

APPENDIX A
EXAMINATIONS, TESTS, SUBSTANCES,
DEVICES, and PROCEDURES (ETSDP)

E.T.S.D.P. EVALUATION QUESTIONS

Clinical Rationale

Is this an exam, test, substance, device or procedure, herein after referred to as ETSDP?

Describe in detail your ETSDP.

Describe the clinical rationale for your ETSDP.

How do you determine appropriate termination of care and/or consultation to other providers with special skills/knowledge for the welfare of the patient?

If this is a diagnostic procedure, are you using it by itself or in addition to generally accepted diagnostic procedures?

Taught at accredited chiropractic school

Is this ETSDP taught at a chiropractic school accredited by the Council on Chiropractic Education or its successor at any time since 1974? If so, which one(s)?

Consensus

Do you have evidence of consensus on safety and/or effectiveness and/or of practices generally and currently followed and accepted by persons licensed to practice chiropractic in this state?

Outcome assessment measures

Choose from the following or list outcome assessment measures:

- visual analog scale
- pain drawing
- oswestry questionnaire
- objective signs
- general patient satisfaction
- other

Literature based references

Cite any literature discussing indications, contraindications, and beneficial, adverse or unintended effects of this ETSDP.

Please indicate the current level of support for this ETSDP from the following:

- 1) One or more randomized controlled clinical trials or experimental studies that address reliability, validity, positive predictive value, discrimination, sensitivity and specificity.
- 2) One or more well designed controlled observational clinical studies such as case control or cohort studies published in referenced journals.
- 3) Clinically relevant basic science studies addressing reliability, validity, positive predictive value, discrimination, sensitivity and specificity published in referenced journals.
- 4) Expert opinion, descriptive studies, case report.

Consistent with generally recognized contraindications to chiropractic procedures

Please list any known or suspected contraindications.

Is there a subpopulation that would be at higher risk for this ETSDP? (e.g. people with osteoporosis, skin lesions, heart disease, etc.)

Potential benefit outweighs the potential risk to the patient.

Does the ETSDP affect any structure (either mechanically, chemically, thermally, or electrically, etc.) in such a way that a beneficial effect can be created?

Does this ETSDP affect any structure (either mechanically, chemically, thermally, electrically, etc.) in such a way that an adverse effect can be created?

Describe the beneficial effects your patients have experienced from this ETSDP.

Describe any adverse or unintended effects your patients have experienced from this ETSDP.

Please rate the risk factor if this ETSDP is used improperly on select populations. Choose from the following categories:

- 1) an extremely remote chance of serious injury
- 2) a remote chance of serious injury
- 3) a slight chance of serious injury
- 4) a significant chance of serious injury
- 5) extremely likely chance of serious injury

Please describe.

Please rate the risk factor if this ETSDP is used properly on the general population. Choose from the following categories:

- 1) an extremely remote chance of serious injury
- 2) a remote chance of serious injury
- 3) a slight chance of serious injury
- 4) a significant chance of serious injury
- 5) extremely likely chance of serious injury

Please describe.

Alternatives

Is there a standard ETSDP for the equivalent condition? If yes, does your ETSDP expose a patient to more risk or harm than the standard treatment for an equivalent condition?

List alternatives to this ETSDP if any.

What are the suspected effects, results or consequences of doing nothing?

General

Are you currently conducting or soon planning to conduct an organized investigation into the use of the ETSDP?

OREGON ADMINISTRATIVE RULE 811-015-0070 E.T.S.D.P.

Scope Of Practice Regarding Examinations, Tests, Substances, Devices And Procedures

(1) The Board may examine any diagnostic and/or therapeutic examination, test, substance, device or procedure, herein after referred to as ETSDP, to determine its acceptability for patient care. The Board may require a Chiropractic physician to provide information on any ETSDP for determination of its status. The Board may take into account all relevant factors and practices, including but not limited to, the practices generally and currently followed and accepted by persons licensed to practice chiropractic in the state, the teachings at chiropractic schools accredited by the Council on Chiropractic Education or its successor at any time since 1974, relevant technical reports published in recognized journals and the desirability of reasonable experimentation in the furtherance of the chiropractic arts.

(2) A Chiropractic physician may use any diagnostic and/or therapeutic ETSDP, which is considered standard. A standard diagnostic and/or therapeutic ETSDP is one in which one or more of the following criteria have been satisfied:

(a) is taught or has been taught by a chiropractic school accredited by the Council on Chiropractic Education or its successor at any time since 1974, or health professions' courses taught by regionally accredited colleges with subject matter that is within the scope of chiropractic practice and has not been disapproved by the Board; or

(b) has been approved by the Board through the petition process.

(A) The petition requires a formalized agreement of ten percent (10%) or more of the Chiropractic physicians, holding an active chiropractic license in Oregon, attesting to the safety and efficacy of a particular ETSDP. The petition shall be submitted in writing to the Board by any party wishing to establish any ETSDP as standard. It is the responsibility of the petitioner to gather the required evidence and supporting statements. It is the sole responsibility and discretion of the Board to review the sufficiency of the evidence in the petition and to make a determination whether to concur and affirm the ETSDP as standard or to deny the petition. The Board may, but is not required to, hold a public hearing on any petition. The Board shall make its determination and reply to the petitioner within 180 days of receipt of the petition unless the Board and the petitioner mutually agree to extend the deadline.

(B) The petition shall specifically address the following issues:

(i) The kind of ETSDP that is the subject of the petition, i.e., whether it is an examination, a test, a substance, a device, a procedure, or a combination thereof;

(ii) A detailed description of the proposed ETSDP;

(iii) The clinical rationale for the ETSDP;

(iv) A method for determination of appropriate termination of care and/or consultation to other providers with special skills/knowledge for the welfare of the patient;

(v) Whether the proposed ETSDP is to be used by itself or used in addition to any other generally accepted or standard ETSDP;

(vi) A description of known or anticipated contraindications; risks, and benefits;

(vii) A description of any subpopulations for which greater risk or benefit is expected;

(viii) A description of any standard ETSDP for the equivalent condition together with its relative risks and benefits; and

(ix) An assessment of the expected consequences of withholding the proposed ETSDP.

(c) is supported by adequate evidence of clinical efficacy as determined by the Board. In determining adequacy the Board may consider whether the ETSDP:

(A) has clinical rationale;

(B) has valid outcome assessment measures;

(C) is supported in peer reviewed literature;

(D) is consistent with generally recognized contraindications to chiropractic procedures;

and

(E) the potential benefit outweighs the potential risk to the patient.

(3) A Chiropractic physician may use any diagnostic and/or therapeutic ETSDP that has not met the criteria of subsection (2)(a) or (b) or (c) of this rule as investigational. It must show potential merit for effectiveness and be of acceptable risk. Documentation requirements are based on potential risk to the patient. All investigational diagnostic ETSDP's must include or be accompanied by standard diagnostic procedures until full Board approval is attained under the criteria cited in subsection (2)(a) or (b) or (c) of this rule. Nothing in this section is intended to interfere with the right of any patient to refuse standard or investigational ETSDP's. In determining risk, the Board may use the following criteria:

(a) For minimal risk procedures, defined as those which when properly or improperly performed on the general population would have a slight chance of a slight injury and when properly performed on select populations have an extremely remote chance of serious injury,

(A) informed consent is suggested but not required; and

(B) the Chiropractic physician is recommended, but not required, to participate in or conduct a formal investigation of the procedure.

(b) For low risk procedures, defined as those which when properly performed on the general population have a slight chance of mild injury, when improperly performed on the general public have a mild chance of mild to moderate injury, and when properly performed in select populations have a remote chance of serious injury,

(A) informed consent is required; and

(B) the Chiropractic physician is recommended but not required to participate or conduct a formal investigation of the procedure.

(c) For moderate risk procedures, defined as those which when properly performed on the general public have a significant chance of mild injury and a mild chance of moderate injury, when improperly performed on the general population have a slight chance of severe injury, and when properly performed in select populations have a slight chance of serious injury,

(A) written informed consent is required; and

(B) the Chiropractic physician is recommended but not required to participate or conduct a formal investigation of the procedure.

(d) For high risk procedures, those which when properly performed on the general population have a significant chance of moderate injury and a slight chance of serious injury, when improperly performed on the general population have a significant chance of serious injury, and when properly performed in select populations have a significant chance of serious injury,

(A) written informed consent is required; and

(B) the Chiropractic physician is required to participate in or conduct a formal investigation of the procedure under the auspices of, or in conjunction with, any other health care professionals knowledgeable and competent in the care and treatment of potential serious injuries.

(e) Board approval is required of all moderate or high risk procedures.

(4) The Board shall maintain a list of ETSDP's which have been reviewed by the Board and have been determined to be unacceptable or approved as investigational.

(5) A Chiropractic physician may not use any diagnostic and/or therapeutic ETSDP's which have been determined by the Board to be unacceptable. (*Statutory Authority: ORS 684; Statutes Implemented: ORS 684.155; Adopted Eff. 12/19/95*)