**Request for expedited status Form**

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| Research Study Title …………………………………………….. |
| PI …………………………………………….. |
| Protocol No |
| Approval Number  Phone ……………………………………………..  Email ………………………….……………………..  Student University(if applicable) |

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| **Instructions** |
| Please read carefully the instructions before completing your request. This form is applicable for the following:  Eligibility for Expedited Review:  The IRB may use an expedited review procedure to review either or both of the following:   1. Research that involves no more than minimal risk 2. Minor changes in previously approved research during the period for which 3. approval is authorized. 4. Research for which limited IRB review is a condition of exemption 5. The categories in this list apply regardless of the age of subjects, except as noted 6. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of any form. 7. The expedited review procedure may not be used for classified research involving human subjects. 8. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened   Applicability for Expedited Review:   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 (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.)    2. Research on medical devices for which (i) an investigational device exemption application 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:    1. 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    2. 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. 3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: 4. hair and nail clippings in a nondisfiguring manner 5. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction 6. permanent teeth if routine patient care indicates a need for extraction 7. excreta and external secretions (including sweat) 8. 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 9. placenta removed at delivery 10. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor 11. 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. 12. 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: 13. 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 subjects privacy 14. weighing or testing sensory acuity 15. magnetic resonance imaging 16. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography 17. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. 18. 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). 19. Collection of data from voice, video, digital, or image recordings made for research purposes. 20. 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. 21. Continuing review of research previously approved by the convened IRB as follows:     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     2. where no subjects have been enrolled and no additional risks have been identified; or     3. where the remaining research activities are limited to data analysis. 22. 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.   Note:   * Instructions are given in *Italic* font style. * Keep the font at 12 pt |

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| **Section 1: Request Details** | |
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| **Research Study** | *[check the response that apply on your samples]*   1. Funding information   External internal Not funded   1. Status of funding   Planned Pending funded   1. Funding source   Government Industry foundation   1. Is the study sponsored by specific agency or program   Yes No , if “Yes” please indicate : *Click or tap here to enter text.*   1. Funding Grant if applicable   *Click or tap here to enter text.*   1. Approval letters for on site research conduct   Yes No , if “Yes” please attach to your application  Please attach the application form and fill in appropriately (section 1-5)  Note: for not applicable item, write down NA.   1. Research study status   New study Renewal Approval Amendment  Approval Number if applicable *Click or tap here to enter text.*   1. Attached copy of appropriate Consent form   Yes NA   1. Attach required approvals from your department, advisor for student and qualified authority for studies performed outside your department.   Yes NA   1. Attach copies of all data collection tools NA 2. Attach copies of all recruitment materials such as fliers, newspaper ads, brochures, and posters. These MUST be approved by the IRB before being used. 3. Training logs for all involved personnel |
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| **Section 2: PI consent** | |
| **Consent by PI** | *[does the event being reported meet the following criteria ]*  I will not begin any study activities until notified of approval of Exempt Status by the University of Jeddah BEC. I carefully read the instructions and hereby I assure the acknowledgement of the listed items.  PI name:  Signature:  Date: ………….…….. |

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| **Section 3 : BEC USE only !** |  |
| **Subcommittee** | Subcommittee : *Click or tap here to enter text.*  Approved Rejected  Comments:  Date : |
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| **Local Committee** | Approved Rejected  Comments:  Date : |
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