UNIVERSITY OF CENTRAL MISSOURI

Human Subjects Committee
Warrensburg, MO 64093
ResearchReview@ucmo.edu
(660) 543-8562

Expedited / Full Review Protocol
Institutional Review Board - Human Subjects

SECTION A: General Information

Principal Investigator (PI):	Dr. Karen Loman
Classification:	expedited
Department:	ECEL
UCM 700-Number:	
University Email:	loman@ucmo.edu
Phone Number:	816-863-4453
CITI Training Completed:	Yes
Co-Investigator(s):	Dr. Nicole Nickens, Dr. Ann McCoy, Dr. Julie Schmidli, Dr. Janet Richards
- If you are UCM faculty, you may skip to the next section –	
Faculty Advisor's Name:	Click or tap here to enter text.
Faculty Advisor's Email:	Click or tap here to enter text.

Check the appropriate boxes below to indicate characteristics of your potential subjects.

Population	Not Included	May be Included	Targeted
Minors (under age 18)	X	☐	☐
Pregnant	☐	X	☐
Women of Childbearing Age	☐	X	☐
Institutionalized Persons	X	☐	☐
Cognitively Impaired Persons	X	☐	☐
Low Income	☐	X	☐
Ethnic/Racial Minority	☐	X	☐
Individuals over age 65	☐	X	☐

X By checking this box, the Principal Investigator (PI) certifies that s/he has not begun recruiting or testing research participants and will not do so until a formal notification of approval has been received from this IRB.

SECTION B: Review Category

FOR EXPEDITED REVIEWS
Check a category below that accurately describes your research below

UNIVERSITY OF CENTRAL MISSOURI

Human Subjects Committee
Warrensburg, MO 64093
ResearchReview@ucmo.edu
(660) 543-8562

☐ CATEGORY 1 – Drug and Medical Device Research

Clinical studies of drugs and medical devices only when condition (i) or (ii) is met.

(i) ☐ Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).

(ii) ☐ Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ CATEGORY 2 – Research Involving Blood Samples

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(i) ☐ From healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

(ii) ☐ From other adults and children[1] considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

☐ CATEGORY 3 – Research Involving Biological Specimens

Prospective collection of biological specimens for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

☐ CATEGORY 4 – Research Involving Noninvasive Data Collection

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing where appropriate given the age, weight, and health of the individual.

☐ **CATEGORY 5 – Non-research or Research Involving Archived Data**

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch 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 participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

X **CATEGORY 6 – Research Involving Audio or Video Recordings**

Collection of data from voice, video, digital, or image recordings made for research purposes.

X **CATEGORY 7 – Psychological, Sociological, or Behavioral Research**

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 participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

☐ **CATEGORY 8 – Continuing Review of Previously Approved Research**

Continuing review of research previously approved by the convened IRB as follows:

(i) ☐ where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up participants; or

(ii) ☐ where no participants have been enrolled and no additional risks have been identified; or

(iii) ☐ where the remaining research activities are limited to data analysis.

☐ **CATEGORY 9 – Continuing Review of Drug or Medical Device Research**

Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

☐ **FULL BOARD REVIEW:**

Any research or training project involving the use of human participants which does not fall into an exempt or expedited review category must be submitted for full board IRB review. Research involving more than minimal risk requires full board review.

SECTION C: Project Details

OVERVIEW

UNIVERSITY OF CENTRAL MISSOURI

Human Subjects Committee
Warrensburg, MO 64093
ResearchReview@ucmo.edu
(660) 543-8562

1. Project Title:	ECEL Case Study CAEP Standard 4: Program Impact through second-year teaching

2. Describe the purpose of your project (500 words or less).
Include goals, rationale, and relevant background information.
Please use language that may be understood by persons unfamiliar with this area of study.

This case study will be in support of the Council for the Accreditation of Educator Preparation (CAEP) accreditation of the elementary and early childhood education (ECEL) program in the College of Education, specifically Standard 4: Program Impact. All providers seeking accreditation through the CAEP must complete a program review to examine the content and efficacy of preparation of teachers. The purpose of this project will be to examine the content and efficacy of the ECEL program by collecting and examining observation and disposition data for senior 1 and student teachers. Collect and examine observation, disposition, and satisfaction data for first- and second-year teachers, and their employers, who graduated from the ECEL program.

3. What is/are your research question(s)?

1. Do the graduates of the ECEL program
   A. effectively contribute to P-12 student-learning growth (as measured by *Missouri Educator Evaluation System [MEES])
   B. apply in P-12 classrooms the professional knowledge, skills, and dispositions the preparation experiences were designed to achieve (as measured by *MEES and *Educator Disposition Assessment [EDA])?
2. Are employers of the graduates with elementary and early childhood degrees satisfied with the completers' preparation for their assigned responsibilities in working with diverse P-12 students and their families?
3. Do graduates of the ECEL program perceive their preparation as relevant to the responsibilities they encounter on the job their first and second year teaching, and their preparation was effective?

*documents observe/record teacher behaviors, not P12 student data

4. What is/are your hypothesis/hypotheses?

1. The graduates of the ECEL program
   A. effectively contribute to P-12 student-learning growth AND
   B. apply in P-12 classrooms the professional knowledge, skills, and dispositions the preparation experiences were designed to achieve.
2. The employers of the graduates with elementary and early childhood degrees are satisfied with the completers' preparation for their assigned responsibilities in working with diverse P-12 students and their families.
3. The graduates of the ECEL program perceive their preparation as relevant to the responsibilities they encounter on the job their first and second year teaching, and their preparation was effective.

5. What do you plan to do with the results of your study (e.g. publish, present at a conference, etc.)?
If this project is only for an internal evaluation or class assignment, IRB may not be required. Please contact the Human Subjects Committee for more information.

The results of this study will be in support of the Council for the Accreditation of Educator Preparation report for the College of Education. The investigators may publish and/or present findings.

UNIVERSITY OF CENTRAL MISSOURI

Human Subjects Committee
Warrensburg, MO 64093
ResearchReview@ucmo.edu
(660) 543-8562

FUNDING

6. Is this research currently, or do you intend for it to be, funded in whole or part by an external (non-UCM) grant or contract?	☐YES X NO
IF YES: i. Is there a completed FCOI on record with the Office of Sponsored Programs?	☐YES ☐NO

ii. Provide the following

- Sponsor Name: Click or tap here to enter text.
- PI on Grant: Click or tap here to enter text.
- Grant Title/Contract: Click or tap here to enter text.
- Estimated Project Period:
  - From: Click or tap here to enter text.
  - To: Click or tap here to enter text.

iii. Copy of Grant Application or Project Summary is Attached	☐YES ☐NO

PARTICIPANT POPULATION

7. Describe the participant population you will target for this research (e.g., sex, age range, ethnic background, health status, or other targeted demographics).

Participants will begin as undergraduate seniors in the ECEL programs who will become first- and second-year teacher graduates from the program. Participants will be randomly selected prior to their senior year. Demographics will vary depending upon the selection of participants and the graduates who consent to participate.

8. How many participants will you need to complete your study?	approximately 15

RECRUITMENT

9. Describe your recruitment process. Include how, where, when, and who will contact potential research participants.

First- and second-year teachers who graduated from the ECEL program and completed their senior 1 block and their student teaching semesters in Raytown, MO will be recruited at the end of student teaching.

10. Attach all applicable recruitment materials. Check all that apply.

X Recruitment Scripts	☐Letter/Cover Letter
☐Flyers	☐Advertisements
X Recruitment Emails	☐Other: **Click or tap here to enter text.**

11. Will you be directly emailing or mailing participants?	☐NO X YES

IF YES, how are you obtaining emails and\or mailing addresses?
participants are undergraduate ECEL students; their email addresses are available

UCM email address

12. Will participants be compensated for their participation?	X NO ☐YES

IF YES, describe how participants will be compensated – include the amounts and method of distribution:

N/A

RISKS & BENEFITS

13. What are the risks and inconveniences to the participants? Describe all known anticipated psychological, physical, sociological, financial, economic risk to participants. Examples include, but are not limited to: loss of confidentiality, identifiable links to individual participants, experiencing guilt for lying in a study requiring deception, emotions distress, physical injury or discomfort.

There is a limited time commitment

14. How will you minimize these risks and their impact to the participants?

Data collection tools will be the same tools used throughout their undergraduate degree program: Missouri Educator Evaluation System (MEES), Educator Disposition Assessment (EDA), and DESE surveys. Additionally phone interviews, to be completed at their convenience, will be administered to first- and second-year teachers and their employers.

15. Describe your plan for an emergency situation. Even if you feel this situation is unlikely, please have a plan in case of emergency (e.g., the researcher will carry a cell phone, etc.).

In case of emergency, participants will contact the primary investigator who will have access to a cell phone at all times.

16. Describe the potential benefits to your participants and/or society.

Participants will receive course and on-the-job feedback to improve their practice. The College of Education will use data collected to review programs and reach CAEP accreditation.

METHOD OF DATA COLLECTION

17. Check all that apply. *Attach copies of all data collection tools to be used.*

X Questionnaire/Survey
X Interviews (attach scripts, questions)
X Observations
X Existing Data
☐Other: Click or tap here to enter text.

18. Indicate all biomedical procedures that apply to your research:

☐ Physical Activity ☐ Body Mass Index
☐ Venipuncture ☐ X-rays
☐ Magnetic resonance imaging (MRI) ☐ Anthropomorphic evaluations
☐ Electrocardiograms (EKGs) ☐ Intravenous catheter insertion
☐ Collection of blood samples by finger stick, heel stick, ear stick or venipuncture
☐ Other: **Click here to enter text.**

19. If applicable, describe any procedures being performed already for diagnostic or treatment purpose.

N/A

20. Describe the research methods or procedures you will use to collect your data.
That is, what exactly are your participants going to do?
Your response should include a step-by-step description of each procedure, including the frequency and duration of each procedure. If analyzing existing data, describe how you will obtain and analyze these data.

As part of their ECEL coursework:
-senior 1 students are observed using MEES six times a semester and EDA once a semester
-student teachers are observed using MEES five times a semester, EDA is completed at the end of the semester, and a MO Student Teacher Survey is administered at the end of the semester
The data collected during their senior 1 and student teaching semester will provide a baseline for completer and employer satisfaction observations and surveys.

First- and Second-year teacher participants will be observed by investigators using MEES twice a semester and EDA will be completed once a year.
First- and Second-year teacher participants will complete a MO Teacher online survey and a 15-minute interview once a year.
Employers of the First- and Second-year teacher participants will complete a MO Admin First Year Teacher online survey and a 15-minute interview once a year.

21. Where will the study take place? I.e., where will participants be observed, complete surveys, etc.?

The senior 1 and student teaching participants will be placed and observed at Little Blue Elementary School in Raytown, MO.
First- and second-year teacher participants will be observed in the school/district of hire, complete a MO First Year Teacher online survey, and a 15-minute interview over the phone.
Employers of the First- and Second-year teacher participants will complete an MO Admin First Year Teacher online survey and a 15-minute interview over the phone.

22. Does your study include plans to recruit participants from or collect data at an external site?	☐NO X YES

(I.e., off UCM campus – for example, at an elementary school, hospital, etc.)	

IF YES, name and describe the external site(s) below.
You must also attach a written acknowledgement indicating that you have permission to use the named facility and/or personnel.

Participants will be working in elementary schools. UCM teacher candidates participating in the study will be completing their clinical semesters (senior 1 and student teaching) at Little Blue Elementary, Raytown MO. Other schools TBD; permission will be granted upon agreement of employers of the First- and second-year teacher participants and their employers.

INFORMED CONSENT

The consent document(s) must contain all the required elements of consent. We recommend you use the appropriate template(s) available on the UCM website.

23. How will you obtain consent?
Describe your process for obtaining informed consent from your participants – include how, when, and where the consent process will take place, and who will collect it.

The primary investigator will obtain consent from the graduating student teachers before the end of the semester. The primary investigator will obtain consent from each employer hiring one of the ECEL graduates at their school site, prior to the beginning of the school year.

24. Which of the following will you use to present the informed consent? *(Attach all.)*

X Paper Consent Form	☐ Minor's Assent Form (Must also include Parental Consent)
☐Web-based Consent Form	☐Parental Consent Form (Must also include Minor's Assent)
☐Cover Letter	☐Other: Click or tap here to enter text.
☐Verbal Consent Script	

25. Will you inform your participants of the full nature and purpose of your study before (during consent) or after (during debriefing) they complete your study?	X Before - During Consent ☐After - During Debriefing
26. Will non-English-speakers be included in your study?	X NO ☐YES

IF YES, include translated versions of your consent documents.

PARTICIPANT PRIVACY & CONFIDENTIALITY

27. Describe any procedures you will use to protect the privacy of your participants during data collection.

(E.g., participants will complete surveys in the privacy of their own homes; interviews will be performed at a location of their choosing, etc.)

First- and second-year teacher participants and their employers will complete surveys in the privacy of their own homes; interviews will be conducted by phone at the time of their choosing. De-identified data from this study may be shared with the research community at large to advance CAEP accreditation.

28. During data collection, will you collect or have access to identifiable information about your participants?

☐NO – Data collection will be anonymous (*The investigators will not collect or have access to identifiable information about the study's participants*)
X YES – Data collect will be confidential (*The investigators will collect or have access to identifiable information about the study's participants*)

29. How will you handle identifiable information?

☐ Identifiable information will not be collected
☐ Identifiable information will be coded, and investigators will not have access to a code key
☐ Identifiable information will be coded, and investigators will have access to a code key
☐ Identifiable information will be collected and will be de-identified for analyses
X Identifiable data will be collected and will remain identifiable for analyses

30. How will the collected data be secured?

☐Locked in a cabinet or office
X Password protected PC, hard disk drive, or other secure electronic storage
☐Encrypted online or cloud storage
☐All data will be destroyed (shredded/deleted/etc.) after use
☐Other: Click or tap here to enter text.

31. Who will have access to the data?

Investigators will have access to the data.

UNIVERSITY OF CENTRAL MISSOURI

Human Subjects Committee
Warrensburg, MO 64093
ResearchReview@ucmo.edu
(660) 543-8562

Section D: Principal Investigator and Faculty Advisor Agreement

I certify that the information provided in this application is complete and accurate. As the principal investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to any stipulations designated by the IRB. I accept and will conform to all federal, state, and institutional provisions concerning the protection of human participants in research. I will ensure all personnel involved in the research will be appropriately trained for all procedures used in this project.

I agree to conduct the research involving human participants as presented in this protocol application as approved by the University of Central Missouri's Institutional Review Board (IRB), and am qualified to perform the procedures described herein. I will submit any proposed changes/modifications for review and approval before they are implemented. I agree to notify the IRB and the Research Compliance Officer of any adverse events that may occur during the study. I also assure that I will follow through with the storage and destruction of data as outlined in the protocol. I understand that the University of Central Missouri owns the research data. If I choose to transfer to another institution, I will need departmental approval to take the data with me.

If a student researcher, I additionally certify that my faculty advisor has an electronic copy of this application as submitted. My advisor has agreed to:

- *Oversee this research by communicating regularly with me;*
- *Assist with the resolution of any problems or concerns encountered during the research;*
- *Assure my research complies with Human Subjects Regulations in the Code of Federal Regulations*
- *Assure that the UCM IRB is notified in the event of an adverse event or protocol deviation.*

_____

Please note:
Failure to work with your advisor as described above will be considered a breach of professional ethics which falls under the academic honesty policy. The consequences of violating standards of academic honesty are extremely serious, costly and may result in the loss of academic and career opportunities.

X **By checking this box, I certify that I have read and agree to the agreement above**

Principal Investigator (Print Name): Dr. Karen Loman **Date:** March 4, 2022

If an unanticipated problem or adverse event should occur, you must immediately complete and submit the IRB Incident Report Form to ResearchReview@ucmo.edu and contact 660 542 8562.