ATTACHMENT A

EXEMPT CATEGORIES OF REVIEW

Research activities in which the only involvement of human subjects will be in one or more of the following categories may be exempt from full committee review. The final determination of status will be made by a subcommittee.*

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (I) research on regular and special education instructional strategies, or (II) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not otherwise exempt if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (IV) possible changes in methods or levels of payment for benefits or services under those programs. Please note: Such projects must be conducted pursuant to specific federal statutory authority, there must be no statutory requirements for IRB review, the research must not involve significant physical invasions or intrusions upon the privacy of the participants, and the exemption must be invoked only with authorization or concurrence by the funding agency.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

*Not all research may be considered exempt. If the research includes vulnerable populations, exemptions do NOT apply, and IRB review is required. This includes research involving children, prisoners, persons who are cognitively impaired, or persons who are economically or educationally disadvantaged.
ATTACHMENT B

EXPEDITED CATEGORIES OF REVIEW
(Effective November 9, 1998)

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. (B) The categories in this list apply regardless of the age of subjects, except as noted. (C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. (D) The expedited review procedure may not be used for classified research involving human subjects. (E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB. (F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children*, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

*Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).
EXPEDITED CATEGORIES OF REVIEW

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) 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 subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electoretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows: (a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) Where no subjects have been enrolled and no additional risks have been identified; or (c) Where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
ATTACHMENT C

ADVERTISING FOR RESEARCH PARTICIPANTS

The UCR Human Research Review Boards (HRRB) is responsible for ensuring the equitable selection of research subjects and must therefore review the methods that investigators use to recruit subjects, including advertisements. Advertising for research subjects is not in and of itself an objectionable practice. However, when advertising is to be used, the IRB should review the information contained in the advertisement, and the mode of its communication, to determine that the procedure for recruiting subjects affords adequate protection.

FDA requires that an IRB review and have authority to approve, require modifications in, or disapprove all research activities covered by the IRB regulations [21 CFR 56.109]. FDA expects an IRB to review all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. The protocol, the consent form, and the investigator's brochure have consistently been cited as specific examples of documents that the IRB should review.

Advertisements used to recruit subjects should be seen as an extension of the informed consent and subject selection processes [21 CFR 50.20, 21 CFR 50.25, 21 CFR 56.111 (a)(3)]. Institutions should, therefore, require IRB review of such advertisements. IRB review is necessary to ensure that the information is not misleading to subjects, especially when a study will involve persons with acute or severe physical or mental illness or persons who are economically or educationally disadvantaged. The IRB is responsible for assuring that appropriate safeguards exist to protect the rights and welfare of research subjects [21 CFR 56.111(b)].

IRB approval of the wording and format of all recruitment material(s) must be documented through the use of a certification stamp on all official, finalized recruitment material(s) that indicates the date of the most recent IRB approval of the document and the expiration date. If the recruitment material(s) is amended during the protocol approval period, it must bear the approval date of the amendment rather than the date of the approved protocol.

Based on FDA regulation and OHSU IRB policy, any advertisement used to recruit subjects should be limited to:

1. the name and address of the clinical investigator and/or the research facility and the IRB number of the study;
2. the condition under study and/or the purpose of the research;
3. in summary form, the criteria that will be used to determine eligibility for the study (a complete list of eligibility criteria is not required);
4. a straightforward and truthful description of the benefits or burdens (e.g. as applicable, payments, no cost treatment, the percentage of subjects who will receive a placebo) to the subject for participating in the study;
5. the time or other commitment required of the subjects;
6. the location of the research and the person or office to contact for further information.
ATTACHMENT C (continued)

ADVERTISING FOR STUDY SUBJECTS

These requirements apply regardless of whether the advertisement is in print, on the radio, on television, or on the Internet, with the exception that it is not required that the IRB number be read aloud for radio and TV ads.

In addition:

• Do not use the phrase “Free medical treatment”
• Do not call the intervention a new treatment, medication, drug, device, etc.
• If the study is a blinded multi-armed investigational drug study, describe the study arms in the following manner. “You will receive a pill (or patch, injection, etc.). This pill (or patch, injection, etc.) may contain the study drug, an inactive substance call a placebo (continue listing any other possible interventions). You have a 1 in “X” chance of receiving the study drug.”
• When submitting an advertisement for review, indicate the media used and whether any subsequent advertisements in different media are planned.

No claims should be made, either explicitly or implicitly, that the drug or device is safe or effective for the purposes under investigation, or that the drug or device is in any way equivalent or superior to any other drug or device. Such representation would also be a violation of the FDA’s regulations concerning the promotion of investigational drugs [21 CFR 312.7 (a)] and of investigational devices [21 CFR 812.7 (d)].

These requirements apply regardless of whether the advertisement is in print, on the radio, on television, or on the Internet.

Also, please be aware that if you plan on posting advertisements, UCR has required Posting Regulations which can be found at: http://fboapps.ucr.edu/policies/index.php?path=viewPolicies.php&policy=700-50.)
ATTACHMENT D
PAYMENT TO RESEARCH PARTICIPANTS

It is not uncommon for subjects to be paid for their participation in research. Payment to research subjects for participation in studies is not considered a benefit; it is a recruitment incentive. Therefore, the HRRB will review both the amount of payment and the proposed timing/method of disbursement to ensure that neither are coercive nor present undue influence [21 CFR 50.20].

The amount and schedule of all payments must be presented to the HRRB at the time of initial review of the protocol so the HRRB can determine if the amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. Also, all information concerning payment, including the amount and schedule of payment(s), must be set forth in the informed consent document.

The general rule is that the entire payment be made to participants, whether they complete the entire study or not. However, the HRRB will consider (and possibly allow for) partial payment if a participant does not complete the entire study, providing that such incentive is not coercive. The method of payment must be laid out in the protocol and the consent document and approved by the HRRB. All Payments must adhere to University policy and sponsor terms and conditions, if applicable.

IF YOU HAVE ANY QUESTIONS:

Please contact the Human Research Review Board staff at the Office of Research Integrity:

(951) 827-4810, (915) 827-4811, or (951) 827-6332