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* * * Expedited Paragraphs * * *

Biomedical Expedited Review

For Expedited Review, all aspects of the research must include activities that (1) present no more than minimal risk to human subjects, and (2) involve one or more of the specific categories listed below. Select the following applicable categories to determine if your research project qualifies under Expedited Review. If none of the categories are applicable to your research project, a Full Committee Review will be required. For Expedited or Full Review, proceed to complete the following application

Select one or more of the following paragraph(s):

1. Clinical studies of drugs and medical devices only when condition (a) and (b) are 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, non-pregnant 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, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50

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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 specimen for research purposes by non-invasive means..

Examples:

a) hair and nail clippings in a non-disfiguring 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.

4. Collection of data through non invasive 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;

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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 given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimen) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph 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 behaviour(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.)

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* * * Purpose, Background, Collaborative Research * * *

Study Title

Example: Biomedical Full/Expedited

Complete each section. When a question is not applicable, enter "N/A". Do not leave any sections blank.

1. Purpose

Provide a brief explanation of the proposed research, including specific study hypothesis, objectives, and rationale.

2. Background

Give relevant background (e.g., summarize previous/current related studies) on condition, procedure, product, etc. under investigation, including citations (attach bibliography in Attachments section) if applicable.

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3. Collaborative Research

a) If any non-SCU institutions or individuals are engaged in the research, explain here.

b) If any non-SCU institutions or individuals are collaborating in the research, complete the table below and attach any relevant IRB approvals in the Attachments section.

4. Qualifications of Study Personnel

a) Explain expertise of Principal Investigator, Student/Postdoc Researcher, Faculty Sponsor (if applicable), any Co-Investigators or other key personnel listed in the application, and how it relates to their specific roles in the study team.

b) Describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, training). Also, explain your knowledge of local community attitudes and cultural norms, and cultural sensitivities necessary to carry out the research.

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* * * Subject Population * * *

5. Subject Population

a) Describe proposed subject population, stating age range, gender, race, ethnicity, language and literacy.

b) State total number of subjects planned for the study and how many must be recruited to obtain this sample size. Explain how number of subjects needed to answer the research question was determined.

c) If any proposed subjects are children/minors, prisoners, pregnant women, those with physical or cognitive impairments, or others who are considered vulnerable to coercion or undue influence, state rationale for their involvement.

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6. Recruitment

a) Explain how, where, when, and by whom prospective subjects will be identified/selected and approached for study participation. If researcher is subject's instructor, physician, or job supervisor, or if vulnerable subject groups will be recruited, explain what precautions will be taken to minimize potential coercion or undue influence to participate.

b) Describe any recruitment materials (e.g., letters, flyers, advertisements [note type of media/where posted], scripts for verbal recruitment, etc.) and letter of permission/cooperation from institutions, agencies or organizations where off-site subject recruitment will take place (e.g., clinic, school district). Attach these documents in Attachments section.

7. Screening

a) Provide criteria for subject inclusion and exclusion. If any inclusion/exclusion criteria are based on gender, race, or ethnicity, explain rationale for restrictions.Provide criteria for subject inclusion and exclusion. If any inclusion/exclusion criteria are based on gender, race, or ethnicity, explain rationale for restrictions.

b) If prospective subjects will be screened via tests, interviews, etc., prior to entry into the "main" study, explain how, where, when, and by whom screening will be done. NOTE: Consent must be obtained for screening procedures as well as "main" study procedures. As appropriate, either: 1) create a separate "Screening Consent Form;" or 2) include screening information within the consent form for the main study.

8. Compensation and Costs

a) Describe plan for compensation of subjects. If no compensation will be provided, this should be stated. If subjects will be compensated for their participation, explain in detail about the amount and methods/ terms of payment.

- Include any provisions for partial payment if subject withdraws before study is complete.

- When subjects are required to provide Social Security Number in order to be paid, this data must be collected separately from consent documentation. If applicable, describe security measures that will be used to protect subject confidentiality.

- If non-monetary compensation (e.g., course credit, services) will be offered, explain how it will be provided.

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provided.

b) Discuss reasoning behind amount/method/terms of compensation, including appropriateness of compensation for the study population and avoiding undue influence to participate.

c) Costs to Subjects. If applicable, describe any costs/charges which subjects or their insurance carriers will be expected to pay. (If there are no costs to subjects or their insurers, this should be stated.)

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* * * Study Procedures, Alternatives to Participation * * *

9. Study Procedures

a) Describe in chronological order of events how the research will be conducted, providing information about all study procedures (e.g., all interventions/interactions with subjects, data collection procedures etc.), including follow-up procedures.

b) Explain who will conduct the procedures, where and when they will take place. Indicate frequency and duration of visits/sessions, as well as total time commitment for the study.

c) Identify any procedures that are experimental/ investigational and explain how they differ from standard procedures (medical, psychological, educational). If applicable, distinguish between procedures that the subject would undergo regardless of enrollment in the study and procedure done specifically for study.

d) If any type of deception or lack of full disclosure will be used, explain what it will entail, why it is justified, and what the plans are to debrief subjects. Also, attach debriefing form(s)/materials in Attachments section.

e) State if audio or video taping will occur. Describe what will become of the tapes after the project (e.g., shown at scientific meetings, erased) and final disposition of the tapes.

10. Alternatives to Participation

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Describe appropriate alternative resources, procedures, courses of treatment, if any, that are available to prospective subjects. If there are no appropriate alternatives to study participation, this should be stated. If the study does not involve treatment/intervention, enter "N/A" here.

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* * * Risks and Discomforts * * *

11. Risks and Discomforts

a) Describe all known risks, discomforts associated with study procedures, whether physical, psychological, economic or social (e.g., pain, stress, invasion of privacy, breach of confidentiality), noting the likelihood and degree of potential harm.

b) Discuss measures that will be taken to minimize risks or discomforts to subjects.

c) Explain how unanticipated negative outcomes/experiences or serious adverse events will be managed. (NOTE: This may apply in social-behavioral as well as biomedical research, e.g., undue stress or anxiety of subject, breach of confidentiality via loss of laptop computer with study data. Provisions should be made and described here if applicable.)

d) Discuss plans for reporting unanticipated problems involving risks to subjects or others, or serious adverse events.

e) Describe plans for provision of treatment for study-related injuries, and how costs of injury treatment will be covered.

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* * * Benefits, Confidentiality * * *

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12. Benefits

Describe any potential benefits to the individual subject, group of subjects, and/or Society. If subjects will not benefit directly from study procedures, this should be stated.

NOTE: Do not include compensation/payment of subjects in this section, as remuneration is not considered a "benefit" of participation in research.

13. Confidentiality

a) Explain how subject privacy will be protected and how confidentiality of subject information will be maintained. Discuss who will have access to study records/specimen and how the records will be secured.

b) Will subjects be asked to give permission for release of identifiable data (e.g., information, videotapes), now or in future? If so, explain here and include appropriate statements in consent materials.

c) Will data be collected anonymously (i.e., no identifying information from subjects will be collected/ recorded that can be linked to the study data)? (NOTE: Data is not anonymous if there is a code linking it to personally identifiable information. Also, audio and video recordings are generally not considered to be anonymous.)

d) If using existing data/biological specimen, will the researchers have access to a code linking the data to personally identifiable information?

e) If identifying information will be collected and linked to data/specimen, explain at what stage identifiers will be removed from the data/specimen. If identifiers will be retained, explain why this is necessary and how confidentiality will be protected.

f) If the data is coded, explain where the key to identifiers will be stored, how it will be protected, and who will have access to it.

g) Indicate whether research data/specimen will be destroyed at the end of the study. If data will not be destroyed, explain why, where, in what format, how long it will be retained and who will have access to it.

h) Explain how data collection instruments, audiotapes, videotapes, photographs, etc. will be stored and who

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will have access to them. Indicate at what point they will be transcribed and/or destroyed (if ever).

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* * * Potential Conflict of Interest * * *

14. Potential Conflict of Interest

Please answer the following questions a through e:

a) Do any of the involved Investigators or their immediate family (as described below) have consulting arrangements, management responsibilities or equity holdings in the sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?

b) Do any Investigators or their immediate family have any financial relationship with the sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment?

c) Is any Investigator(s) a member of an advisory board with the Sponsoring company?

d) Do any investigators receive gift funds from the Sponsoring company?

e) Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol?

"Immediate family" means a spouse, dependent children as defined by the IRS, or a domestic partner.

If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship. i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor. The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment.

If you answer Yes to any of the questions above, you must file a Conflict of Interest disclosure statement.

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* * * Informed Consent * * *

15. Informed Consent

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Attached the appropriate consent form(s)needed for this research; definitions are listed below for your reference. Informed consent must include California experimental subjects Bill of Rights. Model consent forms can be viewed on Human Subjects website.

You will be asked to provide relevant background information for each consent document or waiver. Also, translated/foreign language versions of any consent materials must be attached in the Attachments section.

Consent Form: A document that embodies all of the required information (elements of informed consent) designed to help an individual make an informed decision about whether or not to participate in the research.The form must include a signature line and date line for the "individual to sign if he or she agrees to participate. The Consent Form can also be presented as a "short form" document stating that the required elements of informed consent have been presented orally to the participant. When the short form method is used a "summary" of the information that is presented to the participant must also be provided for IRB approval and there must be an impartial witness to the oral presentation. The witness must sign the summary as well as the short form and the participant must sign the summary. The "short form" method may be used in circumstances where oral presentation of consent is preferable or necessary, e.g., subjects are illiterate in English or their native language.

Consent Waiver: No consent will be sought at all. This means that the IRB is asked to waive the requirement for informed consent. This option is often appropriate for research that involves use of existing data or samples.

Unsigned Consent Form: A document that embodies all of the required information (elements of informed consent), but does not include a place for a participant to indicate with a signature that he or she agrees to take part in the research. This means that the IRB is asked to waiver the requirement for documented (signed) consent. For example, if consent will be obtained verbally or using a button on the web, this option should be selected.

Altered Consent Form: A consent form that has omitted required information. This means that the IRB is asked to waive one or more required elements of informed consent. For example, if the purpose of the study will not be disclosed to participants in order to avoid bias, this option should be selected because the "purpose: is a required element of informed consent. The form must include a signature line and date line for the individual to sign if he or she agrees to participate.

Parent/Guardian Permission Forms: A document that embodies all of the required information (elements of informed consent) designed to help the parent/guardian of a child make an informed decision about whether or not to permit the child's participation in the research. The form must include signature and date lines for the parent(s)/guardian(s) to sign if the child is permitted to take part in the research.

Parent/Guardian Permission Waiver: No parent/guardian permission will be sought at all. This means the IRB is asked to waive the requirement for parent/guardian permission. This option, for example, is often

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appropriate for research designed to study conditions in children or a study population for which parental permission is not a reasonable requirement to protect the children (e.g., neglected or abused children).

Unsigned Parent/Guardian Permission: A parent permission document that embodies all of the required information (elements of informed consent), but does not include a place for a parent to indicate with a signature that he or she agrees to permit the child's participation. This means that the IRB is asked to waive the requirement for documented (signed) consent.

Altered Parent/Guardian Permission Form: A permission form that has omitted required information (elements). This means that the IRB is asked to waive one or more required elements of informed consent. However, the form must include signature and date lines for the parents(s)/guardian(s) to sign if the child is permitted to take part in the research,

Altered and Unsigned Parent Permission: A Parent permission document that has omitted required information (elements) and does not include a place for a parent to indicate with a signature that he or she agrees to permit the child's participation. This means that IRB is being asked to waive on or more elements on consent in addition to the requirement for documented consent.

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* * * Assent Background * * *

16. Assent Background

Attached the appropriate assent or assent waiver document needed for this research; definitions are listed below for your reference. Model assent form can be viewed on Human Subjects website.

Assent Document: A form or script of the information that will be conveyed to the child about the study. In general, researcher must obtain the affirmative agreement of children ages seven years and older for their participation. Assent forms should be written at a level understandable to the child. If the study includes a broad age range of children, more than one assent form may be needed (i.e., an assent from suitable for a 17 year old is not usually suitable for a 7 year old child).

Assent Waiver: No child assent will be sought at all. This means that the IRB is asked to waive the requirement for child assent. Among other circumstances, this option is appropriate when the capability of the child to understand the research is too limited or when the research holds out a prospect of direct benefits that is important to the health or well being of the child.

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* * * HIPAA * * *

17. Health Insurance Portability ' Accountability Act (HIPAA)

The HIPAA Privacy Rule establishes the right of an individual to authorize a covered entity, such as a health plan, health care clearinghouse or health care provider, to use and disclose his/her Protected Health Information (PHI) for research purposes. The Privacy Rule defines the elements of individual information that comprise PHI and establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. It also includes provisions to allow an individual's PHI to be disclosed or used in research without their authorization (i.e. IRB waiver of authorization).

a. **Does the study involve use of Protected Health Information (PHI) from a "covered entity" outside of SCU(i.e. another organization or institution)?**

If Yes, explain what arrangements have been made to comply with the HIPAA requirements of the entity from which the PHI will be obtained:

b. **HIPAA WAIVER/ALTERATION: For each waiver or alteration of the requirement for authorization from the patient for use of his or her PHI, provide justification below.**

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* * * Attachments * * *

18. Attachments

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Add appropriate attachments (e.g., advertisements, data collection instruments, IRB approvals from collaborating institutions, etc.) in this section.

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* * * Assurance * * *

Assurance

Obligations of the Principal Investigator are:

Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes;

Consent Forms - All subjects will be given a copy of the signed consent form. Investigators will be required to retain signed consent documents for six (6) years after close of the grant or three (3) years if unfunded;

Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel;

Adverse Events - All adverse events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than ten (10) working days;

Continuing Review - IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review;

Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select "Final Report."

The Principal Investigator has read and agrees to abide by the above obligations.

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