peer reviewed journal, mention it. Page no. 14 inclusion criteria does not tally with signs & symptoms mentioned on page no. 16. You may add lakshnas of chronic tonsillitis as mentioned with the title. See page no. 22 & 23 also. The inclusion criteria &
		assessment parameter must tally. Consent of parents necessary if the age of patient is below 18 years.
42.	DR. VISHWAKARMA PALLAVI	 Proposal to be drafted scientifically. Botanical name of the Bhringraja should be written with authority. Please use modern synonyms to Ayurvedic conditions. Patient information sheet should be in question answer format. Latin names should be written in standard format. Sample size should be calculated using efficacy compare formula. Primary objectives should be time bound. Dose & duration of study drug to be mentioned in research question & hypothesis.
43.	DR. PATIL SAYALI	Correct & scientific name of Drug should be mentioned.

		 Patient information sheet should be in question answer format. Latin names should be written in standard format. Sample size should be calculated using efficacy compare formula. Primary objectives should be time bound. Dose & duration of study drug to be mentioned in research question & hypothesis. In the title write Randomized controlled & whether "Saptamrut Lauha" is confirmed as treatment for Hypermetropia in Peer reviewed journal or elsewhere.
44.	DR. SWAMI MANJUSHA	 Patient information sheet should be in question answer format. Latin names should be written in standard format. Sample size should be calculated using efficacy compare formula. Primary objectives should be time bound. Dose & duration of study drug to be mentioned in research question & hypothesis. Page no. 32, use simplified terms for Viddha Karma. Sample size is very small.
45.	DR. HULE DIVYA	 Botanical names should be written with authority. Authentification of plants not mentioned. Quantity of plants or drugs not mention. Please use modern synonyms to Ayurvedic terms. Page no. 5 - best among the rest? Page no. 15- inclusion criteria - Point no. 4 not required. Exclusion criteria - Point no. 3 how will you rule out? Page no. 17 - Route of action? Patient information sheet should be in question answer format. Latin names should be written in standard format. Sample size should be calculated using efficacy compare formula. Primary objectives should be time bound. Dose & duration of study drug to be mentioned in research question & hypothesis. Sample size is small.

SHALYA TANTRA DEPARTMENT

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Sr. No.	Name of the Student	Queries
46.	DR. JAGTAP VAIBHAV	 Inclusion criteria differs from signs & symptoms on page no. 16, may be correlated. Page no. 19 Observations - You may write sign & symptoms of Acute Cystitis in bracket. Is criteria "Post catheterization infection "mandatory for inclusion? specify. Add Marathi consent form. Page no. 25, Rectify the matter which was copy pasted. Page no. 22 & 24, use simplified terms for Mutrakriccha. Is it Standard controlled trial? If so title should be change accordingly. Latin names should be written in standard format. Patient information sheet should be in question answer format. Page no. 7, Previous work done should be presented in descending order. Page no. 32, Reference style - should be in Vancouver style Sample size should be calculated using efficacy compare formula. Primary objectives should be time bound. Remove secondary objective no. 3. Dose & duration of study drug to be mentioned in research question & hypothesis.
47.	DR. BHANUSE VISHAL	 The title & inclusion criteria differs. Define dushta vrana as infected wound. Page no. 8. Write criteria on page no. 19 in inclusion criteria. Use simplified terms for dushta Vrana, Page no. 25 &26. Page no. 21, Add "left hand" thumb impression of patient. Is it Standard controlled trial? If so title should be change accordingly. Latin names should be written in standard format. Patient information sheet should be in question answer format. Page no. 7, Previous work done should be presented in descending order. Page no. 32, Reference style – should be in Vancouve style Sample size should be calculated using efficacy compare formula.

		 Primary objectives should be time bound. Remove secondary objective no. 3. Dose & duration of study drug to be mentioned in research question & hypothesis. Latin name of the drug should be written in scientific manner. Authentification certificate should be obtained before preparation of drug. Ethically it will be wrong to write the primary objective as - To see the adverse effect of agnikarma. When you evaluate efficacy of Agnikarma with Guda, You may come across some adverse effects in some patients & you have to note the same during observations.
C. 100	R. PARDESHI RIYANKA	 Write an inclusion criteria – as signs of osteoarthritis in knee joint one or both. Write SOP for agnikarma by Guda (Jaggery). Will the agnikarma be for 7 days daily? Use simplified terms on page no. 26. Is it Standard controlled trial? If so title should be change accordingly. Latin names should be written in standard format. Patient information sheet should be in question answer format. Page no. 7, Previous work done should be presented in descending order. Page no. 32, Reference style – should be in Vancouver style Sample size should be calculated using efficacy compare formula. Primary objectives should be time bound. Remove secondary objective no. 3. Dose & duration of study drug to be mentioned in research question & hypothesis. Please check Latin name of Guda(Jaggery).
	DR. KHANDEKAR DMKAR	 Page no. 26, use simplified terms for Vatashthila. Is it Standard controlled trial? If so title should be change accordingly. Latin names should be written in standard format. Patient information sheet should be in question answer format. Page no. 7, Previous work done should be presented in descending order. Page no. 32, Reference style – should be in Vancouver style Sample size should be calculated using efficacy compare formula.

50.	DR. SHARMA PIYUSH	 Remove secondary objectives should be in question answer format. Patient information should be in question answer format. Patient information should be in question answer format. Patient of the should be calculated using efficacy compare formula. Primary objectives should be time bound. Page no. 32, Reference style – should be in Vancouver style Sample size should be calculated using efficacy compare formula. Page no. 32, Reference style – should be in vancouver style Sample size should be calculated using efficacy compare formula. Primary objectives should be time bound. Remove secondary objective no. 3. Dose & duration of Study drug to be mentioned in research question & hypothesis. Ingredient of Goghrut not mentioned. Botanical name of Prushnaparni should be written with authority.
51.	LONDHE SAYALI	 If it is a controlled study you need not mention Shatdhautghrit. Remove inclusion criteria no. 4 as it is repeated on page no. 2. Questionnaire appears to be part of patient information sheet, If it is so, attach English version of the same. Page no. 31 check spellings. Page no. 12, Use gender instead of sex. Page no. 25, Purpose & nature of study does not match the title. Is it Standard controlled trial? If so title should be change accordingly. Latin names should be written in standard format.

/- I	 Patient information sheet should be in question answer format.
	 Page no. 7, Previous work done should be presented in descending order.
	 Page no. 32, Reference style – should be in Vancouver style
	 Sample size should be calculated using efficacy compare formula.
	 Primary objectives should be time bound.
	 Remove secondary objective no. 3.
	 Dose & duration of study drug to be mentioned in research question & hypothesis.
	 Please mentioned Gopyadi Ghrita & Shatdhaut Ghrita ingredients and preparation procedure.

No. Stu	Queries Queries
52. DR. GADHARI I	 Botanical names of all the drugs should be written in scientific manner. All the drug should get authenticated & authentification certificate must be incorporated in the final report. Informed consent document should be formulated in question answer format. Subjective & objective criterias should be separately elaborated. Page no. 7, Previous work done should be presented in descending order. Page no. 8, Reference style – should be in Vancouver style. Secondary objectives should be to observe adverse effects if any. Scientist name to be mentioned in Latin name. Dose & duration of study drug to be mentioned in research question & hypothesis. Why the study is single arm? Page no. 31, Add "left hand" thumb impression of Patient (follow this suggestion in Marathi on page no 33). No need of left hand thumb impression of person taking consent. (Page no. 31 & 33)

		Page no. 28 check Marathi spellings.
		Botanical names of all drugs should be written in scientific manner.
		Authentication certificate should be obtain prior to
		proceeding for drug preparation.
		Informed consent document should be formulated in
		question answer format. Subjective & objective criterias should be separately elaborated. Page no. 7, Previous work done should be presented.
53.	DR. JOSHI MAYURA	in descending order. • Page no. 8, Reference style – should be in Vancouver
Juli		style. • Secondary objectives should be to observe adverse
		Scientist name to be mentioned in Latin name. Dose & duration of study drug to be mentioned in research question & hypothesis.
		 Why the study is single arm? Page no. 34, Add "left hand" thumb impression of Patient.
		 Page no. 33, check spellings & use simplified terms.
	DR. KALOKHE CHARUSHEELA	 Latin name of the drug should be written with authority. Authentication certificate should be obtained. Which drug is control drug? Or Both are explored & only you want to see comparison? Informed consent document should be formulated in
		question answer format. • Subjective & objective criterias should be separately
		elaborated. Page no. 7, Previous work done should be presented.
Ver		 in descending order. Page no. 8, Reference style – should be in Vancouver style.
54.		 Secondary objectives should be to observe adverse effects if any.
		 Scientist name to be mentioned in Latin name. Dose & duration of study drug to be mentioned in research question & hypothesis.
		 Why the study is single arm? Page no. 27, Add "left hand" thumb impression of Patient (follow this suggestion in Marathi on page no 28).
		 Page no. 25 & 26 use simplified terms.
		 On page no. 14 write completion of 8 days of
	1140 Cab	treatment.

55.	DR. BUVA SHRUTI	 All the drugs should be collected from authentic sources. Identification & Authentication should be done from reputed Institute. Please write correct botanical names of the drugs. Page no. 2, Change word recreation in introduction. Page no. 4, hypothesis, please write details of the basis / the hypothesis on which this work is based. Page no. 8, Please write grammatically correct sentences. Page no. 8, Ongoing previous workdone- elaborate the references properly i.e. if ongoing, where? How many patients? if completed what are the results? Page no. 11, material & methods point no. 6 secondary objective – 1. Remove within one month –. Page no. 11, point no. 7 – How this prevalence & Z values are collected. Page no. 12, flow chart – How will you diagnosed. Scientist name should be non Italic in Latin names. Page no. 32, Add "left hand" thumb impression of Patient (follow this suggestion in Marathi on page no. 33). Page no. 31, Use simplified terms. Informed consent document should be formulated in question answer format. Subjective & objective criterias should be separately elaborated. Page no. 7, Previous work done should be presented in descending order. Page no. 8, Reference style – should be in Vancouver style. Secondary objectives should be to observe adverse effects if any. Scientist name to be mentioned in Latin name. Dose & duration of study drug to be mentioned in research question & hypothesis. Why the study is single arm? Page no. 8 write where the work had been done. Whether ongoing or previous work is done. [no. 3].
	DR. HEMAKE	Botanical names of the drugs should be written with authority. Authentication certificate should be obtained &
56.	BHAGYASHREE	enclosed in the final report. Which one is standard drug?
	True Gopy	 which one is standard drug? informed consent document should be formulated in question answer format.

		elaborated. Page no. 7, Previous work done should be presented in descending order. Page no. 8, Reference style – should be in Vancouver style. Secondary objectives should be to observe adverse
		 Secondary objectives should be defects if any. Scientist name to be mentioned in Latin name. Dose & duration of study drug to be mentioned in research question & hypothesis. Why the study is single arm? Page no. 35, Add "left hand" thumb impression of Patient (follow this suggestion in Marathi on page no. 36). Page 33 & 34, use simplified terms. On page no. 31 write patient information sheet in place of informed consent document.
57.	DR. BHADANGE ANIKET	 Informed consent document should be formulated in question answer format. Subjective & objective criterias should be separately elaborated. Page no. 7, Previous work done should be presented in descending order. Page no. 8, Reference style – should be in Vancouver style. Secondary objectives should be to observe adverse effects if any. Scientist name to be mentioned in Latin name. Dose & duration of study drug to be mentioned in research question & hypothesis. Why the study is single arm? Page no. 24, Remove "legally acceptable representative". Page no. 24, Add "left hand" thumb impression of Patient (follow this suggestion in Marathi on page no. 25). Page no. 12, Operational definition of Vomiting to be rectified. Page no. 7, in present knowledge gap reform the sentences in correct English. Follow Vancure style for previous work done. What is the difference between "Talisadi Vati " & "Talisadi Gutika"?

SWASTHAVRITTA DEPARTMENT

Sr. No.	Name of the Student	Queries
58.	DR. GAIKWAD KOMAL	 Page no. 5, Point no. 4- hypothesis not applicable. Page no. 14, Reference style – should be in Vancouver style. Page no. 33, remove "Foreseeable effect & risk of the study" from point no. 2. (Follow this suggestion in Marathi page no. 32). Either remove the word "Pranyaha Strotas" & write Respiratory System or include Moolsthanam of Pranyaha Strotas exam in the case paper- Hriday & Mahastrotas, Rasavahi Dhamanya.
59.	DR. TANPURE SAYALI	 Title design of the study should be mentioned in the title. Page no. 5, Point 3.1- Dose, duration should be mentioned. Page no. 6, 4.1 & 4.2 Write Ho & H1 should be formulated 6 gm medicine two times in a day for 30 days. Page no. 7, Sanskrit check for shlok. Page no. 12, Scientist name should be mentioned in Latin name. Page no.21, Statistical test Mann-Whitney U test. Group is only one then? How? Page no. 36, Add "left hand" thumb impression of volunteer. (follow this suggestion in Marathi on page no. 37). Check spellings Page no. 36 & 37. Change the title to "Study of the". Remove the word "Detail intervention" from page no. 8. Provide patients a chart of diet to be consumed & at what time such as breakfast, meal, evening snacks & night meal with options.
60.	DR. INGALE RUTUJA	 Details about Swasthavritta regime given to the guards should be mentioned. Same common corrections as per other Swasthavritta suggestions. Page no. 52, check spellings. Page no. 50, Add "left hand" thumb impression of volunteer (follow this suggestion in Marathi on page no. 52). Page no. 46 & 48 add simplified term for Nidra Vegavrodha.
	True Gopy	Are there female security guards? Correction on page no. 15 needed about gender.

		 Mention on page no. 13, when the followup will be done.
		 If possible call me if you want any clarification. Page no. 3, 4.1 & 4.2 Hypothesis not applicable. Page no. 3, Previous work done should be presented in descending order.
61.	DR. MANTE NIKESH	 Page no. 17, Reference style – should be in vancouver style. Page no. 37, Add "left hand" thumb impression of volunteer.(follow this suggestion in Marathi on page no. 38). Page no. 36, Point no. 9 – Remove the word "पैसे". Refer the attachment.
62.	DR. WADATKAR MRUNAL	 Same common corrections as per othe Swasthavritta suggestions. Page no. 3, 4.1 Hypothesis not applicable. Page no. 35, Add "left hand" thumb impression of volunteer. Page no. 34, Point no. 6- Remove "विद्यालगीन हेतु ". Page no. 29, check spellings & use simplified terms. Page no. 23, Qu.No. 4 - Use simplified terms. Page no. 9 add both gender in inclusion criteria. Page no. 29 Marathi language correction. (b).

K.

Member secretary
Member Secretary
, MANTS, S.S.A.M.
& Ayurved Hospital
Sens Gurult Atogys Mandra
Hadapsar, Pune.

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INSTITUTIONAL ETHICS COMMITTEE

Maharashtra Arogya Mandal's Sumatibhai Shah Ayurved Mahavidyalaya and

Ayurveda Hospital – Sane Guruji Arogya Kendra Malwadi, Hadapsar, Pune – 411 028.

week No. - 191-20-29522503, 191-20-29522504 Email: ssayu@rediffmail.com

Minutes

3344 Meeting of Institutional Ethics Committee

date = 24/03/2022.

Time := 10.00 am To 6.00 pm

Venue: SNAM, Hall No. 7.

in approval of Title and synopsis of Ph.D. 2019-2020 Batch. storing attended by Honourable IEC members on 24/03/2022.

or Val. Brightnie Chairman of IEC 17c. Vanidana Avhad Member Secretary : Dr. S.M. Sarbye Member of IEC Dr. Yogini Kulkarni Member of IEC Tir. Satish Pontambekar Member of IEC ic Dr. Phananjay Mhasade Member of IEC 7. Mr. Arun Gujar Member of IEC 31. Dr. Rojendra Huprikar Member of IEC 9. Dr. Pallavi Jamadagni Member of IEC 10. Dr. A. M. Guray. Member of IEC 11. Dr. Pranita Joshi-Deshmukh Research Coordinator ... Or. Proctam Itnar Minute Writing Fellow

- As the Oniphode could not attend the meeting due to personal reasons, so Dr. Sathye exappainted as chairman for today's session.
- Welcome note by Dr. Vandana Avhad, PG Co-ordinator, SSAM, Pune.
- First Offline meeting after Covid-19 Pandemic.

M. A. M's, Sumatibhai Shah

Suggestions given by Honourable IEC members : Common Suggestion :

- 1. Power point presentation is compulsory for Ph.D. synopsis presentation.
- 2. Botanical names to be written in scientific manner as follows:
 - a. Genus name should start with Capital letter.
 - b. Species name should start with small letter.
 - c. Genus & Species name should be in italics & underlined.
 - d. Scientist name should be written at the end & should not be in Italias
- 3. Vancouver Style of referencing to be followed strictly.
- 4. Questionnaire to be validated.
- Generic names to be used instead of brand names for e.g. 'Povidone indine' instead of 'Betadine'.
- 6. Correct spelling mistakes & grammars.
- 7. Include witness name & sign in patients informed consent form if applicable.
- 8. Include left hand thumb impression of patient in case record form.
- 9. Previous work done to be written in chronological order.
- All the documents related to the clinical study to be prepared as per ICMR guidelines (CRF, information sheet etc).
- 11. Qualification of Ph.D. student & Ph.D. guide to be mentioned on title page.

SAMHITA SIDDHANT DEPARTMENT		
Sr. No.	Name of the Student	Queries
1.	Dr. Prajakta Bodakhe	 Patient information sheet to be added. Why hyper cholesterolemia is considered in this study. References quoted are incorrect. Detailed description of all the study drugs to be written e.g. Prayojyang. Research question to be reformulated by mentioning mode of administration, duration etc. Exclusion criteria no. 1 to be deleted. Objectives to be as per SMART criteria. Add operational definition of the excessive thirst. Other lipid levels can be considered. Authentication of raw study drug to be denote. Control drug should be proved by the same method and as your study. Control drug can be dropped. Operational definitions to be added wherever applicable.
2.	Dr. Varun Sawant	Aim to be deleted.
3.	Or. Rupali Mhase	Hypotheses to be deleted. Google form can be prepared. Minimum duration of practice for validyas carries increased to 10 years.

	RACHANA SHARIR DEPARTMENT
Name of the Student	Queries
Dr. Forshad Kulkarni Dr. Swaruupa More	 Patient Information sheet to be prepared as per ICMR guidelines and also in local Language. Genetic factors to be mentioned in exclusion criteria. Additional data of patients who continued the pregnancy can be added. Sample size can be increased. Mention counseling of patient will be done before interview. One more centre can be included. Title to be revised. Mention Snehan Swedan in title. Can be collaborated with NIN (National institute of Naturopathy). 60 % of patients to be registered in admitted college and 40 % patients can be registered in mother college. Page no. 21, omit the word "Compensation". Use "benefit" instead.
	 How will you decide acupressure points? Co-guide (Acupressure experts) can be included. How will you rule out ligaments tear? Whether MRI will be done?
Dr. Samudhan Patit	 Study design to be mentioned in title. Revise all clinical documents as per ICMR guidelines. Add HIV consent documents. Mention female attendants will be present while examining the female patient in consent documents.
	 Mention whether withdrawal patients will be replaced or not? Discrepancy in lakshanas is seen on Page 14 & 26.
Dr. Vaibhav Bhadage	 Mention whether patient will be replaced if withdrawn. Patient information sheet to be added. Use simple language in consent form. Revise consent form. KRIYA SHARIR DEPARTMENT
Name of the Student	
	Queries Page no. 13 and Page no. 20 discrepancy is seen in
Dr. Sheikh Pasha True &	duration of use of smart phone. # How will you justify this study by Kriya Sharir point of view? Patient information sheet to be added.
	Dr. Samadhan Patit Dr. Validiav Bhadage Name of the Student

		Shukra Parikshan from Ayurvedic point of view to be elaborated. There are many others become a things of the control of
		 There are many ethical issues in this study, so, change the topic and represent.
	 Page no. 37, mention body weight in Kg. instead a: pounds. 	
		 Page no. 44- Reference no. 49 to be elaborated.
9.	Dr. Savita Sudewad	 Page no. 60 - Ashti Saar lakshana to be written as per granthokta parameters.
		 BMD can be deleted and Sr. Ca can be added or authenticity of BMD test to be verified before
		commencing study.
		 Page no. 54, Delete Upchar, Add signature of patient at the end of page.
		 Revise Patient information sheet.
		 Remove "Compensation" from page no. 69.
	Dr. Vitthal Khandare	 This study is already done at CARC, Akurdian department of Swasthavritta.
		 Validation of Raag from music expert to be done.
10.		 Raag Bageshree can be replaced with mother Raag or study design can be changed to comparative.
		 Raag can be selected as per criteria required for study. Discuss with Dr. Yogini Kulkarni.
		 How will you verify whether patient is actually in house to the Raag?
		 Sr. Melatonin estimation can be considered.
		 Use any other appropriate word for "Twak flant" ("I wan hras) can be used.
	Dr. Aditi Pimpalkhare	 CDAC software for Prakriti assessment can be used.
11.		 Ek doshaj prakriti can be considered.
		 Remove the word Compensation from consent documents.
		 Subgroups within 40-50 years of age can be made
12.	Dr. Yogesh Shewale	 Page no. 17- Botanical names to be written in proper format.
		 Title to be revised, mention intervention will be parte. Remove "Early" from title.
		 Follow suggestions of Dr. Sathye written on synthme.
	Dr. Payal Gaikwad	 Justify why this particular population [Teachers] are considered.
13.		 Teachers from junior college also can be considered.
1000	77.00.000	 Questionnaire to be validated. Discussion with
	True Copy	Psychologist can be done.
	Principal	 CDAC software for Manas Prakriti assessment can be referred.
	M. A. M's, Sumatibhai Sh	6(90)

		 Reconsider the topic (Dr. Gurav).
		KAYACHIKITSA DEPARTMENT
Unit	Name of the Student	Queries
T	M. Kiran (Jbhe	 Mention that standardization of study drug will be done as per API. Mention Cardinal sign of DM that will be considered for study in inclusion criteria. Range of HbA1C can be taken as 6.5 to 8.5. Mention specific OHA for control group. Objectives to be revised as per SMART format. Page no. 29, 41, 43- Discrepancy is seen in assessment criteria. Page no. 49- Correct point no. 3. Mention rescue medication in case of adverse effects. IEC to be informed within 24 hours in case of ADR. References of preclinical study to be added in review of literature.
(be	Rabul Desgi	 Reform research question. Revise Marathi Consent, spellings of drugs. Page no. 19, 20- Botanical names to be written in proper format. SOP of drug preparation to be added. As there are modifications done in the study drug, it should be considered as new molecule. Toxicity study should be done? Change the topic & represent.
Ora	Maruf Hiroli	 Patient information sheet should be in simplified language. Use ICMR guidelines for clinical documents. Sample size to be calculated using appropriate formula. Mention Cardinal signs/ symptoms of anxiety that will be considered for inclusion criteria. (More than 50 %) Follow suggestions written by Sathye Sir on synopsis.
Dr. I	Principal	 Justify why this control drug is considered. Add appropriate references. As study drug is not textual, mention whether toxicity study will be done or if data is available add it. Mention that standardization will be done in authenticate GMP certified lab. Mention appropriate references wherever applicable.

PANCHAKARMA DEPARTMENT

Sr. No.	Name of the Student	Queries
18.	Dr. Priyanka Keram	 Title can be revised to a comparative clinical tend of Madhutailik Basti and Lekhan Basti in Sthaulya. Page no. 17- Textual reference to be added. Page no. 9 - Mention written informed consent will be taken after selection of patient. Mention procedure consent will be taken. Mention duration of study as 30 days on Page no. 27 and 39. Page no. 38, last point omit "profitable".
		SHALAKYATANTRA DEPARTMENT
Sr. No.	Name of the Student	
19. Dr. Sumedha Kotangale		 Whether methodology mentioned in standard drug, will be used or not? Study design can be change to comparative. Objectives to be as per SMART criteria. Define Rasayan Kaal. Mention proper reference. Page no. 34- Remove the word "Compensation" and order "benefit".

20. Study Title: A Double blind, Multi center, Randomized Prospective, International, place in controlled, clinical study to Evaluate Efficacy and Safety of Yesaka Plus Tablet in patients diagnosed with Type2 Diabetes mellitus.

Protocol No.: YSKTAB/DM/SHPL/2022, Version 1.0, 26th February 2022.

Hard copies of above protocol was distributed to all IEC Members for review and suggestions.

Member secretary

Member Secretary

Sane Guruji Arogya Kondra Hadapsar, Pune. Principal

Principal

I. A. M's, Sumatibhai Shah

Ayurved Mahavidyalaya,

Institutional Ethics Conjecture

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INSTITUTIONAL ETHICS COMMITTEE

Maharashtra Arogya Mandal's Sumatibhai Shah Ayurved Mahavidyalaya and Avurveda Hospital – Sane Guruji Arogya Kandra

urveda Hospital – Sane Guruji Arogya Kendra Malwadi, Hadapsar, Pune – 411 028.

Phone No.: +91-20-29522503, +91-20-29522504 Email: ssayu@rediffmail.com

Minutes

35th Meeting of Institutional Ethics Committee

Date > 26/09/2022 to 28/09/2022.

Time :- 10.00 am To 6.00 pm Venue:- SSAM, Hall No. 7.

11. Dr. Rita Mandle

For approval of Title and synopsis of Pre MD - 2021-22 Batch & Ph.D. 2019-2020 Batch. Meeting attended by Honorable IEC members on 26/09/22 to 28/09/22.

1. Dr. V.V. Doiphode Chairman of IEC 2. Dr. Nilesh Phule Principal, Member of IEC 3. Dr. Vandana Avhad Member Secretary 4. Dr. Yogini Kulkarni Member of IEC 5. Dr. Satish Puntambekar Member of IEC. 6. Dr. Dhananjay Mhasade Member of IEC 7. Mr. Arun Gujar Member of IEC 8. Dr. Pallavi Jamadagni Member of IEC 9. Dr. Pranita Joshi-Deshmukh Research Coordinator 10. Dr. Preetam Itnar Minute Writing Fellow

 Dr. S. M. Sathye, Dr. Huparikar, Dr. Gurav could not attend the meeting due to personal reason.

Minute Writing Fellow

Welcome note by Vice Principal Dr. Kavita Deshmukh.

Principal
M. A. M's, Sumatibhai Shah
Ayurved Mahavidyalaya,
Hadapsar, Pune- 411 028.

- Suggestions given by Honourable IEC members :
- Common Suggestion:
- Follow Vancouver style for references.
- Review of literature- Sequence should be latest to old.
- Remove word 'title' from text box on cover page.
- · Title should be in sentence case.
- Botanical names to be written in scientific manner as follows:
 - Genus name should start with Capital letter.
 - b. Species name should start with small letter.
 - c. Genus & Species name should be in italics & underlined.
 - d. Scientist name should be written at the end & should not be in Italics.
- Academic year 2021-2022.
- · Follow the suggestion given by Dr. S.M. Sathe.

		SAMHITA SIDDHANT DEPARTMENT	
Sr. No.	Name of the Student	Queries	
1.	Dr. Sneha Chitali	 Mention standardization and SOP finished product as per API, AFI. Primary objective - efficacy, Add assessable objective as Mandal size etc. Other in secondary objective. Include ADE in objective and also mention in CRF. Modify information sheet in simple language of local person. 	
2.	Dr. Rohini Dhokane	Spell check IEC. Mention only पटोल Remove Botanical name for controversy	
3.	Dr. Seema Sathe	Remove title word from text box. Objectives should be time bound, mention time clearly. Page no. 28 ' Nisha Kale' translate exactly. Remove secondary objectives. Add Vatarakta chikitsa siddhant in detail.	
4.	Dr. Utkarsha Kulkarni	Study text book of psychology for questionnaire on intelligence. Page no. 50 , Remove 'अरपाई'. Remove Random sampling. Modify statistical test for correlation. Remove hypothesis.	
5.	Dr. Shubhangi Meshram		

r. No.	Name of the Student	Queries
H. IVOS	ryanie of the beddene	
	Dr. Chetan Khetmalis	 Write sequence in review of literature latest to old.
2 1	art. Constant throaten	 Sampling method - Remove Random sampling.
6.		 Operational definition - Add newly exercise.
		 Remove hypothesis as it is an observational study.
		 Remove 'title' word from text book.
- 4		 Remove hypothesis as it is an observational study.
- 1		 Questionnaire - Remove ' Song गाणे' add 'Omkar' or other
7.	Dr. Nikita Sheleke	word.
		 Reframe Questions make it more specific.
		 Modify patient information sheet to be simple.
		 Modify Statistical test as per study.
		Title - Remove' Non randomized' mention 'Rakta Dhatu '
- 1		instead of 'RaktaSarta'.
		 Mention wash out period.
		 Replace 'Rakta Sarta' as 'Rakta Dhatu'.
		 Objective - Modify and reframe and all should include in
		CRF.
		 Mention drug standardization and SOP in material, method
8.	Dr. Hareshwar Shirsat	as per API, AFI. Remove it from objectives.
WE:		 Explain Hb method technique/instrument.
		 Spell check - will be.
		 Exclusion- in between study if patient not willing or
		palatability issue, patient not taken medicine.
		 Modify - Objective & Subjective criteria.
		 Attach patient information sheet.
		 Modify - Statistical test as per study.
		 Take prior permission from IT company.
	Dr. Pooja Vaidya	 Remove hypothesis.
9.		 Page no. 23, mention & clarify अतिष्रमाणात मलप्रवृती.
0000		Reform questions.
		Marathi language modification.
		Remove hypothesis.
10.	Dr. Sonutai Shinde	exclusion criteria - congenital anamolies.
4.1/-		 Mention, clarify vyana vayu, karma in simple language.
		KAYACHIKITSA DEPARTMENT
r. No.	Name of the Student	Queries
		Title - Remove w.s.r.
11.	Dr. Vaibhav Badgujar	COPMention proper instrument name, model name.

		Mention female attendent will be present. Remove sponsor Page no. 45. Spell check, Diabetic etc. Capital. Modify- Primary research question - only mention duration, other should remove. Hypothesis - Mention as 'difference' 'not more'. Title - Compare the efficacy Exclude Pitta Prakruti. Page no. 35. Modify the synopsis if not then change the topic and represent. Justify properly How study is different from previous one Justify how will you monitor drug prepration and administration.	
12.	Dr. Akshada Matey	 Add these details in patient information form. Mention duration clearly in objectives add this in primary object. Modify previous work done latest to old. Descyphylline detail from British Pharmacopia. Mention method of authentication and standardization as per API/AFI. 	
13.	Dr. Kalyani Thote :	Add information sheet. Spell check, Marathi language modification. Modify, correct all inform consent documents. Mention specific modern drug treatment.	
14.	Dr. Dhanashree Thube	 Title- "Randomized control clinical study to evaluate both drug with control drug in Dadru. Modify title as per above. Follow reference article. Modify all other points as per that article. Keep age limit 40-60 years. Primary Objective - To study the efficacy. Modify Research Question - as equal effect. Follow common suggestion. 	
15.	Dr. Mrudula Katake	Title- Remove w.s.r. to urinary track infection, specify only Pittaj Mootrakruchha. Include - Culture sensitivity test if treatment not effective to find specificity. Exclusion criteria - Mention as known case of DM, TB etc. Research question - Is their any difference in effcacy of Gue Compare with Gokshur for 7 days in the management of pittaj mootrakrucha. Include shlok in synopsis 지대 Ference.	
16.	Dr. Lubna Khan	Add duration in research question. Mention time exact duration in objectives. Validate subjective criteria scale. Reframe statistical test. PANCHAKARMA DEPARTMENT	

M: A. M's, Sumatibhal Shah Ayurved Mahavidyalaya,

Sr. No.	Name of the Student	Queries	
		Primary research question "is any effect of Nagkeshar churna add on effect with Panchprasutik basti." Mention interpretation of previous workdone. Mention review of literature in detail.	
17.	Dr. Tejal Patil	Consent form - add detail about photo used, prior permission to use photos specify it. Spell check, grammar check. Mention - method of randomization in detail. In Rugna mahiti patrak - mention follow up days properly. Exclusion criteria - Remove अनेह no need to mention. Follow common suggestion.	
18.	Dr. Mohini Nagre	Mention- Method of Randimization in detail (allogation - NA). Mention Vegetarian diet for sansarjan karma after 5th and also same diet for Non-vegeterian. Follow common suggestion. Exclusion criteria - Mention hypertension fracture. Remove अचेइ from exclusion criteria.	
19.	Dr. Bhagyashree Barse	 Title- "Comparative clinical study to evaluate add on effect of Nabhibasti with shaman sneh in the management of Amlapitta. Mention follow up days in Rugna mahiti patrak 0 - 7- 15. Follow common suggestion. Page no. 27 check list, mention other investigation means what. Trial - Open/labelled. Mention in detail emergency tray, medicine with dose and criteria. Follow common suggestion. 	
20.	Dr. Jayashree Waghmare		
21.	Dr. Prerna Gadhe	Title - Same as Bhagyashree " comparative clinical study to evaluate add on effect of Use "egg गावरान" instead of poultry egg. exclusion - if patient (Vegeterian) not willing for egg treatment. Follow common suggestion. SHALAKYATANTRA DEPARTMENT	
Sr. No.	Name of the Student	Queries	
22.	Dr. Dipali Katwate	Try to find out % of ingredient in kwath. Follow common suggestion.	
23.	Dr. Gauri Badhe	Remove w.s.r. to . Mention only पटोच (No species name). Follow common suggestion.	
24.	Dr. Shivraj Vansure	Add reference S.L. Sathye on myopia.	

Principal

M. A. M's, Sumatibhai Shah

Ayurved Mahavidyalaya,

Hadapsar, Puna, 411 020

		Follow common suggestion.	
25.	Dr. Pooja Chavan	Exclusion criteria - Remove Murchita patient and other term known case of anemia. Add cohexidine comparative in object. Primary hypothesis is only one "To study efficacy of". Use only one term either Mukhpak or stomatitis as per suggestion can used both. Follow common suggestion.	
26.	Dr. Sharayu Gawande	Remove w.s.r. to . Mention ingradient as equal quantity. Follow common suggestion.	
27.	Dr. Neha Marathe	No suggestion. Follow common suggestion.	
		SHALYATANTRA DEPARTMENT	
Sr. No.	Name of the Student	Queries	
28.	Dr. Akshay Sirsat :	 Mention time in objective in the management of parikartika for 7 days. Secondary objective - Add ADE and then add ADE in CRF. Reform Marathi consent. Add lady attendent. Add efficacy ratio of रातधीत धृत then find sample size. Use software "Winpepi", "Epiinfo". Follow common suggestion. 	
29.	Dr. Tamanna Sharma	 Attach consent form + HIV consent. Mention proper useful part of medicinal plant. Justification of Arkapushpa. Allocation consent- Mention procedure of blinding etc. if not NA. Follow common suggestion 	
30.	Dr. Dipak Patil	Attach HIV consent. Mention lady attendant. Follow common suggestion.	
31.	Dr. Unnati Chaudhari	Add reference of Kokhur proven drug. Add reference of Tulasi Beej for মুরকুমভ. Mention appropriate statistical test. Follow common suggestion.	
32.	Dr. Devyani Chalakh	Mention proper SOP for ointment procedure. Add HIV consent. Do pilot study for ointment preparation. Follow common suggestion. Decrease sample size by calculation.	
33.	Dr. Shivam Khatri	 Page no. 21 Medico Renal disease mention, proper term "Medicinal 	
		 Follow common suggestion. 	
		SWASTHAVRITTA DEPARTMENT	

Principal

M. A. M's, Sumatibhal Shah

Ayurved Mahavidyalaya,

34.	Dr. Priyanka Bhange	Remove w.s.r. from title. Time bound + objective outcome body weight. Page no. 29 (Remove परीक्षेचे प्रयोजन). Take prior permission of school for study. Take sample - Same age group of 6-7th standard. Page no. 25 - Mention proper term for जार्च.	
35.	Dr. Pranita Gatlewar	 Take control group if possible. Follow common suggestion. Remove परीक्षेषे प्रयोजन. Questionnaire in Marathi, exclude mobile used anger patient. Change - Sampling method only purposive sampling. Title- Remove - Randomized sample. Check statistical test apply appropriate test. Add reference for जन्म परिचण. Follow common suggestion. 	
36.	Dr. Vaishnavi Kulkarni	 Page no. 37- Remove आधारसंहिता सदस्य. 	
37.	Dr. Kajal Morande	No suggestion. Use one term either T2DM or Prameha. Mostly use Prameha term with BSL, HbA1C for diagnostic criteria. Tall.	
38.	Dr. Nishigandha Patil	Follow common suggestion. No suggestion.	
39.	Dr. Asawari Upadhye	 Add objective parameter - Neck movement, degree of pain. Exclusion- Sinussitis. Include pilot study and mention that study sample is base on pilot study. Patient should be of only neck pain no duration. Remove duration of 6 months. Follow common suggestion. 	
	STRE	EROG PRASUTI TANTRA DEPARTMENT	
Sr. No.	Name of the Student	Queries	
40.	Dr. Misba Chaudhary	 Mention detailed procedure of pessary use in patient information sheet. Objective - mention time duration. Mention objective parameter for evaluation of disease on the basis of strav/kandu. Research question - whether treatment is effective after 7 days. Remove- Ayurvedic terminological definition from operational definition. Modify - Statistical analysis. 	
41.	Dr. Shaheen Shaikh	 Title - "Comparative study of two different sevan karma for mucosa and skin in healing process of Episiotermy as per REEDA scale". Hypothesis and research question modify. Secondary objective- Remove NA, add cosmetical purpose in secondary objectives. 	

M. A. M's, Sumatibhai Shah

		Use sentence case for Research question and objectives. Mention matra of dhawan as 0-5 instead of 500ml.
42.	Dr. Pranali Shelot	 Mention what kind of drug allergy? in patient information sheet.
		 Mention adverse effects will be noted in CRF.
		Modify statistical test.
43.	Dr. Aashika Prajapati	 Review previous work done thoroughly. Mention that patient will be sensitized regarding use of scale in patient information sheet. Remove secondary objectives.
		 Don't use 'etc.' in exclusion criteria.
5.9697	Dr. Prachi Pardeshi	Why DM is excluded?
44.	H11.1.1.8.110.1.31.31.31.31.31.31.31.31.31.31.31.31.3	 Rewrite information consent.
		 Follow common suggestion.
		Application of drug - clockwise.
	100 100 100 November 20 4500	. Inclusion criteria - Remove 4 months & add in exclusion
45.	Dr. Prajakta Pardeshi	- criteria,
		 Mention duration of 4 months in objectives.
		Follow common suggestion.
		AGADTANTRA DEPARTMENT
Sr. No.	Name of the Student	Queries
46.	Dr. Chiranka Ghorpade	 Modify study. Case control study - Two groups - Arsh and non arsh patient having Viruddha Aahar Sevan.
		 Modify synopsis as per above
		 To perform Acute toxicological study use two species 1.
47.	Dr. Shweta Khanapure	Mice, 2. Rat perform in both species.
2.6.		 Justification for 300 mg. dose as starting dise.
		 Add previous studies then modify as per guideline OECD.
48.	Dr. Shivani Kotmire	Same as Shweta Khanapure.
49.	Dr. Saylee Nikam	Same as Shweta Khanapure.
50.	Dr. Nilam Sonwane	Same as Shweta Khanapure.
		Clear the concept of MNC and Consumer court.
		 Mention latest 2022 act.
	Dr. Pratiksha Gujar	 Reform categories of neglegence.
51.	AMERICAN CONTRACTOR	 Modify the study.
		 Read book- Y.V. Singh.
		 Study area/location include state court.
		RASASHASTRA DEPARTMENT
Sr. No.	Name of the Student	Queries

M. A. M's, Sumatibhai Shah Ayurved Mahavidyalaya,

		pharmacutical. Mention in detail Agar media and technique. Include Bacterial identification method for authentication of bacteria. Find exact bacteria and then use that bacteria.	
		for study. Follow common suggestion.	
-	Dr. Sarthaki Deshpande	Write PH properly.	
53.	Wisserthande	 Mention long form of all short term XRD, PSD etc. Follow common suggestion. 	
54.	Dr. Neha Khade	 Research question - Use "finding" instead of "standard". Include 'time period required' for each processing. Mention clearly that all phytochemical test before and after procedure if possible add more essential phytochemical test. Follow common suggestion. 	
55.	Dr. Meenal Dhaware	Mention all test method clearly, reducing sugar finding test etc. Mention table of useful part of medicinal plant. Follow common suggestion. Primary objective - add 'to observe' instead of 'to conduct'.	
56.	Dr. Varsha Pawar	Mention method contimicrobial activity clearly in detail. Do antimicrobial activity of both Kwath and Siddha Gruta. Follow common suggestion. Include Bacterial identification method for authentication of bacteria. Find out exact bacteria and then use it for study. Mention all charateristics of microbes.	
57.	Dr. Mangesh Shinde	 Include all bacterial and fungal identification method for authentication of microbes. Mention characteristic of all bacterial and fungal. Do antimicrobial, antifungal activity of both Kwath and Siddha Gruta. Follow common suggestion. 	
		DRAVYAGUNA DEPARTMENT	
Sr. No.	Name of the Student	Queries	
58.	Dr. Asmita Baraskar	 Anti- Diabetic Capital. Remove Secondary Research Question. Mention- clearly for gene expression, Random Sampling. Mention animal weight, try to keep weight 200-250gm. Modify Reference style, follow Vancouver style. Try to follow Nicotinimide STZ model. 	
59.	Dr. Pratima Dolas	All suggestions like Dr. Asmita Baraskar.	
60.	Dr. Vishakha Kadam	All suggestions like Dr. Asmita Baraskar. Oppy	

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61.	Dr. Rajeshri Khedekar	All suggestions like Dr. Asmita Baraskar.	
62.	Dr. Pooja Sanvatsarkar	All suggestions like Dr. Asmita Baraskar.	
		ROGNIDAN DEPARTMENT	
63,	Dr. Pratik Jadhav	Remove hypothesis. Questionnaire to be validated.	
64.	Dr. Rajnandini Deshmukh	Questionnaire should be validated.	
65.	Dr. Rutuja Jadhao	Remove hypothesis. Validate questionnaire.	
66.	Dr. Ankeeta Dahiwale	 Page no. 9 - Remove modern terms. Page no. 13- add including both gender. 	
67.	Dr. Radha Khaddakar	 Mention clearly relation or correlation and then modify test. (Statistical test). Primary Research Question - Remove significant, only mention relation. 	
		Ph. D. DEPARTMENT	
Sr. No.	Name of the Student	Queries	
68.	Dr. Ritesh Damale	 Modify & add on information sheet as per ICMR. Add Marathi information sheet. Page no. 18, Remove sponsor. Modify written consent. 	
69.	Dr. Sushrut Deshpande	 Try to do all lab investigation at one lab (Same lab.) No suggestion. 	
70.	Dr. Trupti Gawade	 Mention - inform consent form. Mention- Yonipichu, consent form as only consent form. Mention- Pharmacovigilance, ADR information. Mention Inform to IEC (both) within 24 hrs. 	
71.	Dr. Yogesh Narkhede	 Mention dose properly mg/kg. No other suggestion. 	
72.	Dr. Poonam Deshmukh	 Mention - Cadaver study sample. Modification required. Mention three different research questions for 3 steps. Hypothesis only applicable to clinical study. Consent form, three point, remove Pl. Page no. 28 - spell check. Add Marathi information sheet. Attach HIV consent. Check spellings. 	

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- SOP- Mention proper instruments and position of instruments.
- Exclusive Remove patient of age, Remove non cooperative.

Member secretary

Member Secretary , MAH's, 8.S.A.M.

& Ayurved Hospital Sans Gurull Arogya Kendra Madapsar, Puna



Chairman Institutional Ethics Committee SSAM, Hadapsar, Pune

MAM's, S.S.A.M.

8 Ayunved Hospitat Sace Guruji Arogya Kendra Hadapsar, Pune.

True Gopy

- Klov

Principal
M. A. M's, Sumatibhal Shah
Ayurved Mahavidyalaya,
Hadapsar, Pune- 411 028.

INSTITUTIONAL ETHICS COMMITTEE

Maharashtra Arogya Mandal's Sumatibhai Shah Ayurved Mahavidyalaya and

Ayurved Hospital – Sane Guruji Arogya Kendra Malwadi, Hadapsar, Pune – 411 028.

Phone No.:- +91-20-29522503, +91-20-29522504 Email: ssayu@rediffmail.com

Minutes

36th Meeting of Institutional Ethics Committee

Date :- 28/08/2023 to 30/08/2023.

Time: 10.00 am To 5.00 pm Venue: SSAM, Hall No. 7.

For approval of Title and synopsis of Pre MD - 2022-23Batch.

Meeting attended by Honorable IEC members on 28/08/23 to 30/08/23.

1.	Dr. V.V. Doiphode	Chairman of IEC
2.	Dr. Ramesh Ujwale	Member Secretary
3.	Dr. S. M. Sathye	Member of IEC
4.	Dr. Rajendra Huparikar	Member of IEC
5.	Dr. Yogini Kulkarni	Member of IEC
6.	Dr. Satish Puntambekar	Member of IEC
7.	Dr. A.M. Gurav	Member of IEC
8.	Dr. Dhananjay Mhasade	Member of IEC
9.	Mr. Sanjay Maniyar	Member of IEC
10	Dr. Pallavi Jamadagni	Member of IEC
11	Dr. Pranita Joshi-Deshmukh	Ex-officio, PARAS
12	Dr. Rita Mandle	Minute Writing Fellow

Welcome note by Vice Principal Dr. Kavita Deshmukh.

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- · Suggestions given by Honorable IEC members:
- Common Suggestions:
- Tittle not in upper case, write in sentence case.
- Referencing style Vancouver style.
- · Font Calibri -12.
- Do not use short term e.g. W.S.R.
- Drug authentication and standardization of drug as per API and should prepare herbarium of each drug.
- Write proper SOP of drug preparation and standardization of finished product as per AFI.
- For Clinical studies- Mention toxicological studies of every medicinal plant with proper reference from peer review journal and also classical references.
- Botanical name (Italic or underline) species and genus name should be italic, scientist name

 non italic (e.g. Rubia cordifolia Linn.)
- Sample size calculation for comparative study use WINPEPI sample size calculator software.
- For control study mention control group, drug in research question, hypothesis and objectives.
- Mention study duration in research question, hypothesis and objectives.
- Consent form -

Age	Parent Consent required
0 - 12 yr	One
12 - 18 yr	Two
Above 18 yr	No parent consent

- Statistical test mention statistical test chart as per qualitative, quantitative data.
- Modify Gantt chart up to Dec 2025.
- Objectives should be SMART and time bound.
- Validate questionnaire
- Information sheet should be in question- answer format, include sign and left hand thumb
 impression of patient.
- Previous work done should be in chronological order.

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	SANSKRIT SAMHITA SIDDHANT DEPARTMENT		
	Name of the Student	Queries	
1.	Dr. Priyanka Bihade	 Page no. 16 -add list of Hetu. Objectives should be SMART in the format of primary & secondary objectives. Mention prevalence properly with year and proper reference. Mention Diagnostic criteria for Palitya. Mention study design -prospective study or retrospective study. Also include extra hetu other than Ayurveda. Follow common suggestions. 	
2.	Dr. Vaishnavi Jawalekar	 Add critical/comprehensive study instead of analysis. No hypothesis to observation study. Keep primary objective and add nidan. Remove secondary objective, if study of chikitsa included then add as secondary objective. 15 references must. Follow common suggestions. 	
3.	Dr. Nivedita Mane	 Add critical/comprehensive study instead of analysis. No hypothesis to observation study. Keep primary objective and add Adhyaya number with reference Remove secondary objective, if study of chikitsa included then add as secondary objective. 15 references must. Follow common suggestions. 	
4,	Dr. Mahesh Kulkarni	 Information sheet - Use vernacular language for Pandu. Title- Mention cross sectional study. Mention-"to find relation" instead of "to access". Modify objectives - Objective should be SMART. Mention specific name of Samhita for literature study. List of Lakshan and specify minimum number of symptoms. Remove 'Hadapsar'. Sampling method - purposive sampling. Check questions and order of question numbers. Follow common suggestions. 	
5,	Dr. Aditi Mahajan	Add Research question. Mention Takrakalpa at every point. Title should be more descriptive. Mention study in objectives properly. M.A. M's, Sumatibha Ayurved Mahavidy. Ayurved Mahavidy.	

- · Detail objectives.
- Follow common suggestions.

KRIYA SHARIR DEPARTMENT

. No.	Name of the Student	Queries
6.	Dr. Nikhil Bhavke	 Add duration- contact time of Agni Seven. Questionnaire- Reframe in proper language & validate. Include how much heat contact percentage or any measurable heat contact. Follow common suggestions for all PG students.
7.	Dr. Sneha Deokar	 Add प्रकृती आणि सारत्व. Add reference of आर्तवचक्र. Previous work done references in Vancouver style. No hypothesis- write NA. Withdrawal criteria- remove not willing. Add questionnaire. Concise secondary objective. Follow common suggestions for all PG students.
8.	Dr. Rajkumar Jaiswal	 Reform research question & hypothesis. Follow common suggestions for all PG students.
9.	Dr. Pooja Kadam	 Page no. 37, remove word "cyst". Write operational definition of jewelers. Follow common suggestions for all PG students.
10.	Dr. Pooja Munde	 Do not use short form. Validate questionnaire. Revise objectives. Page no. 33- change question no. 6. Follow common suggestions for all PG students.
11.	Dr. Mrunali Bhoyar	Authentify questionnaire, Follow common suggestions for all PG students KAYACHIKITSA DEPARTMENT

Sr. No.	Name of the Student	Queries
12.	Dr. Sneha Chavan TRUE COPY PRINCIPAL MA Ms. Sumatibhai Sh	 Title - Remove w.s.r. Add - Add on effect. Age group - above 18 years, 19 - 60 years. Mention age group properly. Mention Objective criteria properly. Mention line of treatment clearly whether both medicines at a time or after interval. Interval time specify properly. Mention proper inclusion criteria for Rajyakshma or T.B. Use common term as per title either Rajyakshma or T.B. and then modify inclusive criteria and specify it. Mention Ayurvedic lakshan of Rajyakshma.

PRINCIPAL MA Ms, Sumatibhai Shah Ayurved Mahavidyalaya, Hadapsar, Pune-411028

	Page no. 5- chemotherapy - remove it. Remove word adjuvant, use -add on word.
	Modify study rationale, specify it as per ग्रेथोक्त reference. Page no. 23, investigation criteria, mention ESR method properly with references. Mention Sputum examination properly (Sample collection method and all). Mention X-ray findings, time before- after, view PA specify it. Follow common suggestions for all PG students.
Dr. Revati Dhawadkar	 Revise title - Randomise control clinical trial to evaluate Mention time duration in research question then correct alternate hypothesis as per research question Mention- Gender M/F/ both. Mention sign, symptoms of hypothyroidism in inclusion criteria. Revise- Primary objective and secondary objective, should be time bound. Page no. 15 Ayurvedic word in Italic, mention proper collection of drug, mention specifically Vijaya as Haritaki. Page no. 22 not required Pathyapathya. Follow common suggestions for all PG students.
Dr. Jyoti Jaiswal	 Title- Mention only one term either "पित्तज्वर" or Dengue, try for dengue. Modify inclusion and exclusion criteria. Regarding platelet count, lgG, lgM. Inclusion criteria - Mention platelet count 30000 to 100000 with reference. Page no. 21, Dose form of Drakshphal (Remove term भरड पूर्ण). Exclusion criteria page no. 13 known case of HIV.
	 IPD patients compulsory, No OPD patient. Follow up daily. Modify sample size as per Dengue prevalence. Follow common suggestions for all PG students.
Dr. Vidya Jatti TRUE COPY	 Revise title- 'Randomized control clinical trial to evaluate add on effect of Tagar vati in the management
	Dr. Jyoti Jaiswal Dr. Vidya Jatti TRUE COPY

W		No.
		 required so remove from objectives. Mention known side effects of beta blocker and in objective mention that-will see add on effect of tagar vati on that. Mention in selection criteria as patients with raised I with beta blocker treatment will include. Exclusion criteria- mention in term as Known case on Follow common suggestions for all PG students. Page no 23 remove drug addiction.
1	6. Dr. Nikhil Patil	Exclusion criteria- mention in term as Known case of Mention -SOP for kwath preparation, patient will get drug in powder form and will give SOP for kwath preparation. Change Aushadh sevan Kal as Apana kal. Follow common suggestions for all PG students.
17.	Dr. Shruti Shelke	Sign symptoms- use word हरीद्रपीत in proper term. Mention properly as per ग्रंथीवत reference. Mention reference for 15 days treatment. Modify drug formulation material - फलिबकादीचुर्ण SOP for kwatha proportion for patient. Page no. 16 operational definition for 'विविधान कामान लादि' modify it. Follow common suggestions of the state of
. No.	Name of the Student	PANCHAKARMA DEPARTMENT Queries
18.	Dr. Dandavate Padmashree	Mention list of lakshana of vyadhi with reference Pg no 23- remove differential diagnosis. Follow common suggestion for all PG students.
19.	Dr. Sumit Dhengale TRUE COPY PRINCIPAL M.A. M's, Sumatibhai Shah Ayurved Mahavidyalaya,	 Mention list of lakshana of vyadhi with reference. Mention Vatrakta chikitsa sutra with reference. Mention dose of Trivrittlehâ. Remove pharma company name. Justify virechanaanarh – why required in study. Mention snehayuktavirechana, proper drug preparation and include Charak chikitsa sutra with reference. Specify drop out criteria. Mention duration of karma starting from snehapan to sansarjan karma.

19		Follow common suggestion for all PG students.	
20.	Dr. Ankita Nikantha	 Mention list of lakshana of vyadhi with reference Mention and elaborate Goniometer measuring parameter range. Mention Goniometer scale range for inclusion criteria. Follow common suggestion for all PG students. 	
21.	Dr. Srujali Gat	 Mention list of lakshana of vyadhi with reference. Mention dose 8 bindu as - 2.5 ml. Follow common suggestion for all PG students. 	
22.	Dr. Pratiksha Yadav	 Mention list of lakshana of vyadhi with reference. Mention dose and sevankal. Follow common suggestion for all PG students. 	
23.	Dr. Bhagyashri Kale	 Mention list of lakshana of vyadhi with reference Modify title. Follow common suggestion for all PG students. 	
	S	SHALAKYATANTRA DEPARTMENT	
r. No.	Name of the Student	Queries	
	 Objectives - Primary objective should be comparative, Secondary objective - other than primary objectives. Modify Gantt chart with year wise. 22-23, 23-24 Authentication, standardization and SOP of drug & formulation. 		
24.	• Mention microb	oial (contamination) load examination. English terminology in information sheet. Use full form in hypothesis. Revise sample size using WINPEPI software. Mention study duration in hypothesis and objectives. Add authentication & standardization, SOP of drug as per API & AFI. Exclusion criteria - remove त्तीयपटलगतहृष्टी. Mention why excluded diabetic & hypertensive patients. Inclusion criteria- mention cardinal symptoms for selection. Mention 0th day assessment.	
25.	Dr. Supriya Divekar	• Follow common suggestions for all PG students. • Give proper reference for ধ্রীরেরা নিল. (Peer review). • Revise hypothesis and research question. Include standard drug in title, research question, hypothesis and objectives. Process of randomization.	

		 Mention question-whether there is effect or not. Mention Tension headache description in introduction. Add नस्य अर्ह, नस्य अनर्ह check list, नस्य consent form. Revise statistical test. Use Manwhitney U test. Follow common suggestions for all PG students.
26.	Dr. Yogesh Narute	Remove w.s.r. Apthya - Remove tobacco. Revise alternate hypothesis. Page no. 48, mention proper translation of term fornix. Withdrawal criteria - remove blur vision. Mention - এই, এনই consent. Exclusion criteria - remove "patient not ready." Follow common suggestions for all PG students.
27.	Dr. Pallavi Nimalkar:	Remove w. r. t. Proper range of fever. Mention term धारण as चघळणे. Mention study duration in research question, hypothesis and objectives. Mention peer review journal reference for मृदविकादी, if not published then change standard drug. Follow common suggestions for all PG students.
28.	Dr. Karishma Pote	 Page no. 13, withdrawal criteria- remove blurring of vision extreme cases. Follow common suggestions for all PG students.
29.	Dr. Prachi Sartale	Remove w.s.r., use only one term modern or Ayurvect Check standard drug. Mention microbial (contamination) load examination Follow common suggestions for all PG students.

SHALYATANTRA DEPARTMENT

Sr. No.	Name of the Student	Queries
		 Page no. 12, remove second point of Eusol. Mention as disinfectant.
		 Modify research question & hypothesis. Mention study duration (time).
30.	Dr. Sumit Gaikwad	 Remove secondary objectives, can modify primary objective.
		 Sample size calculation by WINPEPI software.
		 Page no. 26, 27 informed consent, sign & left hand thumb impression.
		 Follow common suggestions for all PG students.
	TRUE CO	PY Change study methodology -Group with Diclophenac
31.	Dr. Sneha Auti	& group with agnikarma.
	PRINOPA	Add information sheet.

11		
1		Consent form in both languages.
-		Follow common suggestions for all PG students.
32.	Dr. Niranjan Dusane	 Mention "Shatavaryadi Kalp" name as "Shatawari". Add study duration in research question, objective and hypothesis. Mention only null hypothesis and alternate hypothesis. Mention proper statistical test as per objective criteria. Follow common suggestions for all PG students.
33.	Dr. Sagar Patil	 Must have daily attendance of patient. Add study duration in research question, objective and hypothesis. Mention only null hypothesis and alternate hypothesis. Mention proper statistical test as per objective criteria. Follow common suggestions for all PG students.
	S	WASTHAVRITTA DEPARTMENT
Sr. No.	Name of the Student	Queries
34.	Dr. Snehal Aher	 Single arm study of Lajasattu or group 1- antacid + lajasattu, group 2- only antacid. Follow common suggestions for all PG students.
35.	Dr. Vishal Devade	 Cross sectional study. Validate questionnaire. Sample size- those who are willing or Ayurved faculties 60 % prevalence. Remove मান্धन word. Add health status questionnaire if possible. Follow common suggestions for all PG students.
36.	Dr. Ashiya Goveri	 Title- Not all capital, in sentence case. Specify statistical test. Follow common suggestions for all PG students.
37.	Dr. Ankit Tapase	Title- Not all capital, in sentence case. Specify statistical test. Follow common suggestions for all PG students.
38.	Dr. Kiran Ilay	 Cross sectional analytical study or case control study for those which are studied previously. Information sheet - add patient sign. Statistical test mention properly. Follow common suggestions for all PG students.
39.	Dr. Sonal Tinaikar TRUE	Use term only menopausal. Write page number at lower side. Add study duration in research question and hypothesis. Prim. objective should be time bound. Statistical test mention properly. Modify Gantt chart.

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- Replace मैल as kilometer.
- Reconstruct questionnaire in simple language.
- Follow common suggestions for all PG students.

		G PRASUTI TANTRA DEPARTMENT
Sr. No.	Name of the Student	Queries
40.	Dr. Prachi Bari	 Spell check in primary research question. No hypothesis. Page no. 29- Mention ব্রবাहिक, अवैवाहिक as per MLC. Check this. Study design - observational study. Title- Observational study to find relation between etiological factor of শ্রম্থীপ in relation with IUGR. Statistical test- correlation test. Follow common suggestions for all PG students.
41.	Dr. Sonal Mugdiya	 Objective- Add time duration. Remove secondary objective, Keep last objective. Follow common suggestions for all PG students.
42.	Dr. Pooja Sawai :	 Rewrite Latin Name. Follow common suggestions for all PG students.
43.	Dr. Jigisha Tanna	 Try to keep one Research Question and one hypothesis simple objective. Page no. 13, Age 18-30 years. Follow common suggestions for all PG students.
44.	Dr. Priyanka Tekriwal	 Authentication & Standardization of every drug and finished product. Follow common suggestions for all PG students.
45.	Dr. Chaitrali Tikhole	 Revise- Statistical test as per Qualitative data No Paired "T" test. Follow common suggestions for all PG students.

		 Follow common suggestions for all PG students.
	A	GADTANTRA DEPARTMENT
Sr. No.	Name of the Student	Queries
46.	Dr. Bande Vishal	 Mention proper term Schedule E Revise statistical test (before after, interrelation, in between groups) Attach IAEC certificate. Follow common suggestion for all PG students.
47.	Dr. Bhujbal Nirmiteee	 Mention proper term Schedule E Revise statistical test (before after, interrelation, in between groups) Attach IAEC certificate. Follow common suggestion for all PG students.
48.	Dr. Patil Aniket	 Mention proper term Schedule E COPYRevise statistical test (before after, interrelation, in between groups) Attach IAEC certificate.

11	Constitution of the second	 Follow common suggestion for all PG students.
49.	Dr. Wale Manali	 Mention proper term Schedule E Revise statistical test (before after, interrelation, in between groups) Attach IAEC certificate. Follow common suggestion for all PG students.
50.	Dr. Poonam Gosavi	 Pg no 8 revise web references Revise study duration Mention Amikacin standards as per pharmacopeia and check reversible action of Amikacin. Prim. objective – to compare. Remove secondary objective. Follow common suggestion for all PG students.
51.	Dr. Ganesh Vakle	 Pg no 8 revise web references Revise study duration Mention Amikacin standards as per pharmacopeia and check reversible action of Amikacin. Prim. objective – to compare. Remove secondary objective. Follow common suggestion for all PG students
Sr. No.	Name of the Student	ASASHASTRA DEPARTMENT Queries
A2007-01-201	CALIFORNIA POPULA PARAMETER	
52.	Dr. Ankita Agarwal	Mention Null & alternate hypothesis. Include study duration in hypothesis, research question. Reference style - Vancouver style in sequence. Define objectives, should be time bound. Primary objectives- Mention after lepa (cream). Inclusion criteria - Remove willing point, include patient with সুত্তব্যক্তা in respective of gender/age. Exclusion - not Malignant - use term known case of Operational definition - keep only cream term. Page no. 23- remove where. Include grading scale in subjective parameter. Follow common suggestion for all PG students.
53.	Dr. Dhanashri Gore	 Objective- Pharmaceutical analytical parameter. Follow common suggestion for all PG students
54.	Dr. Shubham Mohite	 Title- Remove संधान करपना only use सुरा. No hypothesis- Write NA. Study design - observational study. Write SOP long form. Follow common suggestion for all PG students.
55.	Dr. Mugdha Phadake	Objective- To evaluate Pharmaceutical analytical parameter of Mention - methodology in review. Remove operational definition Mention procedure in details. PRINCIPAL

M.A. M's, Sumatibhai Shin Amurund Mahavidualava

56.	Dr. Sharayu Shinde	Follow common suggestion for all PG students. Objective- Pharmaceutical analytical parameter. Follow common suggestion for all PG students.
57.	Dr. Ajay Sonwane	Give reference of Ghrut oil preparation antimicrobial activity. Follow common suggestion for all PG students.
	DF	AVYAGUNA DEPARTMENT
Sr. No.	Name of the Student	Queries
58.	Dr. Sampada Bankar.	
59.	Dr. Pratiksha Biradar	 Common Suggestion for all. Sample size should be in Triplicates of 6 = 18 sample. Concern statistician for sample size. Observation – add External appearance - Leaf surface area (Apply formula for quantitative data). Add active principle finding by test (HPLC). Revise hypothesis & research question. Add flavonoid assay in Pharmacognostic study. Identification of plant, specimen voucher number compulsory. Follow common suggestions.
60,	Dr. Dhanashree Deshmukh	
61.	Dr. Poorva Joshi	
62.	Dr. Shreya Kalyankar	
63,	Dr. Rohini Kamble	
	R	OGNIDAN DEPARTMENT
	Common Suggestice Remove hypothesis. Validate Questionnaire. Information sheet in Questions work done not Study Design- Cross sections.	estion-Answer format. In table format.
64.	Dr. Mohit Bhosale	 Mention etiology factors of Charak only with references. Follow common suggestions for all PG students.
65.	Dr. Vinaya Pawar	 Mention list of all Mukh rog, Danta rog. Mention वाग्भट either अष्टांग संग्रह / अष्टांग हृदय. Revise- Primary objective. Follow common suggestions for all PG students.
66.	Dr. Tejashree Kupekar	 Mention - Diagnosed patients of मुत्राश्मरी confirm with दोषज मुत्राश्मरी. Page no. 33- Mention Ayurvedic Lakshanas and

PRINCIPAL

A. M's, Sumatibhai Shah

11		
1.		 then calculate sample size. Remove Aim, only mention primary objective. Follow common suggestions for all PG students.
67.	Dr. Neha Shende	Remove operational definitions. Page no. 9- mention lakshana in order. Follow common suggestions for all PG students.
68.	Dr. Sayali Shinde	Follow common suggestions for all PG students.
69.	Dr. Nishant Taralkar	 Revise Research question & objectives. Remove Aim. Follow common suggestions for all PG students.
		BALROG DEPARTMENT
Sr. No.	Name of the Student	Queries
70.	Dr. Asmita Chaudhari	 Group insurance Mention that pilot study done by prior permission of BORs Mention drug, scientific name and part used in chart format Modify consent form. Withdrawal criteria- mention that if missed two follow ups then will be Withdrawal. Modify inclusion criteria, mention & specify weight parameter (If wt 2.3kg mention included or excluded Remove parent point from exclusion criteria. SOP for massage treatment- detail methodology, hygiene, preparation etc. Prim. objective- mention comparative group coconut oil. Revise consent form as per age group. Follow common suggestion for all PG students.
71.	Dr. Vivek Chothe	 Group insurance. Inclusion criteria mention sign and symptoms of vyadhi. Pg. no. 22 mention separate list of vyadhi lakshana. Mention stambhana chikitsa reference for baby and old age person. Revise consent form as per age group. Follow common suggestion for all PG students.
72.	Dr. Sakshi Narsing	 Group insurance Remove pre-school age - use 3-6 yr Revise dose (1 gm/ day in two divided dose) Use full form of SBM revise consent form as per age group Follow common suggestion for all PG students.
73.	Dr. Mangal Patil	

		Daily follow up. Mention sign and symptoms of vyadhi Try to mention intervention parameter Revise consent form as per age group
74.	Dr. Rutuja Patil	 Group insurance. Mention separate list of vyadhi lakshana. Research question –include word efficacy. Include study duration in research question, hypothesis. Add cardinal signs of kaphaj kas. Correct word 'trial'. Remove calculations in seconds. Mention separate subjective and objective criteria. Revise consent form as per age group. Mention useful part of each drug. Sampling method- computer generated allocation random number use for study Simplify dose method, dose technique, use of dropper and fix dose for age group Follow common suggestion for all PG students.
75.	Dr. Nikhil Pawar	 Group insurance. Spell check of 'agni'. Attach calibration certificate. Mention krimi in hetu and also include stool examination to find out krimi. Mention control group drug in objectives. Try to use standard drug (Ascorbate). Mention clearly control trial or standard control trial and why? Remove etiology and sec objective. Use term for honey (Agmark honey) in anupana. Include study duration in research question, hypothesis. Follow common suggestion for all PG students.

Member secretary



MASV2

PRINCIPAL M.A. M's, Sumatibhai Shah Ayurved Mahavidyalaya, Hadapsar, Pune-411028

Chairman

Institutional Ethics Committee SSAM, Hadapsar, Pune

Chairman MAM's, S.S.A.M. & Ayurved Hospital Sane Guruji Arogya Kendra