|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Study Information** | | | | | | | | | | | |
| **Study Title:** | |  | | | | | | | | | |
| **Principal Investigator or Researcher:** | | | | |  | | | | | | |
| **Co-Investigator(s) or Co-Researcher(s):** | | | | |  | | | | | | |
| **Hospital / Center / University:** | | | | | | | **Email Address:** | | | | |
| **Department:** | | | | | | | **Telephone:** | | | | |
|  | | | |  | | |  | | |  | |
| 1. **Application Checklist** | | | | | | | | | | | |
|  | | | 1. Appropriate Expedited category(ies) checked (see §5, p. 2). | | | | | | | | |
|  | | | 1. List and qualifications of all active participants in the study, including who is authorized to obtain informed consent, if applicable (form need to be designed). | | | | | | | | |
|  | | | 1. Attach a protocol (word format) (for drug or device studies, include all information required for full review). | | | | | | | | |
|  | | | 1. Attach description of study (see §6). | | | | | | | | |
|  | NA: | | 1. Attach informed consent document. | | | | | | | | |
|  | NA: | | 1. If an anonymous survey is proposed, provide a cover letter to be attached to the survey that contains the usual elements of informed consent (purpose of the research, procedures, duration, number of subjects, voluntariness, confidentiality, how to ask questions) except for signature lines. It should clearly state how anonymity will be maintained, that participation is completely voluntary, that a participant can choose not to answer any questions, and that return of the survey will imply consent to participate. | | | | | | | | |
|  | NA: | | 1. Obtain and attach needed signatures and permissions (academic advisor for student protocols, permission of qualified authority for studies performed outside your department). | | | | | | | | |
|  | | | 1. Indicate funding status: Internal\*:  External\*:  Not Funded: | | | | | | | | |
|  | | | Planned:  Pending:  Funded:  NA: | | | | | | | | |
| \* Attach funding details, when applicable. NA: | | | | | | | | |
|  | | | 1. Attach copies of all data collection tools. | | | | | | | | |
|  | NA: | | 1. Attach copies of all survey instruments, questionnaires, etc. | | | | | | | | |
|  | | | 1. Attach copies of all recruitment materials such as fliers, newspaper ads, brochures, and posters. These MUST be approved by the IRB before being used. | | | | | | | | |
|  | | | 1. Submit a permission letter from EACH performance site. If the research is approved, it will only be for sites from which a permission letter has been received. | | | | | | | | |
|  | | | 1. Training logs for all study personnel. | | | | | | | | |
|  | | | |  | | | | | | | |
| 1. **Principal Investigator’s Signature** | | | | | | | | | | | |
| I will not begin any study activities prior to receiving approval by the KFMC IRB. | | | | | | | | | | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **Signature& Stamp** | | | | | | | | | | **Date** | |
|  | | | |  | | | |  | |  | |
| 1. **Department Chairman and/or Section or Unit Head’s Signature** | | | | | | | |  | **For Non-KFMC PI:** | | |
|  | | | | | |  | |  | Name of KFMC Sponsor: | |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | Department: | |  |
| **Signature& Stamp** | | | | | | **Date** | |  | Signature: | |  |
|  | | | | | |  | |  | Date: | |  |
| 1. **Expedited Review Categories** | | | | | | | | | | | |
| Research that involves no more than minimal risk may be assigned Expedited Review Status. | | | | | | | | | | | |
| **Ck** | | | **Category** | | | | | | | | |
|  | | | 1. **Clinical studies of drugs and medical devices only when condition (a) or (b) is met.** | | | | | | | | |
|  | | | 1. Research on drugs for which an investigational new drug application 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, nor is research on drugs using other than the prescribed route or dose/regimen.) | | | | | | | | |
|  | | | 1. Research on medical devices which are cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. | | | | | | | | |
|  | | | 1. **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:** | | | | | | | | |
|  | | | 1. From healthy, non-pregnant adults who weigh at least 50 kg. For these subjects, the amounts drawn may not exceed 10 ml/sample, or 160 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or | | | | | | | | |
|  | | | 1. 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 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. | | | | | | | | |
|  | | | 1. **Prospective collection of biological specimens for research purposes by noninvasive means.** | | | | | | | | |
|  | | | Examples: | | | | | | | | |
|  | | | 1. hair and nail clippings in a no disfiguring manner; | | | | | | | | |
|  | | | 1. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; | | | | | | | | |
|  | | | 1. permanent teeth if routine patient care indicates a need for extraction; | | | | | | | | |
|  | | | 1. excreta and external secretions (including sweat); | | | | | | | | |
|  | | | 1. uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; | | | | | | | | |
|  | | | 1. placenta removed at delivery; | | | | | | | | |
|  | | | 1. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; | | | | | | | | |
|  | | | 1. 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; | | | | | | | | |
|  | | | 1. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; | | | | | | | | |
|  | | | 1. sputum collected after saline mist nebulization. | | | | | | | | |
|  | | | 1. **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: | | | | | | | | |
|  | | | 1. 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; | | | | | | | | |
|  | | | 1. weighing or testing sensory acuity; | | | | | | | | |
|  | | | 1. magnetic resonance imaging; | | | | | | | | |
|  | | | 1. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; | | | | | | | | |
|  | | | 1. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. | | | | | | | | |
|  | | | 1. **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may qualify for Exempt Status. This listing refers only to research that is not exempt. Need clarification.)** | | | | | | | | |
| **Ck** | | | **Category** | | | | | | | | |
|  | | | 1. **Collection of data from voice, video, digital, or image recordings made for research purposes.** | | | | | | | | |
|  | | | 1. **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 qualify for Exempt Status. This listing refers only to research that is not exempt.)** | | | | | | | | |
|  | | | 1. **Continuing review of research previously approved by the convened IRB as follows:** | | | | | | | | |
| NA for initial application | | | 1. 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 | | | | | | | | |
| NA for initial application | | | 1. where no subjects have been enrolled and no additional risks have been identified; or | | | | | | | | |
| NA for initial application | | | 1. where the remaining research activities are limited to data analysis. | | | | | | | | |
| NA for initial application | | | 1. **Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2 through 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.** | | | | | | | | |
|  | | |  | | | | | | | | |
|  | | |  | | | | | | | | |
| 1. **Study Summary:** | | | | | | | | | | | |
|  | | | | | | | | | | | |
| *The summary should be written in language intelligible to a moderately educated, non-scientific layperson. It should contain a clear statement of the rationale and hypothesis of your study, a concise description of the methodology, and a discussion of the expected results. The length should be at least one half of a page and no more than one page. You should not refer the reader to the attached protocol.* | | | | | | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Study Detailed Description** | | | |
| **Attach prepared study protocol that addresses each of the following topics , OR: Please address each section carefully and in detail, and attach as pages 5 through**       **of this application. Failure to do so will delay the review of your study.** | | | |
|  |  |  |  |
| **Protocol Categories** | | **Ck** | **NA** |
| Abstract | |  |  |
| 1. Introduction and background information | |  |  |
| 1. Objectives and rationale | |  |  |
| 1. Results of previous related research | |  |  |
| 1. Study methods | |  |  |
| 1. Resources required | |  |  |
| 1. Role of key members | |  |  |
| 1. Study site(s) | |  |  |
| 1. Duration of study | |  |  |
| 1. Study population (include age, ethnicity, etc.) | |  |  |
| 1. Will vulnerable populations be involved | |  |  |
| 1. Number of subjects (and justification) | |  |  |
| 1. Recruitment methods (advertisements included when applicable) | |  |  |
| 1. Inclusion/Exclusion criteria - equitable selection of subjects including:  * If women are excluded, justification is provided * If subjects under 21 are excluded, justification is provided | |  |  |
| 1. Role of subject and research procedures | |  |  |
| 1. Samples (e.g., blood, tissue, etc.) to be obtained and, for blood, volume and route, e.g.,   venipuncture venous catheter arterial puncture arterial catheter cutaneous | |  |  |
| 1. Payment to volunteers | |  |  |
| 1. Parameters to be measured | |  |  |
| 1. If existing data will be used, specify the source and how the data will be retrieved, reviewed, coded, and stored. | |  |  |
| 1. Data analysis | |  |  |
| 1. Benefits to subject and to society (also in IC) | |  |  |
| 1. Risks to subjects and to society (also in IC) | |  |  |
| 1. How the study will be monitored | |  |  |
| 1. Incentives and research related costs (also in IC) | |  |  |
| 1. Alternatives (also in IC) | |  |  |
| 1. Research materials, records, and confidentiality | |  |  |
| 1. Subject consent/assent or waiver or alteration of consent, and description of process | |  |  |
| **Does the study pose more than minimal risk?** | |  |  |