

DPU ETHICS COMMITTEE D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

**Minutes of the Meeting 47th Meeting of the Ethics Committee –Dr.D.Y.Patil Vidyapeeth,
Pune on Friday 08 September 2023 at 10:30 hours.**

The members present for the meeting were:-

- | | |
|----------------------------|------------------|
| 1. Dr. D.L. Ingole | Chairperson |
| 2. Dr.M.V.Khadilkar | Member |
| 3. Dr. Shubhangi Kanitkar | Member |
| 4. Adv.(Dr.) Ruby Chhatwal | Member |
| 5. Dr. Priti Pravin Dhande | Member |
| 6. Dr.Kalpana kelkar | Member |
| 7. Adv.Pramod Patil | Member |
| 8. Dr. Amit jagtap | Member |
| 9. Mrs. Beena Gokhale | Lay Person |
| 10. Dr.Suprakash Chaudhury | Member Secretary |

Leave of absence was granted to: Dr.Ravinder Singh, Dr.Neelu Nawani, Dr.R.K.Nanda



DPU ETHICS COMMITTEE D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

The agenda of the meeting was as follows:

1. Confirmation of minutes of 46th EC Zoom meeting held on **Friday 21 April 2023**.
2. Report of ongoing Projects.
3. Report of projects completed.
4. Report of projects approved in last Meeting.

Proceedings of the meeting:-

Welcome address by Dr. D.L. Ingole– Chairperson

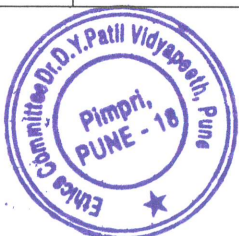
The chairperson welcomed all the members for the 47th Meeting of the Ethics Committee.

EC 1: Confirmation of minutes of 47th EC meeting held on 08 September 2023.

1. The minutes of the **meeting held on 21 April 2023**.were confirmed.

EC 2: Presentation of the research projects in the 46th Zoom EC Meeting-174 project.

Sr.No.	Name of the Faculty/Dept	Topic	Observations& Suggestions	Remarks
1	Dr.Sharad Agarkhedkar (CT)	A Randomized, Open-Label, Assessor Blind, Parallel, Activecontrolled, Multicentric, Bridging Clinical Trial To Evaluate The Immunogenicity And Safety Of Three Dose Thrabis Vaccine (Recombinant Rabies G Protein Vaccine), Administered As A Simulated Post-Exposure Immunization In Healthy Children.		Approved
2	Dr.Megha Kotecha (CT)	“A Prospective,Multi-centre,Single-arm,phase IV study to assess the safety and efficacy of fixed dose combination of brinzolamide and timolol ophthalmic suspension to decrease intraocular pressure (IOP) in adult patients with Open-angle glaucoma or ocular hypertention for whom monotherapy provides insufficient IOP reduction.”		Approved



DPU ETHICS COMMITTEE

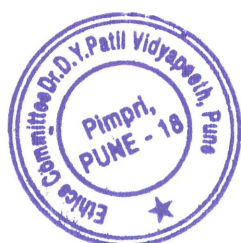
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

3	Dr.Purnachandra Lamghare (CT)	Evaluation of effect of ankle CPM generated by SitWalker on blood circulation in lower extremities in general		Approved
4	Dr. Trupti Tonape (DPU Funding)	Use of Human Amnion Chorion Membrane in clean contaminated and contaminated wounds.		Approved
5	Dr. Sarika Chaturvedi (Amendment)	Effect of yogic kriya on brain functions in healthy adults: A randomised controlled trial in Pune, India		Amendment Approved
6	Dr. Sarika Chaturvedi	“ A pilot randomized controlled study to assess effect of intranasal oil instillation (Pratimarsha Nasya) on nasal barrier function in healthy volunteers”		Approved
7	Dr. Sarika Chaturvedi	ENACTING: UnmEt Needs for heAlth and social care among older people in India and Sweden: a Cross-culTural learning.		Approved
8	Dr.Sachin Shivnitvar (ICMR)	Effect of COVID-19 vaccine on thrombotic events among 18-45-year-old population in india,2022: Multicentric hospital-based matched case control study		Approved
9	Dr.Sachin Shivnitvar (ICMR)	Factors associated with sudden deaths among adults aged 18-45 years, India: Multicentric matched case-control study.		Approved
10	Dr. Shubhangi Kanitkar (Amendment)ICMR	A hospital-based study to understand the role of host and viral factors in predicting severe dengue and the cost of illness of dengue : A pilot study.		Amendment Approved
11	Dr. M.S. Barthwal (Amendment)	TB Aftermath		Amendment Approved
12	Dr. M.S. Barthwal (Amendment)	Post-Tuberculosis Lung Disease		Amendment Approved
13	Dr.Nilesh Giri (Amendment)	LRP/LUBT010/2016/008: A Global, Phase III, Double Blind,		Amendment Approved



DPU ETHICS COMMITTEE

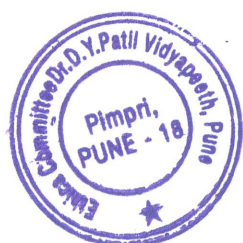
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19; issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		Randomized Controlled Study to Compare the Efficacy, Safety & Immunogenicity of LUBT010 with Lucentis® in Patients with Neovascular Age-Related Macular Degeneration.		
14	Dr.Nayana Karodpati ICMR	Hub and spoke model to evaluate the prevalence of deafness in high risk babies form age zero to five years in rural part of pune.		Approved subject to insurance cover of the babies
15	Dr.Shweta Gaikwad	Recent trends in complete denture fabrication among prosthodontists –A questionnaire survey.		Approved
16	Dr.Salloni Maniyar	A survey on Knowledge and awareness of intra oral scanners amongst the dental practitioners.		Approved
17	Dr. B. Gayathri	A Clinical Survey of patient knowledge, awareness and expectations prior to receiving implant- supported prosthesis.		Approved
18	Dr. Shreya Kabadi	Assessment of provisionalization protocol followed by practicing local dentists		Approved
19	Dr.Krishna Lahoti	Comparative evaluation of the effect of salivary pH on impact strength of heat cure denture base acrylic resins an in-Vitro study.		Approved
20	Dr.Krishna Suryawanshi	Clinical evaluation of effects of Advanced platelet rich fibrin on wound healing after gingivectomy procedure for management of chronic inflammatory gingival enlargement.		Approved
21	Dr. Shraddha Iyer	Comparative evaluation of osteocalcin levels in gingival crevicular fluid (GCF) after surgical management of intrabony defects with and		Approved



DPU ETHICS COMMITTEE

D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		without i-PRF for real time assessment of periodontal regeneration – A pilot study.		
22	Dr. Shreya Rokade	Estimation of HbA1c level in generalised chronic periodontitis patients and its correlation with the severity of periodontal inflamed surface area score in India population – A Prospective study.		Approved
23	Dr.Shivani Yerte	Comparative evaluation of dermatoglyphic patterns and its relation with periodontal status.		Approved
24	Dr.Meghana Guruprasad	Correlation of severity of periodontitis and HbA1c levels in chronic periodontitis patients with low risk of Finnish Diabetes Risk Score.		Approved
25	Dr.Tanmayee Pendse	Comparative evaluation of lip strain, lip thickness lip fall with short and normal lip length in patients undergoing incisor retraction with first premolar extraction – a retrospective study.		Approved
26	Dr.Apoorva Yadav	Fluorescence –aided identification technique (FIT) for efficient removal of different orthodontic bonding adhesives- an in vivo study.		Approved
27	Dr.Linda Merin	An appraisal of orthodontic borderline treatment need using GBON index (Guide for borderline orthodontic treatment need) and AI (Aesthetic index) in local select population.		Approved
28	Dr.Siddhi Lolge	Comparison and correlation of alveolar bone thickness and collum angle in class II division 2 and class I bimaxillary protrusion malocclusion using Lateral Cephalogram..		Approved



DPU ETHICS COMMITTEE

D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

29	Dr.Omkar Jathar	Clinical assessment of hearing loss by pure tone audiometric study in patient with oral submucous fibrosis.		Approved
30	Dr.Samata Parakh	Evaluation of Retromolar foramen and Retromolar canal using cone beam computed tomography : A retrospective study.		Approved
31	Dr.Neha Lanje	Radiographic changes in temporomandibular joint in patients after orthodontic treatment – A retrospective study.		Approved
32	Dr.Priyanka Agrawal	Assessment of compliance and validity of digital application based diet diary with suggestive local food habits for prevention of dental caries in children.		Approved
33	Dr.Surabhi Sinnarkar	Comparative evaluation of a digital diet diary application with existing conventional diet diary in local population.		Approved
34	Dr.Sneha Nair	Maternal perception and attitude towards television food advertising targeting children.		Approved
35	Dr.Purva Doshi	Retrospective study of root canal configuration of permanent mandibular incisor among Indian Sub- population using CBCT.		Approved
36	Dr.Komal Gupta	Comparative evaluation of Microleakage in class II restoration with zirconomer improved and bulk fill composite – A Confocal laser scanning microscopic study.		Approved
37	Dr.Apeksha Gambhir	Comparative evaluation of effect of pretreatment with a hydroxyapatite remineralising agent and diode laser on the shear bond strength of dentin bonding agent : An in vitro-study.		Approved



DPU ETHICS COMMITTEE

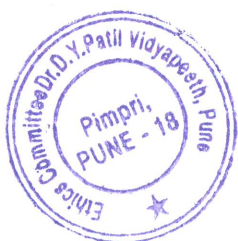
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

38	Dr.C.S.Sherwin Samuel	Assessment of soft tissue wound healing in surgical wound of facial region with and without application of propolis gel.		Approved
39	Dr.Rashi Jain	Evaluation of efficacy of nano-emulsion quercetin gel in wound healing post alveoloplasty		Approved
40	DR.Sakshi Gaikwad	Comparative evaluation of saline gauze dressing and use of glycerine and magnesium sulphate dressing after surgical drainage of space infections.		Approved
41	DrTanvi Tiwarekar	To measure the door to needle time duration required for a patient of facial Trauma in a private teaching institute.		Approved
42	Dr.Bhushan Bhagat	Assessment of perception towards role play learning among final year students in a Pune based Dental College- An Original Research		Approved
43	Dr.Sneha K	Perception towards "Eat Right School" campaign among school teacher.		Approved
44	Dr.Aditi Mathur	Food marketing exposures and packaged food consumption patterns among 10-14 year old children belonging to rural tribal belt of Igatpuri Tehsil, Nashik.		Approved
45	Dr. Sakshi Chawla	Evaluation of the influence of child-parent relationship on the dental fear in children.		Approved
46	Dr.Soumodeep Karmakar	Awareness about use of corals and other marine biominerals dentistry amongst interns, PGs and staff-A survey		Approved
47	Dr.Shristi Prasad	Clinical evaluation of the efficacy 2% curcumin gel as an adjunct to scaling in non-surgical periodontal therapy in chronic generalized gingival.		Approved
48	Dr.Subham Dole	Comparison of two		Approved



DPU ETHICS COMMITTEE

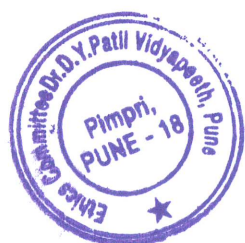
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		commercially available formulation containing triamcinolone acetonide for the management of oral submucous fibrosis : An in vivo study.		
49	Dr.Subham Dole	Motivation levels of dentists regarding use of COVID protocols in private dental practice in the post COVID Era: A questionnaire based study.		Approved
50	Dr.Simran Shakya	Ergonomics in dental undergraduates determined by rapid entire body assessment method- The observational study.		Approved
51	Dr.Avantika Pawar	Muscular skeletal disorders in neck and back region among undergraduates , postgraduates and interns in dental Institute in Maharashtra.		Approved
52	Dr.Siddhant Depura	Evaluation of knowledge , attitude and motor skills in dental interns pre and post clinical training in oral surgery department in a private teaching institute – A questionnaire based study.		Approved
53	Dr. Siddhant Depura	Awareness about management of complications occurring during exodontia amongst dental students in a private teaching institute : A questionnaire based study.		Approved
54	Dr.Chaitaly Munot	Comparative study between 2-5ml syringe with luer lock and 5ml syringe without luer lock for administering local anesthesia.		Approved
55	Dr.Ehan Yadav	Comparative study regarding general awareness, knowledge and practice of infection control and prevention amongst dental students before and after		Approved



DPU ETHICS COMMITTEE

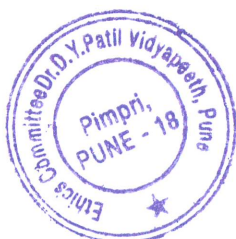
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		briefing in the department of oral and maxillofacial surgery of Dr.D.Y.Patil College and Hospital, Pimpri, Pune		
56	Dr Dron Sethi	Myths and misconception of dental extractions patients perspective : A questionnaire study.		Approved
57	Dr. Diya Sakkhala	Assessment of influence of major and minor OT surgery during internship – A questionnaire survey .		Approved
58	Dr. Sanika Chavan	To study the efficacy of topical anaesthetic agents – Benzocaine v/s lignocaine in reducing pain during needle insertion in mandibular arch – a comparative study.		Approved
59	Dr.Caroline Angela	Assessment of benefits of PRP for scalp and hair growth.		Approved
60	Dr.Chaitali Rakhe	The use of PRP for facial rejuvenation : A Pilot study		Approved
61	Dr.Siddhi Patil	Assessment of knowledge awareness and attitude towards gene therapy and regenerative medicine in dental fraternity		Approved
62	Dr.Siddhi Patil	To evaluate the knowledge , awareness and attitude towards artificial intelligence in dentistry.		Approved
63	Dr.Noufa Ahmed	Prevalence of usage of botox among dental practitioners.		Approved
64	Dr.Noufa Ahmed	Assessment of knowledge awareness and attitude related to sports dentistry among the sports players and coaches.		Approved
65	Dr.Tejas Pol	Knowledge and awareness regarding PEEK implants in dental implantology among		Approved



DPU ETHICS COMMITTEE

D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		dentists and post-graduates practicing implants – a questionnaire study.		
66	Dr.Pinak	Knowledge and awareness regarding interdisciplinary orthodontic among B.D.S. students. Postgraduate students and general dental practitioner- A questionnaire study.		Approved
67	Dr.Azaan Zia	Biodegradation of stainless steel orthodontic wire in the oral cavity: An in vitro study.		Approved
68	Dr. Prerrna Ubale	DTC Aligners an alarming trend – A questionnaire based survey among dental students.		Approved
69	Dr.Prerrna Ubale	Diagnostic flaws in DTC aligners'- A questionnaire based survey among dental professionals		Approved
70	Dr.Rini Dass	Influence of vertical positioning of maxillary canine on smile esthetic perception by general dentists, orthodontists & lay persons.		Approved
71	Dr Prashant Verma	Awareness amongst dental practioner about ideal time for intervention by growth modulation therapy –KAP Survey.		Approved
72	Dr Prashant Verma	Awareness about orthodontic treatment needs in teenage population :- A questionnaire study		Approved
73	Dr.Priya Singh	Perception ,awareness & knowledge of digital dentistry in orthodontics among dental professionals : A questionnaire study.		Approved
74	Dr.Priya Singh	Perception about orthognathic surgery in orthodontic treatment among dental professionals : A questionnaire study.		Approved
75	Dr.Abhirami Premarajan	Assessment of knowledge and attitude towards dental		Approved



DPU ETHICS COMMITTEE

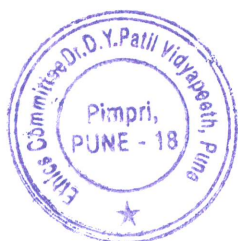
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		problems and treatment among the patients visiting the dental college.		
76	Dr.Anaya Marndi	Knowledge, attitude and practice on rational use of oral antibiotics for endodontic treatment amongst interns-questionnaire study.		Approved
77	Dr.Simran Agarwal Intern PHD	Assessment of oral health among renal dialysis patients affected by end-stage renal disease : A cross sectional study in Pune City		Approved
78	Dr.Shubham Raut	Efficacy of amniotic membrane on healing of facial abrasion wound- A clinical comparative study.		Approved
79	Dr.Damini Goel	Alveolar bone preservation of post orthodontic extraction socket using biodegradable collagen plug-A split –mouth clinico- radiographic study.		Approved
80	Dr.Digvijay Shitole	Comparative evaluation vitamin C and diclofenac sodium as an analgesic in treatment of mandibular fractures- A preliminary study.		Approved
81	Dr.Sushree Mahapatra	Effectiveness of chitosan and gelfoam dressing for homeostasis after extraction of mandibular teeth in patients on oral antiplatelet therapy.		Approved
82	Dr. Tirtha Raj Brahma	Efficacy of surgical performance with and without cognition stimulation exercises –A randomized controlled trial.		Approved
83	Dr.Manoj Kumar U	Comparative evaluation of Efficacy of buffering of 2% lignocaine hydrochloride in apicectomy procedure.		Approved
84	Dr.C. S.Sherwin Samuel	Assessment of efficacy of intra-articular injection of advanced PRF as an adjunct to arthrocentesis for treatment of		Approved



DPU ETHICS COMMITTEE

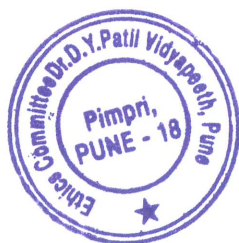
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		internal temporomandibular joint derangement (OLD) Comparative assessment of efficacy and patient tolerance of hybrid arch bar, Erich's arch bar and MMF screw placement in treatment of jaw fractures. (NEW)		
85	Dr.Divya Palanisami	Evaluation of the effectiveness of hemostatic clips versus conventional sutures in vessel ligation during neck dissection in oral cancer patients- A clinical study.		Approved
86	Dr.Aashlesha Raut	Effect of Non-Surgical periodontal therapy on the glycated haemoglobin (HbA1c) levels in generalized chronic periodontitis patients diagnosed with prediabetes – A prospective study.		Approved
87	Dr.Ketan Deshetti	Non-surgical management of isolated shallow wide gingival recession defect by using injectable platelet rich fibrin.		Approved
88	Dr.Vaidehi Patel	The effect of Non-surgical periodontal therapy on serum homocysteine levels and serum vitamin B12 level in chronic periodontitis patients.-An in vivo study.		Approved
89	Dr. Jonathan Verghese	Evaluation of clinical efficacy of laser pocket disinfection combined with laser photoablation as adjunct to scaling and root planning in the treatment of chronic periodontitis – A split mouth randomized trial.		Approved
90	Dr. Krishna Suryawanshi	Periodontal health condition and oral health related quality of life (OHRQOL) in patients with parkinson's disease - A cross sectional study.		Approved



DPU ETHICS COMMITTEE

D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

91	Dr.Sharvari Killedar	Comparative Evaluation of efficacy of a potassium nitrate containing herbal mouthwash to a potassium oxalate mouthwash in dentinal hypersensitivity – A pilot randomised clinical trial.		Approved
92	Dr.Shivani Yerte II MDS	Evaluation of the crestal soft tissue thickness and its correlation to hard tissue measurements using cone beam computed tomography before and after Implant placement. (New Topic)		Approved
93	Dr.Sejal Patil	Effectiveness of educational intervention on dental nutritional knowledge among nursing students		Approved
94	Dr.Aditi Tasgaonkar	Comparative evaluation of the bond strength of various luting agents used for bioflex crowns in primary teeth – An in vitro study..		Approved
95	Dr.Ankita Marathe	Comparative evaluation of attitude and perception of parents for the use of papoose board and comfy wrap physical restraint as a behaviour guidance technique in pediatric patients during dental procedure – A crossover study.		Approved
96	Dr.Neil Godbole	Effectiveness of an educational intervention on knowledge of nurses students regarding oral health care needs of special children.		Approved
97	Dr.Vaishnavi Mathawala	A three dimensional finite element analysis of the von mises stress and strain distributions generated by two commercially available Nickel –Titanium rotary files in primary root dentin		Approved



DPU ETHICS COMMITTEE

D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

98	Dr.Prajakta Kokate	Comparative evaluation of marginal adaptation of MTA and biodentine in combination with bioactive glass nanoparticles as a root end filling material with CLSM ; - An in vitro study.		Approved
99	Dr.Sakshi Agrawal	Influence of endodontic access cavity design on fracture strength when restored with fibre reinforced composite : An in vitro study.		Approved
100	Dr.Pushpal Ingle	Comparative evaluation of 3 techniques of shade matching- VITA shade guide, digital application and a colour corrected light.		Approved
101	Dr Mayuresh Bhujbal	Evaluation of the root canal morphology of permanent maxillary first molar in Indian subpopulation – A Cross – sectional CBCT study.		Approved
102	Dr.Harsha Nihalani	Comparative evaluation of different surface pre-treatment methods on depth of penetration of adhesive resin in sandwich technique- A Confocal laser scanning microscopic study.		Approved
103	Dr.Riddhi Kakodkar	Comparative evaluation of calcium ion release of two commercially available pulp capping agents at different time periods: An in vitro study.		Approved
104	Dr.Shalini Aggarwal	The use of direct observation of procedural skills (DOPS) in eliminating bias during assessment of the clinical procedures done by undergraduate students in the dental colleges.		Approved
105	Dr. Vaishnavi Sawant	Morphologic and Morphometric analysis of crista galli for forensic gender		Approved



DPU ETHICS COMMITTEE

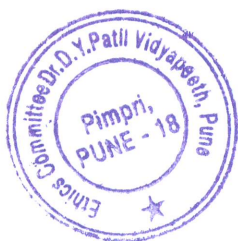
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		determination using cone beam computed tomography : A retrospective study.		
106	Dr.Anupama Chavan	Quantitative evaluation of bone density using hounfield unit (HU) in CBCT- cross sectional radiographic study..		Approved
107	Dr.Ashutosh Dighe	Morphometric analysis of sphenoid sinus in forensic identification r : A CBCT based retrospective study.		Approved
108	Dr.Farha Khatoon	A Novel classification for pneumatisation of maxillary sinus in CBCT of edentulous patient- A cross sectional study		Approved
109	Dr. Chaitanya Bhosle	New regression equation for mixed dentition space analysis to predict size of unerupted canine and premolars using digital model in local select population.		Approved
110	Dr.Larissa D'costa	Evaluation of colour stability of three composite resin used as orthodontic attachments in clear aligner therapy: In vitro study.		Approved
111	Dr. Sanya Dua	Estimation of condylar volume in different skeletal patterns in adult local select population: A retrospective 3D analysis.		Approved
112	Dr. Nidhi Jhavar	Comparative evaluation of of excess adhesive flash and adhesive remnant index of five different adhesive bonding systems – An in vitro study.		Approved
113	Dr.Abhishree Keshan	Photographic assessment of virtually modified nasal morphologies for orthodontic treatment needs		Approved
114	Dr.Siddharth Chakraverty	A novel approach to assess airway volume from a lateral cephalogram using Imager software – A pilot study.		Approved
115	Dr.Preet Lunawat	You tube as an education source in Hindi language for		Approved



DPU ETHICS COMMITTEE

D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		improvement of oral hygiene practices for children-a content analysis study.		
116	Dr.Isha Inamdar	Assessment of food label literacy amongst dental undergraduates : An Interventional study.		Approved
117	Dr.Rajlakshmi Gaikwad	Study of depression, anxiety and stress assessment in oral submucous fibrosis patients and its correlation with salivary flow rate and burning sensation.		Approved
118	Dr.Tanisha Agarwal	A comparative evaluation of the dimensional accuracy of implant impressions using open tray impression coping vs screw retained fixture mount – An In vitro study,		Approved
119	Dr. Ayushi Sharma	Questionnaire study to assess knowledge, attitude and practice for all ceramic restorations in fixed partial prosthesis amongst prosthodontist and general dental practioners.		Approved
120	Dr.Kavita Singh	Awareness among diabetic patients on relationship between diabetes and periodontal disease		Approved
121	Dr. Aashlesha Sureshkumar Raut	Comparative evaluation of volume stable collagen matrix and platelet rich fibrin using coronally advanced flap technique in the management of Isolated gingival recessions.		Approved
122	Dr. Deshetti Ketan Rajesh	Comparative analysis of growth factors panel of injectable horizontal platelet rich fibrin at different heating temperatures – An in vitro study.		Approved
123	Dr. Jonathan Varghese Thomas	Comparative evaluation of the stability of implants coated with and without injectable platelet rich fibrin using resonance frequency analysis during osseointegration period – A split		Approved



DPU ETHICS COMMITTEE

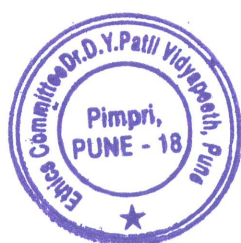
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		mouth randomized trial		
124	Dr. Killedar Sharvari Tanaji	Comparative evaluation of semilunar coronally repositioned flap and modified semilunar coronally advanced flap in the management of Isolated gingival recession type 1 (RTI) defect: A randomized clinical study.		Approved
125	Dr. Vaidehi Kantilal Patel	The comparative evaluation of the effect of A desensitizing toothpaste , diode laser and the combined application of toothpaste and diode laser in the management of dentin hypersensitivity –A randomize clinical study.		Approved
126	Dr. Krishna Suryawanshi	Comparative evaluation of clinical efficy of conventional and microsurgical gingictomy techniques for the management of gingival enlargement (OLD) Evaluation of calprotectin (Human S100A8/A9 protein) and high-sensitivity C – reactive protein levels In gingival crevicular fluid and serum in chronic periodontitis subjects with and without type 2 diabetes. (NEW)		Approved
127	Dr.Meghana Guruprasad	Evaluation of efficacy of diode laser for laser assisted periodontal regeneration in chronic periodontitis with horizontal bone loss – In vivo study.(OLD) Evaluation of advanced platelet =rich fibrin as a carrier for local delivery of antibiotic in tissue regeneration – An vitro study (NEW)		Approved
128	Dr. Abhishree	Comparative evaluation of		Approved



DPU ETHICS COMMITTEE

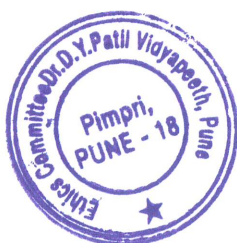
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

	Keshan2	alveolar bone changes in the incisor and molar regions after whole arch distalization with buccal shelf implant- A CBCT study.		
129	Dr. Bhosle Chaitanya Udayabhaskar	Comparative evaluation of salivary bone morphogenic protein 4 levels in fixed orthodontic appliances and clear aligners during orthodontic tooth movement.		Approved
130	Dr. D'costa Larissa	Peak insertion and removal torque values of four self-drilling mini-implant systems: In vitro study		Approved
131	Dr. Dua Sanya Himanshu	Topographical and elemental changes to two orthodontic mini-implants before and after clinical use.		Approved
132	Dr. Jhavar Nidhi Nitin	Effect of reverse pull headgear with rapid maxillary expansion appliance and craniofacial structures : A finite element model study.		Approved
133	Dr. Siddharth Chakravarty	Analysis of the effects of different composite attachments on anchor teeth during canine retraction with clear aligner-A three dimensional finite element analysis		Approved
134	Dr. Agrawal Sakshi Sharad	Comparative evaluation of the remineralisation potential of bio HAP, CPP-ACP and enamel on root dentin		Approved
135	Dr. Bhujbal Mayureh Bapu	Comparative evaluation of volume of removed dentin, canal transportation and centering ratio of three different rotary files using cone-beam computed tomography – An in vitro study.		Approved
136	Dr. Humnabad Vamshi Krishna	Comparative evaluation of antibacterial activity and drug release of calcium hydroxide		Approved



DPU ETHICS COMMITTEE

D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		loaded nanoparticles as intracanal medicaments – In vitro study		
137	Dr. Ingle Pushpal Tushar	Role of C-factor on bond strength of universal adhesives in occlusal cavities.		Approved
138	Dr. Kakodkar Riddhi Jagadish	Evaluation of depth of penetration of intracanal heated sodium hypochlorite under the influence of ultrasonic activation – A clsm study		Approved
139	Dr. Khairajani Dipti Jitendra	Comparative evaluation of removal of calcium silicate based intracanal medicament using different irrigation activation techniques – An in vitro CBCT volumetric analysis.		Approved
140	Dr. Kokate Prajakta Prakash	Effect of biodentine modified with bioactive glass nanoparticles on biocompatibility, osteogenic differentiation and gene expression of human dental pulp stem cells.		Approved
141	Dr. Nihalani Harsha Rajesh	Comparative evaluation of sorption, solubility, pH and flexural strength of wollastonite- modified GIC with MTA : An in vitro study		Approved
142	Dr. Baheti Nikita Sandip	Assessment of serum organ specific fibrotic biomarkers in patients with oral submucous fibrosis		Approved
143	Dr. Gaikwad Rajlakshmi Mahendra	Oral functional health status in oral submucous fibrosis patients and healthy individuals : A comparative observational study.		Approved
144	Dr. Gandhi Deeksha Anil	Ratification of salivary miRNA healthy individuals with habit ,oral submucous fibrosis and oral squamous cell carcinoma patients.		Approved
145	Dr. Swapna	Expression of vascular		Approved



DPU ETHICS COMMITTEE

D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

	Dhanaraj Nikaju	endothelial growth factor-C lymphatic endothelial cell chemokines and myeloid derived suppressor cells in oral squamous cell carcinoma with andwithout lymph noe metastasis.		
146	Dr. Inamdar Isha Abhay	Efficacy of Irimedadi oil and virgin coconut oil pulling on plaque induced gingivitis : A randomized controlled trial		Approved
147	Dr. Lunawat Preet Santosh	Association of permanent tooth eruption time and dermatoglyphic patterns among 5-15 year old Indian sub-group children- A cross sectional study.		Approved
148	Priyanka Kharat	Association of oral lesions and its associated factors among breast cancer survivors of 18 years and above-A cross sectional study.		Approved
149	Dr. Damini Goel	Comparative evaluation of simvastatin gel infused commercially available bone graft in healing after surgical removal of impacted third molars –Split mouth study.		Approved
150	Dr. Manoj Kumar	Efficacy of novel biomaterial in wound healing and postoperative plant management in mandibular fractures		Approved
151	Dr. Pragya Borghate	Comparative evaluation of use of face ice pack wrap and room vac drain in post-operative oedema and pain of mandibular fractures –Randomized controlled Trial.		Approved
152	Dr. Raut Shubham Sharad	Comparative evaluation of salivary exosomes in Pre and post –operative surgery of oral squamous cell carcinoma-A clinical study		Approved
153	Dr. Shitole	Evaluation of injection		Approved



DPU ETHICS COMMITTEE

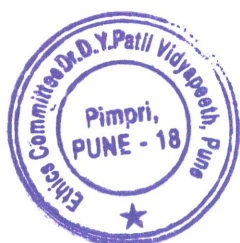
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

	Digvijay Rajendra	hyaluronidase in reduction of periorbital oedema in zygomaticomaxillary complex fractures.		
154	Dr. Somya Pande	Evaluation of the soft and hard tissues healing in the socket preservation using synthetic and autogenic combination bone graft		Approved
155	Dr. Sushree Mahapatro	Comparative evaluation of effect of hyaluronic acid treated and non absorbable suture material in alveoloplasty .		Approved
156	Dr. Tirtha Raj Brahma	Comparative evaluation of aluminium for nasal splint with 3d pen designed nasal splint-randomized controlled trial.		Approved
157	Dr. Deorukhkar Simran Rajan	Comparative evaluation of anxiety and chairside time with three different isolation systems in children :A randomized clinical trial		Approved
158	Dr. Godbole Neil Mahendra	Comparative evaluation of effectiveness of social story and visual pedagogy based pre-appointment behaviour guidance methods in children with autism spectrum disorder.		Approved
159	Dr. Ankita Tapkir	Effect of baghdadite , mineral trioxide aggregate & its combination on biocompatibility and odontogenic and osteogenic differentiation of human dental pulp stem cells,		Approved
160	Dr. Patil Sejal Sharad	Evaluation of the effect of baicalein on the odontogenic differentiation of dental pulp stem cells.		Approved
161	Dr. Tasgaonkar Aditi Prasad	Comparative evaluation of the effectiveness of an audio-visual distraction aid with an augmented reality based app in pediatric patients with dental fear and anxiety.		Approved



DPU ETHICS COMMITTEE

D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

162	Dr. Mathawala Vaishanvi Ketankumar	Comparative evaluation of lesion sterilization & tissue repair protocol and pulpectomy for the treatment of non vital primary teeth : A randomized controlled trial.		Approved
163	Dr. Gaikwad Shweta Anand	Comparative evaluation of optical properties of lithium disilicate crowns fabricated by pressable and CAD CAM method-In vitro study		Approved
164	Dr. Nenwani Chanchal Vasant	Comparative evaluation of marginal accuracy and surface roughness of provisional crowns fabricated with 3D printing and CAD/CAM milled techniques – An In vitro study.		Approved
165	Dr. Patel Dhruv Vikram	Comparative evaluation of the efficiency of different sterilization protocols for used healing abutment –An in vitro study.		Approved
166	Dr. Soni Akhila Sudhir	Comparative evaluation of total occlusal convergence in maxillary anterior tooth preparations to received full veneer crown and bridge restorations prepared by prosthodontic post graduate students in clinical setup-An in vitro study.		Approved
167	Dr. Srishty Pundir	Effect of different ambient light illuminance using digital photography shade selection method on maxillary anterior teeth – an in vivo study.		Approved
168	Dr. Vidhi Kamal Jethwani	Comparative evaluation of the effect of salivary pH on the flexural strength of CAD-CAN milled and conventional denture base acrylic resin : An in vitro study.		Approved
169	Dr. Chavan Anupama Anand	Application of Hounsfield unit (HU) in differentiation of cyst		Approved



DPU ETHICS COMMITTEE

D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19; issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		and tumors of jaw in cone beam computed tomography (CBCT) – A cross sectional study.		
170	Dr. Dighe Ashutosh Sanjay	Effect of in vitro exposure of corticosteroid on gingival stem cells differentiation.		Approved
171	Dr. Farha Khatoon	Efficacy of 3D printed endodontic guide in conservative access preparation – an in vitro study.		Approved
172	Dr. Sawant Vaishnavi Shailesh	Evaluation of salivary and serum vascular endothelial growth factor (VEGF) in patients with oral lichen planus : A comparative study		Approved
173	Dr.Lisha Thole	Ergonomic assessment of the body working poshers among the undergraduate students : A 3 year comparative longitudinal study.(OLD) Ergonomic assessment of body working posture amongst undergraduate dental students – An interventional study.(NEW)		Approved
174	Dr.Mahek Bulan	Parental perception towards nutrition labelling and food packaged of commonly consumed packaged food among children and its influence on purchase behavior.		Approved

A. Discussion on the SAE in “Hybrid Trial for Alcohol reduction among people with TB and HIV in India.” As per principal Investigator’s opinion, Subject No.30005-U06 & Subject No.30001-QE5 the SAE was not related to study.

B. EC 3: Presentation of the new research projects in the 47th EC Meeting- 57

Sr.No.	Name of the Faculty/Dept	Topic	Observations& Suggestions	Remarks
1	Dr.Shrikant Tripathy	Prospective ,multi- center, randomized, open label, active control, phase 2 clinical study		Approved



DPU ETHICS COMMITTEE

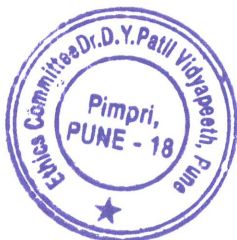
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		to evaluate immunogenicity, safety and tolerability of single heterologous booster dose of RelCoVax (Protein Subunit Vaccine of Reliance Life Sciences against SARS-CoV-2 Virus)with Corbevax(Protein Subunit Vaccine of Biological E Ltd.against SARS-CoV-2 Virus)		
2	Dr.Shrikant Tripathy	A Pilot Study to determine the T and B cell immune response in long COVID-19 patients.		Approved
3	Dr.Nilesh Giri	A Prospective, Multi-Centre, Open label, Single-arm, phase I Study to evaluate the safety of GBL 1204 in patients with neovascular age related macular degeneration		Provisional approval subject to permission of DCGI for clinical site
4	Dr.Nilesh Giri	A prospective,multi-center,single arm, open label, study to evaluate safety and efficacy of RanizuRelTM containing Ranibizumab for intra-vitreous injection, manufactured by Reliance Life Sciences,Pvt.Ltd. India in patients with neovascular (wet) age-related macular degeneration.		Amendment Approved
5	Rahul Salunkhe (PI Change)	A prospective, single-arm, multi-center, post market clinical follow-up study to evaluate the safety and performance of Bioabsorbable Ligament Anchor in Shoulder Rotator Cuff Repair.		Amendment Approved
6	Dr. Chittaranjan Yajnik (Amendment)	Investigation of multi-OMIC effects of low and high dose oral Vit.B12(Methylcobalamin) treatment in volunteers		Amendment Approved
7	Dr.Shailaja Mane	A hospital study to understand		Amendment



DPU ETHICS COMMITTEE

D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

	(Amendment)	the role of host and viral factors in predicting severe dengue and the cost of illness of dengue : A pilot Study		Approved
8	Dr.M.S.Barthwal (Amendment)	TB Aftermath		Amendment Approved
9	Dr.Virendra Athavale	Treatment modalities and immune response in patients with Diabetic Foot Ulcers.	Trade name/ingredient of medication to be mention	Approved
10	Dr.Abhay Saraf	Assessment of processed food consumption and eating habits among medical students at Dr.D.Y.Patil Medical College, Pimpri, Pune.		Approved
11	Dr.Amitav Banerjee	Assessing the impact of COVID-19 on routine immunization (RI) of children in selected study areas : an attempt to design an intervention strategy for difficult to access areas		Approved
12	Dr.Shradha Salunkhe	Metabopsy of first nail clippings and milk teeth for the early diagnosis of inherited metabolic disorders (IMD): A pilot study.		Approved
13	Dr.Sachin Atre	Assessing social stigma and mental health challenges among patients with tuberculosis (TB) and multidrug-resistant tuberculosis (MDR-TB) : a gender perspective		Approved
14	Dr.Puja Padbidri	Identifying pediatrician use of screening tools to detect developmental delays in the districts of Pimpri-Chinchwad and Pune		Approved
15	Dr.Prashant Chandra	Determining Secreted frizzled-related protein 4 (SFRP4), a soluble WNT antagonist multifunctional protein in malignancies for determining		Approved



DPU ETHICS COMMITTEE

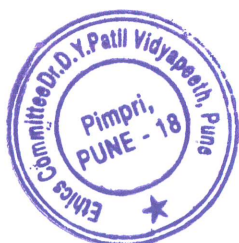
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		prognostic factors of tumours		
16	Dr.Charusheela Gore	Standardization of Her2-Neu by fluorescent in situ hybridization (FISH)		Approved
17	Dr.Chaitali Borgaonkar	Population based seroprevalence of kysanur forest disease (KFD) IgG antibodies in pune district, Maharashtra.		Approved
18	Dr.Samir gupta	Determining various molecular/genetic changes associated with >10mm dept of invasion in head & neck malignancies		Approved
19	Dr.Ajaykumar Sahu	Uncover the Hidden health Journey : Decoding the Morbidity Pattern among the jambhuldara (Gosasi) Tribal Population		Approved
20	Dr.Shweta Chauhan	Transforming Menstrual hygiene in Government School : Assessing Facilities,Knowledge,Attitudes and practices among adolescent girls and developing a model for best practices		Approved
21	Dr. Sadhana Lakhute	Effect of Behavioural Change Communication on Internet gaming Disorder and Smartphone Addiction among undergraduate students at a medical college in western Maharashtra – A Quasi Experimental Study.		Approved
22	Dr.Shital Patil	Knowing the Status – ‘Triple H’ among truck		Approved
23	Dr.Prachi Athavale	The role of DNA Ploidy in Liquid Based Cytology for Cervical Pre-Cancer and Cancer testing using Flow Cytometry		Approved
24	Dr.Rahul band	A Study of assessing response to snake bite in population of		Approved



DPU ETHICS COMMITTEE

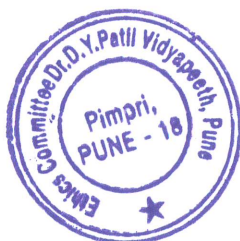
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		pune region		
25	Dr.Vaddi Kavya	An anthropometric study to estimate stature from various percutaneous bodily measurement in young adults		Approved
26	Dr.Tushar Dighe	Combination Of Maintenance Hemodialysis With Hemoperfusion: A Safe And Effective Model Of Artificial Kidney.		Approved
27	Dr Satish Nirhale	Sleep disorders in Parkinsonism patients		Approved
28	Dr. Pravin Naphade	The Role Of Viruses In Demyelinating Disorders Of The Central Nervous System		Approved
29	Ananya gupta	Attitude of medical student to sexual abuse in children		Approved
30	Vishakha Jayram	Study gender differences in social media addiction in medical students with references to social anxiety, well being and personality		Approved
31	Kashish Jain	Acculturative stress in non-resident students		Approved
32	Alamalakala samhith	Evaluation of psychological distress in undergraduate medical students		Approved
33	Shatakshi Lahariya	No mobile phone phobia and its relation to social anxiety, sleep and personality in undergraduate medical students		Approved
34	Shreya Vaibhav Patil	A study to assess factors motivating undergraduate medical student to pursue medicine		Approved
35	Devanshi Singh	Body Dysmorphic Disorder (BDD)in young adults in the age of social media		Approved
36	Dr.Akshay Naik	Relationship between impulsivity, personality traits and social media use in medical students		Approved
37	Dr.Prisha Kelkar	Caregiver burden in relatives		Approved



DPU ETHICS COMMITTEE

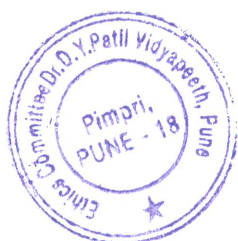
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		of patient with schizophrenia and alcohol use disorder and its association with anxiety, depression and coping strategy		
38	Dr. Poulomi Ghosh	Assessment Of diffuse cortical Atrophy in young alcoholics		Approved
39	Dr.Viniti Vaidya (Biotechnology)	A systematic survey on non-hazardous laboratory agar waste generation by biotechnology companies and educational institutes in pune city		Approved
40	Dr.Shrutika Salunkhe	Comparative evaluation of conventional cutting diathermy and bipolar scissor assisted reconstruction, while raising pectoralis major myocutaneous flap surgery – In vivo study.		Approved
41	Dr.Humeera Mulla	To evaluate the presence of nicotine in the commercially available tooth paste.		Approved
42	Dr.Rahul Mohandas	Evaluation of glucose transporter-1 (GLUTI) and sodium-glucose cotransporter-1 (SGLTI) expression in oral squamous cell carcinoma		Approved
43	Dr.Subhashree Mohapatra	Impact of educational intervention on the knowledge of COTPA laws among interns in a Tertiary Dental Hospital Setting, Pune : An Interventional study.		Approved
44	Dr.Yash Merchant	Reconstruction of oral mucosal defect with ex vivo produced oral mucosa equivalent (EVPOME)- an in vitro pilot study.		Approved
45	Dr.Snehal Jagtap	Evaluation and comparison of change in pharyngeal airway volume in patients affected with oral submucous fibrosis after		Approved



DPU ETHICS COMMITTEE

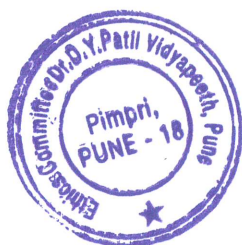
D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		Intervention using polysomnography and CBCT- An experimental study.		
46	Dr.Rahul Mohandas	Evaluation of Irisin expression in patients with Oral Squamous cell carcinoma.		Approved
47	Dr.Humeera Mohammed Ghaus Mulla	Study of dermatoglyphics in Oral Squamous cell carcinoma and oral submucous fibrosis patients.		Approved
48	Dr.Vaibhavi Raut	Efficacy of aqueous formulation using extracts of Ocimum sanctum Linn (Tulsi), Curcuma longa (Turmeric) and Aloe vera in management of oral lichen planus : a randomized controlled trial.	Clinical trial registration will be (CTRI)required	Provisional approved
49	Dr.Pallavi Vaishisth	Comparative evaluation of antibacterial efficacy of mucoadhesive patch containing cymbopogon citratus, green tea extract and their combination with probiotic: .		Not Approved
50	Dr.Lakshmi Thribhuvanan	Impact of sensory adapted Dental Environment in the management of Dental Anxiety In Children –A Randomized Controlled Trial.		Approved
51	Dr.Atharva Prafulkumar Babel	A study of the remineralization effects of The Novel chitosan scaffolds in a tooth model- An in vitro study		Approved
52	Dr.Dhanashree Ravindra Dalal	IoT-Enable application as a fear,anxiety and pain assessment tool for patients in dental clinic setting		Approved
53	Dr.Shraddha Iyer	Prospective clinical evaluation Of demineralised freeze-dried bone allograft (DFDBA) injectable-platelet rich fibrin (i-PRF) and Vit D with DFDBA, i-PRF and DFDBA in human infrabony defects.	Vitamin D level To be included	Approved
54	Dr.Krishna Rajkumar Suryawanshi	Evaluation of association between chronic periodontitis and metabolic syndrome using calprotectin, calgranulin C & Resistin as potential biomarkers: A clinico-biochemical study.	Criteria for metabolic syndrome to be mention	Approved



DPU ETHICS COMMITTEE

D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

55	Dr.Meghana Guruprasad	Effect of different antibiotic incorporated advanced platelet rich fibrin membrane on human gingival mesenchymal stem cells- An in vitro study.		Approved
56	Dr.Dhananjay Gandage	An in vitro and clinical comparative evaluation of optical and mechanical properties of CAD CAM and heat pressable (Monolithic and layered) lithium disilicate ceramic crowns.		Approved

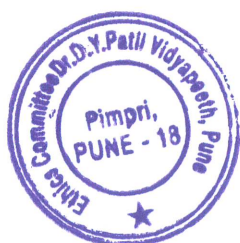
A. Discussion on the SAE in “Randomised Evaluation of Covid-19 Therapy. Serious Adverse Event of Subject 1480475.

Event:- Admitted In Hospital For Coronary Angiography Test.

“The SAE Was Not Related To Study.

Analysis report by the committee for participant with Enrolment ID 1480475

Sr.No.		Observations by the members
1	Adverse effect of the investigational product.	No
2	Violation of the approved protocol, scientific misconduct of negligence by the sponsor of his representative or the investigator leading to serious adverse event	No violation or deviation from approved.
3	Failure of investigational product to provide intended therapeutic effect where, the required standard care or rescue medication, though available, was not provided to the subject as per clinical trial protocol.	Investigational product was provided to the patient, however, no association of the investigational product with onset of SAE
4	Not providing the required standard care, though available to the subject as per clinical trial protocol in the placebo controlled trial.	No
5	Adverse effects due to concomitant medication excluding standard care, necessitated as part of the approved protocol	No adverse effects due to concomitant medication.
6	Adverse effect on a child in-utero because of the participation of the parent in the clinical trial	No
7	Any clinical trial procedures involved in the study leading to serious adverse event	No
8	Causality assessment by members	The SAE was not related to the clinical trial or other treatment/procedure.



DPU ETHICS COMMITTEE

D.Y.Patil VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

9	Whether compensation is recommend.	No compensation is recommended
---	------------------------------------	--------------------------------

EC.4.Vote of thanks was proposed by the Member Secretary, Dr. Suprakash Chaudhury on behalf of Ethics Committee to all the members for being present and for giving their valuable inputs.

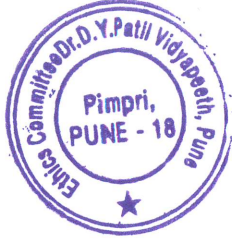
Dr. Suprakash Chaudhury
Member Secretary

Member Secretary
Ethics Committee
Dr.D.Y.Patil Vidyapeeth,Pune.

Dr.D.L. Ingole
Chairman

Chairman
Ethics Committee
Dr.D.Y.Patil Vidyapeeth, Pune

Date: 08/09/2023





ETHICS COMMITTEE
D.Y.PATIL VIDYAPEETH, PUNE

(Reg.No.ECR/361/Inst/MH/2013/RR-19: issued under New Drugs & Clinical Trials Rules 2019)

Dr.D.L.Ingole
Chairman

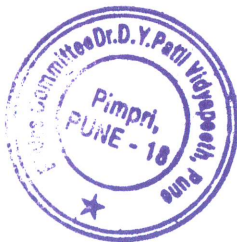
Dr.SuprakashChaudhury
Member Secretary

**Minutes of the Meeting 48th Meeting of the Ethics Committee –Dr.D.Y.Patil Vidyapeeth,
Pune on Friday 02 February 2024 at 10:30 hours.**

The members present for the meeting were:-

- | | |
|----------------------------|------------------|
| 1. Dr. D.L. Ingole | Chairperson |
| 2. Dr.M.V.Khadilkar | Member |
| 3. Dr. Shubhangi Kanitkar | Member |
| 4. Adv.(Dr.) Ruby Chhatwal | Member |
| 5. Dr. Priti Pravin Dhande | Member |
| 6. Dr.Kalpana kelkar | Member |
| 7. Adv.Pramod Patil | Member |
| 8. Dr.R.K.Nanda | Member |
| 9. Mrs. Beena Gokhale | Lay Person |
| 10. Dr.Suprakash Chaudhury | Member Secretary |

Leave of absence was granted to: Dr.Ravinder Singh, Dr.Neelu Nawani, Dr.Amit jagtap



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

The agenda of the meeting was as follows:

1. Confirmation of minutes of 47th EC meeting held on **Friday 08 September 2023**.
2. Report of ongoing Projects.
3. Report of projects completed.
4. Report of projects approved in last Meeting.

Proceedings of the meeting:-

Welcome address by Dr. D.L.Ingole– Chairperson

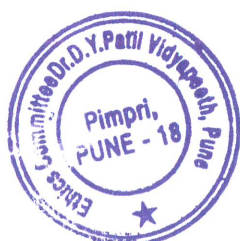
The chairperson welcome all the members for the 48th Meeting of the Ethics Committee.

EC 1: Confirmation of minutes of 48th EC meeting held on 02 February 2024.

1. The minutes of the **meeting held on 08 September 2023**.were confirmed.

EC 2: Presentation of the research projects in the 47th EC Meeting-57 project.

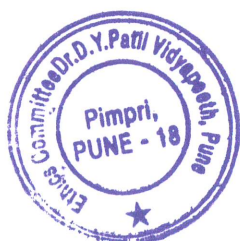
Sr.No.	Name of the Faculty/Dept	Topic	Observations& Suggestions	Remarks
1	Dr.Shrikant Tripathy	Prospective ,multi- center, randomized, open label, active control, phase 2 clinical study to evaluate immunogenicity, safety and tolerability of single heterologous booster dose of RelCoVax (Protein Subunit Vaccine of Reliance Life Sciences against SARS-CoV-2 Virus)with Corbevax(Protein Subunit Vaccine of Biological E Ltd.against SARS-CoV-2 Virus)		Approved
2	Dr.Shrikant Tripathy	A Pilot Study to determine the T and B cell immune response in long COVID-19 patients.		Approved
3	Dr.Nilesh Giri	A Prospective, Multi-Centre, Open label, Single-arm, phase I Study to evaluate the safety of GBL 1204 in patients with neobascular age related macular degeneration		Provisional approval subject to permission of DCGI



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

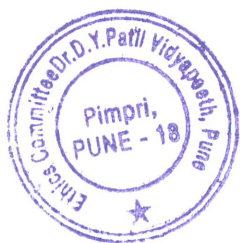
				for clinical site
4	Dr.Nilesh Giri	A prospective, multi-center, single arm, open label, study to evaluate safety and efficacy of RanizuRel™ containing Ranibizumab for intra-vitreous injection, manufactured by Reliance Life Sciences, Pvt.Ltd. India in patients with neovascular (wet) age-related macular degeneration.		Amendment Approved
5	Rahul Salunkhe (PI Change)	A prospective, single-arm, multi-center, post market clinical follow-up study to evaluate the safety and performance of Bioabsorbable Ligament Anchor in Shoulder Rotator Cuff Repair.		Amendment Approved
6	Dr. Chittaranjan Yajnik (Amendment)	Investigation of multi-OMIC effects of low and high dose oral Vit.B12 (Methylcobalamin) treatment in volunteers		Amendment Approved
7	Dr.Shailaja Mane (Amendment)	A hospital study to understand the role of host and viral factors in predicting severe dengue and the cost of illness of dengue : A pilot Study		Amendment Approved
8	Dr.M.S.Barthwal (Amendment)	TB Aftermath		Amendment Approved
9	Dr.Virendra Athavale	Treatment modalities and immune response in patients with Diabetic Foot Ulcers.	Trade name/ingredient of medication to be mention	Approved
10	Dr.Abhay Saraf	Assessment of processed food consumption and eating habits among medical students at Dr.D.Y.Patil Medical College, Pimpri, Pune.		Approved
11	Dr.Amitav Banerjee	Assessing the impact of COVID-19 on routine immunization (RI) of children		Approved



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

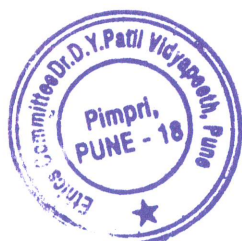
		in selected study areas : an attempt to design an intervention strategy for difficult to access areas		
12	Dr.Shradha Salunkhe	Metabopsy of first nail clippings and milk teeth for the early diagnosis of inherited metabolic disorders (IMD): A pilot study.		Approved
13	Dr.Sachin Atre	Assessing social stigma and mental health challenges among patients with tuberculosis (TB) and multidrug-resistant tuberculosis (MDR-TB) : a gender perspective		Approved
14	Dr.Puja Padbidri	Identifying pediatrician use of screening tools to detect developmental delays in the districts of Pimpri-Chinchwad and Pune		Approved
15	Dr.Prashant Chandra	Determining Secreted frizzled-related protein 4 (SFRP4), a soluble WNT antagonist multifunctional protein in malignancies for determining prognostic factors of tumours		Approved
16	Dr.Charusheela Gore	Standardization of Her2-Neu by fluorescent in situ hybridization (FISH)		Approved
17	Dr.Chaitali Borgaonkar	Population based seroprevalence of kysanur forest disease (KFD) IgG antibodies in pune district, Maharashtra.		Approved
18	Dr.Samir gupta	Determining various molecular/genetic changes associated with >10mm dept of invasion in head & neck malignancies		Approved
19	Dr.Ajaykumar Sahu	Uncover the Hidden health Journey : Decoding the Morbidity Pattern among the jambhuldara (Gosasi) Tribal		Approved



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

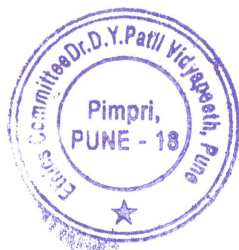
		Population		
20	Dr.Shweta Chauhan	Transforming Menstrual hygiene in Government School : Assessing Facilities,Knowledge,Attitudes and practices among adolescent girls and developing a model for best practices		Approved
21	Dr. Sadhana Lakhute	Effect of Behavioural Change Communication on Internet gaming Disorder and Smartphone Addiction among undergraduate students at a medical college in western Maharashtra – A Quasi Experimental Study.		Approved
22	Dr.Shital Patil	Knowing the Status – ‘Triple H’ among truck		Approved
23	Dr.Prachi Athavale	The role of DNA Ploidy in Liquid Based Cytology for Cervical Pre-Cancer and Cancer testing using Flow Cytometry		Approved
24	Dr.Rahul band	A Study of assessing response to snake bite in population of pune region		Approved
25	Dr.Vaddi Kavya	An anthropometric study to estimate stature from various percutaneous bodily measurement in young adults		Approved
26	Dr.Tushar Dighe	Combination Of Maintenance Hemodialysis With Hemoperfusion: A Safe And Effective Model Of Artificial Kidney.		Approved
27	Dr Satish Nirhale	Sleep disorders in Parkinsonism patients		Approved
28	Dr. Pravin Naphade	The Role Of Viruses In Demyelinating Disorders Of The Central Nervous System		Approved
29	Ananya gupta	Attitude of medical student to sexual abuse in children		Approved
30	Vishakha Jayram	Study gender differences in		Approved



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

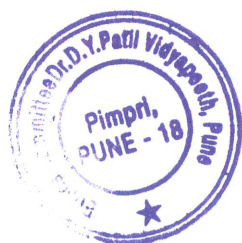
		social media addiction in medical students with references to social anxiety, well being and personality		
31	Kashish Jain	Acculturative stress in non-resident students		Approved
32	Alamalakala samhith	Evaluation of psychological distress in undergraduate medical students		Approved
33	Shatakshi Lahariya	No mobile phone phobia and its relation to social anxiety, sleep and personality in undergraduate medical students		Approved
34	Shreya Vaibhav Patil	A study to assess factors motivating undergraduate medical student to pursue medicine		Approved
35	Devanshi Singh	Body Dysmorphic Disorder (BDD) in young adults in the age of social media		Approved
36	Dr.Akshay Naik	Relationship between impulsivity, personality traits and social media use in medical students		Approved
37	Dr.Prisha Kelkar	Caregiver burden in relatives of patient with schizophrenia and alcohol use disorder and its association with anxiety, depression and coping strategy		Approved
38	Dr. Poulomi Ghosh	Assessment Of diffuse cortical Atrophy in young alcoholics		Approved
39	Dr.Viniti Vaidya (Biotechnology)	A systematic survey on non-hazardous laboratory agar waste generation by biotechnology companies and educational institutes in pune city		Approved
40	Dr.Shrutika Salunkhe	Comparative evaluation of conventional and cutting diathermy and bipolar scissor assisted reconstruction, while raising pectoralis major myocutaneous flap surgery –		Approved



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

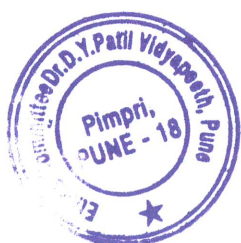
		In vivo study:		
41	Dr.Humeera Mulla	To evaluate the presence of nicotine in the commercially available tooth paste.		Approved
42	Dr.Rahul Mohandas	Evaluation of glucose transporter-1 (GLUTI) and sodium-glucose cotransporter-1 (SGLTI) expression in oral squamous cell carcinoma		Approved
43	Dr.Subhashree Mohapatra	Impact of educational intervention on the knowledge of COTPA laws among interns in a Tertiary Dental Hospital Setting, Pune : An Interventional study.		Approved
44	Dr.Yash Merchant	Reconstruction of oral mucosal defect with ex vivo produced oral mucosa equivalent (EVPOME)- an in vitro pilot study.		Approved
45	Dr.Snehal Jagtap	Evaluation and comparison of change in pharyngeal airway volume in patients affected with oral submucous fibrosis after Intervention using polysomnography and CBCT- An experimental study.		Approved
46	Dr.Rahul Mohandas	Evaluation of Irisin expression in patients with Oral Squamous cell carcinoma.		Approved
47	Dr.Humeera Mohammed Ghaus Mulla	Study of dermatoglyphics in Oral Squamous cell carcinoma and oral submucous fibrosis patients.		Approved
48	Dr.Vaibhavi Raut	Efficacy of aqueous formulation using extracts of Ocimum sanctum Linn (Tulsi), Curcuma longa (Turmeric) and Aloe vera in management of oral lichen planus : a randomized controlled trial.	Clinical trial registration will be (CTRI)required	Provisional approved
49	Dr.Pallavi Vaishisth	Comparative evaluation of antibacterial efficacy of mucoadhesive patch containing cymbopogon citratus, green tea		Not Approved



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		extract and their combination with probiotic:..		
50	Dr.Lakshmi Thribhuvanan	Impact of sensory adapted Dental Environment in the management of Dental Anxiety In Children –A Randomized Controlled Trial.		Approved
51	Dr.Atharva Prafulkumar Babel	A study of the remineralization effects of The Novel chitosan scaffolds in a tooth model- An in vitro study		Approved
52	Dr.Dhanashree Ravindra Dalal	IoT-Enable application as a fear,anxiety and pain assessment tool for patients in dental clinic setting		Approved
53	Dr.Shraddha Iyer	Prospective clinical evaluation Of demineralised freeze-dried bone allograft (DFDBA) injectable-platelet rich fibrin (i-PRF) and Vit D with DFDBA, i-PRF and DFDBA in human infrabony defects.	Vitamin D level To be included	Approved
54	Dr.Krishna Rajkumar Suryawanshi	Evaluation of association between chronic periodontitis and metabolic syndrome using calprotectin, calgranulin C & Resistin as potential biomarkers: A clinico-biochemical study.	Criteria for metabolic syndrome to be mention	Approved
55	Dr.Meghana Guruprasad	Effect of different antibiotic incorporated advanced platelet rich fibrin membrane on human gingival mesenchymal stem cells- An in vitro study.		Approved
56	Dr.Dhananjay Gandage	An in vitro and clinical comparative evaluation of optical and mechanical properties of CAD CAM and heat pressable (Monolithic and layered) lithium disilicate ceramic crowns.		Approved



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

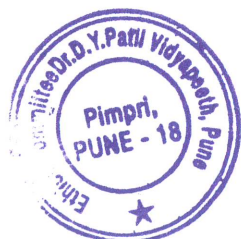
A. Discussion on the SAE in "Randomised Evaluation of Covid-19 Therapy. Serious Adverse Event of Subject 1480475.

Event:- Admitted In Hospital For Coronary Angiography Test.

"The SAE Was Not Related To Study.

Analysis report by the committee for participant with Enrolment ID 1480475

Sr.No.		Observations by the members
1	Adverse effect of the investigational product.	No
2	Violation of the approved protocol, scientific misconduct of negligence by the sponsor of his representative or the investigator leading to serious adverse event	No violation or deviation from approved.
3	Failure of investigational product to provide intended therapeutic effect where, the required standard care or rescue medication, though available, was not provided to the subject as per clinical trial protocol.	Investigational product was provided to the patient, however, no association of the investigational product with onset of SAE
4	Not providing the required standard care, though available to the subject as per clinical trial protocol in the placebo controlled trial.	No
5	Adverse effects due to concomitant medication excluding standard care, necessitated as part of the approved protocol	No adverse effects due to concomitant medication.
6	Adverse effect on a child in-utero because of the participation of the parent in the clinical trial	No
7	Any clinical trial procedures involved in the study leading to serious adverse event	No
8	Causality assessment by members	The SAE was not related to the clinical trial or other treatment/procedure.
9	Whether compensation is recommend.	No compensation is recommended



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

A. EC 3: Presentation of the new research projects in the 48th EC Meeting- 29

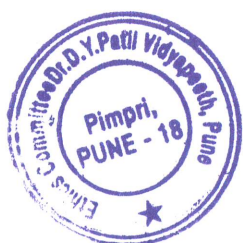
Sr.No.	Name of the Faculty/Dept	Topic	Observations& Suggestions	Remarks
1	Dr.Shailaja Mane	A Prospective, randomized, single blind, parallel, active controlled, multicenter, non-inferiority phase iii study to evaluate the immunogenicity and safety of live attenuated varicella vaccine of Sinovac biotech ltd, China compared to varied ®(varicella vaccine live i.p.by MSD pharmaceuticals pvt ltd, India) in healthy pediatric subject in India.	1. Clinical trial registration will be (CTRI) required. 2. Insurance	Provisional approval
2	Dr.Shrikanth Tripathy	A multicenter, Randomized, Observer-blind, Non-inferiority and safety of Boostagen ^{RED} ™ (combined tetanus toxoid, reduced diphtheria toxoid, reduced recombinant pertussis vaccine) by BioNed-Asia compared to ADACEL® vaccine by Sanofi Pasteur Limited in Healthy Subjects Aged 4-65 years	1. Clinical trial registration will be (CTRI) required. 2. Insurance	Provisional approval
3	Dr.Amit Ramchandra Kale	A Randomized, Double-Blind, Multicenter, Three-Arm, Placebo-Controlled, Parallel-Design, Bioequivalence Study with Clinical Endpoints comparing Diclofenac Diethylamine Gel 1.16% of Encube Ethicals Private Limited, India with Voltaren Schmerzgel 11.6 mg/g (Diclofenac Diethylamine Gel 1.16%) of GlaxoSmithKline GmbH & Co. KG, 80258, Munich, Germany in Patients		Approved



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

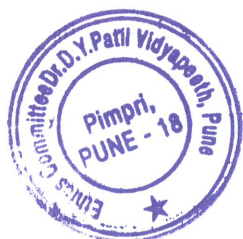
		with Osteoarthritis (OA) of the Knee.		
4	Dr.Shubhangi kanitkar	Randomised Evaluation of covid-19 therapy.(Recovery)		Amendment Approved
5	Dr.Shubhangi kanitkar	A Phase II, Multicenter, Randomized, Double-blind, Placebo-Controlled study to evaluate the efficacy, Immunogenicity and safety of single dose of dengue tetravalent vaccine, live attenuated (Recombinant, Lyophilized) –“DengiAll” of Panacea Biotec Limited in Healthy Indian Adults.	CT- NOC from DCGI approval	Provisional Amendment Approved
6	Dr.Shalinee Yede	A single arm clinical study to evaluate the effect of yoga module in the management of premenstrual back pain.	Exclusion Criteria should include pregnant women.	Provisional Approval
7	Dr.Aayush Gupta	Development of a stand-alone, fully automated device for making sterile, autologous cell-grafted bioscaffold spray for skin transplants.		Approved
8	Dr.Pallavi Vashisth	Comparative evaluation of antibacterial efficacy of mucoadhesive patches containing cymbopogon citrates, green tea extract and their combination with prebiotics.	1.In-Vitro permission can be granted. 2. permission for in-vivo study to be obtained for local ethics committee 3.approval status of new drugs.	Re-Submit
9	Dr. Shahzad Mirza	“Surveillance of multidrug-resistant, extensively drug-resistant and pandrug-resistant organisms for the healthcare facilities using automated antimicrobial		Amendment Approved



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

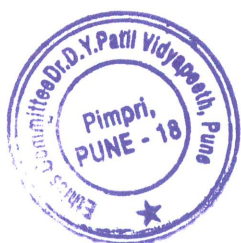
		susceptibility system — A large scale national multicentric study.		
10	Dr. Samir Gupta	Determining various molecular/genetic changes associated with >10mm depth of invasion in head & neck malignancies.		Amendment Approved
11	Dr. prashant Chandra	Determining role of Secreted frizzled-related protein 4 (SFRP4), a soluble WNT antagonist multifunctional protein in malignancies for determining prognostic factors of tumors.		Amendment Approved
12	Shiney Rahul Pandey	Impact Of Mindfulness Practices For Stress Management.	Submit application in the prescribe form.	Re-submit
13	Dr. Khokan Debnath	Use of Insulin and its long term effect on patients health management	Submit application in the prescribe form. methodology to be given in details.	Re-submit
14	Ms. Komal Singh	Primary and Preventive Healthcare Strategies for Cancer Care Management.	Submit application in the prescribe form Sample size Specify Questioners to be used and consent form.	Re-submit
15	NIGAR NISAR SHIKALGAR	Effect of various exercise training intensities on body composition, physiological fatigue and exercises adherence in overweight and obese young adults.		Approved
16	SEEMI ANIKET RETHAREKAR	Establishing Normative PEFR Values in Children and		Approved



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

		Adolescents in Western Maharashtra		
17	Dr.Akshay Naik	Relationship of aggression , attachment styles and personality traits with homophobia in medical students		Approved
18	Dr.Alicia Perti	Stress, burnout & Alcohol use amongst post graduate students in a medical college.		Approved
19	Dr. Fatima Shamla	Quality of online news media reports of sexual violence in India.		Approved
20	Dr.Saumya Agarwal	Prevalence of borderline personality organization in medical students.		Approved
21	Dr.Shubham Kulkarni	Stress, resilience, copying and alcohol use in nursing students.		Approved
22	Dr.Reetika Thakur	Psychometric validation of Marathi version of Athens insomnia scale.		Approved
23	Dr.nikhil Mohan	Assessment of learning styles in undergraduate medical students.		Approved
24	Dr. Aditi Harbola	A study of severity of menopausal symptoms, Insomnia, self-esteem and sexual experience among Indian perimenopausal Women.		Approved
25	Dr.Rishi garg	Expressed emotions in primary caregivers of patients with schizophrenia and alcohol dependence syndrome.		Approved
26	Dr.nikhar Satyapal	A study of cyberchondriasis in medical students and its effect on quality of life		Approved
27	Dr.Tahora Ali	Assessment of burnout in nursing staff working in the intensive care unit.		Approved



Dr.D.L.Ingole
Chairman**Dr.SuprakashChaudhury**
Member Secretary

28	Dr.Nilesh Giri	A prospective, multi-centre, open label, single-arm, phase I study to evaluate the safety of GBL1204 in patients with neovascular age-related macular degeneration.	Approved
----	----------------	---	----------

A. Discussion on the SAE in “Hybrid Trial for Alcohol reduction among people with TB and HIV in India.” Serious Adverse Event of Subject 30060-OY6.
The SAE Was Not Related To Study. The committee concurred with the opinion of Principal investigator.

EC.4.Vote of thanks was proposed by the Member Secretary, Dr. Suprakash Chaudhury on behalf of Ethics Committee to all the members for being present and for giving their valuable inputs.



Dr. Suprakash Chaudhury
Member Secretary

Member Secretary
Ethics Committee

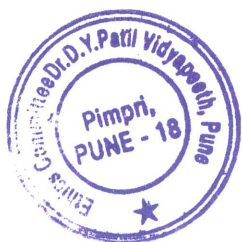
Dr. D Y Patil Vidyapeeth, Pune.



Dr.D.L. Ingole
Chairman

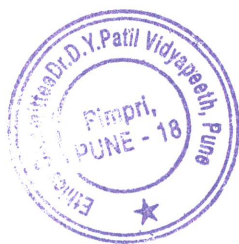
Chairman
Ethics Committee
Dr.D.Y.Patil Vidyapeeth, Pune

Date: 06/02/2024



**Dr.D.L.Ingole
Chairman****Dr.SuprakashChaudhury
Member Secretary****Minutes of the Meeting 49th Meeting of the Ethics Committee –Dr.D.Y.Patil Vidyapeeth,
Pune on Wednesday 20 March 2024 at 10:30 hours.****The members present for the meeting were:-**

- | | |
|----------------------------|------------------|
| 1. Dr. D.L. Ingole | Chairperson |
| 2. Dr.Ravinder Singh | Member |
| 3. Dr.M.V.Khadilkar | Member |
| 4. Dr. Shubhangi Kanitkar | Member |
| 5. Adv.(Dr.) Ruby Chhatwal | Member |
| 6. Dr. Priti Pravin Dhande | Member |
| 7. Adv.Pramod Patil | Member |
| 8. Dr.Kalpana kelkar | Member |
| 9. Dr.R.K.Nanda | Member |
| 10. Dr.Amit jagtap | Member |
| 11. Mrs. Beena Gokhale | Lay Person |
| 12. Dr.Suprakash Chaudhury | Member Secretary |

Leave of absence was granted to:, Dr.Neelu Nawani,

Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

The agenda of the meeting was as follows:

1. Confirmation of minutes of 48th EC meeting held on **Friday 02 Feb 2024**.
2. Report of ongoing Projects.
3. Report of projects completed.
4. Report of projects approved in last Meeting.

Proceedings of the meeting:-

Welcome address by Dr. D.L.Ingole– Chairperson

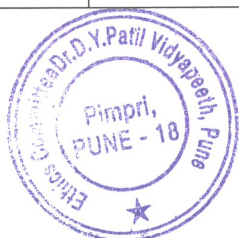
The chairperson welcome all the members for the 49th Meeting of the Ethics Committee.

EC 1: Confirmation of minutes of 49th EC meeting held on 20 March 2024.

1. 1. The minutes of the **meeting held on 02 Feb 2024**.were confirmed.

EC 2: Presentation of the research projects in the 48th EC Meeting-28 project.

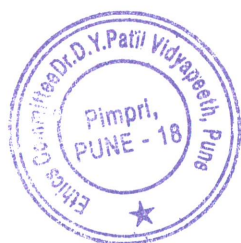
Sr.No.	Name of the Faculty/Dept	Topic	Observations& Suggestions	Remarks
1	Dr.Shailaja Mane	A Prospective, randomized, single blind, parallel, active controlled, multicenter, non-inferiority phase iii study to evaluate the immunogenicity and safety of live attenuated varicella vaccine of Sinovac biotech ltd, China compared to varied ®(varicella vaccine live i.p.by MSD pharmaceuticals pvt ltd, India) in healthy pediatric subject in India.	1. Clinical trial registration will be (CTRI) required. 2. Insurance	Provisional approval
2	Dr.Shrikanth Tripathy	A multicenter, Randomized, Observer-blind,Non-inferiority and safety of Boostagen RED TM (combined tetanus toxoid, reduced diphtheria toxoid,reduced recombinant pertusis vaccine) by BioNed-	1. Clinical trial registration will be (CTRI) required. 2. Insurance	Provisional approval



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

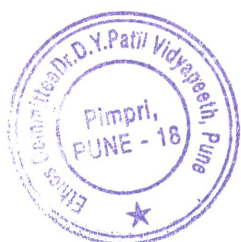
		Asia compared to ADACEL® vaccine by Sanofi Pasteur Limited in Healthy Subjects Aged 4-65 years		
3	Dr.Amit Ramchandra Kale	A Randomized, Double-Blind, Multicenter, Three-Arm, Placebo-Controlled, Parallel-Design, Bioequivalence Study with Clinical Endpoints comparing Diclofenac Diethylamine Gel 1.16% of Encube Ethicals Private Limited, India with Voltaren Schmerzgel 11.6 mg/g (Diclofenac Diethylamine Gel 1.16%) of GlaxoSmithKline GmbH & Co. KG, 80258, Munich, Germany in Patients with Osteoarthritis (OA) of the Knee.		Approved
4	Dr.Shubhangi kanitkar	Randomised Evaluation of covid-19 therapy.(Recovery)		Amendment Approved
5	Dr.Shubhangi kanitkar	A Phase II, Multicenter, Randomized, Double-blind, Placebo-Controlled study to evaluate the efficacy, Immunogenicity and safety of single dose of dengue tetravalent vaccine, live attenuated (Recombinant, Lyophilized) –“DengiAll” of Panacea Biotec Limited in Healthy Indian Adults.	CT- NOC from DCGI approval	Provisional Amendment Approved
6	Dr.Shalinee Yede	A single arm clinical study to evaluate the effect of yoga module in the management of premenstrual back pain.	Exclusion Criteria should include pregnant women.	Provisional Approval
7	Dr.Aayush Gupta	Development of a stand-alone, fully automated device for making sterile, autologous cell-grafted bioscaffold spray		Approved



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

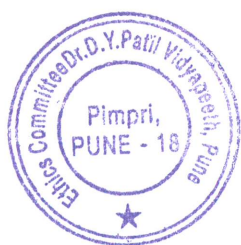
		for skin transplants.		
8	Dr.Pallavi Vashisth	Comparative evaluation of antibacterial efficacy of mucoadhesive patches containing cymbopogon citrates, green tea extract and their combination with prebiotics.	1.In-Vitro permission can be granted. 2. permission for in-vivo study to be obtained for local ethics committee 3.approval status of new drugs.	Re-Submit
9	Dr. Shahzad Mirza	"Surveillance of multidrug-resistant, extensively drug-resistant and pandrug-resistant organisms for the healthcare facilities using automated antimicrobial susceptibility system— A large scale national multicentric study.		Amendment Approved
10	Dr. Samir Gupta	Determining various molecular/genetic changes associated with >10mm depth of invasion in head & neck malignancies.		Amendment Approved
11	Dr. prashant Chandra	Determining role of Secreted frizzled-related protein 4 (SFRP4), a soluble WNT antagonist multifunctional protein in malignancies for determining prognostic factors of tumors.		Amendment Approved
12	Shiney Rahul Pandey	Impact Of Mindfulness Practices For Stress Management.	Submit application in the prescribe form.	Re-submit
13	Dr. Khokan Debnath	Use of Insulin and its long term effect on patients health management	Submit application in the prescribe form. methodology to	Re-submit



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

			be given in details.	
14	Ms. Komal Singh	Primary and Preventive Healthcare Strategies for Cancer Care Management.	Submit application in the prescribe form Sample size Specify Questioners to be used and consent form.	Re-submit
15	NIGAR NISAR SHIKALGAR	Effect of various exercise training intensities on body composition, physiological fatigue and exercises Adherence in overweight and obese young adults.		Approved
16	SEEMI ANIKET RETHAREKAR	Establishing Normative PEFR Values in Children and Adolescents in Western Maharashtra		Approved
17	Dr.Akshay Naik	Relationship of aggression , attachment styles and personality traits with homophobia in medical students		Approved
18	Dr.Alicia Perti	Stress, burnout & Alcohol use amongst post graduate students in a medical college.		Approved
19	Dr. Fatima Shamla	Quality of online news media reports of sexual violence in India.		Approved
20	Dr.Saumya Agarwal	Prevalence of borderline personality organization in medical students.		Approved
21	Dr.Shubham Kulkarni	Stress, resilience, copying and alcohol use in nursing students.		Approved
22	Dr.Reetika Thakur	Psychometric validation of Marathi version of Athens insomnia scale.		Approved
23	Dr.nikhil Mohan	Assessment of learning styles		Approved



Dr.D.L.Ingole
Chairman

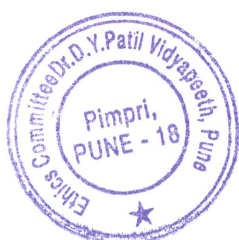
Dr.SuprakashChaudhury
Member Secretary

		in undergraduate medical students.		
24	Dr. Aditi Harbola	A study of severity of menopausal symptoms, Insomnia, self-esteem and sexual experience among Indian perimenopausal Women.		Approved
25	Dr.Rishi garg	Expressed emotions in primary caregivers of patients with schizophrenia and alcohol dependence syndrome.		Approved
26	Dr.nikhar Satyapal	A study of cyberchondriasis in medical students and its effect on quality of life		Approved
27	Dr.Tahora Ali	Assessment of burnout in nursing staff working in the intensive care unit.		Approved
28	Dr.Nilesh Giri	A prospective, multi-centre, open label, single-arm, phase I study to evaluate the safety of GBL1204 in patients with neovascular age-related macular degeneration.		Approved

A. Discussion on the SAE in “Hybrid Trial for Alcohol reduction among people with TB and HIV in India.” Serious Adverse Event of Subject 30060-OY6.
The SAE Was Not Related To Study. The committee concurred with the opinion of Principal investigator.

A. EC 3: Presentation of the new research projects in the 49th EC Meeting- 16

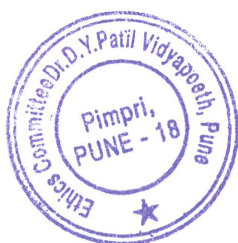
Sr.No.	Name of the Faculty/Dept	Topic	Observations& Suggestions	Remarks
1	Dr. D Gopalakrishnan	Comparative Evaluation Of Clinical Efficacy Of Commercially Available Hydroxyapatite Toothpaste And Fluoridated Toothpastes In The Management Of White Spot Lesions: A	1. Permission from manufacturer for using the commercial; name of the toothpaste. 2. Patient's	Re-submit



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

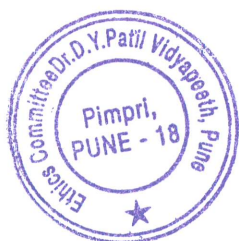
		Randomized Controlled Clinical Trial	information sheet should be attached. 3. Consent from should be attached. 4. Instruction to patients about time of brushing teeth to be specified. 5. Patients dairy must be maintained 6.Provision of rescue treatment should be made. 6. CTRI registration to be done.	
2	Dr. Anita Kulloli	Comparative evaluation of clinical efficacy of two commercially available 5% potassium nitrate containing dentifrices for the management of dentinal hypersensitivity – A Randomized controlled clinical trial.	1. Permission from manufacturer for using the commercial; name of the toothpaste. 2. Patient's information sheet should be attached. 3. Consent from should be attached. 4. Instruction to patients about time of brushing teeth to be specified. 5. Patients dairy must be maintained 6.Provision of rescue treatment should be made. 6. CTRI registration to be done.	Re-submit
3	Dr. Sharath K. Shetty	Comparative evaluation of efficacy of two commercially available fluoride based dentifrices on oral health in patients with periodontal	1. Permission from manufacturer for using the commercial; name of the toothpaste. 2. Patient's	Re-submit



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

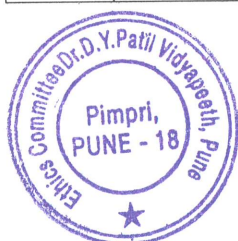
		diseases – A randomized controlled clinical trial.	information sheet should be attached. 3. Consent from should be attached. 4. Instruction to patients about time of brushing teeth to be specified. 5. Patients dairy must be maintained 6.Provision of rescue treatment should be made. 6. CTRI registration to be done.	
4	Dr. Sharath K. Shetty	Comparative Evaluation of Efficacy of two commercially available Mint Based Dentifrices for the Management of Halitosis in Patients with Periodontal Diseases – Randomized Controlled Clinical trial.	1. Permission from manufacturer for using the commercial; name of the toothpaste. 2. Patient's information sheet should be attached. 3. Consent from should be attached. 4. Instruction to patients about time of brushing teeth to be specified. 5. Patients dairy must be maintained 6.Provision of rescue treatment should be made. 6. CTRI registration to be done.	Re-submit
5	Dr. Santosh Martande	Comparative Evaluation Of Clinical Efficacy Of Two Commercially Available Clove Based Dentifrices In Chronic Gingivitis - Randomized Controlled Clinical Trial	1. Permission from manufacturer for using the commercial; name of the toothpaste. 2. Patient's information sheet	Re-submit



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

			<p>should be attached.</p> <p>3. Consent from should be attached.</p> <p>4. Instruction to patients about time of brushing teeth to be specified.</p> <p>5. Patients dairy must be maintained</p> <p>6.Provision of rescue treatment should be made.</p> <p>6. CTRI registration to be done.</p>	
6	Dr. Supriya Kheur	Generate Medical Imaging Datasets (MIDAS) for Tobacco-induced Oral Lesions to Enhance Research in Health in India		Approved
7	Dr Pallavi Vashisth	Comparative evaluation of antibacterial efficacy of mucoadhesive patch containing Cymbopogon citratus, green tea extract and their combination with prebiotics.		Approved
8	Dr.Ayush Gupta	A Phase 3 , Multicenter, Open-Label, Rater-blind, Active-controlled Study to evaluate the Efficacy and Safety of Bedaquiline for the treatment of Multibacillary Leprosy When Combined With Rifampicin and Clofazimine.	subject to permission of DCGI for clinical site.	Provisional Approval
9	Dr.Sachin Atre	Performance evaluation of an Artificial Intelligence based Chest X-ray interpretation algorithm for pulmonary tuberculosis triaging in pediatric population		Approved
10	Dr.Shilpa Deshmukh	Personality profiles of undertrial and convicted inmates of yervada jail		Approved



Dr.D.L.Ingole
Chairman

Dr.SuprakashChaudhury
Member Secretary

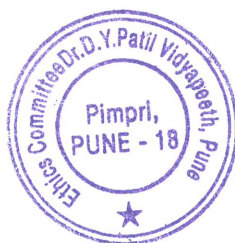
11	Dr.M.S.Barthwal	Phenotype, Progression, and Immune Correlates of Post – Tuberculosis Lung Disease.		Amendment Approved
12	Dr.Parisha kelkar	Translation and validation of various scales in Marathi language.		Approved
13	Dr.Suprakash Chaudhury	Knowledge and attitude to human transplant.		Approved
14	Dr. Tahoor Ali	Sexual Dysfunction in Individuals taking Selective Serotonin Reuptake Inhibitors		Approved
15	Dr. Tahoor Ali	Burnout and Workplace Satisfaction in Nursing Staff Employed in the Intensive Care Units		Approved
16	Dr. Tahoor Ali	Assessment of Levels of Creatine Kinase in Patients with Psychosis.		Approved

EC.4.Vote of thanks was proposed by the Member Secretary, Dr. Suprakash Chaudhury on behalf of Ethics Committee to all the members for being present and for giving their valuable inputs.

S. Chaudhury
Dr. Suprakash Chaudhury
Member Secretary

Member Secretary
Ethics Committee
Dr. D Y Patil Vidyapeeth, Pune.

Date: 22/03/2024



[Signature]
Dr.D.L.Ingole
Chairman
Chairman
Ethics Committee
Dr.D.Y.Patil Vidyapeeth, Pune