**Red Rocks Community College**

Institutional Review Board

# Expedited Review of Research Form

## Human subject research activities involving no more than minimal risk to the subjects may be eligible for expedited review by the Red Rocks Community College Institutional Review Board Chair. The principal investigator/project director is authorized to make the first determination of eligibility for expedited review; however, Red Rocks Community College bears the responsibility for concurring in that determination based on information provided by the principal investigator.

**Research activities eligible for expedited review:**

1. Clinical studies of drugs and medical devices only when condition (a) or (b) [see page 8 of Charter and Standard Operating Procedures] is met.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects according to [45 CFR 46.101(b)(4)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101)).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects according to 45 CFR 46.101(b)(2) and (b)(3)).

Expedited review may also be used to review minor changes in previously approved research. Questions about whether a research activity may be appropriate for expedited review can be directed to the RRCC Executive Director of Planning, Research, and Institutional Effectiveness.

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| \_\_\_/\_\_\_\_/\_\_\_\_ | **Red Rocks Community College**  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Date Submitted** | **Institutional Review Board** | **File Number** |

**Expedited Review of Research Form**

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**Title of Research Project**

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**Principal Investigator/Project Director Department Phone Extension Email address**

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**Co-investigator/Student Investigator Department Phone Extension Email address**

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**Co-investigator/Student Investigator Department Phone Extension Email address**

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| **Anticipated Funding Source:** |  |

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| --- | --- | --- | --- | --- |
| **Projected Duration of Research:** |  | **months** | **Projected Starting Date:** |  |

|  |  |
| --- | --- |
| **Other organizations and/or agencies, if any, involved in the study:** |  |

**Expedited Review Category (see categories on page 1–check one)** 1 [ ]  2 [ ]  3 [ ]  4 [ ]  5 [ ]  6 [ ]  7 [ ]

**SUMMARY ABSTRACT: Please supply the following information below: BRIEF description of the participants, the location(s) of the project, the procedures to be used for data collection, whether data will be confidential or anonymous, disposition of the data, who will have access to the data. Attach copy of the Informed Consent Form and/or the measures (questionnaires) to be used in the project.**

**RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:**

* Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented
* Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair
* The principal investigator is responsible for retaining informed consent documents for a period of three years after the project.

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|  | \_\_/\_\_/\_\_ |  | \_\_/\_\_/\_\_ |
| Investigator/Project Director Signature |  | Co-Investigator/Student Signature (if appropriate) |  |
|  |  |  |  |
| **Signature of IRB Committee Chair:**  | **Date:** \_\_/\_\_/\_\_ |
| **IRB Chair: Check 1 box:** | **[ ] Approved** | **[ ]  Approved with Conditions** | **[ ]  Refer to Full Committee Review** |

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**ELEMENTS OF INFORMED CONSENT**

Researchers must obtain the signed ***informed consent*** of participants. For those less than 18 years of age, the researcher must obtain the signed informed consent of parents or legal guardian and all reasonable attempts must be made to obtain each participant's ***assent***, which is defined as the participant's agreementto participate in the study.

The informed consent must include the following in sequential order and in language which the participants can understand:

1. Statement of purpose of the study.

2. Short description of methodology and duration of participant involvement.

3. Statement of risks/benefits to the participants.

4. Statement of data confidentiality.

5. Statement regarding the right of the participant to withdraw from the study at any time

 without negative consequences.

6. An offer to answer any questions the participant may have.

7. Contact information of all Principal Investigators, and also contact information for the Red Rocks Community College Institutional Review Board (Office of Planning, Research, and Institutional Effectiveness 303-914-6516).

8. Line for signature of participants and/or parents or legal guardian except for questionnaire

 research in which return of questionnaire gives implied consent.

9. Statement that participant is 18 years of age or older unless parent or legal guardian has

 given consent.

In situations where participants will be **deceived**, items 1 and 2 areomitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, **after the study is complete,** each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" in order to guarantee informed consent.

**Red Rocks Community College System**

***SAMPLE* INFORMED CONSENT**

The following suggestions are offered as guidelines. The exact language is the decision of the researcher. Keep in mind, however, that the Institutional Review Board must determine if the participants will be giving ***informed consent*.** (Note: that in the case of children, it is ***assent***).

Dear (student, parent, sir, madam, etc.):

 We are conducting a study to determine \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. In this study, you (your child/ward) will be asked to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Your participation should take about \_\_\_\_\_\_\_ minutes.

 There are no risks to you (your child/ward).

 ***or***

 The only risks to you (your child/ward) include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

 All information will be handled in a strictly confidential manner, so that no one will be able to identify you (your child/ward) when the results are recorded/reported.

 Your (your child's/ward's) participation in this study is totally voluntary and you may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study, simply \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

 Please feel free to contact \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (names(s), title(s) of principal researchers) at \_\_\_\_\_\_\_\_\_ phone) if you have any questions about the study. Or, for other questions, contact the RRCC Executive Director of Planning, Research, and Institutional Effectiveness (303.914.6516).

*If the participant is of age (18 years old or older), use:*

 I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature of Participant Date

*If the participant is not of age, use:*

 I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child/ward to participate with his/her assent when possible.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature of Parent/Guardian Date

*ASSENT format:*

 I understand what I must do in this study and I want to take part in the study.

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 Signature of Child/Ward Date