SUBMITTING RESEARCH PROJECTS WHICH ARE NO MORE THAN MINIMAL RISK: GUIDELINES FOR EXEMPT AND EXPEDITED SUBMISSIONS

According to the Mount Aloysius College's Assurance with the federal government, "the involvement of human participants in research covered by this Assurance will not be permitted until an appropriate IRB has reviewed and approved the research…". As a result, **all** research involving human participants, **must** be submitted to and approved by the IRB **prior** to starting the research.

Instructions for:

I. Exempt studies:

Unless otherwise required by the Office for Human Research Protections (OHRP) or the Food and Drug Administration (FDA), research in which the only involvement of human participants will be in one or more of the following categories is exempt from the regulations.

Please indicate under which category you are requesting exempt status for this protocol. Important note:

☐ 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 or interview procedures, or the observation of public behavior, so long as confidentiality is maintained. If ***both*** of the following are true, exempt status cannot be granted:
   (i) Information obtained is recorded in such a manner that the subject can be identified, directly or through identifiers linked to the subject, **and**
   (ii) Subject's responses, if known outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability or reputation. (*An example of this would be research that deals with sensitive aspects of the subject's own behavior that could be illegal or socially unacceptable, such as drug use, sexual behavior, or use of alcohol, or that the subject might not want publicly known, for any reason.)*

☐ 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under #2, if:

   (i) the human participants 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 participants cannot be identified, directly or through identifiers linked to the participants. (***"Existing"*** means already collected and/or stored before your study starts, not that collection will occur as part of routine care)

☐ 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.

☐ 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

II. Expedited studies:

Expedited review may be granted if ***both*** of the following conditions apply:

(1) The study involves ***no more than minimal risk*** (probability and magnitude of harm or discomfort are no greater, in and of themselves, than those in daily life or in a routine physical or psychological examination or test).

(2) The only involvement of human participants will be one or more of the categories below, carried out through standard methods.

Explanatory Notes

- ***Activities listed below should not be deemed to be of minimal risk simply because they are included on this list***. Inclusion on this list means 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 participants.
- ***The categories in this list apply regardless of the age of participants, except as noted***.
- ***The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk*** of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- The expedited review procedure may not be used for classified research involving human participants.
- ***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.
- Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Please indicate under which category you are requesting expedited review:

☐ **No More Than Minimal Risk and Select One or More of the Following 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 a marketed drug is not eligible if the research significantly increases the risks or decreases the acceptability of the risks associated with the use of the drug.* ***(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 both cleared/approved for marketing and 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)*** Participants are ***healthy, nonpregnant adults*** who weigh at least 110 pounds; amount drawn may not exceed 550 ml over 8 weeks; and collection may not occur more frequently than 2 times per week. ***OR (b)*** Participants are ***other adults and children****, considering the age, weight, and health of the participants; the collection procedure; the

amount of blood to be collected; and the frequency with which it will be collected. For these participants, the amount collected may not exceed the lesser of 50 ml or 3 ml per kg over 8 weeks, and collection may not be occur more frequently than 2 times per week. ***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).*

☐ 3. Prospective collection of biological specimens for research purposes by noninvasive means. ***Examples:*** **(a)** hair and nail clippings, if collected 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 before or during labor; **(h)** supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylatic 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.

☐ 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, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; **(e)** moderate exercise, muscular strength testing, body composition assessment, and flexibility testing, where appropriate to 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 participants. 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 participants. 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 participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or
(b) where no participants 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.