

# Application Workbook for Dental Pilot Projects

## Application Workbook for Dental Pilot Projects Program SB 738



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# Dental Pilot Projects Background Information

In 2011, Senate Bill 738 was passed by the Oregon State Legislature. This bill allows the Oregon Health Authority to authorize a Dental Pilot Project once an application has been approved. The goal of the Dental Pilot Projects is to encourage the development of innovative practices in oral health care delivery systems with a focus on providing care to populations that evidence-based studies have shown have the highest disease rates and the least access to dental care.

The Dental Pilot Projects are intended to evaluate the quality of care, access, cost, workforce, and efficacy by achieving one of the following:

1. Teaching New Skills to Existing Categories of Dental Personnel
2. Developing New Categories of Dental Personnel
3. Accelerating the Training of Existing Categories of Dental Personnel
4. Teaching New Oral Health Care Roles to Previously Untrained Persons

The Oregon Health Authority is responsible for processing initial pilot project applications, approving projects and monitoring approved pilot projects. Program staff shall evaluate approved projects and the evaluation shall include but is not limited to reviewing progress reports and conducting site visits. The program is responsible for ascertaining the progress of the project in meeting its stated objectives and in complying with program statutes and regulations.

# Instructions for Preparing a Dental Pilot Project Application

1. Review Instructions Carefully. If you have questions, please contact program staff at 971-673-1563 or email Sarah Kowalski, Dental Pilot Project Coordinator at sarah.e.kowalski@state.or.us
2. Read Dental Pilot Project Statutes and Oregon Administrative Rules to determine if the proposed project is eligible as outlined under Senate Bill 738 and Oregon Administrative Rules 333-010-0400 through 333-010-0470.
3. Applicants must apply using these forms. Applications **must** be submitted via email. Submission instructions are provided on the final page of the application. Paper applications will **not** be accepted. Only Pages that require a signature are allowed to be faxed or mailed.
4. Download each PDF file and save to your computer.  
Complete each PDF.  
Send completed Application Workbook and attachments in **one email**.  
Each page of an attachment must be labeled per the submission instructions, ie. PN2 in upper right hand corner.  
Attachments must be in PDF format.
5. Provide a Table of Contents. Number pages.
6. Complete Dental Pilot Project Fact Sheet.
7. The application must demonstrate how the pilot project will comply with the requirements of the Oregon Administrative Rules, 333-010-0400 through 333-010-0470.
8. Prepare an abstract (not to exceed two [2] pages). This should clearly summarize the total proposal.
9. Describe project completely under Section III: Project Narrative using Oregon Administrative Rule 333-010-0400 through 333-010-0470 as a guide. These rules provide administrative guidance to the required content of Dental Pilot Project applications, process for review, approval and monitoring of Dental Pilot Projects, and steps to terminate or conclude a Dental Pilot Project.
10. Complete additional sections per instructions in the application.
11. Include evidence that liaison has been established with participating agencies. (Schools, health facilities, colleges, etc.) Attach Memorandum of Agreement(s) or Memorandum of Understanding, Letters of Support, etc.  
**Attachment(s):** Label Attachment(s), SPPT1
12. Provide supporting statistics when you describe the need for this pilot project. Use existing studies or analyses or develop your own. Include pertinent attachments/exhibits such as studies or analysis that substantiate need or desirability of the pilot project. **Attachment(s):** Label Attachment(s), SPPT2
13. Demographic data should be used and cited whenever possible to support the information provided. This section should help reviewers understand the oral health status and the unmet oral health needs of the targeted population that will be served by the proposed project. **Attachment(s):** Label Attachment(s), SPPT3

# Instructions for Preparing a Dental Pilot Project Application

14. The total page limit of the application, including all attachments, is **100 pages** when printed by OHA. Applications exceeding the page limit will **not** be reviewed. All application documents are typed in no less than size 12 point font.
15. Each project application will be reviewed by a Technical Review Board comprised of stakeholders and subject matter experts. For more information, please see [Frequently Asked Questions](#). Applicants may be asked to present to the Technical Review Board.
16. Follow Submission Instructions as noted above and on the final page of the Application.

# Checklist for Applications Deemed Complete

This checklist serves as a general guide for completing the Dental Pilot Project Application.  
Do not return this checklist with the application.

- Table of Contents Included
- Application does not exceed 100 pages, including attachments, when printed by the OHA.
- Only Signature Pages Mailed or Faxed.
- All Attachments are in PDF format.
- Completed Application Submitted under **one email** including all attachments.

## Instructions

- Submit Attachment(s) as necessary, Labeled Correctly

## Dental Pilot Project Fact Sheet:

- Complete Fact Sheet
- Submit Attachments as necessary, Labeled Correctly

## Minimum Standards

- Review Minimum Standards Rules as outlined under OAR 333-010-0410

## Project Overview:

- Complete Project Abstract
- Submit Attachments as necessary, Labeled Correctly

## Informed Consent:

- Complete Informed Consent Plan
- Submit Attachments as necessary, Labeled Correctly

## Modifications

- Review Modification Rules as outlined as outlined under OAR 333-010-0460.

## Project Narrative:

- Complete Summary of Project
- Complete Background Information
- Complete Sponsor Information
- Complete Instructor & Supervisor Information
- Submit Curriculum Vitae's as Directed
- Complete Trainee Information
- Complete Curriculum Information
- Complete Measurable Objectives
- Complete Evaluation Plan
- Complete Monitoring Plan
- Complete Data Plan
- Complete Cost Analysis
- Submit Attachments as necessary, Labeled Correctly

## Adverse Event Reporting

- Review Adverse Event reporting requirements as outlined under OAR 333-010-0435.

## Certification & Acceptance

- Complete Certification & Acceptance, Sign

## Submission

- Follow submission instructions

# Section I: Dental Pilot Project Fact Sheet

1. Title of Project:
2. Sponsoring Agency, Name, Address, City, County, Zip:
3. Sponsoring Agency Contact Name, Phone, Email:
4. Sponsoring Agency Type: Check All that Apply  
Non-Profit Education Institution      Coordinated Care Organization (CCO) or Dental Care Organization (DCO)  
Community Hospital or Clinic      Professional Dental Organization
5. Name of Administrator Signing for Application, Title
6. Purpose of Project Goal/Purpose of Project: (Select One)  
Teaches new skills to existing categories of dental health care personnel.  
Develops new categories of dental health care personnel.  
Accelerates the training of existing categories of dental health care personnel.  
Teaches new health care roles to previously untrained persons.
7. Project Director, Name, Address, Phone, Email
8. Training Supervisor, Name, Degree, Address, Phone, Email
9. Estimated Date of Project Period:  
Start Date:                                      End Date:
10. A Project Timeline will visualize the timeliness of project activities and accomplishments. The Project Timeline will identify for the entire project period: (1) the activities proposed, (2) the time it will take to accomplish these tasks and (3) the responsible staff.
11. Submit a Detailed Timeline as an Attachment. **Attachment:** Label Attachments, FS2.
12. Training and Utilization Project Sites: List where education and training will be conducted during didactic phase.
13. List where graduates of training program will be employed during utilization phase.
14. Submit a detailed narrative of the Training & Utilization Project Sites.  
**Attachment:** Label Attachments, FS3
15. Funding Source(s) for the Project  
Provide source(s) of funding (if known). Include attachments such as Letters of Support, commitment, memorandums of agreement, etc. if available. If Funding sources depend upon approval of the Dental Pilot Project, please provide information identifying the potential source(s) of funding if possible. (The Oregon Health Authority does not fund projects.)  
**Attachment:** Label Attachments FS4
16. Provide the proposed total budget for project implementation.  
The Total Project or Program Costs are the total allowable costs (inclusive of direct and indirect costs) incurred by the recipient to carry out the pilot project.  
Proposed Total Budget (Numerical amount only allowed):

## **MINIMUM STANDARDS: 333-010-0410**

A dental pilot project shall:

1. Provide for patient safety as follows:
  - a. Provide treatment which does not expose a patient to risk of harm when equivalent or better treatment with less risk to the patient is available;
  - b. Seek consultation whenever the welfare of a patient would be safeguarded or advanced by having recourse to those who have special skills, knowledge and experience;
  - c. Provide or arrange for emergency treatment for a patient currently receiving treatment;
  - d. Comply with ORS 453.605 to 453.755 or rules adopted pursuant thereto relating to the use of x-ray machines;
  - e. Not attempt to perform procedures which the trainee is not capable of performing due to physical or mental disability; and
  - f. Comply with the infection control procedures in OAR 818-012-0040.
7. Provide appropriately qualified instructors to prepare trainees.
8. Assure that trainees have achieved a minimal level of competence before they enter the employment/utilization phase.
9. Inform trainees in writing that there is no assurance of a future change in law or regulations to legalize their role.
10. Demonstrate that the project has sufficient staff to monitor trainee performance and to monitor trainee supervision during the employment/utilization phase.
11. Demonstrate the feasibility of achieving the project objectives.
12. Comply with the requirements of the Dental Pilot Projects statute, Oregon Laws 2011, Chapter 716 and rules adopted thereunder.
13. Evaluate quality of care, access, cost, workforce, and efficacy;
14. Achieve at least one of the following:
  - a. Teach new skills to existing categories of dental personnel.
  - b. Accelerate the training of existing categories of dental personnel.
  - c. Teach new oral health care roles to previously untrained personnel.
  - d. Develop new categories of dental personnel.

Stat. Auth.: 2011 OL Ch. 716

Stats. Implemented: 2011 OL Ch. 716

Hist.: PH 5-2013, f. & cert. ef. 2-4-13

I have read the Minimum Standards as outlined under the Oregon Administrative Rules, 333-010-0410.

# Section I: Dental Pilot Project Fact Sheet

## ELIGIBILITY:

Dental Pilot Projects must be sponsored by one of the following: a non-profit educational institution, professional dental organization, community hospital or clinic, or Coordinated Care Organization (CCO) or Dental Care Organization (DCO).

## APPLICATION REVIEW PROCESS:

1. The Oregon Health Authority program staff shall review an application to determine if it is complete within 45 calendar days from the date the application was received.
  - a. If an applicant does not provide all the information required and the application is considered incomplete, the Oregon Health Authority program shall notify the applicant of the information that is missing, and shall allow the applicant 15 days to submit the missing information.
  - b. If an applicant does not submit the missing information within the timeframe specified in the notice, the application shall be rejected as incomplete. An applicant whose application is rejected as incomplete may reapply at any time.
3. An application deemed complete will continue through to a technical review process. For details on the Technical Review Board please see [Frequently Asked Questions](#).
4. The Oregon Health Authority program may have individuals outside the program review applications but no individual who has contributed to or helped prepare an application will be permitted to do a review.
5. The Technical Review Board may ask the project sponsor or other project representative to present to the Technical Review Board.
6. The Oregon Health Authority Program staff may request additional information from an applicant during the review process.
7. Once project staff have completed an application review A Notice of Intent to approve or deny an application will be provided to the applicant. The Notice and application will be posted for public comment for a period of 10 business days.
8. Once the public comment period has closed, the director within the Oregon Health Authority, or his or her designee shall grant or deny approval of a pilot project applicant within 30 calendar days of receiving the application from the Oregon Health Authority program staff.

## PROJECT APPROVAL:

Each project application will be reviewed by a Technical Review Board comprised of stakeholders and subject matter experts. The Technical Review Board will include appropriate community-level personnel and key individuals, who can provide subject matter expertise, including: local dental public health managers; dental providers; and experts on state Medicaid policies, data, and quality improvement. In addition, Board members may include, but will not be limited to, representatives from the professional and private organizations.

The Technical Review Board does not authorize or approve projects. The role of the board is to provide a recommendation to the Dental Director based upon review of the project application.

The Dental Director will grant or deny approval of the dental pilot project within 30 calendar days of receiving the application from the program. If the director grants approval, he or she will specify the length of time the project can operate. The director or his or her designee may extend the length of time a project can operate at his or her discretion. The director's decision shall be transmitted in writing to the applicant.

## **Section II: Project Overview: Abstract**

An abstract shall be submitted with each application. This provides a brief description of the information included in the proposal's narrative. The abstract should include the name of the sponsor, the specific purpose of the project, brief summary of student/trainee selection criteria and the proposed project activities, overall long term and short term objectives, the primary factors to be considered on the evaluation process, and the expected outcome of the project. It would also be appropriate to cite the current statutory/regulatory barriers which prohibit the proposal.

### **Submission Instructions**

- Abstract is not to exceed two (2) pages.
- Submit Attachment (if needed). Label Attachment AB1.

# Section II: Project Overview: Abstract

## Section III: Project Narrative

This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project.

### 1. SUMMARY OF PROJECT:

The summary shall include, but not be limited to the following: (A) The name of the sponsor. (B) The specific purpose of the project. (C) A brief summary of student/trainee selection criteria and the proposed project activities. (D) Overall long term and short term objectives. (E) The primary factors to be considered on the evaluation process (F) The expected outcome of the project and (G) The summary should include criteria for success and the capability of taking this innovation to scale statewide.

Submit a summary of the proposed project.

**Attachment:** Label Attachment, PN1.

### 2. BACKGROUND INFORMATION:

Background information shall include, but not be limited to the following: (A) Documentation of the need for this project. (Submit existing data studies or analysis or develop and submit your own.) (B) A description of the types of patients or clients likely to be seen or treated. (C) A description of the skills trainees are to learn. (D) An identification of existing laws or regulations, or both, that, in the absence of Dental Pilot Project SB 738, would prevent the preparation and utilization of trainees as proposed in this project. (E) A description of employment opportunities for trainees after the project terminates and (F) An identification of other educational programs or groups conducting similar projects.

Submit a description of the background information as outlined above.

**Attachment:** Label Attachment, PN2.

### 3. SPONSOR INFORMATION:

Sponsor information shall include, but not be limited to the following: (A) A description of the sponsor, including a copy of an organizational chart that identifies the project's relationship to the sponsor. (Include a copy of health facility license, as applicable.) (B) A copy of a document verifying the sponsor's status as a non-profit educational institution, professional dental organization, community hospital or clinic, or Coordinated Care Organization (CCO) or Dental Care Organization (DCO). (C) A description of functions of the project director, instructors and other project staff. (D) A description of sponsor's funding sources for the project (E) A description of the composition and functions of an advisory group if one currently exists or will be developed to advise the project. (F) An identification of collaborative arrangements with other educational institutions and/or health care facilities, or both. (G) A description and location of facilities used in the didactic and clinical phases. This shall include the availability of support services such as library, equipment, etc. and (H) Documentation of liability insurance relevant to services provided by trainees.

Submit a description of the sponsor information as outlined above.

**Attachment:** Label Attachment, PN3.

## Section III: Project Narrative

4. **INSTRUCTOR AND SUPERVISOR INFORMATION:** A dental pilot project must have: Instructors: (A) A number and distribution of instructors sufficient to meet project objectives (B) Instructors with current knowledge and skill in topics they will teach. (C) A plan to orient supervisors to their roles and responsibilities. (D) Provide a description of the functions of the project director, instructors, and other project staff. (E) The criteria used to select instructors and supervisors (F) Instructor-to-trainee ratio (G) The background of instructors in training techniques and methodology (H) The number of proposed supervisors and (E) The criteria used to select an employment/utilization site.

Submit a description of the project plan to orient supervisors to their roles and responsibilities.

**Attachment:** Label Attachments, PN4.

5. **CURRICULUM VITAE:** Submit curriculum vitae of project director, instructors, and training supervisors(s) and all key project staff. It should contain information about education (institutions attended and their locations, degrees, and years conferred, fields of study); professional certifications and licensures; professional positions/employment in reverse chronological order; and any additional information that would contribute to the Technical Review Board's understanding of relevant qualifications, expertise and experience.

Submit a curriculum vitae of project director, instructors, and training supervisors(s) and all key project staff.

**Attachment:** Label Attachments, PN5.

6. **TRAINEES:** Participant selection information shall include, but not be limited to the following: (A) Criteria used in selecting trainees and a statement of previous experience in providing related health care services. (Include any pre-requisite conditions or education requirements.) (B) A dental pilot project must have a plan to inform trainees of their responsibilities and limitations under Oregon Laws 2011, chapter 716 and OAR 333-010-0400. (Submit a trainee agreement that spells out expectations and limitations) (C) Number of proposed trainees. (D) A project must provide notice to the Oregon Health Authority program staff within 14 days of a trainee entering the employment/utilization phase. The notice shall include, but is not limited to the following: Name, work address and telephone number of the trainee; and Name, work address, telephone number and license number of the supervisor.

Submit a copy of the Trainee Participant Selection Information.

**Attachment:** Label Attachments, PN6.

Submit a sample copy of the project Trainee Agreement

**Attachment:** Label Attachments, PN7.

**Submit Trainee information**, if known, on prescribed form.

<http://public.health.oregon.gov/PreventionWellness/oralhealth/DentalPilotProjects/Documents/TraineeForm.pdf>

## Section III: Project Narrative

- 7. EMPLOYMENT/UTILIZATION SITE:** The employment/utilization site information shall contain, but not be limited to the following: (A) Criteria used to select an employment/utilization site.

Submit a copy of the Employment/Utilization Site Criteria Information:

**Attachment:** Label Attachments, PN8.

A sponsor of a dental pilot project must have a curriculum plan that includes but is not limited to a description of:

- a. The level of competence the trainee shall have before entering the employment/utilization phase of the project.
  - b. The instructional content required to meet the level of competence.
  - c. The skills trainees are to learn.
  - d. The methodology utilized in the didactic and clinical phases.
  - e. The evaluation process used to determine when trainees have achieved the level of competence.
  - f. The hours and months of the time required to complete the didactic and clinical phases.
- 8. CURRICULUM:** The curriculum plan shall include, but not be limited to the following: (A) The level of competence the trainee shall have before entering the employment/utilization phase of the project (B) A description of the content required to meet this minimal competency. (C) A description of the methodology utilized in the didactic and clinical phases. (D) A description of the evaluation process used to determine when trainees have achieved the minimum level of competence and (E) An identification in hours and months of the time required to complete the didactic and clinical phases.

Submit a Job Description for the Trainee

**Attachment:** Label Attachments, PN9 Submit a copy of the project curriculum plan.

**Attachment:** Label Attachments, PN10

- 9. MEASURABLE OBJECTIVES, MONITORING , EVALUATION & DATA PLANS:** The purpose of the pilot projects are intended to evaluate the quality of care, access, cost, workforce, and efficacy by teaching new skills to existing categories of dental personnel; developing new categories of dental personnel; accelerating the training of existing categories of dental personnel; or teaching new oral health care roles to previously untrained persons. The most critical component of the Dental Pilot Projects will be the measurement of their success or failure towards meeting these intended objectives. Considering the objectives of the pilot program, describe the Measurable Objectives of the project and the Monitoring & Evaluation Plan for the pilot project.

Measurable Objectives, variables or indicators should be determined and will enable essential criteria to be tested and measured. Consider using S.M.A.R.T. goals in describing the measurable objectives. (Specific, Measurable, Attainable, Realistic, Timely)

The Monitoring and Evaluation (M&E) plan should define the data to be collected and how is it going to be collected. Some of the variables or indicators will have numeric values (quantitative) and will be easier to measure (i.e. number of patients seen per day, numbers of sealants provided), while other qualitative indicators will be much harder to measure (i.e. patient satisfaction or clinical competency). A description of how bias will be accounted for should also be included in the M&E plan. Bias is often introduced at the monitoring and evaluation design stage. Bias includes a lack of relevant and appropriate control groups, biases on the part of independent evaluators, and biases on the part of those evaluated (trainees, instructors).

## Section III: Project Narrative

### A. MEASURABLE OBJECTIVES:

Measurable Objectives: Describe the purpose of the project and the measurable objectives to meet the purpose. Indicate the time plan for accomplishing the objectives. Include both short and long term objectives in your description. Provide pertinent attachments/exhibits such as studies or analysis that substantiate need or desirability of such a project.

Considering using S.M.A.R.T. goals in describing the measurable objectives. (Specific, Measurable, Attainable, Realistic, Timely)

Submit a description of the project objectives as outlined above.

**Attachment:** Label Attachments, PN11

### B. EVALUATION:

Dental Pilot project applications must have an evaluation plan that includes, but is not limited to the following: (1) A description of the baseline data and information collected about the availability or provision of oral health care delivery, or both, prior to utilization of the trainee; (The actual baseline data shall be collected and submitted in writing to the program within six (6) months after the project is initially approved) (2) A description of baseline data and information to be collected about trainee performance, acceptance among patient and community, and cost effectiveness. (3) A description of methodology to be used in collecting and analyzing the data about trainee performance, acceptance, and cost effectiveness.(4) The data required in (2) and (3) shall be submitted in writing to the program at least annually or as requested by program staff. (5) A provision for reviewing and modifying objectives and methodology at least annually. (6) Evaluation Plans must identify and utilize an evaluator; an evaluator is defined as an individual who will conduct an evaluation of the pilot project, is unaffiliated with the project and who has no financial or commercial interest in the project's outcome. (7) Results of this evaluation and project modification shall be reported to program staff in writing. (8) The evaluation plan shall include provision for retaining for two (2) years after completion of the pilot project all raw data about trainees and the implementation of the project.

Submit a copy of the project evaluation plan.

**Attachment:** Label Attachments, PN12

### C. MONITORING:

A sponsor of a dental pilot project must have a monitoring plan that ensures at least quarterly monitoring and describes how the sponsor will monitor and ensure: (A) A description of the provisions for protecting patients' safety. (B) A description of the methodology used by the project director and project staff to provide at least quarterly monitoring of the following:

*Patient Safety & Trainee competency:*

1. Supervisor fulfillment of role and responsibilities.
2. Employment/utilization site compliance with selection criteria.
  - a. Acknowledgement that project staff or their designee shall conduct site visits to each employment utilization site.
  - b. The monitoring plan shall also identify a methodology for reporting information to program staff.

### D.DATA:

A sponsor's evaluation and monitoring plans must describe, but is not limited to the following:

- (A) How data will be collected
- (B) How data will be monitored for completeness
- (C) How data will be protected and secured

Submit a copy of the project data evaluation and project monitoring plan.

**Attachment:** Label Attachments, PN13

## Section III: Project Narrative

### 10. COSTS:

Provide the average cost of preparing a trainee, including but not limited to the cost information related to instruction, instructional materials and equipment, space for conducting didactic and clinical phases, and other pertinent costs. Include the predicted average cost per patient visit for the care rendered by a trainee. Include a budget narrative that lists costs associated with key project areas, including but not limited to: (A) Personnel and fringe benefits for project director, instructors, and staff associated with the project (B) Contractors and consultants to the project (C) Materials and supplies used in the clinical, didactic, and employment/utilization phases of the project (D) Equipment and other capital costs associated with the project and (E) Travel required for implementing and monitoring the project.

The Total Project or Program Costs are the total allowable costs (inclusive of direct and indirect costs) incurred by the recipient to carry out the pilot project.)

Submit a detailed copy of budget narrative as outlined above.

**Attachment:** Label Attachment PN14

# Section IV: Informed Consent, Modifications, Adverse Events, Project Completion

## INFORMED CONSENT:

The plan used to obtain prior informed consent from patients to be treated by trainees or those legally able to give informed consent for the patients shall be described. It shall include but not be limited to the following:

- a. A sponsor must ensure that informed consent for treatment is obtained from each patient or a person legally authorized to consent to treatment on behalf of the patient.
- b. A sponsor must submit an informed consent form and any accompanying information to program staff for review.

Informed consent must include but is not limited to the following:

- a. An explanation of the role and status of the trainee, including the ready availability of the trainee's supervisor for consultation.
- b. Assurance that the patient can refuse care from a trainee without penalty for such a request.
- c. Identification that consenting to treatment by a trainee does not constitute assumption of risk by the patient.
- d. Informed consent shall be provided in a language in which the patient is fluent.
- e. Dental pilot project staff or trainees must document informed consent in the patient record prior to providing care to the patient.
- f. Informed consent needs to be obtained specifically for those tasks, services, or functions to be provided by a pilot project trainee.

Provide a Copy of the Informed Consent Form.

**Attachment:** Label Attachment IC1.

## MODIFICATIONS:

1. Any modifications or additions to an approved project shall be submitted in writing to program staff. Modifications include, but are not limited to the following:
  - a. Changes in the scope or nature of the project. **Changes in the scope or nature of the project require program staff approval.**
  - b. Changes in selection criteria for trainees, supervisors, or employment/utilization sites.
  - c. Changes in project staff or instructors.
2. Changes in project staff or instructors **do not** require prior approval by program staff, but shall be reported to the program staff within two (2) weeks after the change occurs along with the curriculum vitae for the new project staff and instructors.
3. All other modifications require program staff approval prior to implementation.

I have read the Modifications as outlined under the Oregon Administrative Rules, 333-010-0460.

## ADVERSE EVENT REPORTING:

A sponsor must report adverse events to the Oregon Health Authority program staff the day they occur as outlined in OAR 333-010-0460. An **Adverse Event Form** must be completed and submitted as outlined in OAR 325-035-0001.

Adverse Event reports are prepared by project sponsor personnel with the intent that such reports will not contain information regarding the patient's identity. The information will be prepared as a brief anecdotal account to be submitted to the Oregon Health Authority on a prescribed form in addition to contacting program staff on the day of the adverse event.

## Section IV: Informed Consent, Modifications, Adverse Events, Project Completion

These guidelines serve only to describe some occurrence requiring a written anecdotal account. The examples serve as a minimal starting point for common reporting of incidents/occurrences so that project sponsors will be cognizant of trainee performances for the purposes of effective monitoring. Your judgment as to what constitutes a deviation from the usual norm of practice for your category of trainee is important.

### EXAMPLES

1. A patient care error that has been identified by the trainee, supervising professional or other professional within the community or practice site.
2. Comments regarding the provision of health care by the trainees which reflect satisfaction or dissatisfaction with the services rendered. This information may originate from the following sources:
  - a. Patients who have received services.
  - b. Relatives or friends of patients receiving services.
  - c. Community professionals such as physicians, pharmacists, dentists, nurses, health care administrators or others who may have knowledge of a trainee-patient interface.
  - d. Other staff members who are employed by the employment/utilization site.
  - e. Project sponsor staff having knowledge of trainee-patient interaction.

I have read the adverse reporting requirements as outlined under the Oregon Administrative Rules, 333-010-0435.

### COMPLETION OF PROJECT:

All dental pilot projects must inform the Program in writing at least **60 days** prior to completion or discontinuation of the pilot project.

1. An approved project must notify the Authority in writing if it intends to discontinue its status as a Dental Pilot Project, at least 60 calendar days prior to discontinuation. Notification must include a closing report that includes but is not limited to:
  - a. The reasons for discontinuation as a pilot project.
  - b. A summary of pilot project activities including the number of persons who entered the employment/utilization phase.
  - c. A description of the plan to inform trainees of the project's discontinuation, and that they are precluded from performing the skills authorized under the pilot project after discontinuation unless the role has been legalized.
2. The project must obtain written acknowledgement from trainees regarding notification of the project's discontinuation and preclusion from performing skills authorized under the pilot project after discontinuation unless the role has been legalized and the trainee has met necessary licensure requirements.
3. The project must inform the Oregon Board of Dentistry that the project is completed and provide a list of trainee names associated with the project at least 14 calendar days prior to discontinuation.

I have read the Completion of Project reporting requirements as outlined under the Oregon Administrative Rules, 333-010-0465.

# Section V: Suspension or Termination of a Project

## SUSPENSION OR TERMINATION OF PROJECT

1. A pilot project may be suspended or terminated during the term of approval for violation of 2011 Oregon Laws, chapter 716 or any of these rules.
2. If the Authority determines that a dental pilot project is in violation of 2011 Oregon Laws, chapter 716 or these rules, the Authority may issue a Notice of Proposed Suspension or Notice of Proposed Termination in accordance with ORS 183.411 through 183.470. A sponsor who receives a Notice may request an informal meeting with the director and program staff. A request for an informal meeting does not toll the time period for requesting a hearing as described in section (3) of this rule.
3. If the Authority issues a Notice of Proposed Suspension or Notice of Proposed Termination the sponsor is entitled to a contested case hearing as provided under ORS chapter 183. The sponsor has 30 days to request a hearing.
4. If the Authority terminates a dental pilot project the order shall specify when, if ever, the sponsor may reapply for approval of a dental pilot project.

I have read the Suspension or Termination of Project requirements as outlined under the Oregon Administrative Rules, 333-010-0470.

## **Section VI: Submission Instructions**

Applications must be submitted via email. Paper applications will not be accepted. Only Pages that require a signature are allowed to be faxed or mailed. We encourage scanning and submitting these electronically whenever possible.

Each page of an attachment must be labeled per the labeling instructions as outline in the application, ie. PN2 in upper right hand corner. Attachments must be in PDF format.

Send completed application and attachments in one email to [sarah.e.kowalski@state.or.us](mailto:sarah.e.kowalski@state.or.us).

A confirmation of receipt will be emailed and mailed upon receipt.

### **Send Signature Pages to:**

Sarah Kowalski, RDH  
Dental Pilot Project Coordinator  
CENTER FOR PREVENTION & HEALTH PROMOTION  
Oral Health Program, Oregon Health Authority  
800 NE Oregon Street, Portland, Oregon 97232  
Office: 971-673.1563  
Fax: 971-673.0231

# Certification and Acceptance

We, the undersigned certify that the statements herein are true and complete to the best of our knowledge and we accept the obligations to comply with the terms and conditions set forth in the Oregon Safe Employment Act and Oregon Administrative Rules

We hereby certify that we will not discriminate on the basis of age, sex, creed, disability, race or ethnic origin, in the selection of participants for Dental Pilot Projects.

We agree to submit monthly progress reports during the first six month period of the utilization/employment phase and quarterly thereafter for the duration of the pilot project. Final progress reports are due within 60 days of the termination or completion of the pilot project. A progress report on the pilot project shall be provided to The Oregon Health Authority no later than 15 days prior to a site visit. At any time, a sponsor must provide a report of information requested by The Oregon Health Authority in a format and timeframe requested.

Progress reports must include, but are not limited to, information on the following:

- 1. Dental Pilot Project name, Project Identification Number, Reporting Period (e.g., 1/1/2015-4/1/2015), Primary Contact Name and Role, Telephone and Email Address**
- 2. Trainee competency**
- 3. Supervisor's fulfillment of roles and responsibilities**
- 4. Employment/utilization site compliance with selection criteria.**
- 5. Progress to achieving each of the stated objectives**

We agree to allow project staff or their designees to visit each employment/utilization site at least monthly during the first six month period and at least quarterly thereafter for the duration of the project. Site visits may occur during the didactic phase of the pilot project and are required during the utilization phase of the project. An unannounced site visit may be conducted by program staff if program staff have concerns about patient or trainee safety

We agree to promptly inform The Oregon Health Authority and Program Manager as to the:

- 1. Starting and completion dates of training cycles**
- 2. Starting and completion dates of preceptorship or employment/utilization (E/U) periods**
- 3. Proposed changes or modifications in the project or project personnel**
- 4. Changes in the names of participating trainees.**

We agree to promptly notify The Oregon Health Authority and Program Manager in the event of an adverse event. We will contact The Oregon Health Authority and Program Manager on the day of the event and complete an adverse event on a prescribed form.

Project Sponsor Signature \_\_\_\_\_ Date: \_\_\_\_\_

Project Director Signature \_\_\_\_\_ Date: \_\_\_\_\_

## *Legal Liability:*

*Sponsors and other participants are advised to ascertain the legal liability they assume when participating in a pilot project.*