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EFFECTIVE: July 2008 REVISED: October 2008	<b>CATEGORIES OF INITIAL REVIEW</b>		

- 1.0 LEVEL OF REVIEW REQUIRED** Depending on the nature of the research, the risk involved and the vulnerability of the research participants, a protocol may be eligible for delegated review, or require a full review by the Health Sciences Research Ethics Board. The ultimate decision as to the appropriate level of review rests with the HSREB.
- 1.1 RESEARCH THAT DOES NOT REQUIRE REB REVIEW**
- 1.1.1 Review of hospital records authorized by the medical records board of the respective hospital or mandated by an appropriate entity e.g. Ministry of Health and Long Term Care, in accordance with legislation or regulations for the purpose of record review but not for identification of potential participants for research
  - 1.1.2 Course or program planning, development or evaluation including quality assurance or improvement studies
  - 1.1.3 Development of case studies for teaching purposes
- 1.2 DELEGATED REVIEW** Protocols may be eligible for Delegated Review if they pose no more than minimal risk, meaning that the risks anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination, or involve non-invasive tests without the use of ionizing radiation or magnetic resonance imaging. Research meeting these criteria for minimal risk may not require a full board review by the HSREB. The authority to review and approve protocols by delegated review is 'delegated' by the HSREB to a person or persons who act on behalf of the HSREB and report back to the HSREB. Applicants must complete the UWO HSREB Delegated Review Submission Form.
- 1.3 FULL BOARD REVIEW** All research not outlined above will require Full Board review and a comprehensive protocol application must be submitted on the UWO Health Sciences REB Full Board protocol submission form.
- 2.0 DELEGATED - REVIEW LEVEL 1** Applicants must complete the UWO HSREB Delegated Review Submission Form. Delegated reviews have their own deadline and review schedule which is posted on the Office fo Research Ethics website..
- 2.1** Investigations primarily epidemiological in nature and where data is anonymous or anonymized involving the retrospective or prospective study of existing data, documents or records including the review of data for research purposes by the participant's physician or health care deliverer
- 2.2** Databases, registries and tissue banking.
- 2.3** Collection of :
- 2.3.1 hair and nail clippings, in a non-disfiguring manner

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- 2.3.2 deciduous teeth; and teeth if patient care indicates a need for extraction
- 2.3.3 collection of excreta and external secretions including sweat and uncannulated saliva
- 2.3.4 blood samples by venipuncture by qualified venipuncturists from participants who are 16 years of age or older, in good health and not pregnant, in amounts not exceeding 450 ml in a 8 week period and or 60 ml in any single 24 hour period
- 2.3.5 additional blood samples taken at the same time of other blood taking by venipuncture by qualified venipuncturists, in amounts not exceeding 450 ml in a 8 week period and or 60 ml in any single 24 hour period. Records must be maintained documenting the amount of blood given by individual Participants, including the date and time of blood sampling.
- 2.3.6 recording of data from participants using non-invasive procedures routinely employed in clinical practice. This includes height and other measurements using a tape measure, weight, blood pressure and temperature.
- 2.3.7 collection of both supra and subgingival plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
- 2.3.8 Surveys, interviews or focus groups involving professional, and/or non-patient, non-vulnerable populations (e.g. physicians, allied health professionals, consumer groups) providing the interviewers are qualified to administer the interview and the questions are not unduly alarming, intrusive or embarrassing.

**3.0 DELEGATED REVIEW LEVEL 2** Applicants must complete the UWO HSREB Delegated Review Submission Form. These protocols will be reviewed in accordance with the published HSREB deadline and meeting schedule

- 3.1** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement).
- 3.2** Research involving survey or interview procedures of patients or vulnerable persons providing the interviewers are qualified to administer the interview and the questions are not unduly alarming, intrusive or embarrassing.
- 3.3** Recording of data using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance, and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy. It would include such procedures as testing sensory acuity, speech competence, electrocardiography, electroencephalography, electromyography, thermography, detection of naturally occurring radioactivity, diagnostic ultrasound procedures (cardiac, abdominal). It

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does not include exposure to electromagnetic radiation (MRI) outside the visible range. However, research projects involving the use of ultrasound and/or thermography in pregnancy for research purposes will require review by the full REB.

- 3.4** Collection of blood samples by venipuncture by qualified venipuncturists from Participants who are less than 16 years of age, or pregnant or not in good health, in amounts not exceeding 450 ml in an 8 week period and/or 60 ml in any single 24 hour period or from infants in age-appropriate amounts. Records must be maintained documenting the amount of blood given by individual Participants, including the date and time of blood sampling.
- 3.5** Voice-recordings made for research purposes such as but not limited to investigations of speech defects.
- 3.6** Moderate exercise by healthy volunteers
- 3.7** Protocols involving MRI (less than or equal to 3.0 T ) in healthy participants (except children)
- 3.8** Muscle biopsies in healthy participants or taken at the time of surgery