Proposal for Content of a Special Topic Paper

(This form is to fill an existing Special Topic code with content; or to create a new trial paper. If a new paper code for a generic special topic is required, then a Form 3ST must also be completed.)

Name of Department: Mathematics and Statistics

Subject Code, Number and Title of New Paper: STAT 499 Special Topic: Clinical Trials

Year of Introduction (Year Proposal Takes Effect): 2019

Special Topic will be taught as a 'one-off'?	
Special Topic is a 'tester' paper & may become permanent?	X
When is the Special Topic to become available?	Semester 2 2019

The number of times the same Special Topic will be offered should be no more than three times, or two years at which point a proposal will need to be made for a named paper using a Form 3 (See Special Topic Guidelines)

Purpose of Special Topic and Expected Duration

(A succinct description of the purpose of the proposal including the introduction of new papers and any consequential amendments such as deletions of existing papers and amendments to schedules. See *Special Topic Guidelines.)*

The purpose of the proposal is to provide an opportunity for post graduate students at the University of Otago in Dunedin to take a paper on clinical trials through collaboration with the University of Auckland.

Justification

(Provide a brief rationale for the content of the proposed Special Topic.)

Clinical trials are an area of research strength for the University of Otago, but the University does not currently teach a paper in clinical trials methods. There has been interest in such a paper for some years at Otago, but uncertainty as to the number of students who would want to take a full paper rather than a short course. An opportunity has arisen to join the University of Auckland in teaching a paper that has been offered in the past several years by the Department of Statistics in Auckland. The Auckland paper was developed and is convened by the Professor of Biostatistics, Thomas Lumley, and Professor Lumley has invited Associate Professor Katrina Sharples to collaborate to deliver the paper in both Auckland and Dunedin. Professor Lumley and Associate Professor Sharples have substantial experience in clinical trials, and work together on the Health Research Council Data Monitoring Committee.

The proposed Special Topic paper would provide an opportunity to explore interest in Dunedin, with a view to establishing a permanent paper if it proves successful. The paper would be accessible to students in both the Health Sciences and Sciences.

The proposed paper has been taught previously by the Department of Statistics, University of Auckland, and the plan for 2019 is to teach the paper as is. However, if a clinical trials paper

were to go ahead more permanently in Dunedin further consultation regarding learning outcomes and delivery methods would be undertaken.

We anticipate 1-2 students from Statistics and 3-4 from Health Sciences will be interested in the paper.

Qualifications Affected

BSc(Hons), PGDipSci, MSc, PGDipAppStat, , PGCertHealSc, PGDipHealSci, MHealSci, PGCertPH, DPH, MPH

Prescription

(Refer to *Guide to Enrolment* for format. Include proposed subject code, paper number, points value and anticipated EFTS, prerequisites, restrictions, programmes the paper is 'limited to', whether it will offered on-campus and/or by distance learning, and whether it is to be taught in the 1st and/or 2nd Semester, during the whole year or Summer School. The description of the content should be no longer than 30 words. Refer to the Form 3 *Important Notes* for guidance on title, prescription and prerequisites etc.)

STAT 499 Clinical Trials
S2 0.15 EFTS OL, OC 20 points
Statistical, scientific, ethical, and practical issues in designing, conducting, and reporting randomised trials in humans.
P STAT 110 or 115 or equivalent
SC Arts and Music, Science, Health Science

Occurrence Details

Basic details of each occurrence of the paper, each listed separately. Include campus being taught at or from (Dunedin, Christchurch, Wellington, Invercargill, Auckland), teaching period (S1, S2 etc.), indicative start date (for each occurrence – if not standard), indicative end date (for each occurrence – if not standard), teaching method (i.e. on campus or by distance). Refer to the 'Form 3 - Important Notes' for guidance on the definition of an occurrence, teaching period and start/end dates.

Campus Taught From	Teaching Period	Indicative Start Date (if Non-Standard)	Indicative End Date (if Non-Standard)	Teaching Method
Dunedin	S2			On campus, Dunedin

Consequential Amendments to Regulations and/or Schedules and/or Other Papers

(All changes to regulations, schedules and the paper rules of related papers (e.g. prerequisites, corequisites, and restrictions) as a result of introducing this paper must be detailed below. It may be useful for both current and proposed forms of words for publication to be provided, with changes or additions in bold or italic type. This includes changes that will need to be made to Schedules, including Schedules A, B and C. Include Calendar page numbers. Changes to the Programme information in the *Guide to Enrolment* are not required. Consequential deletion(s) of papers must also be reported here (in which case a separate Form 5, proposal to delete a paper, does not need to be completed).

No consequential amendments are required

Academic Consultation with other Departments/other Divisions

(Outline the consultation that has been undertaken with interested parties including other Departments and Divisions. Detail any professional accreditation requirements.)

An email was sent to all schools in the Health Sciences Division, to Heads of Departments with staff whose research may involve randomised controlled trials, and to individuals known to be interested. All email responses are provided with this submission.

The table below summarises specific comments and our responses to them.

Person	Comment	Response
Professor Barry Taylor Dean, Dunedin School of Medicine	I would be very supportive. I would like all our joint clinical staff to think about doing such a paper! If it gets agreed, would happily push it.	Thank you
Professor Rachael Taylor Deputy Head, Department of Medicine	I think this looks excellent and I most certainly would have postgrads who would benefit from having such a paper available.	Thank you
Professor Michael Schultz Head, Department of Medicine	Excellent idea. Will the paper be open for Research nurses and coordinators as well?	We would definitely encourage motivated RNs and trial coordinators who are interested in the design of trials to take the course.
Professor Paul Glue Hazel Buckland Chair of Psychiatry	Katrina, superb proposal. Happy to participate if this would be helpful.	Thank you
Professor John Crump Co-director, Centre for International Health	Looks good to me Katrina and I would be very supportive of the idea. I guess it is hard to know where to draw the boundaries on this topic, but I note that there doesn't seem to be (specific) content on GCP, GCLP, clinical trials management, and monitoring/audit although elements of each are covered in other areas.	We note that the key ICH Guideline is included as a course reading, so they will see GCP as a 'whole', but quite a bit of the detail would be outside the syllabus as it currently stands. I note that GCP courses and online training are available to supplement this paper.
Professor Rob Walker Department of Medicine	I would support this as it is an excellent initiative. How will it be taught? Can it be done by distance learning as I think this	Many thanks. Currently the course is set up to have lectures over the zoom network, but otherwise to be internal. The

	would be a very good option for our medical registrars (all registrars in fact) which hopefully they can get recognised by the colleges as part of their training requirements. Obviously it would have to fit in with their clinical work schedules to be feasible.	lectures will be recorded, so registrars could potentially take the paper even without getting to all lectures, and we could arrange tutorials around work schedules
Professor Philip Hill Co-director, Centre for International Health	I'm very supporting of this Katrina and note the international component. Personally, as I can't speak for our wider department, I suspect the university public health people would benefit from an increasing focus on interventions (including evaluation by RCT where possible) too. Therefore you may want to consider whether the 'clinical' bit is too narrow?	Many thanks. We will certainly be discussing other types of interventions and populations in the paper, so I agree the name ‘clinical trials’ is not fully descriptive. However, it is probably still the name that best suits the course as it’s familiar to many people. If we make the paper permanent I would revisit this.
Associate Professor Lynley Anderson Head of Department, Bioethics Centre	Thanks for sending this - it looks very interesting. We see you have a significant ethics element in the paper, including: –Ethics of randomization –Vulnerable populations –Scientific misconduct: types and causes, impact –Trials without informed consent This is core material that we also have in our Research Ethics paper BITC406 and Advanced Research Ethics, BITC407. These are complex areas and we wonder who would be teaching this. Perhaps we could meet up and discuss this further. Also Neil Pickering is part of the team (NEAC) that are creating the guidelines for intervention studies and observational studies so he could be particularly useful.	I met with Lynley and Neil. I am very supportive of having a bioethicist involved in this teaching. This section is currently taught by Auckland, and they have not yet determined who will be teaching it. If there is no bioethicist, or collaborative teaching with someone from Dunedin is not possible I will work with Neil Pickering to arrange session for the Dunedin students.
Professor Patrick Manning Department of Medicine	I would echo Robs views. This would be excellent training for medical registrars and all clinical trialists in the Department of Medicine. Very supportive.	Thank you
Professor Roland Broadbent Head, Paediatrics and Child Health	Very positive reaction from our department/section. You will have no trouble filling places.	Thank you
Professor Tim Stokes	This is a great new initiative for	Thank you

Head, Department of General Practice and Rural Health	which I expect there will be an excellent take up.	
Professor Mark Thompson-Fawcett Head Department of Surgical Sciences	Sounds good to me too.	Thank you
Professor Bob Hancox Department of Preventive and Social Medicine	It seems like you are getting a lot of approvals - it sounds good to me too.	Thank you
Dr Lianne Parkin Department of Preventive and Social Medicine	I think this looks good	Thank you
Professor Carlo Marra Dean, School of Pharmacy	I too support this paper. It will be interesting to see the syllabus - do you anticipate that adaptive designs will be taught as well?	We will cover SMART (Sequential Multiple Assignment Randomized Trials) and Bayesian adaptive design are included as a potential poster topic for the students.
Dr Motohide Miyahara School of Physical Education	This sounds like a great paper, and all Honours and postgraduate students of our school who conduct intervention studies of any sort will benefit from this paper. One significant element missing from the lecture topics is the issue of "treatment fidelity". A majority of clinical trials just name a treatment and fail to describe the replicable details. If it is a pharmaceutical treatment, the name of drug would suffice, but for any psychological, or exercise and physical activity intervention, exact observable behavioural procedures need to be specified in the protocol and any deviations from the protocol need to be noted in the report to allow future replication of the trial. Hope this helps.	We will include a component on treatment fidelity, both in terms of description of the intervention (for reproducibility) and also protocol compliance.
Professor Chris Button Dean, School of Physical Education, Sport and Exercise Sciences	A full RM paper on clinical trials alone probably wouldn't suit the majority of our students	At some stage creating a short course based on this material may be useful.
Professor Patricia Priest Head, Preventive and Social Medicine	Responses are positive, noting that this will be a useful paper for those undertaking RCTs in clinical research or post-graduate study.	Thank you
	Learning Outcome 3 refers to a Treaty of Waitangi framework, however there doesn't seem to	This will be covered either in a zoom lecture, if the material is covered in the Auckland

	be any reference to this in the lecture schedule, so it's not clear how this will be addressed.	sessions, or locally in a separate Otago session if not, and we will ensure that it is taught by an appropriate expert.
	Hopefully the paper will facilitate more thoughtful and collaborative consultation of researchers with those in the Biostatistics Unit	We agree this is likely to be one of the positive outcomes of the paper.
	We wonder whether this paper might be a useful optional paper in the proposed Postgraduate Diploma in Biostatistics, and we would value a discussion about whether / how it would fit in to that qualification at an appropriate time.	We agree it would be very useful, and look forward to that discussion
	In the medium term, this paper could be paired with a clinical epidemiology paper, which PSM has previously considered developing, aimed at people embarking on a clinical PhD or a career in academic medicine.	We agree this would be extremely useful
	While this is not explicit in the documentation, it seems that this paper is focussed on trials of individual interventions, particularly drug trials (the background focusses on EBM and pharmacology/physiology, and lectures 11,12, and 28 are specifically drug-related). RCTs are used so much more widely than for trials of drugs that it would be a shame for those doing other kinds of trials to feel that this course is not for them. It would be good to consider amending the title to 'Randomised Trials', to encourage those doing trials other than of clinical interventions to take the paper, and to include some specific discussion of RCTs in other areas.	We intend that trials of interventions other than drugs will be covered through examples. We also have specific sessions on cluster randomised trials, and examples there will include community prevention studies. Changing the name is not that straightforward as it will discuss non-randomised trial as well. We agree that this needs careful thought and discussion if we introduce this as a permanent paper.
	I see that you have suggested that the DPH and MPH could be affected by this paper. Have you consulted the Chair of the Board of Studies for postgraduate PH? I imagine that if the methods could be taught with explicitly broader	I have not consulted separately with the Chair of the Board of Studies for postgraduate Public Health at this stage. We intend to do so when we consider the nature of a permanent paper in this area.

	application than drug trials, it would be appropriate for the list of optional papers for the postgraduate Public Health programme, but obviously that decision would require an assessment of the paper by the Board of Studies.	
Associate Professor Robin Turner Head, Biostatistics Unit Dunedin School of Medicine	In general I'm very supportive of a clinical trials paper being adopted	Thank you
	If I understood correctly this paper would be targeted at clinical people as well as statistics students but there is a pre-requisite STAT 110 or 115 or equivalent. I would expect that this pre-requisite would exclude many of the clinical people from taking the course and would limit the papers ability to attract the right audience.	We are bound to a large extend in this special topics paper by the level the paper is taught at in Auckland. I have required first year statistics to indicate that some understanding of statistical methods will be assumed. Many of our registrars and clinical researchers do have some training from overseas, so I think would be able to manage the paper fine. I have planned tutorials and will be able to provide additional help if required there. The bigger issue for people with clinical commitments is being able to get to lectures and tutorials. I am planning to meet with clinical colleagues to discuss the best way to make the paper available to those with clinical commitments.
	The other aspect I am confused about is the STAT coding of the paper. As a 400-level statistics paper it seems very light on statistics and looking at the course content it reads much more like a public health/health sciences paper, with a substantial target audience from health sciences. I would have thought it should be coded as a health sciences paper in some way to align with the content and audience. I would also expect that there may be overlap with the subjects taught in public health so it would be important to ensure the paper sits alongside those and adds to what exists already.	I view the content of the paper as inherently multidisciplinary, rather than either statistics or medicine or public health. The reason it is being taught for now as a STAT special topics paper reflects the way it has come about - the paper in Auckland is aimed at statistics students, I've been offered the opportunity to co-teach it and that is where I am based (my position in the Department of Medicine is research only). As I'm sure you're aware, this material is often taught by clinical trial statisticians internationally, and is core material in biostatistics post grad qualifications, so it is an important paper for statistics students. We teach a couple of

		other papers which are similarly multi-disciplinary - the Official Statistics paper (also taught across several NZ universities) and the Data Analysis for Bioinformatics paper (which is taught by Mik Black) - so it isn't entirely out of place. I have been very pleased by the support this paper has received from colleagues in the health sciences division, and none have raised concern regarding the STAT paper code, so I don't think that per se is likely to be a issue. In the future though, if it becomes a permanent paper, another paper code may be more suitable. I am fairly sure that at present there is no paper taught in Dunedin with significant overlap with the proposed paper. It's not been mentioned by anyone from the Clinical School or Public Health. Trish noted in her summary of comments from Preventive and Social Medicine that the paper may be appropriate for some public health students. It would be up to the Public Health Board of Studies to determine that, but overall her comments indicated there was no concern from Public Health regarding conflict or overlap of content. There is of course some overlap with general research methods papers but this paper has much more detail and depth in clinical trials than any others I'm aware of.
Professor Catherine Day Head of Department Biochemistry	Members of the Biochemistry Department read the proposal with interest and approval. The topic is useful and the involvement of Professor Lumley is seen as a strength. However, given the proposed focus, this paper seems unlikely to attract GENE and BIOC students. If in the future, a short course is developed from this paper as suggested by Professor Button, it could be of interest to our students.	Many thanks for your feedback and support. I note your comment that a short course would suit the GENE and BIOC students better than a full course. I think there may be several groups like this, and I will certainly consider developing a short course in the future.

Professor Richard Cannon. On behalf of the Faculty of Dentistry	All those who responded to my email supported your initiative and thought it worthwhile.	Thank you
	They thought that it would be of use to some of our PhD students, DClinDent students and to some staff, however there would be some barriers to enrolment. One is the time commitment: 240 hours over one semester would be too much for our DClinDent students and staff. The DClinDent programme is already full with clinical and research papers. Staff would struggle to find sufficient time and it would be more attractive if it could be undertaken over a longer period.	We understand that this paper will not suit all students, and will certainly consider developing a short course for those unable to do a full paper. Running the paper over a longer time would be difficult within the University's semester structure. When we have run the course once, I will be looking to meet with people to discuss ways in which we could make the material more accessible.
	It was felt that some of our students and staff might not have the prerequisite statistics knowledge.	At present the 100 level statistics pre-requisite is in place because in Auckland the paper has been taught only to statisticians. When I first discussed the paper Professor Lumley indicated that the paper could be taught to non-statistics students except for the section survival analysis (which we have removed from the Otago paper). We will be expecting that students have an understanding of basic principles of statistics, but not familiarity with specific statistical analyses or facility with carrying out statistical analyses. I think it very likely that Dentistry students and staff will have the necessary background. If not they could consider taking a short course which will be offered by the Biostatistics Unit.
	It was not clear what "a little scientific background: pharmacology, physiology" in the first two lectures meant. These are potentially huge topics and there is no indication of what was to be included or why.	The students taking the paper in Auckland were all statisticians. These lectures (delivered by Professor Lumley) are very broad brush and introductory. The aim is to provide the students with a little background to help them understand the examples used in lectures.

	It was felt that only one lecture on systematic reviews and meta-analyses was a bit light.	I have taught a similar session to epidemiology students in the same time frame (one lecture plus a tutorial). I agree there will not be much detail, but it is a very general topic, and many students will have covered it in other research methods papers. We will focus here on aspects specific to clinical trials, linking to the Cochrane collaboration and their resources.
Dr Hilda Mulligan, Assoc Dean of PG Studies in the School of Physiotherapy	I support the paper in principle (it appears already to have wide support from various and varied depts.), and support many of the comments (for example to widen it wider than 'clinical trials', and to include how to synthesise non RCT trials). Please therefore accept this email as support for the paper from Physiotherapy.	Thank you

Part (ii)

Learning Outcomes (Aims and Objectives) of Paper

(Learning outcomes (aims/objectives) for individual papers can be described in a range of styles and should indicate what learners are able to do on successful completion of the paper. Outcomes for the paper should also contribute to the Graduate Profile of the programme – ***please identify which attributes of the Graduate Profile are achieved by the paper.*** See Section 10 of the *Form1S and Form 1 Important notes for applicants* for further information and a best practice example, or the *Teaching and Learning Plan* at http://www.otago.ac.nz/staff/)

The course design should ensure alignment between learning outcomes, teaching and learning methods, and assessment. When considering outcomes, be sure to consider the different domains such as knowledge, skills (generic and subject-specific) and attributes. Note that assessment tasks later in this form will need to be aligned with the outcomes for the paper.)

The aim of this paper is to equip students with knowledge and skills in the design, conduct, analysis and reporting of clinical trials.

Specifically, on completion of this course students will be able to:

1. Determine an appropriate design for a clinical trial, in order to address a given hypothesis.

2. Justify the choice of design characteristics, including choice of randomisation unit, outcome measure(s), control strategy, and statistical analysis.

3. Write a protocol for a clinical trial, including consideration of recruitment, randomisation process, mechanisms for ensuring compliance, and reducing loss to follow-up, data handling and record keeping, sample size justification,

interim analyses, safety, ethics, Treaty of Waitangi framework, and procedures for handling missing data.

4. Synthesize evidence from a systematic review of trials.

These aims will contribute to the Otago Graduate Profile as follows:

Global perspective	Appreciation of global perspectives in the design and conduct of clinical trials
Interdisciplinary perspective	Clinical trials are inherently multidisciplinary. This course is designed to be appropriate for a range of graduates including doctors, research nurses and statisticians. The mix of expertise among the students will demonstrate the essential interdisciplinary nature, and respect for different perspectives, including that of the trial participants.
Lifelong learning	This paper will provide an understanding of the principles of clinical trial design, and an ability to apply those principles to new settings.
Scholarship	The development of knowledge of clinical trials is fundamental to understanding the scientific method and development of new knowledge in the Health Sciences.
Communication	The protocol is the key document for a multidisciplinary team working on a clinical trial, Students will gain skills in writing protocols and also in presenting their work as a poster.
Critical thinking	Will be fostered as an essential ability for designing trials.
Cultural understanding	Will be addressed when considering design and implementation of trials within the framework of the Treaty of Waitangi, as well as design and conduct of international trials.
Ethics	Knowledge of ethical conduct of research is essential to the design of clinical trials.
Research	Ability to design high quality clinical trials.
Team-work	Students will work in pairs on their projects.

Paper Outline

(Please provide an outline of the structure and content of lectures, laboratories and tutorials, and a description of the assessment tasks – see also Section 12 of the *Important Notes for Completing Forms.*)

The paper will consist of 33 lectures (held over the zoom network) and local tutorials. There will be short assignments, approximately weekly, which will be discussed in

class the day they are due. The aim of these assignments is to guide learning of the lecture material and assigned readings. They contribute 20% to the final mark; reasonable attempts will receive full marks. The remaining components of assessment are a project (40%) and a final exam (40%). The project will be done in pairs where possible, and will culminate in a short, written report and a poster. This project is a substantial proportion of the grade, so care will be taken to ensure the criteria for assessment of the project, and the expectations around group work, will be set out early in the course and agreed up.

Lectures	Lectures	Tutorials	Assessments
1-2	Background: – Why do we randomise? Who randomises? Issues of confounding, generalisability – Brief history of evidence-based medicine. – A little scientific background: pharmacology, physiology.	Lectures, tutorials, set readings, assignments	
3-5	Scientific issues in design – Choice of outcome: hard and soft; real, intermediate, and surrogate; primary and secondary; composite; timing of assessment. – Definition of intervention – Choice of control: active or not, masking, the placebo effect and its relatives; run-in – Choice of comparison: why intent-to-treat rather than per-protocol or as-treated. – The complier average causal effect and related quantities.	Lectures, tutorials, set readings, assignments	Assignment 1
6-8	Sample size/power calculation Issues in analysis – Analysis plans are necessary – Subgroup analysis: threat or menace? – Conditioning on response	Lectures, tutorials, set readings, assignments	
9-10	Non-inferiority studies – margin, choice of comparator, equivalence creep	Lectures, tutorials, set readings, assignments	Assignment 2
11-12	Drug development process	Lectures,	

		tutorials, set readings, assignments	
13-15	Randomisation - Balanced randomisation, blinding Trial conduct - compliance, loss to follow-up Trial protocols, analysis plans, data handling, record keeping	Lectures, tutorials, set readings, assignments	Assignment 3
16-18	Cluster-randomized trials Factorial designs Crossover designs	Lectures, tutorials, set readings, assignments	Assignment 4
19-21	Ethics - Ethics of randomization - Vulnerable populations - Scientific misconduct: types and causes, impact - Trials in developing countries - Trials without informed consent - Role of statisticians	Lectures, tutorials, set readings, assignments	Assignment 5
22-24	Statistical analysis of randomised controlled trials	Lectures, tutorials, set readings, assignments	Assignment 6
25-27	Monitoring and interim analysis Reasons for monitoring: safety, efficacy, futility, data quality, recruitment rate Role of DSMBs Simple group-sequential methods	Lectures, tutorials, set readings, assignments	Assignment 7
28	Pharmacogenetics and other individualized treatment problems	Lectures, tutorials, set readings, assignments	
29	Missing data	Lectures, tutorials, set readings, assignments	
30	Meta-analyses and systematic reviews.	Lectures, tutorials, set readings, assignments	Assignment 8
31	Other topics	Lectures,	

		tutorials, set readings, assignments	
32	Poster presentations	Poster presentations	
33	Review		

Sessions on non-inferiority trials, and DMCs will be taught from Dunedin. The statistical analysis sections will be taught separately in the two centres. The reason for this is that the Auckland paper is currently aimed at statistics graduates. However, the only section of the course which requires a statistics background is a section on survival analysis. For Dunedin, we wish to widen the availability of the paper by replacing the survival analysis section with a statistical analysis section that will only require introductory level understanding of statistics. All assessment will take this difference into consideration, so some assessments and the final exam will be specific to Dunedin.

Workload Expectations

(For undergraduate study 1 point = 10 hours (except in many Health Sciences papers), e.g. the expected student workload is 180 hours for a 18-point paper, 240 hours for an 24-point paper, and 360 hours for a 36-point paper. For postgraduate students 1 point = 12 hours (except in Health Sciences), e.g. expected student workload is 240 hours for a 20-point paper.

Every paper has a point value that indicates its contribution to the qualification enrolled for (or to any other qualification to which that paper can contribute). These values have been derived on the basis of an equivalent full-time year of enrolment being 120 points.

It is recognised that Divisions may have guidelines for workload (total hours per point) for the undergraduate papers in their Division, including the ratio of contact to non-contact hours. If this is the case please state any differences to the University "norm".

The required workload for a paper should include provision for lectures (50-minute lectures factored as 1 hour), seminars, tutorials, laboratories, use of computer resource rooms, field work, examinations and tests, preparation and private study. Allocations for each component should be specified in hours and the basis of the allocation given in brackets (suggestions are provided below). A paper that does not include a final examination will normally demand more work of a student during the 13 teaching weeks of a semester.

These workload expectations should be part of the information provided to students at the beginning of the paper.)

(i) Contact hours

	hours	*derivation*
Lectures	39	(3 per week for 13 weeks)
Tutorials	13	(1 per week for 13 weeks)
Sub-total	*52*	

(ii) Non-contact hours

	hours	*derivation*
Class preparation	39	(1 hour per lecture pre-reading)
Written assignments	40	(8 short reports requiring 5 hrs each)
Poster/report preparation	55	(Project work, report writing, poster)
Private study	42	(approx. 2 hours per lecture)
Final Exam preparation	10	
Final exam	2	
Other		
Sub-total	*188*	

(iii) Total number of hours: 240

(iv) Evidence of consultation with student body in deriving the above workload expectations.

This course has been successfully delivered in Auckland, with good evaluations from students there.

(v) Impact on semester workloads in relation to existing papers that could be expected to be taken in combination with the paper being introduced.

We anticipate students in this paper will come from a variety of areas, so it is not possible to formally plan semester workload in conjunction with other papers.

Terms Requirements

(Some departments require that a student gain terms before they sit final examinations i.e., fulfil certain specified conditions (e.g. attending classes; completing oral, written and practical work to a satisfactory level). If students are required to gain Terms before being permitted to sit the examination, please give details of these requirements. If there are no Terms Requirements please state this.)

There are no terms requirements

Assessment Procedures

(Please provide details of the assessment procedures for the new paper. This table should show clear alignment between the main learning outcomes and how they will be taught and assessed.)

Key Learning Outcomes	**Teaching and Learning Method**	**Summative Assessment (Internal or Final Exam)**
1. Determine an appropriate design for a clinical trial, in order to address a given hypothesis	Lectures, discussion and written assignments	Written assignments, project and exam
2. Justify the choice of design characteristics, including choice of randomisation unit, outcome measure(s), control strategy, and statistical analysis	Lectures, discussion and written assignments	Written assignments, project and exam
3. Write a protocol for a clinical trial, including consideration of recruitment, randomisation process, mechanisms for ensuring compliance, and reducing loss to follow-up, data handling and record keeping, sample size justification, interim analyses, safety, ethics, Treaty of Waitangi framework, and procedures for handling missing data.	Lectures, discussion and written assignments	Written assignments, project and exam
4. Synthesize evidence from a systematic review of trials	Lectures, discussion and written assignments	Written assignments, project and exam

(Add more rows if required)

i)Summative (graded) Internal Assessment

Type of Task	**Percentage Contribution to Final**	**Non-contact hours**

	Grade (figure should align with non-contact hours assigned to these tasks)	
Written assignments	20%	48
Project	40%	40

(Add more rows if required.)

ii) Formative (non-graded) Internal Assessment (*For more information, see section 8 of the Important Notes for completing Form 3 or Section B of Form 1*)

Type of Task	**Type of Feedback**
Lecture and tutorial discussions	Verbal

(Add more rows if required.)

iii) Final Examination

Duration	**Percentage Contribution to Final Grade**
2 hrs	40%

(If a final examination is worth 50% or less of the final grade it would normally have a 2 hour examination. If the final examination is worth more than 50% of the final grade the examination is 3 hours. If not please provide a brief justification here.)

(If a minimum grade has to be achieved in the final examination to pass the paper as a whole, please state the minimum and provide a brief justification for the requirement here.)
A minimum grade of 40% will be required in the final exam in order to pass the paper

(Will plussage apply to the paper? If so, please supply a justification here.)
No plussage

Internet-Based Learning

(Please indicate whether teaching and learning in the paper is available in part or as a whole via the Internet by stating which one of the four classifications it falls under)

[ ]	**No Access**	is where no part of the paper or course is accessible on line
[ ]	**Web – Supported**	is where a paper or course expects students to access limited online materials and resources. Access is optional, as online participation is likely to be a minor component of study.
[ ]	**Web – Enhanced**	is where a paper or course expects students to access online materials and resources. Access is expected, as online participation is likely to make a major contribution to study.
[X]	**Web – Based**	is where a paper or course requires students to access the accompanying online materials and resources. Access is required, as online participation is required.

Online Learning Management System used (Choose one)

[ ] **Blackboard** [ ] **Moodle** [ ] **OceanBrowser** [ ] **Other** [X] **None** [ ]

(If you are using Moodle, OceanBrowser or Other, how will this be supported?)

In Dunedin the Department of Mathematics and Statistics Resources pages will be used for Dunedin-specific material, but there will also be a web page hoisted by Auckland for accessing materials.

Proposed Timetable

(Timetable Services must be contacted in the early planning of the introduction of the paper. They can provide advice and information and they will need to know your intentions. Timetable allocations are dependent on the availability of suitable teaching space. Also please attach written confirmation from the Timetable Services that requested facilities are available (contact Timetable Services at timetables@otago.ac.nz). Please note that timetable consultation is not required for research only papers or where a paper is taught within departmental facilities to a circumscribed group of students taking no other subjects e.g. 400 level papers.)

When consulting with the Timetable Services, please take into account the following, **and supply the details below**:

(i) Lectures (for each stream)

(ii) Laboratories (for each stream)

(iii) Field Trips

(iv) Tutorials and any other teaching activity

(v) Identification of possible timetable clashes with other papers that could be expected to be taken in combination with the paper being introduced.

☐ **Statement is attached**

Part (iii)

Resources:

Confirmation of Availability of Resources

(Please note that resource information regarding the paper being introduced should be provided in Part (iii) and will be considered by each relevant Division. If the academic and/or financial responsibility for the new paper is shared by more than one Division, or the paper resides academically in one Division but is the financial responsibility of another, then Part (iii) should be submitted and will need to be approved by each relevant Division. You should contact the relevant Divisional Office(s) in case there are any additional requirements regarding information on resources for the new paper. By signing this proposal, signatories are not only approving the academic soundness of the new paper, they are also confirming and approving the capacity for the sustained delivery of the new paper taking into account the consideration of relevant resources including library resources, teaching facilities, equipment and staff (human resources). Consideration should also be given as to where potential students will be drawn from. Is there evidence of demand for the paper? Does the paper align with the strategic direction of the department and division? The proposal should be approved by the Pro-Vice-Chancellor upon the approval by the Divisional Board.)

Library Resources (Please identify the initial library purchases and the ongoing annual requirements. You should include all monographs, serials and electronic databases. Written confirmation from your library contact is required and should be attached:

Commerce, Humanities, Sciences and Health Sciences (Dunedin campus)
Marilyn Fordyce, Information Resources Manager (extn 8923, marilyn.fordyce@otago.ac.nz)

Health Sciences Christchurch
Marg Walker, Health Sciences Librarian, Canterbury Medical Library (extn 364 0505, marg.walker@otago.ac.nz)

Health Sciences Wellington
Kareen Carter, Medical Librarian, Wellington Medical Library (1 04 385 5348, email kareen.carter@otago.ac.nz)

The text for the paper is:

Friedman, Furberg, and DeMets. Fundamentals of Clinical Trials.(5th Edition).

It is available as an e-book at the University library.

☐ **Library Impact Statement attached**

Laboratories/ IT/Other physical resources

(Attach details of any additional costs for laboratory, IT or other resources related to teaching. If new staff are required, will there be a need for additional office or research space (see also Staffing Workload)?)

Equipment

(Attach details of any major new equipment required for the paper including computers.)

Staffing Workload

(Attach details of the impact introduction of this paper will have on the workload of the Department. You should address the following issues: Will any new staff be required? If so what percentage of their time will this paper require? Will any new tutors be required? If no new staff are required, how will the workload of the Department be managed in order to meet the increased responsibilities of the paper, i.e., is the teaching of the new paper in place of or in addition to present commitments? Does the new paper require administrative or technical support in addition to the responsibilities of the academic staff? What impact, including benefits or synergies, will the introduction of this paper have on research in the Department?)

No new staff will be required. The teaching is shared between Auckland and Otago (in approximately an 80%/20% split) so the additional workload of this paper is not anticipated to be large. No administrative support is required, but technical support for the video teaching and recording will be required.

Staff Member Responsible for Drafting Proposal

(Please give the name and contact details of the staff member who drafted the proposal if different from the Head of Department)

Associate Professor Katrina Sharples

From: **Timetables Admissions and Enrolment** timetables@otago.ac.nz
Subject: Special Topic Proposal STAT499 - Clinical Trials
Date: 21 June 2018 at 3:56 PM
To: Katrina Sharples katrina.sharples@otago.ac.nz

Tēnā koe Katrina,

Thank you for the opportunity to comment on the proposal for Special Topic STAT499 – Clinical Trials.

The proposed lecture times are Tuesday 2:00 -4:00 pm and Thurs 2:00 -3:00 pm during S2, 2019.

When assessing new paper proposals from a timetabling perspective we have two main areas of concern; potential student clashes and venue availability.

The department has consulted with us on the most suitable times to avoid potential clashes. Solutions to clashes that may arise have been identified. Further to this, lectures will be recorded using Zoom and available for students to view if they are not in attendance. Times are to be confirmed based on final timetable details from University of Auckland with whom this class is being taught and this variation has been factored into our timetabling considerations.

We do not foresee any issues with rooming and as this is expected to be a very small class a departmental area is available for use if need be. Ideally these classes will be booked into one of the audio conferencing rooms at the ISB, however almost any pool room with microphones can be used for Zoom if the eConferencing team go over with their camera.

This considered, we are happy to add Timetable Services endorsement to this proposal.

Ngā Mihi,

Marnie Walters
Customer Services Representative
Timetable Services

Admissions and Enrolment
University of Otago
PO Box 56
Dunedin 9054,
New Zealand

Tel + 64 3 479 5808
Email marnie.walters @otago.ac.nz

University of Otago on Facebook
University of Otago on Twitter

UNIVERSITY OF OTAGO LIBRARY

Library Impact Statement

For new or changing courses and programmes

Name of Division/School/Department: Sciences/Mathematics and Statistics
Title of New Paper/Programme: Clinical Trials
Course code: STAT499
Distance Course Code: (if offered): N/A
Year & Semester of Introduction: S2 2019 **Predicted Enrolments:** Up to 120 at the 300 level
Coordinator: Dr Katrina Sharples
Email: katrina.sharples@otago.ac.nz **Ext:** 7605

This paper is offered as a special topic to test interest in the subject of clinical trials among University of Otago students. It will be run in collaboration with the University of Auckland, and may become permanent.

Monographs (print & electronic): *(What are the needs? Does the existing collection support the introduction of the course/programme? What (if any) additional resources are required?)*

The course coordinators have advised the following for the new course:

Title: Fundamentals of Clinical Trials
Author: Lawrence M. Friedman, Curt Furberg, David L. DeMets, David Reboussin, Christopher B. Granger
Edition: Fifth edition.

This title is available through the University of Otago Library as an electronic book. There are no limitations on access to this title outlined in the publishers licence, within the provisions of fair use.

The subject librarian for Mathematics and Statistics will liaise with the course coordinators to ensure any other required resources are purchased, but there is no indication that any other purchases will be necessary.

Serials (print and electronic) resources: *(What are the needs? Does the existing collection support the introduction of the course/programme? What (if any) additional resources are required?).*

The University Library subscribes to a wide variety of high quality resources including online serials and databases. The course coordinator expects all recommended readings to be sourced from existing subscriptions.

It is not expected that expenditure in this area is required.

Summary: *(of impact on Library Services)*

There will be minimal impact on library collections or services resulting from the creation of this course.

Details of Additional Costs: *(if any):*

None

Form completed by: Justin Farquhar

Consultation emails

I would be very supportive. The Divisional guru in this area is probably Lois Surgenor first and possible Pat Cragg. I will copy to them for their comments!

I would like all our joint clinical staff to think about doing such a paper! If it gets agreed, would happily push it.

Nga mihi

Barry

Barry Taylor, Dean, Dunedin School of Medicine

****

Hi Katrina
I think this looks excellent and I most certainly would have postgrads who would benefit from having such a paper available. R

Professor Rachael Taylor
Deputy Hod, Medicine
Director, Edgar Diabetes and Obesity Research Centre
A Better Start National Science Challenge
University of Otago
Dunedin, New Zealand

****

Katrina, superb proposal. Happy to participate if this would be helpful.

Paul
(Professor Paul Glue, Psychological Medicine)

****

Looks good to me Katrina and I would be very supportive of the idea. I guess it is hard to know where to draw the boundaries on this topic, but I note that there doesn't seem to be (specific) content on GCP, GCLP, clinical trials management, and monitoring/audit although elements of each are covered in other areas.

Best
John
(Professor John Crump, Centre for International Health)

> Hi John,
>
> Thanks, yes, I agree it is hard to know where to draw the line. They will get the key ICH Guideline as a course reading, so will see GCP as a 'whole', though quite a bit of the detail would be outside the syllabus as it currently stands. The areas of management and monitoring/audit are not covered in much detail at all, apart from emphasis on following the protocol and having processes in place to ensure that happens.
>
> If we were to add these topics we would need to drop something - I am open to suggestions, although I note that many organisations run GCP courses and others are probably better placed to do it than us.
>
> Cheers
> Katrina

Sounds reasonable Katrina. At Duke all staff had access to GCP and GCLP training through University online resources (CITI). Does Univ Otago have something similar? Until now, I have done this by getting students guest status at Duke to get them free access to CITI. I feel pretty uncomfortable with the amount of that sort of training routinely available to postgraduate students during human subjects research at Univ Otago, even for observational studies (let alone clinical trials)...but there might be resources that I am not aware of?

Best
John

Hi John,

I'm not aware of any resource locally or for free online. Students in my cancer trials group do a course in Ak run by people from Australia as do all staff, but haven't seen that course offered here.

I will look into it and let you know what I find!

Cheers
Katrina

****

Hi Katrina,
I would support this as it is an excellent initiative. How will it be taught? Can it be done by distance learning as I think this would be a very good option for our medical registrars (all registrars in fact) which hopefully they can get recognised by the colleges as part of their training requirements. Obviously it would have to fit in with their clinical work schedules to be feasible.
Regards Rob
(Professor Rob Walker, Department of Medicine)

Hi Rob,

Many thanks. Currently the course is set up to have lectures over the zoom network, but otherwise to be internal. I have given some thought to registrars but am not sure of the best option yet - it would be good to chat,. The lectures will be recorded, so they could potentially take the paper even without getting to lectures, and we could arrange tutorials around work schedules.

Are you around next week for a chat? If so when would suit?

Cheers
Katrina

HI Katrina,
It looks like a number of senior colleagues are expressing interest on behalf of their trainees, so might be better to call a more general meeting to discuss.
Regards Rob

****

Excellent idea. Will the paper be open for Research nurses and coordinators as well? You might want to look at NZACRES for collaboration and dissemination. Their aim is enhance clinical research in NZ. Michael
(Professor Michael Schultz, HoD Department of Medicine)

****

I'm very supporting of this Katrina and note the international component.
Personally, as I can't speak for our wider department, I suspect the university public health people would benefit from an increasing focus on interventions (including evaluation by RCT where possible) too. Therefore you may want to consider whether the 'clinical' bit is too narrow?

Philip

McAuley Professor of International Health,
Co-Director, Centre for International Health,
Department of Preventive and Social Medicine,
University of Otago Medical School,
PO Box 56, Dunedin 9054,
New Zealand

Ph +64 3 479 9462 Cell 021 279 7214
Fax +64 3 479 7298

> Hi Philip,
>
> Many thanks. Yes, I had wondered about the 'clinical' in the name. We will certainly be discussing other types of interventions so the paper would be appropriate to others, the issue is the balance for marketing in terms of the familiarity of "clinical trials' vs people not realising the paper will suit all types of intervention studies. I will certainly add this to the list of topics to discuss if we decide to make the paper more permanent (both the title and the focus).
>
> Cheers
> Katrina

****

Hi Katrina
Thanks for sending this - it looks very interesting.
We see you have a significant ethics element in the paper, including:

- Ethics of randomization
- Vulnerable populations
- Scientific misconduct: types and causes, impact
- Trials in developing countries
- Trials without informed consent

This is core material that we also have in our Research Ethics paper BITC406 and Advanced Research Ethics, BITC407. These are complex areas and we wonder who would be teaching this. Perhaps we could meet up and discuss this further. Also Neil Pickering is part of the team (NEAC) that are creating the guidelines for intervention studies and observational studies so he could be particularly useful.

Best wishes
Lynley

Te Pokapū Matatika Koiora/The Bioethics Centre
Lynley Anderson
Associate Professor & Head of Department
Te Pokapū Matatika Koiora / The Bioethics Centre
Te Whare Wānanga o Otāgo / University of Otago
Pouaka Poutāpeta 56 / PO Box 56
Ōtepoti / Dunedin 9054,
Aotearoa / New Zealand
Waea / Tel 00 64 3 471 6132
īmēra / Email lynley.anderson@otago.ac.nz

****

Hi Katrina - I would echo Robs views. This would be excellent training for medical registrars and all clinical trialists in the Department of Medicine. Very supportive. Regards Patrick (Professor Patrick Manning, Department of Medicine)

****

Very positive reaction from our department/section. You will have no trouble filling places.

Roland Broadbent

****
Hi Katrina,

This is a great new initiative for which I expect there will be an excellent take up.

Best
Tim

Professor Tim Stokes
Head of Department
Department of General Practice & Rural Health
Dunedin School of Medicine
T: +64 3 479 7446
M: +64 21 279 7446

****

Sounds good to me too.
Mark

Mark Thompson-Fawcett
Associate Professor
General and Colorectal Surgeon
HOD Department of Surgical Sciences
Dunedin School of Medicine
University of Otago
****

I too support this paper. It will be interesting to see the syllabus - do you anticipate that adaptive designs will be taught as well?
(Professor Carlo Marra, Dean, School of Pharmacy)
****

It seems like you are getting a lot of approvals - it sounds good to me too.

Cheers

Bob

Bob Hancox
Department of Preventive & Social Medicine
Dunedin School of Medicine
University of Otago
Phone +3 479 8512
Fax +3 479 7298
****

Dear Chris,
This sounds like a great paper, and all Honours and postgraduate students of our school who conduct intervention studies of any sort will benefit from this paper. One significant element missing from the lecture topics is the issue of "treatment fidelity". A majority of clinical trials just name a treatment and fail to describe the replicable details. If it is a pharmaceutical

treatment, the name of drug would suffice, but for any psychological, or exercise and physical activity intervention, exact observable behavioural procedures need to be specified in the protocol and any deviations from the protocol need to be noted in the report to allow future replication of the trial. Hope this helps.

Moto

-----Original Message-----
From: Chris Button
Sent: Monday, June 11, 2018 9:54 AM
To: Mark Falcous <mark.falcous@otago.ac.nz>; Elaine Hargreaves <elaine.hargreaves@otago.ac.nz>
Cc: Motohide Miyahara <motohide.miyahara@otago.ac.nz>; Sandra Mandic <sandra.mandic@otago.ac.nz>; Peter Lamb <peter.lamb@otago.ac.nz>
Subject: FW: Proposed postgraduate paper in clinical trials

Dear colleagues,

pls see attached request for feedback by 22 June.

A full RM paper on clinical trials alone probably wouldn't suit the majority of our students I'm thinking but would be interested in your thoughts.

Ngā mihi mahana,
Chris

Associate Professor Chris Button
Dean of School of Physical Education, Sport and Exercise Science, University of Otago,
46 Union St West,
Dunedin. 9016
New Zealand.
Tel: +64 3479 9122
http://www.otago.ac.nz/sopeses/staff/academic/christopher_button.html
https://www.facebook.com/OtagoPESES
New article on water survival skills in Scandinavian Journal of Medicine & Science in Sports:
http://onlinelibrary.wiley.com/doi/10.1111/sms.12997/full

> Hi Moto and Chris,
>
> Many thanks for your feedback, yes I agree content on treatment fidelity is important and it will certainly be discussed. My apologies for missing this in the list of topics. I will add it in formally as a topic to be covered alongside choice of control.
>
> I agree that for many students coursework requirements will make it difficult to fit in a whole paper in clinical trials. It may well be that there is sufficient demand for a shorter module, and I would certainly be keen to consider that in the future if that was useful.
>
> Best wishes
> Katrina
>
> > Dear Katrina,
> >
> > Thank you for taking my suggestion on board. I think the issue of treatment fidelity fits better under Lecture 25-27 Monitoring and interim analysis rather than under Choice of control in Lecture 3-5 Scientific issues in design.
> >
> > While preparing for my upcoming workshop in UK, I also realised that an important statistical topic is missing. It is about how to perform meta-analysis for non-randomised studies of intervention (NRSI), when RCT is unavailable or inappropriate. A frequently used example of an unethical RCT is to test the effect of wearing a helmet for bike accidents. I can imagine that many injury and poisoning studies don't use RCT with human participants.
> >
> > The standard procedures for meta-analysis of NRSI are to: 1) justify combining the data from different trials; 2) use appropriate weighted technique to combine results from different studies, and adjust for heterogeneity if present; 3) statistically combine effect estimates adjusted for confounding rather than combining raw data, or justify why raw data are combined.

Probably the students, who will take the proposed paper, not only conduct meta-analysis of RCT, but also conduct meta-analysis of NRSI in the future. I believe that an inclusion of the contemporary standard procedures of meta-analysis for NRSI would strengthen the proposed paper.

Best wishes,

Motohide Miyahara PhD
School of Physical Education, Sport and Exercise Sciences
University of Otago
POBox 56
Dunedin, 9054 New Zealand
http://www.otago.ac.nz/sopeses/staff/academic/motohide_miyahara.html

> Hi Moto,
>
> Thanks, the material in lectures 25-27 is about monitoring of accumulating safety and efficacy data rather than monitoring protocol adherence, so I'm not sure it would work there but we'll have a think about where best to place it.
>
> I agree there are many intervention studies where randomisation is not possible. The section on meta-anaylsis will probably focus first on RCTs as they are easier, but I will investigate adding some comment about meta-analysis of non-randomised intervention studies.
>
> Best wishes
> Katrina

****

Dear Katrina

Thank you for the opportunity to provide feedback on your proposed paper. I have sought input from epidemiologists and biostatisticians in PSM, and comments include:

- Responses are positive, noting that this will be a useful paper for those undertaking RCTs in clinical research or post-graduate study.
- Hopefully the paper will facilitate more thoughtful and collaborative consultation of researchers with those in the Biostatistics Unit
- Learning Outcome 3 refers to a Treaty of Waitangi framework, however there doesn't seem to be any reference to this in the lecture schedule, so it's not clear how this will be addressed.
- We wonder whether this paper might be a useful optional paper in the proposed Postgraduate Diploma in Biostatistics, and we would value a discussion about whether / how it would fit in to that qualification at an appropriate time.
- In the medium term, this paper could be paired with a clinical epidemiology paper, which PSM has previously considered developing, aimed at people embarking on a clinical PhD or a career in academic medicine.
- While this is not explicit in the documentation, it seems that this paper is focussed on trials of individual interventions, particularly drug trials (the background focusses on EBM and pharmacology/physiology, and lectures 11,12, and 28 are specifically drug-related). RCTs are used so much more widely than for trials of drugs that it would be a shame for those doing other kinds of trials to feel that this course is not for them. It would be good to consider amending the title to 'Randomised Trials', to encourage those doing trials other than of clinical interventions to take the paper, and to include some specific discussion of RCTs in other areas.
- I see that you have suggested that the DPH (not PGDipPH) and MPH could be affected by this paper. Have you consulted the Chair of the Board of Studies for postgraduate PH? I imagine that if the methods could be taught with explicitly broader application than drug trials, it would be appropriate for the list of optional papers for the postgraduate Public Health programme, but

obviously that decision would require an assessment of the paper by the Board of Studies.

Best wishes

Trish

****

Hi Katrina,

Apologies for the delay in returning feedback to you, I'm only just back at work after taking bereavement leave.

In general I'm very supportive of a clinical trials paper being adopted, it's an important area that needs to be taught. I did have some queries about the proposal that I believe needs further consideration to ensure the paper is available to those who need it most.

The first question I had was around pre-requisites. If I understood correctly this paper would be targeted at clinical people as well as statistics students but there is a pre-requisite STAT 110 or 115 or equivalent. I would expect that this pre-requisite would exclude many of the clinical people from taking the course and would limit the papers ability to attract the right audience.

The other aspect I am confused about is the STAT coding of the paper. As a 400-level statistics paper it seems very light on statistics and looking at the course content it reads much more like a public health/health sciences paper, with a substantial target audience from health sciences. I would have thought it should be coded as a health sciences paper in some way to align with the content and audience. I would also expect that there may be overlap with the subjects taught in public health so it would be important to ensure the paper sits alongside those and adds to what exists already.

As we have discussed in the past this is an important area that needs to be taught well so I'm pleased to see this developing but I worry it might miss its target audience in the present form and that the people I would want to be able to take this course might be excluded.

Apologies again for the delay in sending this feedback, hope that helps and very happy to meet and discuss further with you if that is useful.

Cheers
Robin

****

Hi Katrina

I am providing this feedback on behalf of the Faculty of Dentistry - it appears that there has been little feedback from us previously. I forwarded the email below to staff involved in clinical trials and will summarise the main points that they raised.

First a bit of background. Clinical trials are carried out in the Faculty of Dentistry by

staff members, Doctor of Clinical Dentistry (DClinDent) students and by PhD students.

All those who responded to my email supported your initiative and thought it worthwhile. They thought that it would be of use to some of our PhD students, DClinDent students and to some staff, however there would be some barriers to enrolment. One is the time commitment: 240 hours over one semester would be too much for our DClinDent students and staff. The DClinDent programme is already full with clinical and research papers. Staff would struggle to find sufficient time and it would be more attractive if it could be undertaken over a longer period. It was felt that some of our students and staff might not have the prerequisite statistics knowledge.

Some additional comments; it was not clear what “a little scientific background: pharmacology, physiology” in the first two lectures meant. These are potentially huge topics and there is no indication of what was to be included or why.

It was felt that only one lecture on systematic reviews and meta-analyses was a bit light.

I hope this is useful.

Regards

Richard Cannon.

****

Tēnā kōrua

Members of the Biochemistry Department read the proposal with interest and approval. The topic is useful and the involvement of Professor Lumley is seen as a strength. However, given the proposed focus, this paper seems unlikely to attract GENE and BIOC students. If in the future, a short course is developed from this paper as suggested by Professor Button, it could be of interest to our students.

Nāku, noa nā

Catherine Day

Catherine Day | Professor and Head of Department | Biochemistry Dept | University of Otago | PO Box 56 Dunedin | New Zealand | Tel: +64 3 479 7871

****

Afternoon Katrina,
Information about the proposed STAT 499 paper was forwarded to me as Assoc Dean of PG Studies in the School of Physiotherapy by my Dean for discussion at our next PG meeting. As this is not until next week, and therefore will miss the deadline to reply to you, I think it pertinent to let you know that I support the paper in principle (it appears already to have wide support from various and varied depts.), and support many of the comments (for example to widen it wider than 'clinical trials', and to include how to synthesise non RCT trials).

Please therefore accept this email as support for the paper from Physiotherapy.

Kind regards, Hilda Mulligan