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**Memorandum**

**Office of** ................................................................................................

**Ref..**……………/..................................................**Date**..............................................................................

**Subject** HREC-SUT Submission Form for Expedited Review as per SUT’s Announcement

**To** Chair of Human Research Ethics Committee, Suranaree University of Technology

 I, ..........................................., of (Office/Faculty of Affiliation) .....................................................

Would like to submit a research proposal entitled “..................................................................”
for approval of ethics in human research. I have submitted the following documents online via HREC-SUT’s Online Submission system (<https://ec.sut.ac.th>) for your considerations (Please select relevant items).

[ ]  HREC-SUT’s Submission Form for expedited review as per SUT’s Announcement with version number and date specified (Please note that the information in the submission form should be consistent with that in the research proposal.)

[ ]  Research proposal with version number and date specified.

[ ]  Information Sheet for research subjects with version number and date specified, *if applicable*

[ ]  Informed Consent Form for research subjects with version number and date specified, *if applicable*

[ ]  Research tools with versions number and date specified (e.g., case record forms, investigator’s brochure, advertisement posters, etc.)

[ ]  Copy of approved form for thesis / independent study (in case of graduate students).

[ ]  Request permission for use of biological specimens from a hospital director, *if applicable*

[ ]  Signed permission to use leftover specimens from Principal Investigator and Subjects’ Information Sheets from previous protocol, *if applicable*

[ ]  Letter of permission request to use the data from the hospital director or from a person who has authority to grant permission for data use, *if applicable*

[ ]  Signed permission from Principal Investigator to use data from previously approved research, *if applicable*

[ ]  Signed permission to use biospecimens deposited in a biobank, *if applicable*

[ ]  Certificate for Ethics in Human Research (Signed and date)

[ ]  Principal Investigator’s and Thesis Advisor’s Curriculum Vitae in English with signed and date

[ ]  Conflict of Interest Form

[ ]  Submission fee receipt

Thank you for your kind consideration.

|  |  |
| --- | --- |
| Signature……………………………….…………… | Signature …………………….………….… |
| (……………………………….…………) | (……………………………….……………) |
| Project Advisor (In case principal investigator is a student/resident)/Co-InvestigatorDate............................................................... | Principal investigator Date............................................................... |
| Signature……………………………….…………… | Signature …………………….………….… |
| (……………………………….…………) | (……………………………….……………) |
| Head of departmentDate............................................................... | Head of researchDate............................................................... |
|  Signature………………………………….……….......... |
| (……………………………….…………………….) |
| Dean of faculty  |

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**HREC-SUT’s Submission Form for Expedited Review as per SUT’s Announcement**

|  |
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| **Part 1: General information about the research project**  |

1. Research title in English

………………………………………………………………………………………………………………………….

2. Principal Investigator and affiliation in both Thai (if applicable) and English with mobile phone number and email address

………………………………………………………………………………………………………………………….

3. Co-investigator and affiliation in both Thai (if applicable) and English

………………………………………………………………………………………………………………………….

4. Significance of the research questions (Briefly summarized, no longer than 1 page)

………………………………………………………………………………………………………………………….

5. Research objectives

………………………………………………………………………………………………………………………….

6. Benefits of this research project once the study is completed.

………………………………………………………………………………………………………………………….

**Notes**: Please make sure that all researchers listed have been trained in Ethics for Research in Humans and have uploaded their training evidence via Online Submission system [ <https://ec.sut.ac.th> ].

|  |
| --- |
| **Part 2: Choose the category under which this proposed research is applicable for expedited review as per SUT’s Announcement which is available at** [**https://ec.sut.ac.th**](https://ec.sut.ac.th) |

 Please indicate that your research protocol is qualified for expedited review as per SUT’s Announcement according to which of the following conditions by making the mark X in the circle ⚪ for the conditions that apply to your research protocol. Please also complete the details that are relevant. (More than one item can be selected).

|  |  |
| --- | --- |
| 5.1 Research related to collections of blood specimens  | [x]  **(Answer Part 2, Item 1)** |
| 5.2 Research related to collecting biological specimens via non-invasive methods that do not cause injuries to the subjects. | [x]  **(Answer Part 2, Item 2)** |
| 5.3 Research with non-invasive procedures of data collection that is routinely employed in usual treatment of patients without the use of anesthetics or sedatives and does not involve X-rays or microwaves. If medical devices are involved, only those approved for general use are permitted. | [x]  **(Answer Part 2, Item 3)** |
| 5.4 Research that uses data from medical records, documents, records, specimens, voice recordings, video recordings, photographs, digital images collected solely for non-research purposes such as for diagnosis or treatment of disease. The research must not involve post-marketing research.  | [x]  **(Answer Part 2, Item 4)**  |
| 5.5 Research that uses data in the forms of voice, videos, digital or image recordings that were collected for research purposes. | [x]  **(Answer Part 2, Item 5)**  |
| 5.6 Research that uses leftover specimens and/or surplus blood, or laboratory research that uses the same specimens as those used in earlier protocols that were approved by an ethics committee | [x]  **(Answer Part 2, Item 6)**  |

|  |
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| **Part 2, Item 1 as per Announcement item 5.1 — Research related to collections of blood specimens that are collected from**  |
| [x]   | 5.1.1 Blood sampling by finger stick, heel stick, or ear stick, with no more than 2 collections per dayPlease give the following details.1. Areas where blood is collected..................................................
2. Please indicate.

 Number of collections per day ………………….. Total number of collections for the whole protocol ………………….. |
| [x]   | 5.1.2 venipuncture from adults (excluding pregnant women) — only a maximum of 20 milliliters and a maximum of two collections are allowed.Please give the following details.1. Amount of blood collected each time……………………milliliters.
2. Number of collections per protocol………………
 |

| **Part 2, Item 2 As per Announcement item 5.2 — Research related to collecting biological specimens via non-invasive methods that do not cause injuries to the subjects (Click 🌕 to select applicable items).**  |
| --- |
| [x]   | 5.2.1 hair and nail clippings in a non-disfiguring mannerPlease give the following details. 1. Specimens collected …………………………………….………
2. Specimen collection methods …………………………………..……
3. Number of specimen collections……………..………………..
 |
| [x]   | 5.2.2 urine, stool, sweat, nasal mucus.Please give the following details.1. Specimens collected ………………………….…………………….………
2. Specimen collection methods …………………………………..……
3. Number of specimen collection …………….………………..
 |
| [x]   | 5.2.3 saliva, collected NOT via tube insertion. Please give the following details.1. Specimen collection methods …………………………………..……
2. Number of specimen collection…………………..…………..
 |
| [x]   | 5.2.4 placenta removed after delivery.Please specify method of specimen collection …………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |
| [x]   | 5.2.5 amniotic fluid obtained at the time of rupture of the membrane prior to or during labor.Please specify method of specimen collection …………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |
| [x]   | 5.2.6 Supra- and subgingival dental plague and calculus collected via the procedure that is not more invasive than routine prophylactic scaling of the teeth and that is accomplished in accordance with accepted prophylactic techniques. Please specify method of specimen collection …………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |
| [x]   | 5.2.7 deciduous and permanent teeth extracted due to routine patient care indications. Please give the following details (Click □ to select applicable item).1) Specimen collected [ ]  deciduous teeth [ ]  permanent teeth. 2) Specimen collection method…………………………….……3) Number of specimen collections…………….……………….. |
| [x]   | 5.2.8 mucosal skin cells collected by buccaneers scrapping, mouth washing, or skin swabPlease give the following details.1. Specimen collection method…………………………………..……
2. Number of specimen collections …………….………………..
 |
| [x]   | 5.2.9 skin cells collected by scrapping or skin swabPlease give the following details.1. Specimen collection methods …………………………………..……
2. Number of specimen collections …………….………………..
 |
| [x]   | 5.2.10 sputum collected from spitting or after saline mist nebulizationPlease give the following details.1. Specimen collection methods …………………………………..……
2. Number of specimen collections …………….………………....
 |
| [x]   | 5.2.11 Non-invasive collection of secretions or other biospecimenPlease give the following details 1. Secretions or biospecimens collected....................................
2. Specimen collection methods …………………………………..……
3. Number of specimen collections …………….………………..
 |

| **Part 2, Item 3 As per Announcement item 5.3 —** Research with non-invasive procedures of data collection that are routinely employed in usual treatment of patients without the use of anesthetics or sedatives and does not involve X-rays or microwaves. If medical devices are involved, only those approved for general use are permitted. |
| --- |
| [x]   | 5.3.1 Measuring body weight, height, blood pressure, body temperature, heart rate, or breathing ratePlease give details.…………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |
| [x]   | 5.3.2 Sensor attached to the skin e.g., fingertip pulse oximeter Please give details…………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |
| [x]   | 5.3.3 Testing or measuring sensory acuity e.g., visual acuity, audiometry, algometry, smell test.Please give details.…………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |
| [x]   | 5.3.4 Magnetic Resonance Imaging (MRI) without use of contrast mediaPlease give details.…………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |
| [x]   | 5.3.5 Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography.Please give details.…………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |
| [x]   | 5.3.6 Moderate exercise, muscle strength testing, body composition measurement, flexibility testing that are appropriate for the subjects’ age, weight, and health. Please give details.…………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |

| **Part 2, Item 4 As per Announcement item 5.4 —** Research that uses data from medical records, document, records, specimens, voice recordings, video recordings, photographs, digital images collected solely for non-research purposes such as for diagnosis or treatment of disease. The research must not involve post-market research.  |
| --- |
| **Please give details. Click □ to select applicable items.****Sources of data.**[ ]  Medical records, please specify. [ ]  Suranaree University of Technology Hospital [ ]  Others, please specify………………………… (*Note*: Attach a letter of permission request to use the data from the hospital director or from a person who has authority to grant permission for data use). [ ]  Data from documents or records. Please specify. Types of data ............................................................................Sources of data ...................................................................(*Note*: Attach a letter of permission request to use the data from a person who has authority to grant permission for data use).[ ]  Data from voice recordings, video recordings, photographs, digital images. Please specify. Types of data ............................................................................Sources of data ...................................................................(*Note:* In case the data is not accessible by the public, attach a letter of permission request to use the data from a person who has authority to grant permission for data use).**Dates of data to be studied (More than one items that are applicable to your research can be selected).**[ ]  Data already collected from ………….(date/month/year)…………… to ……………( date/month/year)…………..……[ ]  Data to be prospectively collected from ……………(date/month/year)……… to ………( date/month/year)………**Collected data** **General**: [ ]  age [ ]  sex [ ]  body weight [ ]  height [ ]  marital status [ ]  level of education[ ]  occupation [ ]  income [ ]  domicile [ ]  Others, please specify ……………………………………………**Specific data**: [ ]  diagnosis [ ]  stage of disease [ ]  comorbidity [ ]  blood results, please specify …………………………………[ ]  pathological test results, please specify………………………………………………………………………………………….. [ ]  results of radiological / diagnostic images, please specify.…………………………………………………………….. [ ]  others, please specify …………………………………………………………………………………………………………………………**In case the research involves clinical data from patients’ medical records, a physician or dentist specializing in the topic / disease to be researched is included in the investigative team. Please specify their name: Dr**.…………............................................................................................................................................. |

| **Part 2, Item 5 as per Announcement item 5.5 — Research that uses data in the forms of voice, videos, digital or image recordings that were collected for research purposes.** |
| --- |
| **Please give details. (Click □ to select).****Types of data to be used** [ ]  voice recordings [ ]  video recordings [ ]  image recordings [ ]  digital recordings **Method of data collection** Please specify…………………………………………………………………………………………………………… **Period of data collection** from ………….……. (date/month/year)………………… to ……………….( date/month/year)……………… |

| **Part 2, Item 6 as per Announcement 5.6 —** Research that uses leftover specimens and/or surplus blood, or laboratory research that uses the same specimens as those used in earlier protocols that were approved by the ethics committee. |
| --- |
| **Please give details. (Click □ to select applicable items).****Types of specimens to be studied** [ ]  Blood [ ]  Urine [ ]  Stool [ ]  Tissue biopsy [ ]  Others, please specify…………………………………………….**How the specimens are obtained** [ ]  ***From routine medical service***Which organization .....................................................................................................................How the specimens are obtained ..........................................................................................(*Note*: Attach a letter of permission request to use the data from the hospital director or from a person who has authority to grant permission for data use)[ ]  ***Leftover specimens from research that was previously approved by an ethics committee*** Name of research protocol.........................................................................................................................................Names of ethics committee that approved the previous research..................................................................(*Note: Attach a signed letter expressing permission to use the leftover specimens from the previous research’s principal investigator, Information Sheet from the previous research, and ethics committee’s certificate of approval of the previous research*).**Do the biological specimens that will be used contain information that can be linked directly or indirectly to the subjects, e.g., name, citizen identification number, hospital number, social security number, or other identification card numbers?** [ ]  Data cannot be linked to the subjects[ ]  Data can be linked to the subjects, but the researcher will de-identify the data to remove direct linkage to individual subjects **(Note: The researcher must carefully carry out the research in order to protect the subjects’ confidential information by removing linkage to the subjects or the owners of the information both during the research process and publication).** |

|  |
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| **Part 3: Information for ethic consideration (Click □ to select applicable items).** |

1. **Data collection**

|  |  |
| --- | --- |
| [ ]  | Prospective data collection (Subjects’ consent must be obtained) |
| [ ]  | Retrospective data collection **only with no prospective data collection nor request for additional information from the subjects** (Attach a letter of permission request to use the data from the hospital director or from a person who has authority to grant permission for data use). |
| [ ]  | Prospective and retrospective data collections (Subjects’ consent must be obtained for prospective data collection and attach a letter of permission request to use the data from the hospital director or from a person who has authority to grant permission for data use).  |

1. **The subjects**
	1. **Is data collected from any of the following vulnerable subjects (those who cannot make decisions in a critical situation)? (Click to select applicable items).**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [ ]  | No |  |  |  |
| [ ]  | Yes, please specify |  |  |  |
|  | [ ]  Infants, children  | [ ]  Pregnant women | [ ]  The elderly  | [ ]  Patients with chronic diseases  |
|  | [ ]  The disabled  | [ ]  Prisoners  | [ ]  Alien labors | [ ]  The socially disadvantaged  |
|  | [ ]  Those who cannot give consent on their own behalf | [ ]  Subordinates  |
|  | [ ]  Students (In case the researcher is their teacher) |
|  | [ ]  Others, please specify ................................................................................................................ |

* 1. **What method is used in recruiting potential research subjects?**

|  |  |
| --- | --- |
| [ ]  | **There is no** recruitment of potential subjects.  |
| [ ]  | Potential research subjects **are recruited** by |
|  | [ ]  asking for cooperation from the potential subjects’ attending physician [ ]  posters, please state where the posters will be posted……………………………………………………(*Note*: Please submit the poster for the ethics committee’s consideration).[ ]  Advertisement in prints or radio, please give details ……………….…………………………….…….…(*Note*: Please submit the advertisement message or content for the ethics committee’s consideration).[ ]  Advertisement via online social media or other chat applications where measures are put in place to prevent adding inducing statements or any modification of the messages initially approved by the ethics committee, during the process of online sharing. Please give details…...…………………………………………………………………………………………………………………………………………………………… [ ]  Others, please give details ………………………………………………………………………………………………………  |

* 1. **Are monetary compensations or rewards given for subjects’ time and travel expenses?**

|  |  |
| --- | --- |
| [ ]  | No |
| [ ]  | Yes [ ]  Monetary compensation, please indicate number of payments ………., and amount of each payment ……………………. baht[ ]  Rewards or gifts, please give details.………………………………………………………………………… |

1. **The process of obtaining subjects’ consent**

|  |  |
| --- | --- |
| [ ]  | **Waiver of informed consent** as this is a study of existing data or biological specimens without further prospective data collection from or direct interactions with the subjects  |
| [ ]  | **Waiver of informed consent as all** the following conditions are present. 1. The research involves no more than minimal risk to the subjects (no greater than those encountered in daily life). Please give details...........................................................................
2. Waiving the informed consent does not affect the rights and welfare of the subjects. Please give details ..........................................................................................................................
3. The researcher cannot carry out the study if the informed consent is not waived. Please give details…………………………………...................................................................
4. Will the subjects be further notified about the study, and how will they receive the information? Please give details…………………………………....................................................
 |
| [ ]  | **Signed written** consent (Please attach the Information Sheet and informed consent).  |
| [ ]  | **Verbal consent** asboth of the following conditions is present (Please attach the Information Sheet).1. The research involves no more than minimal risk to the subjects (no greater than those encountered in daily life) and does not involve procedures for which written consent is normally required (e.g., diagnostic procedures, treatment procedures). Please give details and reasons…………………………………………………………………………………………………….
2. Signing the informed consent form is the only information that links the identity of the subjects with the research study, and the major risk to the subjects is danger due to having their identity revealed through data breach.

Please give details and reasons…………………………………………………………………………………… |
| [ ]  | **Implied consent by action**, that is, anonymously completing a self-response questionnaire and returning the questionnaire to the researcher |

1. **Explain the process of asking for consent from the subjects, if applicable.**
	1. Who asks for consent from the subjects?.......................................................

(Note: The person who asks for consent should be a person who does not have influence over the subjects as to unduly induce the subjects to comply, e.g., doctors should not ask for consent from their patients nor should teachers ask for consent from their students).

* 1. When are the subjects asked for consent?........................................................

(Note: Specify the period of time or situation in which the researcher asks for consent. Ample opportunity and time must be allowed for the subjects to study the information regarding participation in the research and are allowed to ask any questions they may have regarding participation).

* 1. Where does the consent take place?.............................................................

(Note**:** Clearly specify the place where consent is asked — the place must provide privacy and keep confidentiality of the subjects as well as convenience for the subjects to ask questions about the research and understand the process of becoming a participant in the study).

1. **What methods does the researcher use to carefully keep the subjects’ confidentiality and remove linkage to the patients or owners of data both while conducting research and publication. Please give details.** ……………………………………………………………………………………………………………………………………………………..…
2. **Is this a multicenter study?**

|  |  |
| --- | --- |
| [ ]  | No |
| [ ]  | Yes, please specify. Name of a main organization responsible for the research study………………………………………………….……………………………………………………………………………………………………………………………………………………………. Name of the principal investigator from the main organization responsible for the research study ……………………………………………………………………………………………………..………………………………………..…Name of all participating organizations 1. …………………………………………..…………..
2. …………………………………………..…………..
3. …………………………………………..…………..
 |

1. **Sponsors**

**Please specify the source of budget for this study**

|  |  |
| --- | --- |
| [ ]  | Researcher’s private fund  |
| [ ]  | Suranaree University of Technology funds, please give details.…… |
| [ ]  | External source of governmental funds, please give details ……………………………………….…………….… |
| [ ]  | External source of funds from NGOs, please give details ……………………………………………………………... |
| [ ]  | External source of funds from private companies, please give details…………………………………………  |

1. **Researchers’ conflict of interest**

|  |  |
| --- | --- |
| [ ]  | The principal investigator AND co-investigators do not have a conflict of interest in this study.  |
| [ ]  | The principal investigator OR co-investigator(s) do have a conflict of interest in this study. Please give details. 1. Name of investigator who has the conflict of interest……………………………………………………
2. Characteristics of conflicts of interest

[ ]  Holding shares of the sponsoring company, please give the number of shares held.[ ]  Holding copyright or patent of the drug or medical device used in the study. [ ]  Receiving a monthly salary of ..................................baht for consultancy from the sponsoring company [ ]  Being invited to be a lecturer at the company or receiving support to attend a conference abroad in the past year, please give details. .............................................[ ]  Others, please give details………………………………………………………………………… How will the researcher handle the conflict of interest so that the well-being of subjects and accuracy of research data are not affected? Please specify ………………………………………………… |

1. **This research study will proceed only after approval from the ethics committee and** is expected to spana total period of………. year(s) ………. month(s)

1. **I hereby verify that the above information is truthful,** **and that I clearly understand all the information given.**

|  |  |
| --- | --- |
| Signature………………………………….……… |  Signature ………………….…………… |
| (……………………………….…………) |  (……………………………….……………) |
| Project AdvisorIn case the principal investigator is a student/ /resident |  Principal investigator |

 Signature ……………………….………

 (……………………………)

 Co-investigator

 Signature ……………………….………….…

 (……………………………………)

 Co-investigator

 Signature ……………………….………….

 (……………………………)

 Co-investigator

**This protocol has been approved by the affiliated organization.**

Signature ………………………………….………….……………

 (……………………………….……………)

 Chair, School of …………………………

Signature ………………………………….………….……………

 (……………………………….……………)

 Head, research department

Signature ………………………………….………….……………

 (……………………………….……………)

 Dean, Institute of……………………………………….