Date: Thursday, July 04, 2013 10:30:33 AM

The University of British Columbia
Office of Research Services
Behavioural Research Ethics Board
Suite 102, 6190 Agronomy Road
Vancouver, BC V6T 1Z3

H13-00606 **Analgesic & Antibiotic prescription by Vancouver dentists (Version 1.0)**

Principal Investigator: Jolanta Aleksejuniene

1. Principal Investigator & Study Team - Human Ethics Application [View Form]

1.1. Principal Investigator Please select the Principal Investigator (PI) for the study. Once you hit Select, you can enter the PI's name, or enter the first few letters of his or her name and hit Go. You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.

Last Name	First Name	Employer.Name	Email
Aleksejuniene	Jolanta	Oral Health Sciences	jolanta@dentistry.ubc.ca

Enter Principal Investigator Primary Department and also the primary location of the PI's Institution:

Oral Health Sciences

1.2. Primary Contact Provide the name of ONE primary contact person in addition to the PI who will receive ALL correspondence, certificates of approval and notifications from the REB for this study. This primary contact will have online access to read, amend, and track the application.

Last Name	First Name	Rank
Buttar	Rene	Graduate Student

1.3. Co-Investigators List all the Co-Investigators of the study. These members WILL have online access which will allow them to read, amend and track the application. These members will be listed on the certificate of approval (except BC Cancer Agency Research Ethics Board certificates). If this research application is for a graduate degree, enter the graduate student's name in this section.

Last Name	First Name	Institution/Department	Rank
Shen	Ya	UBC/Dentistry/Oral Biological & Medical Sciences	Clinical Assistant Professor
Coil	Jeffrey M.	UBC/Dentistry/Oral Biological & Medical Sciences	Assistant Professor

1.4. Additional Study Team Members - Online Access List the additional study team members who WILL have online access to read, amend, and track the application but WILL NOT be listed on the certificate of approval.

Last Name	First Name	Institution/Department	Rank

1.5. Additional Study Team Members - No Online Access Click Add to list study team members who WILL NOT have online access to the application and will NOT be listed on the certificate of approval.

Last Name	First Name	Institution / Department	Rank / Job Title	Email Address

Tri Council Policy Statement2 (TCPS2) Tutorial All undergraduate and graduate students and medical residents are required to complete the TCPS2 Tutorial (CORE) before submission. This tutorial provides an

Yes

essential orientation to Canadian human research ethics guidelines. The Principal Investigator and all Co-Investigators must be familiar with the TCPS2. Indicate completion of the TCPS2 (CORE) tutorial below: 1.6.A. All Undergraduate/Graduate Students:	
1.6.B. All Medical Residents:	No
Comments:	
1.7. Project Title Enter the title of this research study as it will appear on the certificate. If applicable, include the protocol number in brackets at the end of the title. If this is a class-based project, see guidance on the right.	Analgesic and Antibiotoic Prescription by Dentists During Endodontic Treatments
1.8. Project Nickname Enter a nickname for this study. What would you like this study to be known as to the Principal Investigator and study team?	Analgesic & Antibiotic prescription by Vancouver dentists
2 Study Dates and Funding Information - Human Ethics Application [View Form]	
You plan to start collecting data immediately after obtaining ethics and any other required approvals (the start date on the ethics certificate will reflect the approval date),	yes
You plan to start data collection at a later date i.e., 2 months or more after approvals are obtained. Click the calendar icon below to select the dates (Internet Explorer) or enter the dates manually using the format yyyy-mm-dd. Estimated start date:	March 6, 2013
2.1. B. Estimated end date:	May 26, 2014
2.2.A. Types of Funds Please select the applicable box(es) below to indicate the type(s) of funding you are receiving to conduct this research. You must then complete section 2.3 and/or section 2.4 for the name of the source of the funds to be listed on the certificate of approval.	No Funding
2.2.B. For Industry Sponsored studies, please provide a sponsor contact.	
2.3. Research Funding Application/Award Associated with the Study that was Submitted to the UBC Office of Research Services Please click Add to identify the research funding application/award associated with this study. Selecting Add will list the sources of all research funding applications that have been submitted by the PI (and the person completing this application if different from the PI). If the research funding application/award associated with this study is not listed below, please enter those details in question 2.4.	UBC Number Title Sponsor
2.4. Research Funding Application/Award	UBC Number Title Sponsor

Associated with the Study not listed in question 2.3. Please click Add to enter the details for the research funding application/award associated with this study that is not listed in question 2.3. When you press Add you can do a search for your funding award by doing a search in the Sponsor box - over 7000 options are listed	
2.5.A. Is this a DHHS grant? (To view a list of DHHS funding agencies click on add in 2.5.B below)	no
2.5.B. If yes, please select the appropriate DHHS funding agency from the selection box, and attach the grant to box 9.8. of the application.	DHHS Sponsor List: Order: Active:
Attach DHHS Grant Application for each sponsor listed above	
2.6. Conflict of Interest Do any of the following statements apply to the Principal Investigator, Co-Investigators and/or their partners/immediate family members? Receive personal benefits in connection with this study over and above the direct cost of conducting this study. For example, being paid by the funder for consulting. (Reminder: receiving a finders fee for each participant enrolled is not allowed). Have a non-financial relationship with the sponsor (such as unpaid consultant, advisor, board member or other non-financial interest). Have direct financial involvement with the sponsor (source of funds) via ownership of stock, stock options, or membership on a Board. Hold patent rights or intellectual property rights linked in any way to this study or its sponsor (source of funds).	no
4. Study Type - Human Ethics Application [View Form]	
4.1. UBC Research Ethics Board Indicate which UBC Research Ethics Board you are applying to and the type of study you are applying for:	UBC Behavioural Research Ethics Board
N/A	no
4.2.A. Institutions and Sites for Study	Institution Site UBC Vancouver (excludes UBC Hospital)
4.2.B. Please enter any other locations where the research will be conducted under this Research Ethics Approval (e.g., private physician's office, community centre, school, classroom, participant's home, in the field - provide details).	
4* Behavioural Study Review Type [View Form]	
4.3.A. If this proposal is closely linked to any	No

other proposal previously/simultaneously submitted, enter the Research Ethics Board number of that proposal.	
4.3.B. If applicable, please describe the relationship between this proposal and the previously/simultaneously submitted proposal listed above.	
4.3.C. Have you received any information or are you aware of any rejection of this study by any Research Ethics Board? If yes, please provide known details and attach any available relevant documentation in question 9.7.	no
4.4.A. External peer review details:	Department Review
4.4.B. Internal (UBC or hospital) peer review details:	The proposal was peer-reviewed by a UBC Faculty of Dentistry Research Committtee.
4.4.C. If this research proposal has NOT received any independent scientific/methodological peer review, explain why no review has taken place.	N/A
Participant Vulnerability	Low
Research Risk	Low
4.5.B Explain/justify the level of risk and group vulnerability reported above.	Questionnaires will have code ID, i.e. no personal identifiers are used on data collection forms. The personal information, fax numbers will only be used to track who has and has not completed the questionnaire and enable us to send reminders to complete the questionnaire. After the completion of the data collection, all personal identifiers are destroyed and data entered anonymously for the subsequent analyses.
4.5.C Does your application fall under minimal risk (i.e., it was assigned an overall risk level of 1 on the minimal risk matrix) and therefore is eligible to be considered for Delegated Review?	yes
4.6. Harmonized Review of Multi-Jurisdictional Studies Is this study a multi-jurisdictional study that requires review by one or more institutions? (Note: If submitting an amendment for an already approved study, you must respond No to this question)	no
4.7.A Creation of a Research Database or Registry Does this study involve the creation of a research database or registry for future unspecified research? [if no, skip to 4.8]	no
4.7.B Is the purpose of this application exclusively to obtain approval for the creation of a research database or registry? [Note: if the creation of the database or registry is part of a bigger project also included in this application, you must answer no below].	no
4.8. Class-based research and the department level research ethics review	no

process Is this study a minimal risk class-based research project conducted for pedagogical purposes, e.g., a research methods course exercise, or other exercises designed to give students training in conducting and/or presenting research? The activity should not be an undergraduate or graduate thesis/dissertation.	
If Yes, please state whether your department has a Departmental Ethics Officer (DEO) and, if so, indicate their name below.	
5. Summary of Study and Recruitment - Human Ethics Application for Behavioural Study [View Form]	
5.1.A Provide a short summary of the project written in lay language suitable for non-scientific REB members. DO NOT exceed 100 words and do not cut and paste directly from the study proposal.	The misuse of medications has been on the rise and has been expressed as a concern in a recent US study. Therefore, we aim to identify the current pattern of the medication presrciption by dental specialists (endodontists) and general dental practitioners in Vancouver area. The findings of this study will form the basis to prepare guidelines for the prescription of antibiotics and analgesics while providing diverse endodontic treatments.
5.1.B Summarize the research proposal:	The misuse of antibiotics can cause side-effects and result in the emergence of antibiotic resistant bacterial strains. This resistance is partly gained when microorganisms adapt gradually during prolonged therapy with antibiotics. A recent review paper indicated that has the indications for the use of systemic antibiotics is limited, and they concluded that dentists over-prescribe antibiotics. Thus, it is important to know whether these medications are being over-prescribed in British Columbia. A number of surveys of general dentists and endodontists have been conducted over the last 35 years to examine trends in how endodontic emergencies are dealt with. Most of these studies were conducted in the U.S., and no such survey has been conducted in Canada. In addition, most of these surveys focused on either endodontists or general dentists, but not both groups of dental practitioners. Moreover, if analgesics or antibiotics were used, the type of medication was not specified. Also, the previous studies did not inquire about the combined use of multiple medications. Study Hypotheses: There is a difference in the analgesic and antibiotic prescription between general dentists and endodontists in British Columbia. There is a difference in the analgesic and antibiotic prescription habits of general dentists based on the location of their office in the city of Vancouver.
5.2. Inclusion Criteria Describe the participants being selected for this study, and list the criteria for their inclusion.	All dentists from Vancouver will be included in the present survey.
5.3. Exclusion Criteria Describe which participants will be excluded from participation, if any, and list the criteria for their exclusion.	There are no exclusion criteria.
5.4. Recruitment Provide a detailed	The addresses of dental offices are freely available for public

description of the method of recruitment. For example, describe who will contact prospective participants and by what means this will be done. Ensure that any letters of initial contact or other recruitment materials are attached to this submission on view 9 (section 9.7).	access. All dentists practising in Vancouver area will be included in the present study.
5.5. Use of Records If existing records (e.g., health records, course grade sheets or other records/databases) will be used to IDENTIFY potential participants, please describe how permission to access this information, and to collect and use this information, will be obtained.	N/A
5.6. Summary of Procedures	Initially, the questionnaires will be faxed to the offices. After 2 weeks, these offices will be contacted by phone and encouraged to have a dentist complete and return the questionnaire. After an additional 2 weeks, the offices will be contacted again and asked if they returned the questionnaire. If they have not returned it, we will ask if there is anything we can do to facilitate the process, e.g. providing a return postage. The prescription of medications will be compared between general dentists and endodontists using Chi-squared or Fischer's exact test. A similar comparison will be made between two groups of dentists, based on the location of their practices in Vancouver (East vs. West dental practices).
5.7. Checklist for Research Methods Are any of the following procedures or methods involved in this study? Check all that apply.	None of these Methods
6. Participant Information and Consent Process - Human Ethics Application for Behavioural Study [View Form]	
6.1. Time to Participate How much time will a participant be asked to dedicate to the project?	20 minutes to complete the questionnaire.
6.2. Risks Describe what is known about the risks of the proposed research for participants.	There are no known risks to participate in this study.
6.3. Benefits Describe any potential benefits to the participant that could arise from his or her participation in the proposed research.	There are no potential individual benefits, but participants will contribute to their profession (development of guidelines for medication use).
6.4. Impacts on Community If your research involves an identified group or 'community', outline the likely impacts of the research on the community.	N/A
6.5. Reimbursement Describe any reimbursement for expenses (e.g., meals, parking, medications) or payments/gifts-in-kind (e.g., honoraria, gifts, prizes, credits) to be offered to the participants. Provide full details of the amounts, payment schedules, and value of gifts-in-kind.	N/A
6.6. Obtaining Consent Specify how potential participants will be invited to take part in the	Participants consent to the study by completing the questionanire.

study. Include details of where the consent will be obtained and documented, and under what circumstances.	
6.6.A. Waiver of Consent If you are asking for a waiver or an alteration of the requirement for participant informed consent please justify the waiver or alteration and confirm that the study meets the criteria on the right. Please address each criterion individually.	N/A
6.7. Time to Decide How long after being provided with detailed information about the study will the participant have to decide whether or not to participate? Provide your rationale for the amount of time given.	The potential subjects are given two weeks to make a decision.
6.8. Capacity to Consent Will every participant have the capacity to give fully informed consent on his/her own behalf? Please click Select to complete the question and view further details.	Will the participant have the capacity to give fully informed consent? / Details of the nature of the incapacity / If not, who will consent on his/her behalf? / If not, will he/she be able to give assent to participate? / If Yes, explain how assent will be sought. Yes / yes [Details]
6.9. Renewal of Consent Describe any situation in which the renewal of consent for this research might be appropriate, and how this would take place.	This project is a Pilot and subsequent study may follow.
6.10. Provisions for Consent What provisions are planned for participants, or those consenting on a participant's behalf, to have special assistance, if needed, during the consent process (e.g., consent forms in Braille, or in languages other than English).	N/A
6.11. Restrictions on Disclosure Describe any restrictions regarding the disclosure of information to research participants (during or at the end of the study) that the funder/sponsor has placed on investigators, including those related to the publication of results.	N/A
7. Number of Participants - Human Ethics Application for Behavioural Study [View Form]	
7.1. External Approvals External approvals for research involving other institutions and other jurisdictions: Provide written proof of agency approval for projects carried out at other institutions and, when applicable, other jurisdictions. Indicate external approvals below: A. Other Institutions:	no
B. Please select Add to enter the name of the institution and if you have already received approval attach the approval letter.	Name of Institution
C. Other Jurisdiction or Country (if answer is No go to 7.1.G):	no

D. Please select Add to enter the name of the jurisdiction or country and if you have already received approval attach the approval letter.	Name of Jurisdiction or Country
E. Has a Request for Ethics Approval been submitted to the institution or responsible authority in the other jurisdiction or country? (Send a copy to the Research Ethics Office when approval is obtained).	no
F. If a Request for Approval has not been submitted, provide the reasons below:	
G. Does this research focus on aboriginal peoples, communities or organizations?	no
If Yes, ensure that you are familiar with the guidance documents linked on the right. Also attach a copy of the research agreement with the community (if available) in question 9.7. Please describe the community consent process. If no community consent is being sought, please justify.	
H. Registration for Publication of Clinical Trials. Does this study fall within the clinical/intervention trial definition stated on the right (in the guidelines)?	no
If 'Yes', click 'Add' to enter the following information. (Please note that registration by UBC ORS administration requires the prior ethical approval of the study. In that case, registration information should be added when it becomes available).	Has it been registered? / Indicate the Authorized Registry used: / Enter your Clinical Trial unique identifier:
7.2. Number of Participants A. How many participants will take part in the entire study (i.e., the entire study, world-wide)?	350 of general practitioners and 50 endodontists
B. How many participants will take part at institutions covered by this Research Ethics Approval (i.e., only at the institutions covered by this approval)?	400
7.3. Researcher Qualifications Who will actually conduct the study and what are their qualifications to conduct this kind of research? (e.g., describe relevant training, experience, degrees, and/or courses).	Principal investigator is an Assistant Professor in Dentistry and has conducted many similar studies. Jeff Coil is an Assistant Professor in Dentistry and is a Director of Graduate Endodontic program. Dr. Ya Shen is an Assistant Professor and has the necessary expertise for this study.
8. Confidentiality - Human Ethics Application for Behavioural Study [View Form]	
8.1. Security of Data During the Course of the Study How will data be stored? (E.g., computerized files, hard copy, videotape, audio recordings, personal electronic communications device, other.) How will security of the data be maintained? (For example, study documents must be kept in a secure locked location and computer files should be password protected and encrypted, data should not be stored or downloaded onto an unsecured computer, back up files	The data (without participants name) will be securely locked in the PI office.

should be stored appropriately.) If any data or images are to be kept on the Web, what precautions have been taken to prevent them being copied?	
8.2. Access to Data Who will have access to the data (e.g., co-investigators, students or translators)? How will all of those who have access to the data be made aware of their responsibilities concerning privacy and confidentiality issues?	Only the PI will have access to data, the summaries of data will be shared with co-investigators.
8.3. Protection of Personal Information Describe how the identity of research participants will be protected both during and after the research study, including how participants will be identified on data collection forms.	Questionnaires will have code ID, i.e. no personal identifiers are used on data collection forms. The personal information, fax numbers will only be used to track who has and has not completed the questionnaire and enable us to send reminders to complete the questionnaire. After the completion of the data collection, all personal identifiers are destroyed and data entered anonymously for the subsequent analyses.
8.4. Transfer of Data Will any data that identify individuals be transferred (available) to persons or agencies outside of the University?	no
If YES, describe in detail what identifiable information is released, to whom, how the data will be transferred, how and where it will be stored and what safeguards will be used to protect the identity of participants and the privacy of their data. Attach the data transfer agreement if applicable.	
8.5. Retention and Destruction of Data UBC policy requires that data be kept for at least 5 years within a UBC facility. If you intend to destroy the data at the end of the storage period describe how this will be done to ensure confidentiality (e.g., tapes should be demagnetized, paper copies shredded). UBC has no explicit requirement for shredding of data at the end of this period and it may be kept indefinitely. Please note that the responsibility for the security of the data rests with the Principal Investigator.	All paper data will be stored in a locked cabinet in the Faculty of Dentistry for 5 years, then shredded.
8.6. Future Use of Data Are there any plans for future use of either data or audio/video recordings? Provide details, including who will have access and for what purposes, below.	This is a Pilot study. A later survey might follow.
8.7. Feedback to Participants Are there any plans for feedback on the findings or results of the research to the participant? Provide details below.	No
9. Documentation - Human Ethics Application for Behavioural Study [View Form]	
9.1. Research Proposal Examples of types of proposals are listed on the right. Click Add to enter the required information and attach the documents.	Name: Research Protocol; Version: 1; Date: February 26, 2013 [View]

9.2. Documentation of Consent Examples of types of consent documents are listed on the right. Click Add to enter the required information and attach the documents.	Name / Version / Date
9.3. Documentation of Assent Examples of types of assent documents are listed on the right. Click Add to enter the required information and attach the documents.	Name: The Cover Letter; Version: 1; Date: March 4, 2013 [View]
9.4. Advertisement to Recruit Participants Examples are listed on the right. Click Add to enter the required information and attach the documents.	Name / Version / Date
9.5. Questionnaire, Questionnaire Consent Cover Letter, Tests, Interview Scripts, etc. Please click Add to enter the required information and attach the documents.	Name: Questionnaire for Dentists; Version: 1; Date: February 26, 2013 [View] Name: Questionnaire for Dentists; Version: 2; Date: February 28, 2013 [View]
9.6. Letter of Initial Contact Please click Add to enter the required information and attach the forms.	Name / Version / Date
9.7. Other Documents A. Other documents: Examples of other types of documents are listed on the right. Click Add to enter the required information and attach the documents.	Name / Version / Date
B. If a Web site is part of this study, enter the URL below. Since URL's may change over time or become non-existent, you must also attach a copy of the documentation contained on the web site to one of the sections above or provide an explanation.	
10. Fee for Service - Human Ethics Application for Behavioural Study [View Form]	
Mechanism for Submitting Fee. Please indicate which of the following method of payment will be used for this application:	
Contact information regarding where to send the invoice.	
12. Save Application - Human Ethics Application [View Form]	

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2199 Wesbrook Mall
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Fax: (604) 822-3562

Project: Analgesic & Antibiotic prescription by Vancouver Dentists

The Cover Letter

Dear Doctor,

This letter is to invite you to participate in a study that aims to examine the prescription of medications while providing endodontic treatments. The collected information will serve as a basis for developing guidelines for medication use in treating endodontic patients.

In the questionnaire we will inquire about different aspects of medication use. Thus, we invite you to take 15-20 minutes to complete the questionnaire. You do not need to answer questions that you are not comfortable answering and return questionnaire to us by fax.

All information received will be confidential. Submission of the questionnaire confirms your agreement to participate and your understanding of the research study.

If you have any questions about this project or if you do not wish to participate or receive any follow-up reminders by mail or telephone you may contact, Dr. Jolanta Aleksejuniene at
604-822-7800 jolantaa@interchange.ubc.ca

If you have any concerns about your rights or treatment as a research subject, please contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598 or, if long distance, e-mail to RSIL@ors.ubc.ca.

Thank you in advance for your participation. Remember that your responses will be kept confidential.

Sincerely,
Dr. Jeff Coil, Assistant Professor, Director of Graduate Endodontics Program, Faculty of Dentistry.

Dr. Jolanta Aleksejuniene, Assistant Professor, Chair Community Dentistry Division, Faculty of Dentistry.