IRB Submission Checklist

To facilitate the review of your IRB application, please use the following as a checklist (Check all boxes when completed):

☐	1. Completed an IRB approved training and submit record of the training completion with application;
☐	2. Filled out an IRB Review form and respond to all questions;
☐	3. Included a copy of the consent form (or script for oral consent when applicable) with required components as suggested by the sample consent form;
☐	4. Provided copies of research protocols and instruments
☐	a. Interview questions for each type of participant included (e.g., one for student participants and one for faculty participants, if applicable)
☐	b. Description of procedures for study conditions
☐	c. Copies of questionnaires or instruments
☐	d. Translations of materials if your participants are not highly proficient in English
☐	5. Included examples of recruitment materials (e.g., flyers, texts of email recruitment, verbal scripts, etc.);
☐	6. Submitted all documentation at **least 30 days prior** to the desired research start date;
☐	7. Responded to IRB questions as soon as possible (within two working days) to facilitate a more timely decision to the IRB application; and
☐	8. Do **NOT** begin research until receiving approval from the Renton Technical College IRB!

For questions, please contact:

Lia Homeister
Director of Institutional Research & Effectiveness
lhomeister@rtc.edu
(425) 235-2212

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FOR IRB OFFICE USE ONLY

APPLICATION NUMBER:		☐ **APPROVED**	**DATE RECEIVED STAMP:**
☐ **MASTER COPY**		☐ **REVISIONS REQUIRED**	
☐ **RESEARCHER COPY**		☐ **DISAPPROVED**	
IRB STAFF SIGNATURE:			
SIGNATURE DATE:			

Institutional Review Board
Application to Use Human Participants in Research

1. **PROJECT REVIEW**
   The Faculty Advisor(s), Student Researcher(s), and External Researcher(s) MUST complete an online training in Human Subjects before submitting an IRB application (see training options). Include a completed copy of training or a summary and log (date, time, training attended) of the training with the IRB application.

   ◉ New IRB Project (ID # assigned by IRB):
   ○ IRB Resubmission project (Enter IRB ID # assigned):
   For resubmission include date of most recent previous review:

2. **DATA COLLECTION DATES**: From to
   Required Information: Data collection dates should give time for the IRB to review your protocol. Please allow 30 days from the date you turn the application in as the protocol start date (Example: if today's date was January 1, 2XXX please use January 31, 2XXX as the start date).

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3. **INVESTIGATOR(S)**
(Copy and paste additional investigator names as needed. If this is a student project, the faculty advisor should be listed as a Co-Investigator and as the approving faculty advisor).

Student or Faculty Investigator Name:	
Department:	
Phone Number:	
Email:	
Faculty Advisor Name:	
Department:	
Phone Number:	
Email:	
Purpose of the Research:	

4. **PROJECT TITLE:**

5. **PARTICIPANTS** (approximate number and all applicable categories):
Number of participants proposed: ( )

☐ Female ☐ Male ☐ Other:

☐ RTC students
☐ Children (17 or younger)
☐ Prisoners
☐ Patients in institutions
☐ Pregnant women
☐ Other:

6. **FUNDING:** Project period from ( ) to ( )

Are you seeking funding for this research? ◉ No ○ Yes
If yes, submit one copy of the proposal summary or abstract with the application.

Does the funding agency require IRB approval? ◉ No ○ Yes ○ N/A
If yes, provide all relevant forms, instructions, etc. with this application.

7. **REVIEW CATEGORY**: Please mark all items that apply.
Note: Most research with children cannot be reviewed under expedited review. The protocol would require either expedited or full board review. See OHRP regulations.

For Exempt Project status consideration, please complete the Exempt Review Form.

☐ **Expedited Review** (See OHRP Expedited Review Criteria List):

Note: Submit original and one copy of all application materials.

- ☐ Collection of data from voice, digital, or image recordings made for research purposes
- ☐ Moderate exercise, muscular strength testing, body composition and flexibility testing from healthy volunteers (excludes x-rays, or microwaves)
- ☐ Non-manipulative, non-stressful research on individual or group behavior
- ☐ Collection of biological specimens by noninvasive means
- ☐ Collection of blood samples by finger prick, heel stick, ear stick or venipuncture
- ☐ Study of existing data, documents, records, or pathological or diagnostic specimens
- ☐ Other: ( )

☐ **Full Board Review**: Involves vulnerable populations including children, prisoners, pregnant women, neonates, and fetuses.

Note: Include original application and one copy of all application materials.

8. **ATTACHMENTS**: All relevant project materials and documents, including:

- ☐ Surveys, questionnaires, interviews, and measurement instruments
- ☐ Informed Consent Form
- ☐ Assent script (for children when applicable)
- ☐ Include letters of approval/permission on letterhead from cooperating agencies, schools, board of education, school districts, and other agencies
- ☐ Debriefing statement or explanation sheet if applicable
- ☐ Participant recruitment materials (e.g., fliers, advertisements)
- ☐ Other: ( )

9. **AFFIRMATION OF COMPLIANCE**:

Note: Investigators or researchers are required to notify the IRB of substantive changes to protocol, unanticipated adverse, serious events experienced by participants, and project completion. Projects lasting longer than one year require an annual Request for Continuation (Protocol Renewal) or Notice of Project Ending by emailing the IRB staff member. Failure to submit may result in disciplinary action under the Research Misconduct Section XII of the RTC IRB Policy. The consent forms and data must be kept at least three years after the study ends.

I agree to follow the procedures outlined herein and to ensure that the rights and welfare of human participants are properly protected. I will commence the study only after receiving approval from the IRB and having complied with required modifications. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB by contacting the IRB staff member. If the project continues for more than one year from the approval date, I will submit the required documentation.

I affirm that I have read and reviewed the accuracy of this application and accept responsibility for the ethical conduct of this research, supervision of human participants, and maintenance of data and informed consent documentation as required by the IRB.

Signature of Investigator	**E-mail Address**	**Date**
Signature of Co-investigator	**E-mail Address**	**Date**

APPROVAL FROM FACULTY ADVISOR OR SPONSOR:

I affirm that I have proofread and reviewed the accuracy of this application and accept responsibility for the ethical conduct of research, student supervision, and documentation maintenance.

I agree to follow the procedures outlined herein for my student(s) and to ensure that the rights and welfare of human participants are properly protected. I will ensure the study does not commence until the study has been approved by the RTC IRB and having complied with required modifications. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB by contacting **the IRB Staff member**. ***If the project continues for more than one year from the approval date, I will submit the required documentation (copy and paste additional faculty advisor approval signatures and contact information lines as needed below.).***

Printed Name of Faculty Advisor	School/Department	Phone
Signature of Faculty Advisor	E-mail Address	Date

APPROVAL FROM LICENSED PHYSICIAN:

This signature is required only if the project involves medical procedures and neither the investigator nor the faculty advisor is a licensed physician.

Printed Name of Physician	E-mail Address	Phone
Signature of Physician	Date	

Filling out the Form Guidance: When writing each section below please be clear, concise, coherent. Define appropriate theories, methods used, and define abbreviations and acronyms as needed).

10. **RECRUITMENT OF PARTICIPANTS**:

Describe sources of potential participants, how they will be selected and recruited, and how and where you will contact them. Include all relevant characteristics with regard to age, ethnicity, sex, institutional status (i.e., patients or prisoners), and general state of physical and mental health.

Note: Recruitment issues can be especially critical when any federally defined "vulnerable population" is involved. This includes children, pregnant women, prisoners, others who are institutionalized, and anyone who might be at particular risk or whose cooperation might be dependent on coercions, no matter how slight.

(This section should be about 1-2 paragraphs – please attach info)

11. **DESCRIPTION OF THE PROJECT**:

Briefly describe the objectives and methodology of your research (including hypothesis and/or research questions), data collection procedures, and features of the research design that involve specific procedures or special conditions for participants (including frequency, duration, and location of participation.

It would be most helpful to organize this section with the following sub-headings:

a. Objectives of the Study
b. Hypothesis or Research Questions
c. Methodology (the design of the study)
d. Data Collection
e. Data Analysis
f. Dissemination

(This section should be about 2-3 pages – please attach info)

12. **CONFIDENTIALITY OF DATA**:

Clearly indicate specific procedures (e.g., coding of responses, aggregate reporting, etc.) to protect the confidentiality of participants and safeguard identifiable records and data. This includes safe and secure storage of the collected information and when the data will be destroyed after the data collection process has been completed. If not possible, state why.

(This section should be about 1-2 paragraphs – please attach info)

13. **RISKS AND BENEFITS**:

Describe in detail any immediate, short-term, or long-range risks that may arise for participants as a result of procedures associated with your study. Risks may be physical, psychological, social, legal, or economic; they would include side effects, risks of placebo, delay in customary treatment, etc. Indicate any precautions that will be taken to minimize risks. Also indicate any anticipated benefits to participants and/or society from the knowledge that may reasonably be expected to result from the study. Risks and benefits MUST BE included in the protocol and in the informed consent document.

(This section should be about 1-2 paragraphs – please attach info)

14. **INFORMED CONSENT**:

Informed consent is usually written; however, in some circumstances it may be oral or electronic in nature. Waivers of informed consent may be granted under certain limited conditions, and any request for such should include explicit justification. Remember that the informed consent should be unique to each study being proposed and should also be written at the 6th grade reading level or lower if needed. Attach the proposed informed consent form to this application.

The IRB requires a text of the proposed statement to be used for oral or electronic consent. Like written consent, they should include.

a. Identification of the researcher(s)
b. The nature and purpose of the study
c. Expected duration of participant involvement
d. How confidentiality or anonymity will be maintained
e. The voluntary nature of participation
f. Participants' right to withdraw at any time without penalty
g. Information about foreseeable risks and benefits (or none)

h. Contact information for questions or additional information
i. First paragraph should have a statement that the research has been approved by the Institutional Review Board at Renton Technical College.

A copy of the Informed Consent or text for oral consent must accompany this application. For non-English-speaking participants, be sure to include an accurate translation. See sample consent forms at the RTC IRB Website, or visit the OHRP website.

14(a): CHILD ASSENT (for research involving children under the age of 18):

"Assent" is defined by the regulations as follows: "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. (See federal regulation at 45 CFR 46.402 (b)). Assent should be in addition to getting the consent of the child's parent or guardian.

This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether children are capable of assent, the IRB is charged with taking into account the ages, maturity, and psychological state of the children involved. The IRB has the discretion to judge children's capacity to assent for all of the children to be involved in a proposed research activity, or on an individual basis.

15. **DEBRIEFING STATEMENT**:
A debriefing statement is required only if any type of deception is used in the study. Participants may also be debriefed about their behavioral response(s) to the study. The two major goals of debriefing are de-hoaxing and de-sensitizing. Any undesirable influence the study may have on participants should be minimized or eliminated.

The debriefing statement should describe the reason(s) for conducting the research, how participants can obtain results of the study, and contact information for additional details or answers to questions. Any potential predictions about study outcomes should be non-directional. It would also be advisable, for methodological purposes, to request that participants not reveal the nature of the study to other potential participants. Note that debriefing is normally only used when deception is utilized in the research otherwise it does not need to be included. If you are a student researcher, please check with your faculty advisor on whether you should include a debriefing statement.

Also, some researchers use an information form at the end to include relevant follow-up contact information of the faculty or student investigator(s). This may also include additional information for counseling services or emergency hotline numbers for those

experiencing distress after a research/study procedure has ended and results in the participant recalling past instances of psychological or physical trauma. You may include an information or emergency contact form (so titled) if needed. It is advised that student researchers work closely with their faculty advisor in completing the IRB application.