Purpose: This Application is designed to help you apply for IRB approval for research involving human subjects and to ensure that the IRB receives the appropriate information to make a determination.

Before you fill out this form: *If this project has been reviewed by any other IRB, stop completing this application and contact the IRB Personnel to determine whether a Cooperative Agreement can be entered.*
• Review the IRB Manual. • Complete the CITI training. Training is required for all individuals involved in data collection and analysis on this protocol. Training is also required for student advisors.
YOU MAY NOT CONDUCT RESEARCH ACTIVITIES INVOLVING HUMAN SUBJECTS WITHOUT IRB APPROVAL.

Instructions: Complete the application thoroughly. All pages must be completed. Incomplete submissions will be returned and will result in the delay of your study being reviewed. Explain your research as you would to a peer who is not an expert in your field, avoid jargon and acronyms. All information pertinent to your research must be included in the Application itself and your research must be understood without the supplemental attachments. Do not rely on information presented in attachments. Submit completed application and required attachments to irb@pacific.edu.

Submission Checklist: The last page of this Application includes a submission checklist. Please use the checklist to confirm all required documents are submitted with this Application.

Signatures: Obtain all signatures prior to submitting to the IRB Personnel. A Faculty Advisor signature is required if the student is the principal investigator.

If you have any questions, please contact the IRB Personnel at: irb@pacific.edu or 209.946.3903.

FOR IRB OFFICE USE ONLY:			
IRB Protocol Review Number:		**Date Received:**	
☐ Approved ☐ Conditionally Approved (*See IRB Approval Letter*) ☐ Disapproved (*Activity is considered Human Subjects Research and Requires IRB Approval*) ☐ No Determination (*Activity is not research or does not involve human subjects. IRB Approval not required.*) ☐ Exempt Review: Category _____ ☐ Expedited Review: Category _____ ☐ Full Review ☐ Limited Review Required			
IRB Co-Chair Approval:		**Approval Date:**	

REQUIRED RESEARCHER CONTACT INFORMATION:			
Lead Researcher/ Principal Investigator (PI):	Bruce Wayne	**PI University Email:**	bwayne@pacific.edu
College/School: *(e.g. Conservatory of Music)*	Dental school	**Department:** *(e.g. Music Therapy)*	Periodontics
PI Status:	☐ Student ☒ Faculty ☐ Administrator ☐ Other: _____	**Expected Graduation Date:** (*If Student*)	N/A
Date CITI Training was Completed by PI: (Attach CITI certificate)	Not Sure	**Date CITI Training was Completed by Faculty Advisor:** (Attach CITI certificate)	N/A
Faculty Advisor: (required for student research)	N/A	**Faculty Advisor Email:**	N/A
Research/Activity Title:	The Efficiency of the 1064 XLASE laser on Dental Patients		
Has this Research Been Reviewed by Another Institutional Review Board?	☐ Yes ☒ No (If yes, Stop completing this Application and contact the IRB Personnel to determine whether a Cooperative Agreement is possible.)		
Project Funding	☐ Funded ☒ Unfunded	**If Funded, list source:**	
Any Conflict of Interest Between Funding Source and the PI?	☐ Yes ☐ No ☒ N/A (Refer to the University's Conflict of Interest Policy)	**If Yes, Describe:**	

Additional Personnel/Research Team Members (only list personnel that will have interaction with subjects or access to identifiable data.) CITI CERTIFICATE MUST BE ATTACHED FOR ALL LISTED	**Name**	**School/Dept.**
	Clark Kent	UOP
	Diana Prince	UOP
	Selina Kyle	UOP

NO SIGNATURE = WILL NOT BE REVIEWED

Assurances, Signatures and Certification / Researcher Responsibilities

LEAD RESEARCHER/PRINCIPAL INVESTIGATOR

In submitting this proposed research project and signing below, I certify that:

1. I have read and understand the IRB Manual regarding research involving human subjects.
2. I will conduct the research involving human subjects as presented in this Application and approved by my faculty advisor (if applicable), and the IRB.
3. I will present any proposed modifications of the research activities to the IRB for approval prior to implementation.
4. All conflicts of interest, if any, between myself and any funding agencies have been resolved to the satisfaction of the University's Office of Sponsored Programs.
5. All data/specimens were/are collected in an appropriate and ethical manner.
6. I will report to the IRB any problems that occur to subjects related to the research activities.

_____ Date: _____
Signature of Lead Researcher

FACULTY ADVISOR (IF LEAD RESEARCHER/PI IS A STUDENT):

My signature below verifies that:

1. I will provide continued supervision and guidance to the student during the course of this student's research project, as appropriate.
2. I confirm that I am responsible for working with the student researcher to ensure that this research is performed in an ethical manner that complies with federal regulations and University policies regarding research involving human subjects.
3. I have reviewed and concur with this research application, including the purpose, design, methodology, procedures, subjects and the provided description of risks and benefits.
4. I will assist the student and the IRB as requested if any problems develop with the research.
5. If I will be unavailable (such as during a sabbatical leave or vacation), I will arrange for an alternate faculty advisor to assume responsibility during my absence.

_____ Date: _____
Signature of Faculty Advisor

Typed Name:

A. PURPOSE AND OBJECTIVES OF RESEARCH

A.1. Please explain the purpose and objectives of the research. Attach additional pages as needed.

The purpose is to determine the capability of scaling and root planing (deep cleaning) with an adjunctive diode laser [1064 XLASE (Fotona LLC, Dallas, TX)] gingival sulcular curettage in the treatment of moderate to advanced chronic periodontitis. The diode laser has gained in popularity in recent years because of its ability to produce an almost blood-free surgical field. It can be used for minor periodontal (gum) surgeries such as crown lengthening, gingivectomy and gingivoplasties, gingival retraction prior to impression taking, esthetic crown lengthening, labial and lingual frenum relief, biopsy removal, and soft tissue gingival curettage. It is now receiving wider clinical use in laser excisional new attachment procedures.

The diode laser is not designed for use on hard tissues such as bone, tooth, and root surfaces. The diode laser provides the therapist with an instrument that easily removes the ulcerated and inflamed pocket epithelial lining (curettage) and greatly reduces the pathogenic organisms (disinfection). When the laser is used with proper caution, injury is minimized on the adjacent root surfaces. The diode laser is not useful for calculus removal. Calculus removal is routinely accomplished through scaling and root planing using ultrasonic scalers and or hand instruments. Probing depths exceeding 5 millimeters (mm) are difficult to maintain as complete calculus removal may be less than 40%. Bactericidal medications are used to reduce the level of microorganisms within the gingival sulcus and to enhance healing potential. The diode laser provides a medication free alternative to reduce pathogenic organisms during therapy. Curettage in a blood free surgical field further enhances the therapist's visualization and may further increase the proficiency in removing offending root deposits.

Laser therapy as either an adjunct or replacement for conventional periodontal therapy has shown increasing popularity. The prospect of less possible post-operative pain and no sutures has widespread public appeal. Possible biostimulatory effects with low level laser exposure has led to increased interest on possible regenerative potentials within the soft and hard tissues of the periodontium. The 1064 XLASE has the same wavelength as the Nd:YAG laser, and its bactericidal and penetration properties should be comparable.

Presently, we take pre- and post-treatment radiographs when placing dental implants, during treatment and following treatment in endodontic therapy, and to assess the effect of osseous grafting in pre- and post-surgical periodontal intervention. The use of the dental Cone Beam Computerized Tomography (CBCT) facilitates the therapist's ability to monitor healing responses. It is a special type of x-ray equipment that is used when two-dimensional (2-D) dental radiographs such as a full mouth radiographic series, for example, are not sufficient. This technology is used to produce three-dimensional (3-D) images of teeth, soft/hard tissues, and nerve pathways in a single scan. To validate the effect of therapy, it is necessary to accurately assess hard tissue (bone) changes, either gains or losses, and to document them following the course of our treatment. The CBCT scan eliminates the need of re-entry surgery to view the hard tissue changes, either regenerative or resorptive brought about by the operative procedures. A 3D Accuitomo device (J. Morita Mfg. Corp., Irvine, CA) will be used to take the 4 centimeter (cm) x 4 cm volume scans. Each 4 cm x 4 cm volume scan has an exposure dose of 20 μSv (microsieverts). Comparative activities and their μSv exposure doses include the following: 4 dental bitewing radiographs 38 μSv, a chest x-ray 170 μSv, a full mouth radiographic series 171 μSv, a medical CT head scan 2,000 μSv, and a routine yearly mammogram 700 μSv. The Federal Occupation Safety limit per year is 50,000 μSv.

Incidentally, radiation exposure from a round-trip flight from San Francisco to New York City is 60 µSv. The CBCT 3D Accuitomo 4 cm x 4 cm volume scan is well within the safety level recommendation and would impose minimal hazard to the individual. In this study, 2 sites (teeth) will each receive a CBCT 3D Accuitomo 4 cm x 4 cm volume scan pre-treatment for a dose of 40 µSv (20 µSv + 20 µSv). One year post-treatment, the same 2 sites will each receive a CBCT 3D Accuitomo 4 cm x 4 cm volume scan for a dose of 40 µSv (20 µSv + 20 µSv). Since the pre- and post-treatment exposures will be one year apart, the ionizing effect of the CBCT 3D Accuitomo 4 cm x 4 cm volume scan on each patient will be further diluted. The CBCT 3D Accuitomo 4 cm x 4 cm volume scan eliminates the need for a second surgery in the treatment sites to assess bone and tooth changes, and because it produces a 3-D view, its accuracy is superior to routine dental radiographic views.

The radiation exposure is comparable to routine dental radiographs (full mouth and bitewing series and is well below medical exposures such as chest films, CT head scans, and routine mammograms. Each of the planned procedures is expected to result in improvement in the patients' gingival health as seen by reduction in both the amount of inflammation and the depth of the periodontal pocket. It is anticipated that there may be a variation in the degree of repair based on the type of procedure done and effect of laser curettage and laser disinfection within the site.

A.2. CONTRIBUTION TO, OR DEVELOPMENT OF, GENERALIZABLE KNOWLEDGE.
Please explain how the research will contribute to, or help develop, generalizable knowledge.

To date, we investigators are not aware that any research using the dental laser has been done in conjunction with the use of a pre-operative and post-operative CBCT radiography to check for hard tissue (bone) changes, either gains or losses. The accuracy of the CBCT supersedes other less reliable and invasive methods (i.e., surgical re-entry of the treatment sites) and will confirm any success of the diode laser in bone regeneration. The results of our study will provide a significant contribution to our specialty of Periodontics, to Dentistry, and the medical field, in general.

B. DESCRIPTION OF SUBJECT POPULATION(S)	
B.1. Provide a description of the target subject population: *(Include the geographical location of the target subject population e.g. cities, states, country.)*	Dental Patients
B.2. What is the maximum number of subjects you will enroll?	No Cap
B.3. Describe the recruitment process in detail. *(If applicable, include how you will gain access to contact information e.g. email addresses, telephone numbers etc.)*	Dental patients at Dugoni.

B.4. Indicate how the participants will be recruited (select all that apply): ***Note: Include a copy of applicable recruitment materials (e.g., flyer, email, verbal recruitment script.)***	
☐ In Person (Verbal Recruitment) ☐ Telephone ☐ Email ☐ Flyer *(Indicate flyer locations in section B.3.)* ☐ Online *(Specify social media platform or forums to be utilized):*	☐ Mail ☐ Marketing Pool ☐ Database or record review ☐ N/A Existing Data/Specimen (*no contact with subjects)* ☐ Other: *(describe)*
B.5. Describe the inclusion and/or exclusion criteria of the subjects below:	
Inclusion Criteria: Anyone interested.	**Exclusion Criteria Explained:** None
B.6. Does this study include minors?	☐ Yes - *If Yes, state minimum and maximum ages:* ☐ No
B.7. Does this study include adults?	☒ Yes - *If Yes, state minimum and maximum ages:* ☐ No
B.8. Will all research be conducted in English?	☒ Yes ☐ No – *If No, what language(s) will be used:* (*Note: All applicable research materials need to be submitted in the language being used with the participants (unless no written version exists), along with English translations/script. The name of the translator and a statement about the translator's qualifications must be provided with this IRB Research Application*.)
B.9. Where will research activities involving subjects occur? (e.*g., Stockton campus, specific address, [City, Country], etc*.) (*If online, state the hosting website).*	In the dental clinic
B.10. If any vulnerable populations are being used, please justify. (See page 70, XV. in IRB Manual for description of vulnerable populations.)	N/A

C. RESEARCH ACTIVITIES INVOLVING HUMAN SUBJECTS

C.1. Describe the research activities involving each subject group described in Section B. Include the expected amount of time subjects will be involved in each activity. *Attach the methodology section of your grant proposal, dissertation or thesis if applicable*.

I will just use the laser on patients and hope the it is more efficient then the dental tools that I currently utilize.

C.2. How will the information/biospecimen be collected from subjects? Check all that apply.

☐ Questionnaires (attach a copy)
☐ Interviews (attach a list of questions)
☐ Observances (briefly describe below

☐ Standardized tests (list names of tests ***and*** attach copy of each test)

☐ Other:

D. INFORMATION/BIOSPECIMENS

D.1. How will the information/biospecimens be recorded (e.g., notes, tapes, computer files, completed questionnaires, tests, etc.)?

D.1	Data will be recorded by hand on hard copy (paper) and will be later entered into an electronic computer file.

D.2. Will medical records or other patient data be accessed? Refer to the IRB Manual (page 62, Section XIII) for more information on HIPAA regulations and a sample HIPAA authorization.

Yes: ☐ No: ☐	*If Yes, complete the HIPAA Questionnaire and provide a copy of the HIPAA Authorization Form that will be used to obtain subjects' authorization.*

D.3. Who will have access to the gathered data/specimens, and how will confidentiality be maintained *during* the study, *after* the study, and *in reporting* the results?

D.3	The research team will have access to the data.

D.4. What are the plans for the information/biospecimens after the completion of this study (publication/presentation) and how and when will the information/biospecimens be maintained during the retention period (see page 77, Section XVII of the IRB Manual for more information). Describe method(s) of destroying the data, including any audio/visual recordings.	
D.4.	I will delete all the data when I'm done with it.

E. BENEFITS, RISKS, and COSTS

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. See IRB Manual for more information on assessing the risk to subjects.

Please select all potential risks that apply to your research project and explain below:
Note: If minimal risk or greater than minimal risk is selected, you are required to describe that potential risk and safeguard as appropriate.

Type of Risk	E.1. Provide a description of the potential risk.	E.2. What safeguard(s) will you use to eliminate or minimize the risk?
Physical ☐ N/A ☐ Minimal Risk ☒ Greater than Minimal Risk	The laser can cause pain.	We know what we are doing.
Psychological (*emotional, behavioral, including anxiety, etc.*) ☐ N/A ☒ Minimal Risk ☐ Greater than Minimal Risk	Patients are always worried.	The subjects will just have to trust us.
Sociological (*embarrassment, loss of respect of others, labeling a subject in a way that will have negative consequences*) ☐ N/A ☐ Minimal Risk ☐ Greater than Minimal Risk		
☒ **Loss of Confidentiality** *(always applicable for research in which a subject can be identified).* ☐ Greater than Minimal Risk ☐ N/A (*Subject cannot be identified for participating in-person, through identifiers, or subject will volunteer to waive confidentiality).*	There is a minimal possibility that the data from this research project could be breached.	HIPAA rules will be strictly followed regarding patient records and test results will be known by assigned code identifiers known only to the investigators. All digital data will be kept on a password protected computer.
Criminal or Civil Liability *(e.g., mandated reporter)* ☐ N/A ☐ Minimal Risk ☐ Greater than Minimal Risk		
Deception ☐ N/A ☐ Minimal Risk ☐ Greater than Minimal Risk		
Economic *(e.g. research with economically disadvantaged subjects).* ☐ N/A		

E. BENEFITS, RISKS, and COSTS		
☐ Minimal Risk ☐ Greater than Minimal Risk		
Other Type ☐ N/A ☐ Minimal Risk ☐ Greater than Minimal Risk		

E.3. If applicable, what are the costs to the subjects (monetary, time, etc.)?	
E.3.	The dental visits could last many hours.
E.4. What are the potential benefits to the subjects?	
E.4.	The subjects may or may not benefit in participating in this study; however, benefits may include: decreased bleeding, decreased probing depths, possible gum attachment, possible regeneration of bone, and prevention of additional periodontal attachment loss. The subjects will also receive a periodontal maintenance cleaning (supportive periodontal therapy) at 3 months (visit #4), 6 months (visit #5), and 9 months (visit #6) post-treatment at no charge.
E.5. What compensation or reimbursement, if any, will be offered to subjects (e.g., time, travel, meals, expenses, general incentive to participate, etc.), how will payment be scheduled throughout the study and what is the method of payment (e.g., cash, check, gift certificate, gift item, academic/extra credit, drawing)? How is compensation funded? (e.g., principal investigator, department etc.)	
E.5.	All visits will be provided and treatment will be at no charge for the patient. Compensation is in the form of free treatment for all procedures.

F. INFORMED CONSENT, ASSENT, and PERMISSIONS	
Copies of all informed consent materials must be submitted with this Application. In general, an informed consent procedure that includes all of the elements of informed consent and written documentation is required. The IRB may waive all or portions of these requirements as further explained in the IRB Manual Section XII. Justification for any waiver or alteration of requirements must be provided below.	
F.1. Considering all participant groups, indicate the consent/assent process(es) involved in the research (select all that apply). ☒ In person ☐ Remote (*Explain the remote consent process in detail e.g., online, phone, Skype, etc.):* ☐ Other:	
F.2. Will the consent process include all of the elements of the informed consent procedure (including all required elements in the informed consent form and the required documentation)? See IRB Manual Section XII.E-F for a description of the informed consent form requirements and Section XII.H for a description of the documentation requirements.	
Yes: ☒ No: ☐	*If No, please explain below the justification to waive or alter the elements of informed consent which must be approved by the IRB (e.g., why oral consent should be approved, etc.).*
Expl. of Waiver or Alteration	[insert explanation here]
F.3. Will the consent and/or assent process be documented by the use of a written consent form that will be signed by the subject or the subject's legally authorized representative? See IRB Manual Section XII for a description of the documentation requirements.	

F. INFORMED CONSENT, ASSENT, and PERMISSIONS	
Yes: ☒ No: ☐	*If No, please explain below the justification to waive or alter the documentation requirements of informed consent which must be approved by the IRB.*
Expl. of Waiver or Alteration	[insert explanation here]
F.4. If the research activities involve only the storage, maintenance, or secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes), will the broad consent procedure be used? See IRB Manual Section XII.G for a description of the "broad consent" requirements.	
Yes: ☐ No: ☐ N/A: ☒	*If No, please explain if informed consent will be obtained pursuant to the full informed consent requirements (See IRB Manual Section XII.E-F) or provide the justification to waive or alter the documentation requirements of informed consent which must be approved by the IRB. The "broad consent" requirements may not be altered or omitted.*
Expl. of Waiver or Alteration	[insert explanation here]
F.5. Will the informed consent procedure include an oral presentation to the subject/legally authorized representative? See IRB Manual Section XII.J for a description of the "oral consent" requirements.	
Yes: ☐ No: ☒	*If Yes, a copy of the short form informed consent document and summary of the oral presentation must be approved by the IRB.*

G. OTHER COMPLIANCE ISSUES
G.1. If this project may be subject to other regulations, such as state or local laws protecting special populations, please identify and explain:
G.2. If this project involves any of the following activities, requiring consideration by another committee, please check: (*It is the Principal Investigator's responsibility to submit the research project for the approval of the other committee*.) ☐ **Animal Use and Care** ☐ **Radiation Safety** (including the use of x-rays, microwaves, etc.) ☐ **Biological Safety** (including recombinant DNA, biohazards, etc.) ☐ **Chemical Safety** (including hazardous waste materials, chemical carcinogens, flammable materials, lab safety, etc.)

Submission Checklist		
Incl.	**N/A**	**Items**
☐		IRB Research Application, completed and signed by the PI and Faculty Advisor (if applicable)

☐		CITI Completion Report for the Protection of Human Subject Research Training. Training is required of all personnel on the research team involved in data collection/analysis and is valid for 3 years.
☐	☐	Research Investigator Financial Interest Disclosure Statement (regarding Conflicts of Interest)
☐	☐	Recruitment Materials (Emails, letters, scripts, flyers, posters, brochures, etc.)
☐		Informed Consent/Assent Materials
☐	☐	Translator/Transcriber Qualifications
☐		Data Collection Materials (Questionnaires, surveys, data collection forms, focus group/ interview scripts, etc.)
☐	☐	For funded and/or sponsored research: the human subjects portion of the grant proposal.