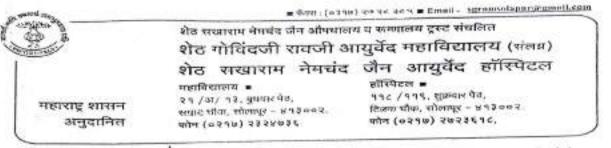
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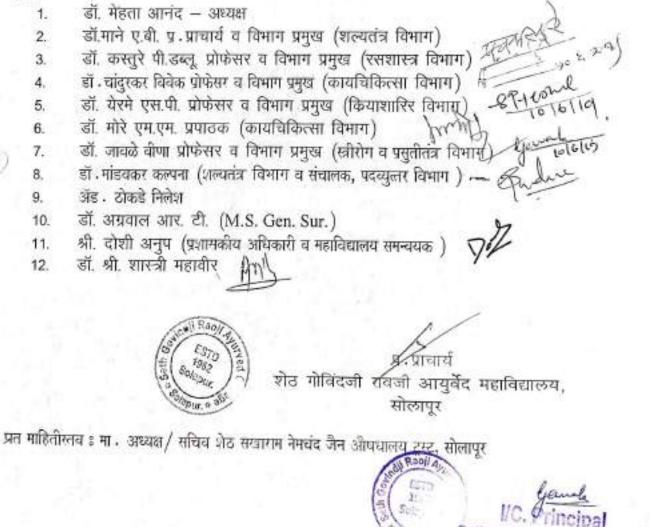
### कार्यालयीन आदेश

आपणांस या पत्राद्वारे आदेश देण्यात येतो की, आपण सन 2019-20 पासून पुढील आदेश येईपर्यत इथिकल समिती सदस्य (Ethical Committee) म्हणून काम पहावे. तसेच वर्षभरात किमान चार किंवा त्यापेक्षा जाग्त वैठकी आयोजित कराव्यात व त्या वैठकीचा अहवाल इथिकल समितीच्या रजिस्टर मध्ये वेळोवेळी लिहावा. शैक्षणिक वर्षभरात होणा-या पदवी, पदव्युत्तर व पीएचडी विद्यार्थ्यांचे शोधप्रवंधावावतीत सर्व नियोजन व इतर संवंधीत सर्व कामे जवावदारीने पार पाडावीत व तसा अहवाल समिती रजिस्टर मध्ये लिहून वेळोवेळी प्राचार्य कार्यालयास सादर करावा.

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Partian: 27/04/2020

## कार्यालयीन आदेश

आपणास या पत्राव्दारे आदेश देण्यात येतो की, Indian Council of Medical Research 2017 यांच्या National Ethical Guideline for Biomedical and Health Research involving Human Participants नुसार आपण सन २०२०-२१ पासून पुढिल आदेश येईपर्यंत इथिकल समिती सदस्य (Ethical Committee) म्हणून काम पहाचे. तसेच वर्षभरात किमान चार किंवा ल्यापेक्षा जास्त समा आयोजित कराव्यात व ल्या सभांचा अहवाल इथिकल समितीच्या रजिस्टर मध्ये वेळोवेळी लिहावा.तसेच समितीचे दस्तऐवज यांचे व्यवस्थित नियोजन करावे. शैक्षणिक वर्षभरात होणा-या पदवी, पदव्युत्तर व पीएचडी विद्यार्थ्यांचे शोधप्रवंधावावतीत सर्व नियोजन व इतर संबंधीत सर्व कामे जवावदारीने पार पाडावीत व तसा अहवाल समिती रजिस्टर मध्ये लिहून वेळोवेळी प्राचार्य कार्यालयास सावर करावा.

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1.	1.Dr. Anand H. Mehta (M.D. Kaumarbhritya)	Chairperson
2.	<ol> <li>Dr. Mukund Maruti More Associate Professor, Kayachikitsa Dept.</li> </ol>	Member Secretary
3.	<ol> <li>Dr. Pradeep W. Kasture Professor, Rasashastra &amp; B. K. Dept.</li> </ol>	Basic Medical Scientist
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4.	<ol> <li>Dr. Vivek S. Chadurkar Professor, Kayachikitsa Dept.</li> </ol>	Clinicians
	<ol> <li>Dr. Veena G. Jawale Professor, Prasutitantra &amp; Streerog Dept.</li> </ol>	Clinicians
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	<ol> <li>Dr. Pramod P. Ingale Assistant Professor, Kaumarbhritya Dept.</li> </ol>	Clinicians
5.	9. Adv. Prashant Mhetras	Legal Expert
6.	10. Dr. Mahaveer Shastri (Ph.D.) / Mr. Anoop A. Doshi	Philosopher / Ethicist
7.	11. Mr. Parag Shah / Mrs. Vidya Dhole	Lay Person



पान्मरी

्र प्राचाय शेठ गोविंदजी रावजी आयुर्वेद महाविद्यालय, सोलापूर

प्रत माहितीस्तव ३ मा . अध्यक्ष / सचिव शेठ सखाराम नेमचंद जैन औषधालय ट्रस्ट, सोलापूर

Racil ESTD 1962 ioleput. Seth Govindiji Raoji Ayurved plapat Mahavidyalaya, Solapur.

शेठ सखाशम नेगसंद जेन अप्रेषधालय व कम्णालय ट्रस्ट संसलित शेठ गोविंदजी रावजी आयूर्वेद महाविद्यालय (संलग्न) शेठ सखाराम नेमचंद जैन आयूर्वेद हॉस्पिटल कोषिपेटल -महाविधालय 🔳 ११८ / १९९, भूझवार पेछ, 24 /at/ 13, gume 40, महाराष्ट्र शासन हिल्ला चौधा, परितापुर - ४१३००२. নদ্যাত ৰাজ, জালোপুৰ – ৮৭২০০২. अनुदानित कोन (०२१७) २७२३६१८. गोन (०२२७) २३२४७३६ Partian: 23 106 12021

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कार्यालयीन आदेश

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प्रति,

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6.	10. Dr. Mahaveer Shastri (Ph.D.) / Mr. Anoop A. Doshi	Philosopher / Ethicist
7.4	11. Mr. Parag Shah / Mrs. Vidya Dhole	Lay Person



ESTD 1982

र्पाचार्य शेठ गोविंदजी रावजी आयुर्वेद महाविद्यालय, सोलापुर

प्रत माहितीस्तव ३ मा . अध्यक्ष/ सचिव शेठ सखाराम नेमचंद जैन औषधालय दूसर, सोलापूर

VC. Principal

Seth Govindji Raoji Ayurved Mahavidyalaya, Solapur.

	शेठ राखाराम नेमचंद जैन औषधाल शेट गोविंदजी रावजी अ	व व कम्मानम द्रश्ट संचलित गयुर्वेद महाविद्यालय (शंलश्र)
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## कार्यालयीन आदेश

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4,	<ol> <li>Dr. Prashant Lande Assistant Professor, Panchakarma Dept.</li> </ol>	Clinicians JVY
5.	<ol> <li>Dr. Pramod P. Ingale Assistant Professor, Kaumarbhritya Dept.</li> </ol>	Clinicians GR
	9. Adv. Prashant Mliefras	Legal Expert Annihite.
6.	10. Dr. Mahaveer Shastri (Ph.D.) / Mr. Anoop A. Doshi	Philosopher / Ethicist De
7.	11. Mr. Parag Shah / Mrs. Vidya Dhole	Lay Person glad

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प्राचार्य गोविंदजी रावजी आयुर्वेद महाविद्यालय, सोलापुर

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#### कार्यालयीन आदेश

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4	<ol> <li>Dr. Vivek S. Chadurkar Professor, Kayachikitsa Dept.</li> </ol>	Clinicians
	<ol> <li>Dr. Satish S. Hadimani Assistant Professor Shalakya Dept.</li> </ol>	Clinicians
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6	10. Dr. Mahaveer Shastri (Ph.D.) / Mr. Anoop A. Doshi	Philosopher / Ethicist
7.	11. Mr. Parag Shah / Mrs. Vidya Dhote	Lay Person

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रोड गोवियली सनर्का आसुवेंद महाविद्यास्त्रय, संस्कार

प्रत माहितीरतव 🛚 मा . अध्यक्ष / सचिव शेठ सखाराम नेमचंद जैन औपधालय ट्रस्ट, सोलापूर



क्षेत्र अञ्चलंख्याना मंग्या धासन अनुदानित रोव मस्तामान सेनचंद जेंग जीवसालय द्रश्व मंचलित अमृत महोत्क शेर गोविंदजी रावजी आयुर्वेद महाविद्यालय रोड सखाराम जेमचंद जेंग आधुर्वेंद रूग्णालय matheman ma /444, opti unosci /444, opti unosci /6340/2445242, 2422244 / (6340/2442542, 2422244 / (6340/244244) / (6340/244244) / (6340/24444) २१/२१/१३, भुषणार थेठ, सामाट सीमा, सोलगुर - ४१३ ००३ eiter : (6259) 2229935 E-mail : principal@sprayurved edu in

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### कार्यालयीन आदेश

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प्रति.

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	<ol> <li>Dr. Pramod P. Ingale Assistant Professor, Kaumarbhritya Dept.</li> </ol>	Clinicians Committee Coordinator
5.	9. Adv. Prashant Mhetras	Legal Expert
6.	10. Dr. Mahaveer Shastri (Ph.D.) / Mr. Anoop A. Doshi	Philosopher / Ethicist
7.	11. Mr. Parag Shah / Mrs. Vidya Dhole	Lay Person

1057 प्र.पाचार्य aoff, र्शठ गोविंदजी रावजी आयुर्वेद ESTO 1953 I/C. Principal महाविद्यालय, सोलापूर Solapus Seth Govind Reol Ayurved Mahavidyalaya, Solapur.

प्रत माहितीस्तव ३ मा. अध्यक्ष / सचिव शेठ सखाराम नेमचंद जैन औषधालय ट्रस्ट, सोलापुर

	12010 - 25/08/2020
	साज दिनोक 25/08/0020 रोगी यदनी यतने विदया श्रासिमाही
	de of Ethics वा संत्र्शाल सार्व धादवीयुलर विशावातील
20	BEILIGE CHARGE AND
-6	हशायकारी meeting वाणेश लेल रोशे होण्शत माली लात
19	विद्य विध्यांवर च्यू होऊन खालील विध्यांवर यहमती साली.
(1)	क्रीठः पाः ने जे आयुर्वेद अञ्जालशात ज्या त्याद्यी के ज्ञा येतात
C	याचे अवलोकन करून सोबतच इतर कमी संख्यीने असलेल्या
8	माजारेज लातत ही कछा व्याधीनी तिवउ करत आपल्या मार्गवर्श
R	गेरूत 'विषयाची निवड कराती.
(2)	विदयापीठात, होल्या लीन वर्षति एखादया व्यासीवर विशिहर
(4)	कल्पाचेर संशोधन झाल्यास ती विषय टांकन संग्रोधनासाठी
2	গ্রহার আরা 🔆
(3)	कल्प ट्रतिवउलेला २ से को हाता मू होएसाप्रुवी भान आवत पु कलन च
	ाहा संशोधनायाठी विषय माहीदर्शताच्या सल्यानुयार हयाता.
(4)	प्रसेकवेही काणानी लिखित संसती होणे सावश्यक आहे.
(5) f	रेसर्च केसेच होतल्यानैतर त्याच्या समाप्तानैतर लगेच केसेस
14 M	पास्त हथान्यति.
(6) L	र्वायुत्तर विद्धार्थ्यांनी निमिर्शत लॉक कुठ तपासून ह्यावेत.
(7) 4	दवीयुत्तर विद्यार्श्यांनी माज्यता प्राप्त शब्दीय व भोतराहरीय
0	रिष्ठबाना हजर राहून केसपेपर अख्यान करावेत. व आपने स्वतःचे
4	ान वृष्ट्यांगत उछाते.
्रा	TOT YEARD CONTON
(8) (8)	ापमापल्या सार्गदर्शकांच्या सन्याने विविध छोद्य निवंध निद्धन
	ान्यताप्राप्त Journals मच्चे प्रसिद्ध कावेत.
	रवीऱ्युलर विदया्रश्यींनी मार्गदर्शक 'यांच्या' मागदर्शनाखाली' ताणिला
d	टानिटिङ इयावेत.
10) 43	तीचूलर विदयाच्यीनी महाविदयालसीत विष्णाभीय झेतरविष्णाभीच
	minar मध्ये आग होगे case discuttion करणे इ. कार्यक्रमात
	भाभी खोगो ज्ञावश्यक आहे.
	नीयुत्तर विदयाश्यसि नेमूणन दिलेल्या Unit नुसार OPD व IPD-री
-	। जनानदारीने यार पाउनि
	गियुत्तर विदयाङ्शींना पश्वामी जिवारा रुक्णालयील परिसर सोउता
210	गए नाही.
3) पदव	गियुलन विद्याश्याच्या सुरख्या कण्णालयीन कामठाजारी २वक्रा वखून

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संजूर करण्यात योतीलः विदशाश्यनी कण्णालशीन व महाविदणालथीन जिल्त (14) पदश्लन बंधनकोश्क शहील UTODT 1.1 @ डॉ. आंगाशणी मेडीदार Redsdor 🛈 डॉ. ऱ्यूती ताशपुरे ④ डॉ. प्रशांत लॉर्ड © डॉ. जितेंद्र खीत 6 विदया विवेक -सांदुरकर/ ( Si am stad general 11 1 51 12 विजशाशी () डॉ. चनमा हिरेमळ दा. Garlo (3) St Aye 11/2 7.17 249 2 2.1 5110 Solapur I/C. Principal 林門 大山下 3 Govinciji Raoji Ayurved 1 Miles Sec. 1. 6 - 111.195 14. Mahavidyalaya, Solapur. 14.1.1 Ψ₽ A 100 1 3.40 3.450 9 11 12 533 LSTD : 1-1-5- 1-1 AND A HILLING Sourpur. 151514 Principal Seth Govinial Raoil Avurver! TALK TRATES TO THE TRANSPORT 11 11:00 ( IDEN: 1 1 1 2 6 S. M. Sett 1.9% 14.10 A Her Halter of 12.1 141251 11.71) 3.742 an the data of the process 11-11 Cr. Merrer 1 . 1 . 12.13 11. 1. 1. 11.17 11 Patt 11.-2. 1 ....

#### Code of Ethics

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- १. तीन वर्षात प्रकारचे संबंधीत विषयाचे काय झाले अथवा नाही. ते विविध विद्यापीठाच्या वेब साईटवर जावून तपासणे आणि अशा प्रकारचे वाङमय चौर्य होणार नाही, याची काळजी घेणे व विद्यार्थ्याना सुचना करणे
- २. संज्ञोधनामध्ये जे औषधी वापरल्या जातील ते खात्रीपूर्वक योग्यच औषधी आहे याची खातर जमा करणे.
- ३. संन्नोधनामध्ये वरील औषधामध्ये वापरले जाणारे एकत्रीत चूर्ण, क्वाथ, कल्क, काढे,घृत, क्षीरपाक योग्य पद्धतीने तयार होतील याची काळजी घेणे.
- ४. ज्या पद्धतीने रुग्ण आपल्या ओ.पी.डी. व आय.पी.डी. मध्ये मिळतील. त्या त्या आजाराबाबतचे रुग्णाच्या आजारावर संन्नोधनासाठी घेणे.
- ५. रुग्णांचा नियमित फालोअप घेवून बेळीच मार्गदर्शन करुन तपास करुन घेणे.
- ६. Synopsis तयार झाल्यानंतर इथिकल कमेटीसमोर घेण्यापूर्वी कमीत कमी आठ दिवस आधी प्रत्येक सदस्याला Synopsis ची प्रत मिळेल याची खबरदारी घेणे.
- ७. दुरुस्ती सुचवल्यानंतर विहित मुदतीत दुरुस्ती करुन योग्य त्या अधिकाऱ्यांना दाखवून परत नव्याने Synopsis सादर करावेत.
- Dissertation केलेल्या कामाचे प्रत्येक तीन महिन्याने अहवाल संबंधीत मार्गदर्शकांकडे सादर करावा.
- ९. संबंधीत रुग्णांचे अवस्थानुरुप फोटो, व्हीडीओ, विविध प्रयोग, शालेय तपासण्याचे अहवाल जपून ठेवणे.

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I/C, Principal Seth Govindji Raoji Ayurved Mahavidyalaya, Solapur.

आज दिनोक २५७८१०००० रोजी धदनीयुत्तर विदया श्लीसाही <u>code of Ethics</u> या संदर्शाल धार्व धदनीयुत्नर विष्णाणातील आध्यापकांसी <u>फल्टमाव्य</u> माप्रेश लेल रोशे होणगत साली. ज्यात विविध विध्यांवर चर्न्स होऊन खालील विद्यरांतर झहनती साली
आध्यायकार्या meeting हाएंश लोल रोशे होएगत साम्यी जान
Idial during the state of the contract of the
(1) 210. भाषा ज आयुर्वेद रुठणालगात ज्या व्यात्रीने कुला जोता ।
ल्याच अवस्थालन केकेन स्थातन्त्र उत्ते कर्मा संस्कृति कार्यन्त्र
अग्रिल लावत हो के उग्रहीनी तिवर करत सापर्यंग सार्वहरू
साधत तिश्याचा निवेड कराती.
<ul> <li>विदयापीठात, होल्या तीन वर्षात एखादया, व्याष्टीवर विग्रिस्ट</li> </ul>
कल्पाचेर अंशोद्यत आल्यास ती विषय टाळत अंग्रोद्यनासाती
धण्यात याता.
(3) कल्प ट निवउलेला > झंळोधनाम् होण्यापुर्वी भाव झववय करूनच
भग संगाहानासाठा विषय मागेदशेताऱ्या याज्यात्रसार हयाता.
(4) प्रसेकवेही करणाची लिखित संमती होगे झावश्यक आहे.
(5) रिसर्च केसेच होतल्यानैतर त्याच्या समाप्तानँतर लगेच केसेस
तपासून देशाव्यतिः
(c) पदर्वा युत्तर विदशार्थ्यां नी निमिशीत लॉक कुछ तपायून हथावेत.
(१) पदवीयुलर विक्यार्श्यांनी माज्यता प्राप्त राहरीय व आंतराहरीय
परिषर्वाना हजर राहुन केसपेपर फण्डणन करावेत. व झापले स्वतः चे ज्ञान वृष्टवींगत करावे.
(८) आपमापल्या मार्गवर्श्वांच्या सन्याने विविध ओद्य निवंध निद्नन मान्यताप्राप्त Journals मच्छे प्रसिधद करावेत.
जान्यताप्रापत 380 mas मच्छा प्रायहद करावत. (ब) पदवी युलर विदयार्श्यांनी मार्गदर्शन 'यांच्या' मागदर्शनाखाली' तासिला
(क) पद्यायुंतर विदयाखाला मागदशक याच्या मागदशताखाला तासिका व clinics ह्यावेत.
ाः पदनीयुत्तर विदयार्थ्यानी महाविदयालयीन विद्यांगीय झंतर्रावद्यात्रीत्र
seminar महूरी आग कोए। ट्युर वांडर्यकर्मांत करणी इ. कार्यक्रमात
अल्माभी खीणे ज्ञातश्यक साहे.
त) पदवीयुत्तर विद्रणाश्यसि नेमूणन दिलेल्या Unit नुसार OPD व IPD-रो
काम जनानदारीने यार याउनिः
्र पदनीयुत्तर विदयास्थनि पश्चामी क्रिवास रुक्णलयील पश्चिम् सोउता
रोणाव माही.
अ पदवीं युलर विद्वाश्यीच्या सुरख्या काणालयीन कामकाजारी व्यक्त वयून

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मंजूर करण्यात येतील. विदशाश्श्यनि अञ्णालशीन त महाविदवालथीन जिल्त (14) पदशुला? बहानकांश्क याहील पाळा @ डॉ. आंशाशणी मेडीदार Ralador 1.6 🛈 डॉ. अुती ताशपुरे ④ डॉ. प्रशांत लाँडे 🕲 डॉ. जितेंद्र खोत विदयाः विवेक चांदुरकर 🕝 डॉ. विणा जावळे 6) 12 तिज्ञशास्त्री दवसाळ हिरेमल (3) उा. चन्नमा 0 1.1 11 11 ESTO 195 Solop IC. Principal Govindji Raoji Ayurved eth 7.10 Mahavidyalaya, Solapur. 1112. Ada, Str 115 - 13 .1 1315. 2.0405 3 6 8 - 16 de -Tab. M. 12. 41.3 1. 11 Prog. Part 1. 1. 1. 1. Ţ - T F 1.111 11 2.41 2.1.11 TITL's 1 111 1-11 1162 +1-1-1-5 14. 29.8 1.13 ٩î 117 1. 1. 14 11.111 1 11411/25\*\* 13.  $C^{\dagger}$ 1 21 1 1.11 1.1.1 14,117 - 1.1

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- १. तीन वर्षात प्रकारचे संबंधीत विषयाचे काय झाले अथवा नाही. ते विविध विद्यापीठाच्या वेब साईटवर जावून तपासणे आणि अशा प्रकारचे वाडमय चौर्य होणार नाही, याची काळजी घेणे व विद्यार्थ्याना सुचना करणे
- २. संशोधनामध्ये जे औषधी वापरल्या जातील ते खात्रीपूर्वक योग्यच औषधी आहे याची खातर जमा करणे.
- ३. संशोधनामध्ये वरील औषधामध्ये वापरले जाणारे एकत्रीत चूर्ण, क्वाथ, कल्क, काढे,घृत, क्षीरपाक योग्य पद्धतीने तयार होतील याची काळजी घेणे.
- ४. ज्या पद्धतीने रुग्ण आपल्या ओ.पी.डी. व आय.पी.डी. मध्ये मिळतील. त्या त्या आजाराबाबतचे रुग्णाच्या आजारावर संशोधनासाठी घेषे.
- ५. रुग्णांचा नियमित फालोअप घेवून वेळीच मार्गदर्शन करुन तपास करुन घेणे.
- ६. Synopsis तयार झाल्यानंतर इयिकल कमेटीसमोर घेण्यापूर्वी कमीत कमी आठ दिवस आधी प्रत्येक सदस्याला Synopsis ची प्रत मिळेल याची खबरदारी घेणे.
- ७. दुरुस्ती सुचवल्यानंतर विहित मुदतीत दुरुस्ती करुन योग्य त्या अधिकाऱ्यांना दाखवून परत नव्याने Synopsis सादर करावेत.
- Dissertation केलेल्या कामाचे प्रत्येक तीन महिन्याने अहवाल संबंधीत मार्गदर्शकांकडे सादर करावा.
- संबंधीत रुग्णांचे अवस्थानुरुप फोटो, व्हीडीओ, विविध प्रयोग, शालेय तपासण्याचे अहवाल जपून ठेवणे.

Principal Seth Govindji Raoji Ayurved Mahavidyala SOLAPUR.



Seth Govindji Raoji Ayurved Mahavidyalaya, Solapur.

35 16/3/2020. 11/3/2020 रोगी महाविद्यालयासील चरव्यत् विक्याक्तरीयो Synopsis. Presentetation doesig 31100 , 4 मिः हाडा २०२० नेमा धुराने जुसार सर्व भरव्यू मेर् diartel 4171421-0 ALAAT ALAA Andivisial Room HEL - 15 Studual any stranzonal yis and AHLOII-भहातित्या तथात्वे. Helle ST 3110 K-21611 शुभोन्छा । भिल्ला सूनना Harlageneelten surad synopsis PP+ यानंतर् SRT Present alit का भीषा समीती अहरत्वांती ने को ने देते वियारक्या स निक्याओना झावरयके भी 3741 मू य विको Field equopsis final Durd, BORS Zidita समोर मोडल्यानगरिता झानव्यक भोज लागेकेशी काय विकिसा विभागप्रमूच थे. राष्ट्रकर योगी समीती समय्वांती एक जिन यहो 24101 4? चारी उठरीय प्रतेक विक्याओं ज फाउर्थ्यक ता सु-यन Gores 1 1 क्रमा हिनीने हि: 16/2/200 को जीनी र मिन्छल छय्यिकित्सा, म बिरोज बस्तिनेव विश्वाचीर व्यामेमान ह्यान्त्र हो क्रमाने हैंदीने यमा , संयक्त भामी. 94021101 विकेस गयानान THREAL तम्भीन 3110 DIDZITA S ESCORD PROVIDE ALL मीली समय ज्यानय स्टला --3110 3 24 a Althe Boundary 1 1 ESTD yours 1962 Solapur, I/C. Principal Seth Govindji Raoji Ayurved Solapul-

Mahavidyalaya, Solapur.

3.5 16/3/2020. 10/3/2020 रोजी महाविद्यालयासीक GADI WATE SYMONSIR. 1 रव्यत्र Presentebution yourd 3-110 ..... मिं हो 212020 नेमा भूराने जुसार सर्व 4202 नर Attel Andiviound विष्याही 41211210 मना 10 bak HEL foon \$10 at 152 Pan 20 112 41 (3) AHLOII-Stognal 42412414 HENdial Auro K-2101 31 HIA Heller Auguarenter sugar synopsis. PP+ स्यना 211004 A 10 SRT Preser रामीनी स्रात्योनी BUR BUR 3mint Acoustin सावन्ध के 12-112021 F मू स बिल synopsis final abund, BORS Zidita) ALA मोडल्यानग्रिता ... मानव्यक ने नागेवरा समार मिमाण्यमूच्य वे. याद्रकर यांगी अय थिनिसा रुक जिल पको समीती समयोगी 211014 Aquisity mussen arry un प्रतेन -1021-7 22 Gaer 1 हामा हिनीने किंदा 1013 200 मोलीनी 2 Page क विक्रीजा त्रस्तिनेव विक्याक्रीय यानिकल्ला. न्साम prominel Bertit यभा संपन्त भाम. synply sol विजय गयानी सभा 212121 94024101 त्रम्हान 3110 020211A Strong the state of the 21142 मि भूरता --24 ATHY DANK 20 0 yours ESTD 1962 I/C. Principal Solapur, eth Govindji Raoji Ayurved Solaput Mahavidyalaya, Solapur.

36 しいらんわん speare 0 Ger ちり Grides A 134,01 3 Flet2 अञ्चलाले 3 महानीइ 11251 e fiald कान् प वरिल क etto as न्मनिनीन्या माज्यमेनुसार ज्यती प्रयम वर्ष Parmetal Appendix B Report of Ethics पदनी पदन्मुलर THES STROPSIS TELLA वक्लील भुभाग Committee outward No Gould आला FERIST Reference No काथनिकित्भा TelHan Relevance No) acmut-St जावक क्रमल पुनम जुमाएलालमी क्योरियाः SUR [E.C. 61] 2020-21 Di. 08/05/2020 0 दिखया आसीषु कोले SUR/EC./ 52/ 2020 -21 Di - 08/05/2020 0 41217)31 UI SON SUR /EX /63/2020-21 D7. 08/05/2020 Mani 3 0130 412 er 668/EL-164/2020-21 Dr.08/05/1020 - अन्मम 3 20 21 21-21 2 2014121 , SUR/E. ( 85/2020-21 D). 08/08/1020 0 प्रसुनीतंत्र 1amisr at fin 0 तीलम समेश जेल SGR/E. 0/66/2020-21 Dr 08/05/10020 3 AUBI ~ METHIC 3132 SURIE C/67/400021 DA. 08/00/000 a ममता सानेल जयर . SUR/E.C/58/2020-21 Dt 08/05/2020 (8)

31 16-27/04/2020 ज्ममा वन्तांतिका ्दिनांक 27/04/2000 सोजी कोठ ठोगिवंडजी रावजी आयुर्वेद-Hered and there and and and committee of ant समितिन्दो अध्यय (chairperson) हो आनंद मेहता व महाविद्यालयाचे हमारी प्राचार्थ होच्या अष्ययनेखाकी संद्याकाठी ५:३० जाजना ग्रान्यार्थ दालनान केल्लान अलेन्य अन्नेत्व अन्नेत्व पद्धनीने (मक्तु क्रू ) video conferancing à douir sucher distin and मन्माननीच लमाखद उपस्थित ठोते रामिनी सारमोनी जाते 31.55 स्मरुमा ST. HING EET. JEHT ( Chairperson) 0 ST Age CH. Alt (member Senetary) 1 st Alau marter (Basic medical scientist) 0 (4) Si Riour of text ( basic medical scientify () Ji · laday Ett. - aigrosz ( cliniciane) (8) . रे. तीगा जी. जातके. ( cuinicians) ST. Boyen 224 · List ( ( Lind vone) 5 ST - APIA Al sond ( (Linicians.) 8 35. min itat (Legal Expert) 0 st Heralz anost ( Philosopher) (10) . ज्ञी. अनुष ढोन्सी ( Ethicist) 0 (1) Il quist aller ( Lay person) and (13 alt. Peur ziet. ( Lay person) 3

38 विभय के 1- मार्ग्स समेदे वनिष्टन वायून कामम उरके ात्रमय म 1)-> माश्रास जामरा जान्य कार्यना ठाँ प्रमोह रेगले, स्वभिनी हरात फ. 1)-> माशीस लाकेरो लतिवृत्त ठाँ प्रमोह रेगले, स्वभिनी हरात फ. 1)-> माशीस लाकेरो लाख्यक व प्रमारी प्राचार्थ योच्या मान्मतेने डायम छरण्यान आले तिषम क्र 2) > महाविद्यालयान सरम स्मितीन कार्यरत उपिकवराक्ति (Ethical Committee) attailed and 2020-21 4112-भग्रायायन दुरने बाबन जर्मा Bald 3: 2) -> Inotion Council of Medical Research 2000 National Ethical Guideline for Giomedical and Health Research, involving Human participants 2017 जुसार जोत्तविक वर्ष 2020-21 प्साही प्रभारी प्रास्तार्थ जोनी प्रामेनी जाटगमानन बुरब्याचे ठरले त्या अनुरांगाने प्रमारी प्राराम जोनी तेरा (13) सरक्ष्योंनी जनीम समिती महिन केली ज्या सामितीमच्चे अपरोक्त Guide Line च्या Horning . ) & changerson : 2) member servetary 3) basic medical Scientist. 4) (linicians 5) Legal Expert O Philosopher /Ethilist D Lay Person But and (7) Harting Angel Barning Show Show Sileman HA Email at 418 acount may small. विषय का: - 3) - atiming wan der der unal month (Practioner.) योनी कोबीउ-19 या नोगावर आयुर्वेदिक आंध्रष्टी यांचा -रियार्च ( (Ilmical - mail) आपल्या महाविद्यालका झेमग्रीन रिम्मर कुरण्याची उत्ता व्यक्त कुरुन प्रवानगी आगीतला आहे. याबाबन न्यर्चा करते. ठगव क: 3) → O जपद रिमार्चि हार्विङ वैधा मुंक्रेंद मोट्रे असल्याने भिम्त्रि तथा क्रमोनकर अपल्याने जकर रिसर्च मधविद्यालय अतर्गत करव्यान भावा @ अवर रिसर्च हा नवीन इष्टिल समिती कडे video Conferancing alter alsouth siter Bar present करण्यात जालाः (MARINE INC.) 的情報

39 ·@ स्पत्र ऑनमाईन लेरानमच्चे सहर रिक्षेची व्या ऑधटा मात्रा कालावधी असा बोदमीन हम्म का स्वामिनीने व्यल -सुन्धिक्यान आहे. @ वरील क्दल इंगल्पानेनर क्दर शिमचे (श) हमवे छ) पुन्हा एक्टरा ऑनलाईन प्रधानीने हम्लाटका लगिनी समोर जारा छरावा 1 Sections 114131 1-9-1-1-2 · Damerstand 15 10231 - A 18. mierra -ie-12 Constant in decast ? (e)ASDA DOWN - JUNE 1. Transition . 1.3 10491

40 क्षमा हलोनिका बोह कोगिबेदजी · VIDST आज रिनोक 29/04/2020 लोनी fa BIERA Ethical Committee झान्नुवेद महाविसा लघ् होचे 87 समा अभिनीचे आध्यक्ष ( Chairperson) छो. अभिनी जीवेम खुरण्याचे अधिकाद असगारे प्रान जननेव Hen मानार्थ dEI मान्या अध्यक्षनेखाली) मुंझोजकुर (बैठकीसाही आमेत्रित) Hangout TR BOIST अनिल शिक्ष विष 3 वानना प्राचार्य दालनान 3100021 पर्धनीने c video conterancing) रबाकील समिती सप्टम खपम्पित नाम्वर्व 31-2010ील व्यरभग व्यमिती व्यवस्थांची मावे. ST 95. JI - HIHA HEAT ( (nairperson) 6 25 JT . Mar Il (member Servetary) 3 डो. प्रदिप उत्मनुरे 6 ( Basic Medical Scientist) डा बिल्पा चेरमे (4) जि जें विवेक चोंद्ररहर C डॉ· सीना जावले ((linivians)) जी फल्पना पांडरे (3) डी. ममोर कंगले ( 33. yaint dent . ( Legal Expert) 1) 31. aft: Heralt 21most. (Philosopher) 1) aft. sigg a)all . C Ethoist) ( जी पराग कारा ? (Lay tersons) (3)

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41 12: 23/04/2020 रिषय फ्रान छ → माभील रुमझेने उतिवृत्त मामून आमम छरेगे. हराव के:- छ → माभील समेने उद्यनिवृत्त औं फल्पना पांढरे साविती-स्वरूष्ट् मोनी समिती फाइम्रस् व प्रान्ताची सान्त्या RIGST ERIO सात्मनेने कायम करण्यान डाले. 白みりかる 5972) 2) -> . कोलापूर क्वात त्रेया पत्लवी कुलकाी (ms. snalakya न् महत विजय %. tonten) त त्यांच्या जोवन रिसर्चर ठरव्यन तेया जीता एम देवापांडे (m.o. मत्यापुर)) ज वैद्य विद्यानेद कुंमोनकर सम्बद्ध (mo: oranyaguna) योग्ट्या could - 19 या कोठारच्या अनुकोठगते जो रिस्ट्री-जेला आदे त्यातर् न्यची फारतन त्या 241 रिश्नची न्या मान्यतेखावन न्यची छरते हराव का- छ- २. वंसा प्रत्यती कुलकणी व त्यांच्या कोवन दिसन क्रमारे विसर्वा आंग जॉबनाईन पढ्टातीने आते गा माभील इत्रिक्रम मामितीच्या जमोत त्यांचे 3153 तेय मेह्नेद सोरे व दाधकल जामिनेस्या सबस्योंनी कीरी वदल मुन्धीवेशे होते. व वटल उठल पुन्ध एकदा रिस्तरी Presentation देव्यास सोगिनले हो त्या अनुवांगाने रिस्तर जोली कटल उठन zou esal synopsis is presentation online altered to Ethical समिनी समोर साद केने Ethical सामना समार स्वार ज्या का का माना ते शदम त्यानेनर स्वतिसिंस व त्यांने गण्डे व्योना ते शदम च्या स्वरक्षोंनी ह्या रिस्स्टी स्वतिमने मान्यना दिली. स्विनिन्या अध्यक्षांत्या व्यक्ति रिस्स्टीर ज्यांना Institution Ettical Growance Committee MG Approval of IEC 49 20412 2125-11-1 2207.

42 अभा ब्रतीत (2) दि २६-०८ २०२० रोजी दुगरी ३ वाजता कुल्पुरेट meet यारे ठगांगट मिटिंज खुरु झाली. आची सुकवात कार्या प्रटा मेटिंज खुरु झाली. डॉ. आनंद महता यांच्या स्तरानांनी झाली. डॉ. चांदुरकर सर, यांनी सर्व विखाण्याप्या उ. चांदुरकर सर, यांनी सर्व विखाण्याप्या सुनियोजीन presentation साठी त्यांची क्रमवारी कुरुन विलेल्या वेळेत presentation होला. साठी सर्व सराना विल्या साहर करण्यान आले. 题 10 1 24 山田 「日本 一日日日 二日本 Margaret Property 27 2012 8 1 11 20 2116 20210 わいのはつ 一世 通知法言 13 101 200 0000 144.0 Support of the party weat the set of the set of the Constant Cleanered threader compared threader 「「「「「」」」」」」」」」」」」」」」」」

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अभा व्रतांत

R. 20.10-2020 रोजी 301री 3 amin google meet द्वार online मझेस रहरतात साली IEC चेश्मन डॉ- आनंद मेरता यांनी प्रास्तविक व समेशाहीच्या क्रस्तावाची माहीती दिली. Ha MAINAIAI Acardar (Combo pack clinical Trial study Protocol) Jacya 407 व्यवॉनी आपल्या स्चना व सल्ले सी जितले स्व कामदोपती प्रतेता व्यवस्थीत असल्याची खातरजगा करणात लाली सर्व कागदीयत्री पुलेता पूर्व असल्पाचे निद्रानास उनाले. अवाँची मते व्यवस्थीत समजून छेतल्या नैतर भाः चेरमन योनी, सदर प्रस्ताव IEC बारे सान्य करण्यात आल्याने जाहीर केले. व युहील कार्यवाही व कामकानाची प्रतेता करण्याल सत्त्वना दिल्या न समेचे कामकान संपल्याचे जाहीर करव्यात आले. google weet द्वारे दोतलेल्या संदर समेचे Recording JAA ARCOULD STIM. O ST MOR HEAT (champerson) alut O ST. Tadas - TGRAL (Clinician) RAW J. Riour Digh ( Chasic Medical (3) Steonl SI- Tabi Jiga - ( Clinician) 5 @ आरे. अनुप दोरम - Crehicuit) AT - TAUT STA - (lay person) जेंड प्रसान म्हेन्नस् - (legal Expert) बि डा . प्रसाद रहाने ath Coving hand **VC.** Principal Seth Govindii Raoji Ayurved Mahavidyataya, Solapur.

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(4) समा व्रतांत.

a. 24.06.2021 21 1 7 3011021110 गठोबा हॉल" समाग्रहा महये काय विकिला pre. m. p. विदयार्थांचे ्दुपारी ् वानतर पासून presentation ago zind since and Tazarezulat and Ethical Comittee Jazi -ट्या उपत्थीली महये, presentation युद्ध केलेand of y flor ysion presentations Da. एक्वर्या मगडुम. Topic - Randomized Clinical study to evaluate the efficacy of Chincha Kshara & Yavakshara in Management of Mutrashmari E S.R.T. Urolithiasis. 2 तो. अह्या पारील Topic - Randomized (linical study to evaluate the efficacy of asana kashaya & triphala kashaya in the management. of sthaulya. 3 के अखीनी रोटे. Topic - A Comparative clinical study to evaluate the efficacy of Amrutadi Kwathy & Laghy Manjishtadi Kwatha in the management of vicharchika. w.s.r. to Eczema. a . Unnal gerud. Topic - To evaluate the efficacy of indravaruni churna with & without janubasti in mangement of janusandhigat-avata - A randomized clinical study. benste I/C. Principal Seth Govintiji Radji Ayurved Mahavidyalaya, Solapur.

NOPEQ ..... 47 सर्व विद्वार्थ्यानि IEC च्या मेंवर्श्वच्या प्रश्नांची समाधान कारक उत्तरे दिली तन्येच मेंवर्सच्या खुचनां प्रमाणे योज्यते वदल करण्यास सहमती ERlamt. pus ST. MINA HEAT (Choirman) 0 कस्तुरे न्दाहरकर 27 डॉ- प्रदिय त्रिवेक र्छ. 0 जावले (A) Ji. Taon 4162 Ē andat 3 देशपीउँ জাযনী 6 51 3018 त्रसोद 9 ar. VC. Principal Seth Govindji Racji Ayurved Mahavidyalaya, Solapur.

5) जमा ब्रताल.

. दि : 28 . 0 . 20 20 21 रोजी काल्यातील " राठेल्श-हाल "कर्वमाय्हा संस्थे रुजी केना प्रयूति विषयातीक पदवीलन पदवी विद्यार्थी व एक १७०० (पंचकर्म) विद्रभाद्यी योग्री synopsis, presentation दुपारी ्राळ वाजता ज्युरु कर्ष्यात आले.

widea yelos ynd presentation around sind. वैद्य स्तनमाला मराजन

Topic - To evaluate the combined effect of Test S triphala kashaya yonirranaprakshalan followed by trikadi Ghnita application 9n the management of episiotomy wound -A clinical study.

ि तैम. अबोली जांधी Topic - To Evaluate the effect of Tankan Kshar vran with s.r. to cervical erosion A clinical trial.

3 वैग्र- प्रगाली देखार

1 7 1 .....

Topic - Randomized Comparitive Study. to evaluate efficacy of Manjishtha Churna & Shatapuchpa Churna in Kashtartara w.s.r. Dysmenorrhea.

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(B) Ph. D. (scholar) मैथु: जाशाराजी मेडीदाय:

Popici - A open tabelled randomized parallel group comparative clinical trial to evaluate the efficacy of classical virechana to/versus vajagerpanabast in management of pakehaghata.

स्मत विद्यार्थ्यांनी विधापीठ नियमांचे anazeria timon and sympson presentation RaojiA and lund ESTD 1962 I/C. Principal

> Soth Govind Mahavidyalaya, Solapur.

50 (5) WARE SERVICE यातील क्लिगेज-प्रस्तितंत्र विभागातील १.५. Con Contraction of the विद्रभाष्ट्र्याच्ची - presentation. माल्यानतर त्यौन) do 18 1 Tale D बदल करव्याचा तस्त रिष्ट्रि . इलिहिल्यासाठी स्तिन ेवेषात आल्याः तसच किमेर्या साल्यानेतर wenfications त्याचे Han comittee members व नोरमन अयारी dos of elouididid dobot स्त्रेगत याल्यान याल्या. (scholar) dry ASIGIS Ph. D. योच्धा गा Topic & HERM Content Z ACHIHEI अस्मगारे Udoj माम संस्थेच्या अर्दी छोना 324 6 ञ्चालयाचे Q18105 संस्थेत्या a celtan वापर रुआलयात करण HRIDE असल्याने सहर Acen-en 2142 40400 S.S.N.J. Ayu. Hospital -मह्य research 00200121 प्रतिबंध अलल्याने संबर synopsis लग स्वान्हमते 42010151 - नाकारखात परंतुः SHOD. सम्घच्या उद्दीच्ठाना बाह्या . रोठारि अधिस्ती 0 aluzhi उत्तर ब्रुव प्रव्यामध्ये बदल करणे- शक्य अतन्याय CELIAHIOL अग्रेम पुन्हा नविन विषय किंवा Gal andfor Synopsis presentation करण्यीचा सलना জালা. देव्यात TISHAT . S. R. 134s mellolike (t)HEAT (chairman) 37. BIAL NO/4 10 प्रदिय æ to+g? adas 3 35. 215702 A 9011 stiga 5/6 रायत्री 31 R21411 T a cruptl 16 त्रमाद 2/05 ST. 92151 8 21 Seth / Allerichter house CRITEIOTO VC. Principal 1118 E D 15 Both Govindji Raoji Ayurved mit Mahavidyalaya, Solapur.

51 6) समा वृत्तान्त. (नद्द. 21.09.2021) वि. 21.09.2021 दोन् द्यारी 2 ता पास्त क्रा?- रोग प्रस्ति तंत्र व काय्चिकित्ला विधयाच्या पत्र युत्तर पद्वी विद्यार्थांचे pre-submission Ethical presentation clouis mind sinder. @ कोनम बी पारील (रूनीरोग व प्रस्ती तेत्र) ८ विजया रोटरी (-"-व -"-) (क) निक्तिमा केजानी (काय चिकिला)
(म) प्रांजल जेन (-----) डी आरती मोडासे Con -11-21 at Tazarezirt https://meet.google. com/nem-hikw-enm?hs=224 211 Togo de online पद्धतीने presentation काले. सर्व विख्याद्धीनी त्यांनी केलेल्या research work it Result, Dissoussion a Conclusion सादर केहो. तसेच सर्व कमीटी सेंबर च्या प्रश्नांची समाद्यानकारक 3rela Rof. असर वजी मेंबर व चेरमन योच्या संमतीने सर्व विदयाद्यी ये Reserch work है, स्वीकृत कर्ळ्यात आलेः व भा चेरमन योचे परवानगाने meeting जैपविष्यात SIMT. 51. अानद मेहता. Out डों - प्रदीध करतुरे. डों - विवेक चौद्धरकर (FX)(S) PAN 4 डों किंगा जाबू है (4)(2)(4)(2) ड्री - अनुप 21215 9. कल्पना याँदरे इंगले. 'प्रझोद 31-खी. पराज सोहा. Sil. महावीर आस्त्री Raoil, yourle END 1962 I/C. Frincipal Salapur, Seth Govindji Raoji Ayurved OUDUT Mahavielysiss

53 ि समा ब्रत्नान्त. २१. 22.09.2021 रोजी दु. २ वा. पायत दि. 21.09.2021 स्टा link द्वारे पुन्हा उर्वहीत a दोन पदछालर पदवी व तीन ph.D. विद्यार्थ्याचे presentation आयानीत करण्यात 2 31m यामहरो स्विप्रमथ डॉ. सोनम आर पार्टल (रूभी रोज व प्रसूती तंत्र) व त्यानंतर डॉ ग्रेम्य न कील (कार्याचे किला) चा पदब्युला परवी TORENTENTO Research work -श्मादरीकरण केले. त्यानंतर Pb.D. (scholar) योचे synaps75 presentation खेळ्यात आले. यामरथे पुरीले presentations thing. 0 हॉ आनंद मादराँडी -An effect of Padgat Siravedha two fingures above Ksheepra marma in vicharchikaa clinical study. @ डॉ - स्तोष स्वामी -Open Labelled Comparative study of Ayuned treatment protocol with thyroxine . is in Hypothyroidism. छ डॉ. आशाराठारि मेडीयार -An open labelled randomized clinical trial to evaluate the efficacy of Avasthanusara treatment protocol over Virechana in the management of Pakshaghta. केले जो ले. समेचे माठी कमिटी में HOREDI

शैंका व प्रक्षांची योग्म उत्तरे मिळाली सबब कार्ट्यात आलेल्या सप्र मिटिंग महूद्ये Ph.D. scholar (3) याना राणालयामहथे Research work करण्याल स्वीकृती दरविव्यात आली. डा. जान्द मेह ला. Bur 0 रा. प्रतिय कस्तुरे टा. जित्वेक चांडरकर जा. विठा जावत्वे जी- आवुष दोश्री ろに 20141 - UICZ/HISAAN . Hule 100 31 ¥1. पराकीर शास्त्री Z 2

अम्म वृत्तान्त

दि 28 04 2022 बोनी उपारी 3:00 वनता महाविद्यालय मिटिंग होल महये हफारवी comittee बैठक उद्धर बनाली यामहये रातप्रभग डॉ किल्या थेरमे मंडम यांनी लगत्या protorma चे तावन केले. त्यानंतर डॉ प्रियंका हनमाने त्यांच्छा त डॉ जोवा जोरव हाता यांती वजुझमे ph. D. proforma = presentation aport . IT fait presentation fax त्याला चार्यकी ब्हुचना व सल्ला देण्यात ज्ञाला arren Ph. D. Bayizzitet correction complite मात्यामुळे ब स्तर्व कमिटी सदस्यांच्या नार्ये अंती enon Ethical comittee clearance contificate देखान, आले डा. भेरमे मेरम योजी Questionary a Topic video record नयल्याने त्यांना ते comittee समीर अदेखाने व त्यानंतर online पहतीने presentation करण्यापाठी पत्र email दारे पाठविष्यान्ता स्मवन्त्रिमने, निर्वाय देवन्यान आला. अभेच्या क्षेत्रही डॉ विवेक यांदुरकर कर जोनी कार्व अपश्चित भान्युवर सुदस्यांचे आझार मानले क मधा भौपत्यारे जाहीर केले. blog 0 डा जानंद महता, ठा- प्रदिधं कम्बुरे में विषेक्र न्याद्वर्कर 3 जा कीठा जावदे -लाई ..... त. प्रशात 5 रां गामती देशाया डे जोः अजित्कुमाद हेरवाडे राशी 201 -42151 (8) sti 3134 प्रमोध

अभा वत्तान

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वि 12.05.2022 चोनी उपारी 2:30 = वानता Online Meet app and ethical comittee of मिटिंग सुरु आली. डा. शिल्या झेरमे मंडम यांनी, त्यांना त्याच्या topic tates of tament suggestions after and explanations and ability equations मंडले व त्यांनी <del>प्रश्व</del> प्रश्तावली देखिल जमा केली त्यानंतर अव सदस्यांच्या क्रीकांचे जिरसन झाल्याची खात्री केल्यावर व सर्व सदस्यांच्या सहमती ने प्रापर 9 सेव सेदस्याच्या समिता न ICMR guideline section og रे अनुपालन कफन proforma complete केल्यावर व या section त्या आधीन बाइन डॉ. शिल्पा थेरमे मंउम यांना हस्फांटवी Cleanance हेल्यारे यान्य करण्यात जाले. सम्रच्या सावटी त्रेद्या. अनितकुमार सम्रच्या सावटी त्रेद्या. अनितकुमार हरवारे यानी संबचि अन्नार, मान्जन कार्यक्रमार्ची सांगता साल्यार्च जाहीर केले तेम आनंद मेहता केएम तेम प्रदिप करतर मनगढ़ तेम जितक चांडरकर कि तेम प्रसात लांडे हिर्मने हो. प्रसात लांडे हिर्मने हो. प्रसात लांडे हिर्मने तेम जजितकुमार हरवारे केल्ली F - प्रमोद इंगले

61. (10) समा वृत्तान्त the. 2.9.06.2022 जोनी IEC दारे आयो जित pre- Submission Dessentation presentation of आभोजन करण्यात आले कार्व विद्वाध्यति त्यांचे presentation Tit - abort. and presentation star a and marchight The year yor Dessentation anos IEC complithen quataran prosta astrain. Vd. Mamata S. Nahar. - Evaluation the effect of Kanajatan Chronna in Sutaka Udas Vrudhi. Vd. Neelam K. Jain - Comparetive clinical study to evaluate the efficacy of Madhin whadh siddha Keheer f Iron - Calcium supplements in management of 6th 4 7th mo . I st prakent Garbini ) Not. Priyoung R. Kurkute . - To evaluate efficacy of mistadi gana Kwath you'd havan in management of Kaphay yonivyayad. Vd. Asshwarga A. Kole Comparative clinical study to evaluate the etticacy of Rushthadi Lapa with and without Darryadi Kashjay in mangement of Dadmi Kuphtha Vd. Bhakti P. Patil Randomized clinical Trial to evaluate the Individual & combined effect of Shankha Bhasma & Shalmalikantita Lepr in mangement of Tammyapitika (Home)

62 @ Yd. Punam S. Katariya - Comparative clinical Andy of phalatrikadi Kashaya and patoladi rashaya in the Management of Urdhwag ampagitta ( Vol. Shweta A. Pedasani Comparative Clinical study to evaluate the efficacy of punarmanadi Kwath and . phaltrikadi kwatha in Management & F Pander. (Anemia) NET - A PROVIDE AND AND @ Vd. Shubham. S- Pasil · Comparative clinical study to evaluate the efficacy of Kutajadi Kwatha and Mustadi kwathe in management of Madhumcha. O Dr. Anand Mehta blus @ Dr. Pradeep. Kasture. Dr. Vivek Chanderkar. Dr: Gayatri Deshponde gyposte Dr. Promod Ingde Dr. Shri Parag Shah. Sis. Lot Statistics in the state of the the second and - Datagen , and - - 1 The star terrent present 1470.000 Ho The Marshall 12 Ser Sertites

🕕 सञा- वृत्तान्त 63 12. 398 ऑक्टोबर 2022 रोजी IEC मिटिंगचे आधोजन 1st yr. P.G. विद्यार्थ्यचा synopsis presentation साठी आगोजीत करणात आले. X-2105: SGR AY4. College, FITZST ETA. ander goler synopsis (Protocole) The 03.90.2022 21st present anzwein ett आले () बेधा पायल बिलास यावन Title - A clinical study to evaluate the combined Sheacy of Ammitadya Guggilla of Udverben ettb Bashpa sueda in the management of sthaulyre. वैवा यूजा अनोहर कोकांसी का नावार जाता क Title - A comparative clinical study to evaluate the etticacy of Wishadi kwath & Khadirachlake kwath in the management of Virharchika 6 वैरया निक्रिता माजगढिव वाकगी Title - A Randomized comparative clinical study to evalua the efficacy of Laghumany is thad had had Advusted kwath in the management of Dadra kushtha 6) वेष्णाः आग्रानां खुरेश जेन Title: - " A comparation clinical study to evaluat the evaluate the efficiency of Nagrodi twath of House pout. in the manugement of Urdhulager Amlapite" दि. 08 90.2022 रोजी काथ चिकित्सा खे विश्वयाच्या एका व स्त्री रोग प्रमुति विषयाच्या होन दिव्याच्यन्य preservation त्याच स्थळी दुपारी 2:30 वानता दुरीक क्रमण के दाव्यान आले.

64 राम बबनराव मुद्दलकर Topic - A single Arm elinical trial study to evaluate The efficacy of katanhateriyadi kwath in the ć management of Madhumeha (DM Type 2). जिला विजयसमार माधो Topic - A-clinical study to evaluate the efficacy of shwadanship Taila uttanhasti in the mangement of vanchytra due to anavulation अश्विनी दिलिपराव सोरे 3 Topic - A clinical study to evaluate the combined efficacy of schachanadi taila matra basti with onal administration of shatpushpa channa in the management of Arrtankshaya due to poly sustic overnan syndrome. atta the acentation oras the a fast chairman ziter समासद COMET protocol & Etical comittee चर्च अन्ती सर्व दारे approved करन्त प्रमाणपत्त देण्यास महभती हरीविष्यात आली. ( Dr. Anand Mehta 4-PPK Dr. Pradeep Kasture 2 chandurkar Vivek Dr. Dr Prashant Land 4 Dr Gaytin Desh 5 Or Satish Hadima 6 Di framod Ingala shall Shis Parag 9 Dr. Ajilkumar Herwade Dr. Harifo Illiaiter (10) Davida

22

(12) जमा वतान्त

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His 1	
	The research topic, "A singal arm
aluate	clinical Trial to evaluate the efficacy of
the	anti-diabetic tormulation in management of
-	Madhumeh," by Dr. Santosh swami sir,
	is approved by IEC in the meeting
	held on 27.12.2022 with following
adanshin	recommendations 0
audation	
	1. Two groups with each as patients, that is total 130 patients should be included in the study
1	the study
ficary	2. The patients having following Parameters
	2. The patients having following Parameters throughout the study should be included
	in the study .
fic	Parameters - 1. BSL @ 110-200
-t+	A. BSL (PP) 160 - 300
c I	3. HbA1c 5.7-9%
<del>-</del>	If parameters will increase more than above
I	mentioned, then patient should be discontinued &
e	shifted to allopathic medicines.
4	3. Dose of meditime should be 3 grams (Three)
	twice daily.
	4. Drug standardization should be done from
R.La	authentic Laboratory.
	5. Duration required for this study should be
10 1	as per norms.
1	IEC Comittee -
	1) Dr. Anand Mehta - Our
	Dr. Pradeep Kastyre - For
	3 Dr. Nivek Chandarkan -
	@ Dr. Prashut Lande - Palue
	(5) Dr. Ajitkumar Herwade - Alande.
	6 Dr. Framed Ingale - En"
-	() Di-satish Hadimani - 4
1-8	C DI SACISTI TICOLITICITI
1	
	the second se
RET STATES	23

() समा वतान्त दि. 01.03.2023 कोजी SGR-2EC -EUT Sandran Jad steer Ph.D. scholar रेग. सातिश हारे गठी यांनी 'A Rondomized controlled clinical study of application of saindhavadi Ghrita orvament in Shushkakshipaka with special rob. of dry eye syndrome "IT synopsis it presentation 327 4 51 200 2010. मरर संहकीत ते अलिश हादिसकी Dirat SGR-JEC Tit gliss research साठी परवामगी देव्याचे सर्वानुमते मान्यु करण्यान आले IEC Comittee O Dr. Anand Mehta ( Di. Vivek Chandurkar 3 Dr. Prashat Lande 3 Or. Ajithuman Hermade Attende (3 br. framod Ingale June /C. Principal Seth Govinoji Raoji Ayurved Mahavidyalaya, Solapur. 24

Standard Operating Procedure (SOP)

For

Institutional Ethics Committee

S. G. R. Ayurved College, Solapur



# Standard Operating Procedures (SOP) for Institutional Ethics Committee (IEC)

S G R Ayurved Mahavidyalaya, Solapur

SOP prepared by:

Approved by:

Contents:

- 1. Introduction
- 2. Objectives
- 3. Authority under which SGR Ayu-IEC is constituted
- 4. Composition
- 5. Role & Responsibilities of SGR Ayu-IEC
- 6. Quorum requirements
- 7. Convention and Conduct of SGR Ayu-IEC meetings
- 8. Application procedures
- 9. Details of documents to be submitted for EC review
- 10. Details of documents to be included in the protocol
- 11. Review procedures
- 12. Review of research proposals involving vulnerable populations
- 13. Independent consultant/Invited subject experts
- 15. Decision-making & Communication of decision
- 16. Record keeping and archiving of documents
- 17. Terms of reference
- 18. Administration and management
- 19. Web page for SGR Ayu-IEC
- 20. Contact details

#### 21. Annexures

Annexure1: template - Invitation letter to a member

Annexure 2: template -Consent letter from a member

- Annexure3: Appointment order
- Annexure 4: Application for initial review
- Annexure 5: Continuing review /Annual report format
- Annexure 6: Application /notification for amendments
- Annexure 7: Protocol violation/deviation reporting form
- Annexure 8: Serious Adverse event format (Biomedical Health research)
- Annexure 9: Premature termination/suspension/discontinuation of study report format
- Annexure 10: Application form for clinical trials
- Annexure 11: Serious Adverse event format for clinical trials
- Annexure 12: Study completion /Final report
- Annexure 13: Participant information sheet (PIS)
- Annexure 14: Informed consent
- Annexure 15: Undertaking by the investigator

## 1. Introduction:

S G R Ayurved Mahavidyalaya, Solapur is one of the Ayurvedic healthcare institutes established in 1917 by S S N J Aushadhalay Trust, Solapur with a mission to establish an excellence in Ayurved education and Ayurvedic practice training for students and patient-focused ayurvedic health care that is readily accessible, cost effective and meets the needs of the communities and offer scientific research opportunities.

Bio medical research involves a number of ethical issues that need to be addressed. The Institutional Ethics Committee (IEC) plays an important role in guiding researchers in the ethical aspects associated with the biomedical research. Apart from ethical issues, IEC will also review the research proposals for the scientific relevance and risk involved in research. IEC functions as per the ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participant-2017 (ICMR National Ethical Guidelines).

#### 2. Objectives:

The objective of this SOP is to maintain effective functioning of the IEC and to ensure quality and technical excellence and consistent ethical review of all submitted biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR National Ethical Guidelines and New Drugs and Clinical Trials Rules 2019.

3. Authority under which IEC is constituted

SGR Ayu-IEC is an Institutional standing ethics committee which functions independently. The Principal of S G R Ayurved Mahavidyalaya, Solapur will appoint the Chairperson and all the committee members, based on their qualifications, competence and experience in reviewing and evaluating the scientific and ethical aspects of biomedical research proposals. The tenure/ period of IEC members will be for 3 years or till further orders.

#### 4. Composition:

The number of members in an IEC may range from 7 to 15. The IEC will be multidisciplinary in

composition and independent. As per the ICMR National Ethical Guidelines2017, S G R Ayurved Mahavidyalaya should have the following categories of members

Chairperson - Non affiliated

Member Secretary- Affiliated

Basic medical scientist-non-affiliated/affiliated

Clinicians -Non-affiliated/affiliated

Legal expert -Non-affiliated/affiliated

Social Scientist /representative of NGO/Philosopher/ethicist/theologian-non-affiliated affiliated

Lay person from the community -Non-affiliated/affiliated

5. Responsibilities of SGR Ayu-IEC:

The main responsibility of SGR Ayu-IEC is to review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of research participants before approving the research proposals. It should ascertain that all the ethical principles of research, informed Consent, Respect for Human Dignity. Respect for Vulnerable Persons, Respect for Privacy and Confidentiality and Justice are taken care of in planning, conducting and reporting of the proposed research. IEC will review each study proposal for its both scientific and ethical review. Members of IEC are expected to attended all IEC meetings and prior information should be provided if a member is unable to attend meeting.

5.1 Responsibilities of each member is mentioned below

Member	Responsibility
Chairperson	<ul> <li>Conduct EC meetings and ensure active participation of all members during meeting</li> <li>Ratify minutes of the previous meetings</li> <li>Seek COI declaration from members and ensure quorum and fair decision making.</li> <li>Handle complaints against researchers, EC members, conflict of interest issues and request for use of data, etc.</li> </ul>
Member Secretary	<ul> <li>Interest issues and request for use of user of and the procedure for receiving, preparing. circulating and maintaining each proposal for review</li> <li>Schedule EC meetings, prepare the agenda and minutes</li> <li>Organize EC documentation, communication and archiving</li> <li>Ensure training of EC secretariat and EC members</li> <li>Ensure SOPs are updated as and when required &amp; adherence of EC functioning to the SOPs</li> <li>Prepare for and respond to audits and inspections</li> <li>Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.</li> <li>Assess the need for expedited review/ exemption from review or full review.</li> <li>Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.</li> <li>Ensure quorum during the meeting and record discussions and decisions</li> </ul>
Basic scientist	Scientific and ethical review - emphasis on intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report, drug safety and pharmacodynamics in case of clinical trials

clinician	Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and
	statistics Ongoing review of the protocol (SAE, protocol deviation or violation, progress and
	completion report) Review medical care, facility and appropriateness of the principal investigator,
	provision for medical care, management and compensation. Thorough review of protocol, investigators brochure & all other protocol details
Legal expert	Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other
	site approvals, researcher's undertaking, protocol specific other permissions (NAC- SCRT, HMSC etc) compliance with guidelines etc.
Social scientist/ philosopher/ ethicist/theologian	Ethical review of the proposal, ICD along with the translations. Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
	Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
Lay person	Ethical review of the proposal, ICD along with translation(s). Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
	Serve as a patient/participant/ community representative and bring in ethical and societal concerns. Assess on societal aspects if any.

Members are expected to show their full commitment, responsibility, respect for divergent opinions, maintain confidentiality review proposals from bias and without any external influences.

All IEC members must be familiarized with guidelines related to research and ethics such as ICMR

National Ethical Guidelines2017, New Drugs and Clinical Trials Rules 2019, ICH-GCP guidelines.

When there is any change in SOP the same will be communicated to the members and necessary training will be imparted. Record will be maintained regarding the training of members and change in the SOP/guidelines.

Members are expected to declare conflicts of interest, if any, before commencement of the

meeting. IEC members should not take part in discussion or decision making on research proposals in which they are PI or Co –investigators or if there are any other conflicts of interest.

The IEC has the rights to revoke its approval accorded to scientific study/clinical study protocol, and

further, it has to record the reasons for doing so and communicate the same to the Investigator as well as to the Licensing Authority/ other relevant stakeholders.

IEC may review progress of the approved studies periodically till the completion of the study

through periodic study progress report /internal audit reports.

The investigator is responsible for reporting all SAEs including hospitalization or prolongation of

hospitalization, clinical trial related injury or death, regardless of causal relationship to the EC within 24 hours of knowledge. Reporting of SAE may be done through email or fax communication (including on non-working days). A report on how the SAE was related to the research must also be submitted within 14 days. SAEs must be reported for all trials and if applicable timelines as specified by regulators to be followed (within 24 hours to the sponsor, EC and regulator, if applicable, followed by a due analysis report in 14 days).

The IEC shall forward the report on any SAE (including, death), after due analysis, along with

Its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, to

the Chairman of the Expert Committee constituted by the Licensing Authority. The copy of the report has to be submitted the Licensing Authority within twenty-one calendar days of the occurrence of the SAE.

# 8. Convention and Conduct of IEC meetings

The Chairperson will conduct all meetings of the SGR Ayu-IEC. In the absence of the Chairperson

an alternate Chairperson will be elected from the other members on the day of meeting (or

Chairperson should nominate a committee member as Acting Chairperson for that meeting) by the

members present, who will conduct the meeting. The alternate or acting chairperson should have the powers of the chair person and should be non-affiliated person. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned.

Member Secretary will prepare the minutes of the meetings and get it approved by the Chairperson

and all the members. In the absence of Member Secretary alternate Member Secretary among the

members, will organize the IEC meeting.

All proposals will be received at least 3 weeks before the meeting and after initial scrutiny by

Member Secretary the proposals will be circulated to the IEC members.

The recommendations by the IEC will be communicated to all the PIs and guides/HODs in case of student's proposals If required additional review meetings can also be conducted with a short notice period.

## 9. Application procedures

All proposals should be submitted to IEC on any working day 3 weeks in advance of scheduled Meeting in the prescribed application form along with relevant documents.

Eight (8) hard Copies and soft copy of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators /should be submitted to IEC.

Principle Investigators shall be forwarded their application to the Chairperson IEC, through Member Secretary and the receipt of the application will be acknowledged by the IEC office.

Every application will be allotted an IEC registration number to be used for all future

Correspondence and reference. The date of IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members. IEC can suggest for online meetings and virtual presentations of the investigators in special situations such as COVID-19 pandemic, etc.

If revision is to be made, the revised proposal in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

All research proposals/clinical trials funded/sponsored by pharmaceutical companies,

Agencies, Multinationals etc. will be charged an administrative fee/ processing fee of 5% of their sanctioned budget. Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non-Profitable Organizations etc.

# 10. Details of documents to be submitted for EC review

a) Cover letter to the Member Secretary

- b) Type of review requested
- c) Application form for initial review
- d) Permission of using copyrighted proforma/ questionnaire
- e) A complete protocol
- f) Approval of the project for Institute Scientific Committee

g) The correct version of the informed consent document (ICD) in English and the local

language(s).

h) Case record form/questionnaire

- i) Recruitment procedures: advertisement, notices (if applicable)
- j) Patient instruction card, diary, etc. (if applicable)
- k) Investigator's brochure (as applicable for drug/biologicals/device trials)
- 1) Details of funding agency/sponsor and fund allocation (if applicable)
- m) Brief curriculum vitae of all the study researchers
- n) A statement on COI, if any

o) GCP training certificate (preferably within 5 years) of investigators (Sponsored clinical trials)

p) Any other research ethics/other training evidence, if applicable as per EC SOP

q) List of ongoing research studies undertaken by the principal investigator (if applicable)

r) Undertaking with signatures of investigators

s) Regulatory permissions (as applicable)

t) Relevant administrative approvals (such as HMSC approval for international trials)

u) Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)

v) MoU in case of studies involving collaboration with other institutions (if

applicable)

w) Clinical trial agreement between the sponsors, investigator and the head of the institution(s)

(If applicable)

x) Insurance policy (if applicable)

10. Details of documents to be included in the protocol

The protocol should include the following:

A. The first page carrying the title of the proposal with signatures of the investigators;

B. Brief summary/ lay summary of the protocol;

C. Background with rationale of why a human study is needed to answer the research question;

D. Justification of inclusion/exclusion of vulnerable populations;

E. Clear research objectives and end points/ outcome;

F. Eligibility criteria and participant recruitment procedures;

G. Detailed description of the methodology of the proposed research, including sample size

(With justification), type of study design (observational, experimental, pilot, randomized,

blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any;

H. Duration of the study;

1. Justification for use of placebo, benefit-risk assessment, plans to withdraw and rescue medication. If standard therapies are to be withheld,

J. Procedure for seeking and obtaining written informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. Informed consent for storage of samples; assent; re-consent K. Plan for statistical analysis of the study;

L. Plan to maintain the privacy and confidentiality of the study participants;

M. For research involving more than minimal risk, an account of management of risk or

injury;

Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period and insurance policy

N. Provision of ancillary care for unrelated illness during the duration of research;

O. An account of storage and maintenance of all data collected during the trial; and

P. Plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity.

Q. Ethical considerations and safeguards for protection of participants

11. Review procedures

I. The meeting of the IEC will be held periodically, unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.

II. The proposals should be sent to the IEC at least 3 weeks in advance of scheduled meeting.

III. The Member-Secretary with the support of the secretarial staff shall screen the proposals for

their completeness and depending on the risk involved categorize them into three types,

namely, exemption from review, expedited review and full committee review.

IV. Decisions will be taken by consensus after discussion, and whenever needed voting will be done.

V. The PI / Research Scholar will then, present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co-PI will be allowed to present the

proposal. Researchers will be invited to offer clarifications on case-to-case basis, if needed

VI. The review discussions/ decisions will be charted down and the final minutes will be

approved by the Chairperson.

VII. After the IEC meeting, the decision of the IEC members regarding the discussed proposals to obtained on the same day of the meeting.

VIII. The proceedings of the meeting will be video recorded with prior permission from all the members attending the meeting.

1X. The type of EC review based on risk involved in the research, is categorized as follows

Type of risk	Definition/description
Less than minimal risk Minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. Research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.
Minor increase over minimal risk or Low risk	<ul> <li>Increment in probability of harm or discomfort is only a little more than the minimal risk threshold.</li> <li>Routine research on children and adolescents; Research on persons incapable of giving consent</li> <li>Delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials;</li> <li>Use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing;</li> <li>Trying a new diagnostic technique in pregnant and breastfeeding women etc.</li> <li>Research should have a social value. Use of personal identifiable data in research also imposes indirect risks.</li> <li>Social risks, psychological harm and discomfort may also fall in this</li> </ul>
More than minimal risk or High risk	category. Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures

# IX. Types of reviews

11.1 Exemption from review Proposals which present "less than minimal risk" fall under this category Following situations may come under this "less than minimal risk" category:

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

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

2. When interviews involve direct approach or access to private papers

11.2 Expedited Review The proposals presenting "no more than minimal risk" to research participants may be subjected to expedited review. The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve 1. Minor deviations from originally approved research protocol during the period of approval. 2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis. 3. Research activities that involve only procedures listed in one or more of the following categories

• Clinical studies of drugs and medical devices only when -

(1). Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or

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

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

(4). When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study.

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

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

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

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

iv. If Data Safety Monitoring Board (DSMB) is constituted to review the data; b. Research on disaster management It may also be unethical sometimes not to do research during disaster. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

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

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

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

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

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

(5). Expedited review may also be taken up for nationally relevant proposals requiring urgent review.

11.3 Full Review

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

a) Research involving vulnerable populations, even if the risk is minimal;

b) Research with minor increase over minimal risk

c) Studies involving deception of participants;

d) Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;

e) Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, case record forms etc.) involving an altered risk;

f) Major deviations and violations in the protocol;

g) Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit-risk assessment;

h) Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need:

i) Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

12. Review of research proposals involving vulnerable population Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent. Include economically and socially disadvantaged; children (up to 18 years); women in special situations; tribals and marginalized communities; refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations: afflicted with mental illness and cognitively impaired individuals, differently abled -mentally and physically disabled; terminally ill or are in search of new interventions having exhausted all therapies; suffering from stigmatizing or rare diseases; or have diminished autonomy due to dependency or being under a hierarchical system and unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent. IECs should carefully determine the benefits and risks of the study and examine the justification provided and risk minimization strategies Additional safety measures should be strictly reviewed and approved by the IECs. IEC must ensure that the informed consent process should be well documented and recording of assent in case of research studies involving children aged 7 to 18 years and reconsent, when applicable. Informed consent from vulnerable populations may be obtained from LAR (Legally authorized representative) in presence of impartial witness after through explanation of risks and benefits

13. Review of multicentric research Multicentre research is conducted at more than one centre by different researchers usually following a common protocol.

• All sites are required to obtain approval from their respective ECs, which would consider the local needs and requirements of the populations being researched and safeguard the dignity, rights, safety and well-being of the participants.

• The ECs/Secretariats of all participating sites should establish communication with one another

• If any EC does not grant approval for a study at a site the reasons must be shared with other ECs and deliberated upon.

• The EC can suggest site-specific protocols and informed consent modifications as per local needs.

• Separate review may be requested for studies with a higher degree of risk, clinical trials or intervention studies where conduct may vary depending on the site or any other reason which requires closer review and attention

• Common review for all participating sites in multicentric research - In order to save time, prevent duplication of effort and streamline the review process, the ECs can decide to have one designated main EC, the decisions of which may be acceptable to other ECs.

• Common review process may be applied to research involving low or minimal risk, survey or multicentric studies using anonymized samples or data or those that are public health research studies determined to have low or minimal risk.

• The common review is applicable only for ECs in India. In case of international collaboration for research and approval by a foreign institution, the local participating sites would be required to obtain local ethical approval

14.Independent consultant/Invited subject experts. Subject experts will be called to provide special review for selected research proposals, if required. They can give their opinion/specialized views but they do not take part during decision making by IEC members.

15. Decision-making& Communication of decision

a. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.

b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and the same should be conveyed to the Chairperson prior to the review of the application and recorded in the minutes.

c. Decision will be made only in meetings where quorum is complete.

d. Only the members can make the decisions. The expert consultants (subject experts) will only offer their opinions.

e. Decision may be to approve, reject, or revise the proposals. Specific suggestions for modifications and reasons for modifications and reasons for rejection will be given.

f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.

g. Modified proposals will be reviewed by an expedited review through identified members.

h. Decision taken on the proposals will be communicated by the Member Secretary/secretariat in writing to the PI / Research Scholar within two weeks after the meeting at which the decision was taken in the specified format

i. IEC approval will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re- approved after one year, where required.

j. The communication of the decision will include:

- a. Name and address of IEC.
- b. The date, place and time of decision.
- c. The name and designation of the applicant.
- d. Title of the research proposal reviewed.

e. The clear identification of protocol no., version no., date, amendment no., date.

f. Along with protocol, other documents reviewed- Clear description of these documents along with Version No. and Date.

g. List of EC members who attended the meeting- clear description of their role, affiliation and gender.

h. A clear statement of decision reached.

i. Any advice by the IEC to the applicant including the schedule / plan of ongoing review by the AIIMS IEC

j. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.

k. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.

l. Signature of the member secretary with date

16. Record keeping and archiving of documents All Research proposals (8 hard copies along with soft copy) along with the information and documents submitted will be dated and filed the documents will be archived for a minimum period of 3 years and for sponsored clinical trials for 5 years after completion/termination of the study. IEC members should not retain any documents with them after the meeting is over. List of documents to be filed and archived

1. Constitution of IEC

2. SOP

3. CV & consent of IEC members

4. IEC Registration

5. Honorarium details, Income and expenses

6. Agenda & minutes of the meetings

7. One copy of proposal

8. Copy of recommendations/decision communicated to applicant

9. Review reports, documents received during the follow up period and final reports of the study

17. Terms of reference Terms of reference will be maintained in the office of IEC. This includes

A. Membership Requirements

B. Terms of Appointment with reference to the duration of the term,

C. The policy for removal, replacement, resignation procedure,

D. Frequency of meetings, and

E. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts etc.

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage (35 to 50%) of members could be changed on regular basis. Preferably, IEC would appoint persons trained in bioethics or persons familiar with ethical guidelines and laws of the country.

18. Administration and management of S. G. R. Ayurved college, Solapur should have an office for the IEC which have adequate space, infrastructure and staff to the EC for maintaining full-time secretariat, safe archival of records and conduct of meeting. A reasonable fee for review may be charged by the IEC to cover the expenses related to optimal functioning in accordance to Institutional policies for industry sponsored projects/funded projects. There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC. Honorarium of INR 5000/- to 10,000/- per sitting will be paid by the institute to the Non-affiliated members attending the meeting

19. Web page for IEC: A dedicated webpage will be created and maintained for IEC. Details of composition, SOP, registration details, circulars/notifications related to IEC meetings and status of submitted proposals and ongoing projects, submission forms, guidelines and contact details will be displayed on this page.

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\* V.C. Principal Seth Govindji Raoji Ayurved Mahavidyalaya, Solapur.