**Dear Researcher,**

The scope of Yeditepe University, Non-Interventional Clinical Research Ethical Board is listed below:

* Survey studies
* Studies based on retrospective archive scanning (Previous file records, image recordings, etc.)
* Research to be carried out with materials obtained during routine examination, examination, analysis or treatment
* Cell or tissue culture studies
* Studies to be carried out with human genetic material outside of gene therapy clinical studies, and for identification purposes
* Research to be carried out within the boundaries of nursing activities
* Nutritional research
* Research on human body physiology (Exercise, etc.)
* Research based on anthropometric measurements
* Evaluation studies of living habits

Even though ‘Medicational observation studies and/or medical device observational studies’ are non-interventional these studies are not evaluated within this board.

If the researches that are planned involve ‘**blood collection, tissue collection, urine collection, medical or dental examination, dental extraction, medical imaging**, etc.’ these are considered as interventional studies and are **OUT OF THE SCOPE.**

Researches that require the **direct intervention of a human physician (medical doctor, dentist)** are considered as interventional studies and are **OUT OF SCOPE**.

Ethical principles and rules are evaluated by the methods of expressing opinions, monitoring, terminating, making decisions, and creating new principles and rules when necessary.

The outcome for the evaluation of the ethical board will be one of the “**Approval**,” “**Conditional-Approval**,” or “**Rejection**”.

**CONTENTS**

[CHECKLIST 3](#_Toc95058514)

[LETTER OF APPLICATION 4](#_Toc95058515)

[APPLICATION FORM 5](#_Toc95058516)

[APP 1. INFORMED CONSENT FORM 8](#_Toc95058517)

[APP 2. LETTER OF UNDERTAKING - 1 9](#_Toc95058518)

[APP 3. LETTER OF UNDERTAKING - 2 10](#_Toc95058519)

[APP 4. LETTER OF UNDERTAKING - 3 11](#_Toc95058520)

[APP 5. LETTER OF UNDERTAKING - 4 12](#_Toc95058521)

[APP 6. LETTER OF UNDERTAKING - 5 13](#_Toc95058522)

[APP 7. LETTER OF UNDERTAKING - 6 14](#_Toc95058523)

[APP 8. DECLARATION OF HELSINKI FORM 15](#_Toc95058524)

[APP 9a. RESEARCHER RESUME FORM – First-Author 19](#_Toc95058525)

[APP 9b. RESEARCHER RESUME FORM – Principal Investigator 20](#_Toc95058526)

[APP 9c. RESEARCHER RESUME FORM – Co-Author 1 21](#_Toc95058527)

[APP 9d. RESEARCHER RESUME FORM – Co-Author 2 22](#_Toc95058528)

[APP 9e. RESEARCHER RESUME FORM – Co-Author 3 23](#_Toc95058529)

[APP 9f. RESEARCHER RESUME FORM – Co-Author 4 24](#_Toc95058530)

[APP 9g. RESEARCHER RESUME FORM – Co-Author 5 25](#_Toc95058531)

# CHECKLIST

|  |
| --- |
|[ ]  Yeditepe University Non-Interventional Clinical Research Ethics Board **Application Form** has been filled completely following the issues explained in this document, and a printout has been obtained. |
|[ ]   **Informed Consent Form** has been generated for the submitted research specifically and meets the minimum requirements (The minimum requirements have been explained on the Ethics Board website). |
|[ ]   **Letter of Undertaking Forms** have been **wet-signed** by all the researchers. |
|[ ]  The designated sign section under each page of the **Helsinki Declaration Form** has been **wet-signed** by all the researchers. |
|[ ]  **Resume Forms** have been filled and **wet-signed** by each researcher. |
|[ ]  All the pages of this application document have been filled, printed, and the pages with the wet-signs have been scanned as A4 size pages, and this document is saved as **one single PDF file**. This PDF file has been ready to be uploaded to the Electronic Application system. Also, the PDF file has been saved on a storage medium (CD, DVD or USB stick).  |
|[ ]  The first-author or principal investigator has declared that they will send the hard-copy of this document with wet-signs, and the storage medium, to the Ethics Board Secretariat, within five (5) business days following the Electronic Application. |
|[ ]  The first-author or principal investigator has declared that the hard-copy document and the storage medium delivery will be performed prior to the scheduled meeting of the Ethics Board. |
|[ ]  The first-author and/or principal investigator and co-author(s) have agreed to participate the board meeting if requested. |

**FOOTER**

* The footer section of this form will be filled out by **double clicking** on footer below.
* The **Title of Research** and **Researchers** sections which can be found as a footer on all pages of the document should be filled with the names of all the researchers with their respective titles and full names (surnames will be capitalized). (e.g. Dr. Demir KARA). (**Do not use any titles for the students**).
* If the researcher is a thesis student, the first name should be the **thesis student (First-Author),** and the secondary name should be the **thesis advisor (Principal Investigator)**.

**(e.g. to fill out the Researchers section below: Tom JONES, Lec.Dr. Tom SILVER, Prof.Dr. Celine ALLY)**

# LETTER OF APPLICATION

 Click to choose a date

**YEDİTEPE UNIVERSITY**

**TO THE NON-INTERVENTIONAL CLINICAL RESEARCH ETHICAL BOARD,**

I kindly submit this research project, of which I am the Principal Investigator, titled Click to enter Research Title to be evaluated ethically to Yeditepe University Ethical Board for Non-Interventional Clinical Research.

(Note: The Principal Investigator is the thesis advisor for thesis projects, while the first-author is the thesis student. (One Principal Investigator may submit **a maximum of two (2) projects** to the same meeting.)

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator (Thesis advisor/ last name in projects) |  |  |  |
| Title, Full Name | Phone Number | E-Mail Address | Signature |
| Click to input text | Click to input the number | Click to input text |  |
|  |  |  |
|  |  |  |
| Institution | Faculty, Department |  |  |
| Click to input text | Click to input text |

# APPLICATION FORM

Click to choose a date

|  |
| --- |
| **Applications in which all the articles below the titles have not been filled appropriately will be rejected.****TITLE OF THE RESEARCH** * The title should provide an idea about the whole research.
* It should neither be too short nor too long.
* The title should include the research group and variables and provide information regarding the type of research.
* The title should not include abbreviations.
* The title should be clear and easy to understand and cover the study’s type, variables, and sample.
 |
| Click to input text |
| RESEARCHERS (The names and titles will be written as indicated below)* Titles, full names, institutions, phone numbers, and e-mail addresses of the researchers should be included.
* Principal Investigator: He / They are the researcher responsible for conducting the research (In thesis research, the principal investigator is the **thesis advisor**). In personal research studies, the principal investigator is the researcher with a minimum Ph.D. / Specialist title.
* First-Author: He / They are the researcher conducting the research (If the research is a thesis, they are the **thesis** **student**).
* Other Researchers: The other researchers sorted by their contribution to the research.

 (e.g Tom JONES, Lec.Dr. Tom SILVER, Prof.Dr. Celine ALLY) |
| Click to input text |
| TYPE OF RESEARCH (The relevant box type will be checked)* The type of research should be determined by marking the correct option provided within the form.
* If the “Other” option is chosen from the boxes, additional information will be provided.
 |
|[ ]  Personal Research Project |[ ]  Doctoral Thesis |[ ]  Dissertation |[ ]  Master’s Thesis |[ ]  Undergraduate Thesis |
|[ ]  Other, Please Specify:  | Click to input text |

|  |
| --- |
| SIGNIFICANCE AND DISTINCTIVE VALUE (The bullets indicated below will be all included)* The problem/question of the research should be disclosed fully and explicitly..
 |
| Click to input text |
| * Sufficient information (Known and unknown details regarding the topic) should be provided about the problem/question of the research.
 |
| Click to input text |
| * Topics and concepts investigated within the research should be identified, and necessary explanations should be provided.
 |
| Click to input text |
| * The genuineness of the research should be disclosed.
 |
| Click to input text |
| AIMS AND OBJECTIVES (The bullets indicated below will be all included)* The research aim should define the variables, target audience, and scope of the work..
 |
| Click to input text |
| * The type and/or pattern of the research should be identified
 |
| Click to input text |
| * The question/s posed by the research or hypotheses will be disclosed appropriately.
 |
| Click to input text |

|  |
| --- |
| METHOD (The bullets indicated below will be all included)* The type of research will be appropriate for the problem and aim..
 |
| Click to input text |
| * If the study is experimental, its design will be explained in detail.
 |
| Click to input text |
| * Dependent and independent variables of the research should be disclosed.
 |
| Click to input text |
| * The location where the research will take place should be disclosed.
 |
| Click to input text |
| * Population and sampling should be disclosed.
 |
| Click to input text |
| * Sample selection method/s should be disclosed.
 |
| Click to input text |
| * Sample size should be disclosed.
 |
| Click to input text |
| * The method to determine the sampling size should be explained.
 |
| Click to input text |
| * Data collection methods and tools should be explained in detail.
 |
| Click to input text |
| * Data collection methods and tools should be appropriate for the sample properties.
 |
| Click to input text |
| * The validity and trustworthiness of the measurement tools should be explained.
 |
| Click to input text |
| * Measures to be included or not included in the research should be disclosed.
 |
| Click to input text |
| * How to measure/evaluate the variables should be disclosed.
 |
| Click to input text |
| * Statistical methods to be used should be disclosed.
 |
| Click to input text |
| * Chosen statistical methods should be appropriate.
 |
| Click to input text |
| * For significance tests, the level of significance should be disclosed
 |
| Click to input text |
| MANAGEMENT OF THE RESEARCH (The bullets indicated below will be all included)* If there is a pre-application of the research, the relevant processes should be disclosed.
 |
| Click to input text |
| * How, under which conditions, when and for how long the data is to be gathered should be disclosed.
 |
| Click to input text |

|  |
| --- |
| WIDESPREAD IMPACT (The bullet indicated below will be all included)* The contribution of the research to the related scientific field should be disclosed.
 |
| Click to input text |

|  |
| --- |
| PERTINENCE OF THE BUDGET AND REASON (If applicable)* The budget of the research (if necessary) should be prepared. (Budget source also has to be disclosed)
* If there is none, it should be disclosed.
 |
| Click to input text |
| TIMEFRAME AND CONVENIENCE (Timetable will be added in line with the application date)* The whole timeframe in which the study will be conducted should be prepared in a **table** (**timetable format**), and within the table, the actions to be taken in each step should be disclosed.
 |
| Click to input table |
| REFERENCES (Vancouver format will be used and 8 references will be added at least as 5 of them will be up to date)* References should be prepared in **Vancouver** format. [Click here to get the format.](http://www.osirjournal.net/old/upload/files/2013/VANCOUVER_Reference_guide.pdf)
* All the literature cited in the reference list should be **clearly shown** **in the text** (at the end of a sentence, in parenthesis, in the order they appear).
* The literature used should be **up-to-date and adequate**.
 |
| Click to input text |

|  |
| --- |
| APPENDICES (Used appendices will be indicated and written to the section below)* Letter of undertaking with original signature by all the researchers should be present.
* An informed consent form should be prepared for the participants. The form for informed consent should be included in the appendices (Minimum requirements will be met when creating the informed consent form. These requirements are provided at the website).
* The permission to use the measurement tools (scales, inventories, etc.) should be taken. The documents for the permission should be included in the appendices. These appendices should begin with APP10

 (e.g. APP10: Scale use permission APP11: Questionnaire use permission) |
| Click to input text  |

# APP 1. INFORMED CONSENT FORM

* The researcher will prepare the Informed Consent Form **uniquely for their research**.
* The **existent consent form of the institution will not be acceptable**.
* **Minimum requirements** for adults, children, and retrospective researchers are provided on our website.
* Researchers will prepare an Informed Consent Form including all the minimum requirements and other conditions that their research requires and add it below.
* If the Informed Consent form font size is not precisely the same as was the text on this page, **the form will also be added as appendix**. Click on the box below to place the image of the document.

|  |
| --- |
|  |

# APP 2. LETTER OF UNDERTAKING - 1

Click to choose a date

**YEDİTEPE UNIVERSITY**

**TO THE NON-INTERVENTIONAL CLINICAL RESEARCH ETHICAL BOARD,**

As all the researchers participating in the research entitled Click here to input the Research Title, we declare and undertake that the responsibility of obtaining the necessary permissions from the institution where the data collection part of the research proposal will be made belongs to all researchers named in the research.

|  |  |  |
| --- | --- | --- |
| First-Author (Thesis Student/ First name) |  | Principal Investigator (Thesis Advisor/ Last name)  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Other Researchers |  |  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |

TO READ AND ACCEPT THE LETTER OF UNDERTAKING, ALL RESEARCHERS WILL WRITE THEIR NAMES AND SIGN

# APP 3. LETTER OF UNDERTAKING - 2

Click to choose a date

**To whom it may concern,**

As all the researchers participating in the research entitled **Click to input Research Title**, we declare and undertake that we have read the latest version of the World Health Organization’s Declaration of Helsinki and all the relevant guides of the Ministry of Health, our study will be conducted in accordance with the national and international regulations, we acknowledge all the legal and financial responsibilities that may arise during the research, and all the participating departments and participants have been informed.

|  |  |  |
| --- | --- | --- |
| First-Author (Thesis Student/ First name) |  | Principal Investigator (Thesis Advisor/ Last name)  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Other Researchers |  |  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |

TO READ AND ACCEPT THE LETTER OF UNDERTAKING, ALL RESEARCHERS WILL WRITE THEIR NAMES AND SIGN

# APP 4. LETTER OF UNDERTAKING - 3

Click to choose a date

**To whom it may concern,**

Research proposal titled Click here to input Research Title

|  |
| --- |
|[ ]  Have never been previously proposed in any ethical board in Turkey. |
|[ ]  Have been proposed to an ethical board\*, asked for corrections, and withdrawn. |
|[ ]  Have been proposed to an ethical board\* and “Rejected”. |
|[ ]  Have been proposed to an ethical board\* and withdrawn before evaluation. |
| \* | Click to input the name of the ethical board |

|  |  |  |
| --- | --- | --- |
| First-Author (Thesis Student/ First name) |  | Principal Investigator (Thesis Advisor/ Last name)  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Other Researchers |  |  |
| Title, Full name | Signature |  | Title, Full name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Title, Full name | Signature |  | Title, Full name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Title, Full name | Signature |  | Title, Full name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |

TO READ AND ACCEPT THE LETTER OF UNDERTAKING, ALL RESEARCHERS WILL WRITE THEIR NAMES AND SIGN

# APP 5. LETTER OF UNDERTAKING - 4

Click to choose a date

**To whom it may concern,**

During the research entitled **Click to input Research Title**, we undertake that no procedures are not present in the research budget and might incur additional charges to the volunteer or the Social Security Institution. We will take full responsibility for that matter.

|  |  |  |
| --- | --- | --- |
| First-Author (Thesis Student/ First name) |  | Principal Investigator (Thesis Advisor/ Last name)  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Other Researchers |  |  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |

TO READ AND ACCEPT THE LETTER OF UNDERTAKING, ALL RESEARCHERS WILL WRITE THEIR NAMES AND SIGN

# APP 6. LETTER OF UNDERTAKING - 5

Click to choose a date

**To whom it may concern,**

To be followed during the research entitled **Click to input Research Title** we have read and been informed about the memorandum number 2020/02 “TREATMENT APPROACHES AND SCIENTIFIC RESEARCHERS IN COVID-19 PATIENTS”, dated 16.04.2020 and with E.96795 document number by the R.T. Ministry of Health and Turkish Medicines and Medical Devices Agency.

|  |  |  |
| --- | --- | --- |
| First-Author (Thesis Student/ First name) |  | Principal Investigator (Thesis Advisor/ Last name)  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Other Researchers |  |  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |

TO READ AND ACCEPT THE LETTER OF UNDERTAKING, ALL RESEARCHERS WILL WRITE THEIR NAMES AND SIGN

# APP 7. LETTER OF UNDERTAKING - 6

Click to choose a date

**To whom it may concern,**

To be followed during the research entitled **Click to input Research Title**, we have read and been informed about the memorandum number 2020/02 “RESEARCH APPLICATION PERMISSIONS”, dated 21.01.2020 and with E.1563890 document number by the R.T. Ministry of Education, Directorate of Innovation and Educational Technologies

|  |  |  |
| --- | --- | --- |
| First-Author (Thesis Student/ First name) |  | Principal Investigator (Thesis Advisor/ Last name)  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |
| **Other Researchers** |  |  |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title, Full Name | Signature |  | Title, Full Name | Signature |
| Click to input text |  |  | Click to input text |  |
|  |  |  |

TO READ AND ACCEPT THE LETTER OF UNDERTAKING, ALL RESEARCHERS WILL WRITE THEIR NAMES AND SIGN

# APP 8. DECLARATION OF HELSINKI FORM

Click to choose a date

Declaration of Helsinki, Ethical Principles in Medical Research Involving Human Subjects, Prepared by WMA

A. INTRODUCTION

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. The Declaration is intended to be read as a whole, and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.
2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.
3. It is the duty of the physician to promote and safeguard the health, well-being, and rights of patients, including those who are involved in medical research. The physician’s knowledge and conscience are dedicated to the fulfillment of this duty.
4. The Declaration of Geneva of the WMA binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that “A physician shall act in the patient’s best interest when providing medical care.”
5. Medical progress is based on research that must ultimately include human subjects’ studies. Groups underrepresented in medical research should be provided appropriate access to participation in research.
6. The subject’s well-being must precede all the other benefits in medical research involving human subjects.
7. The primary purpose of medical research involving human subjects is to understand the causes, development, and effects of diseases and improve preventive, diagnostic, and therapeutic interventions (methods, procedures, and treatments). Even the best-proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility, and quality.
8. In medical practice and medical research, most interventions involve risks and burdens.
9. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or incurring additional harm. All vulnerable groups and individuals should receive specifically considered protection. Among these groups, those who cannot give or refuse to consent themselves and those exposed to oppression and adverse effects can be named.
10. Physicians must consider the ethical, legal, and regulatory norms and standards for research involving human subjects in their own countries and applicable international norms and standards. No national or international ethical, legal, or regulatory requirement should reduce or eliminate any protections for research subjects set forth in this Declaration.

B. FUNDAMENTAL PRINCIPLES IN ALL MEDICAL RESEARCH

1. It is the duty of physicians involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.
2. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.
3. Adequate care must be paid to when conducting research that may be harmful to the environment.

|  |
| --- |
|  |

TO READ AND ACCEPT THE DECLARATION, ALL RESEARCHERS WILL SIGN BY THEIR NAMES IN ORDER

1. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol. The protocol should contain a statement of the ethical considerations involved and shindicate how this Declaration's principlesave been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects, and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol must also describe the arrangements for subjects’ access to the treatments, defined as beneficial during the research, after the research is conducted, or access to other appropriate treatments and provisions.
2. Before the study begins, the research protocol must be submitted for consideration, comment, guidance, and approval to the concerned research ethics committee. This committee must be transparent in its functioning, independent of the researcher, the sponsor, and any other undue influence, and duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards, but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee.
3. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training, and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for protecting research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.
4. Medical research with a vulnerable group is only justified if the research is responsive to this group’s health needs or priorities and the research cannot be carried out in a non-vulnerable group. In addition, this group should benefit from the knowledge, practices, or interventions that result from the research.
5. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research compared to foreseeable benefits to them and other individuals or groups affected by the condition under investigation.
6. Every research study involving human subjects must be registered in a publicly accessible database before the recruitment of the first subject.
7. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and satisfactorily managed. When the risks outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must immediately stop the study.
8. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.
9. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.
10. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and minimize the impact of the study on the physical, mental, and social integrities of the subjects.
11. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage, and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations, the research may be done only after consideration and approval of a research ethics committee.

|  |
| --- |
|  |

TO READ AND ACCEPT THE DECLARATION, ALL RESEARCHERS WILL SIGN BY THEIR NAMES IN ORDER

1. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Particular attention should be given to the specific information needs of individual potential subjects and the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must seek the potential subject’s freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.
2. When seeking informed consent for participation in a research study, the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations, informed consent must be sought by an appropriately qualified individual who is entirely independent of this relationship.
3. For a potential research subject incapable of giving informed consent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.
4. When a potential research subject who is deemed incapable of giving informed consent can give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject’s dissent should be respected.
5. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances, the physician must seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with the condition that renders them unable to give informed consent have been stated in the research protocol and a research ethics committee has approved the study. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorized representative.
6. Researchers, authors, sponsors, editors, and publishers all have ethical obligations concerning the publication and dissemination of the results of research. Researchers must make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative, inconclusive, and positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations, and conflicts of interest must be declared in the publication. Reports of research not following the principles of this Declaration should not be accepted for publication.

C. ADDITIONAL PRINCIPLES REGARDING CLINICAL TRIALS COMBINED WITH CLINICAL TREATMENT

1. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

|  |
| --- |
|  |

TO READ AND ACCEPT THE DECLARATION, ALL RESEARCHERS WILL SIGN BY THEIR NAMES IN ORDER

1. The benefits, risks, burdens, and effectiveness of a new intervention must be tested against those of the best-proven intervention(s), except in the following circumstances; Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; Or, where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention. The patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best-proven intervention. Extreme care must be taken to avoid abuse of this option.
2. All medical research subjects have the right to be informed about the general outcome and results of the study, to share all the benefits as a result of the research; for instance, methods deemed beneficial in research, or other appropriate treatments and benefits.
3. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient’s decision to withdraw from the study must never adversely affect the patient-physician relationship.
4. In the treatment of an individual patient, where proven interventions do not exist, or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician’s judgment it offers hope of saving a life, re-establishing health, or alleviating suffering. This intervention should subsequently be made the research object, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.

|  |
| --- |
|  |

TO READ AND ACCEPT THE DECLARATION, ALL RESEARCHERS WILL SIGN BY THEIR NAMES IN ORDER

# APP 9a. RESEARCHER RESUME FORM – First-Author (Thesis Student/ First name)

Click to choose a date

|  |  |  |  |
| --- | --- | --- | --- |
| A. Personal Information |  |  |  |
| Title, Full Name | Phone Number | E-mail (Institutional) | Signature |
| Click to input text | Number | Click to input text |  |
|  |  |  |
|  |  |  |
| Birthplace and Date | Assigned Position  |  |  |
| Click to input text | Click to input text |
| Postal Address |  |  |  |
| Click to input text |

|  |
| --- |
| B. Educational Information |
| Year | Degree | University |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

|  |
| --- |
| **C. Academic Information** |
| Year | Title | University |
|  Click  | Click to input text | Click to input text |
|  Click  | Click to input text | Click to input text |
|  Click  | Click to input text | Click to input text |

|  |
| --- |
| **D. Principal Publications** (Up to three) |
| Year | Title | Journal |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

# APP 9b. RESEARCHER RESUME FORM – Principal Investigator (Thesis Advisor/ Last name)

Click to choose a date

|  |  |  |  |
| --- | --- | --- | --- |
| **A. Personal Information** |  |  |  |
| Title, Full Name | Phone Number | E-mail (Institutional) | Signature |
| Click to input text | Number | Click to input text |  |
|  |  |  |
|  |  |  |
| Birthplace and Date | Assigned Position  |  |  |
| Click to input text | Click to input text |
| Postal Address |  |  |  |
| Click to input text |

|  |
| --- |
| **B. Educational Information** |
| Year | Degree | University |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

|  |
| --- |
| **C. Academic Information** |
| Year | Title | University |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

|  |
| --- |
| **D. Principal Publications (Up to three)** |
| Year | Title | Journal |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

# APP 9c. RESEARCHER RESUME FORM – Co-Author 1

Click to choose a date

|  |  |  |  |
| --- | --- | --- | --- |
| **A. Personal Information** |  |  |  |
| Title, Full Name | Phone Number | E-mail (Institutional) | Signature |
| Click to input text | Number | Click to input text |  |
|  |  |  |
|  |  |  |
| Birthplace and Date | Assigned Position  |  |  |
| Click to input text | Click to input text |
| Postal Address |  |  |  |
| Click to input text |

|  |
| --- |
| **B. Educational Information** |
| Year | Degree | University |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

|  |
| --- |
| **C. Academic Information** |
| Year | Title | University |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

|  |
| --- |
| **D. Principal Publications (Up to three)** |
| Year | Title | Journal |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

# APP 9d. RESEARCHER RESUME FORM – Co-Author 2

Click to choose a date

|  |  |  |  |
| --- | --- | --- | --- |
| **A. Personal Information** |  |  |  |
| Title, Full Name | Phone Number | E-mail (Institutional) | Signature |
| Click to input text | Number | Click to input text |  |
|  |  |  |
|  |  |  |
| Birthplace and Date | Assigned Position  |  |  |
| Click to input text | Click to input text |
| Postal Address |  |  |  |
| Click to input text |

|  |
| --- |
| **B. Educational Information** |
| Year | Degree | University |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

|  |
| --- |
| **C. Academic Information** |
| Year | Title | University |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

|  |
| --- |
| **D. Principal Publications (Up to three)** |
| Year | Title | Journal |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

# APP 9e. RESEARCHER RESUME FORM – Co-Author 3

Click to choose a date

|  |  |  |  |
| --- | --- | --- | --- |
| **A. Personal Information** |  |  |  |
| Title, Full Name | Phone Number | E-mail (Institutional) | Signature |
| Click to input text | Number | Click to input text |  |
|  |  |  |
|  |  |  |
| Birthplace and Date | Assigned Position  |  |  |
| Click to input text | Click to input text |
| Postal Address |  |  |  |
| Click to input text |

|  |
| --- |
| **B. Educational Information** |
| Year | Degree | University |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

|  |
| --- |
| **C. Academic Information** |
| Year | Title | University |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

|  |
| --- |
| **D. Principal Publications (Up to three)** |
| Year | Title | Journal |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

# APP 9f. RESEARCHER RESUME FORM – Co-Author 4

Click to choose a date

|  |  |  |  |
| --- | --- | --- | --- |
| **A. Personal Information** |  |  |  |
| Title, Full Name | Phone Number | E-mail (Institutional) | Signature |
| Click to input text | Number | Click to input text |  |
|  |  |  |
|  |  |  |
| Birthplace and Date | Assigned Position  |  |  |
| Click to input text | Click to input text |
| Postal Address |  |  |  |
| Click to input text |

|  |
| --- |
| **B. Educational Information** |
| Year | Degree | University |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

|  |
| --- |
| **C. Academic Information** |
| Year | Title | University |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

|  |
| --- |
| **D. Principal Publications (Up to three)** |
| Year | Title | Journal |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

# APP 9g. RESEARCHER RESUME FORM – Co-Author 5

Click to choose a date

|  |  |  |  |
| --- | --- | --- | --- |
| **A. Personal Information** |  |  |  |
| Title, Full Name | Phone Number | E-mail (Institutional) | Signature |
| Click to input text | Number | Click to input text |  |
|  |  |  |
|  |  |  |
| Birthplace and Date | Assigned Position  |  |  |
| Click to input text | Click to input text |
| Postal Address |  |  |  |
| Click to input text |

|  |
| --- |
| **B. Educational Information** |
| Year | Degree | University |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

|  |
| --- |
| **C. Academic Information** |
| Year | Title | University |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

|  |
| --- |
| **D. Principal Publications (Up to three)** |
| Year | Title | Journal |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |
| Click | Click to input text | Click to input text |

*In case there are more than five Co-Authors, a Resume Form for additional co-author should be prepared and included in the application file.*