PROTOCOLS

#2576 - EXCITE Program Evaluation

Protocol Information

Review Type	Status	Approval Date	Continuing Review Date
Expedited	**Approved**	**Jan 11, 2022**	**--**

Expiration Date	Initial Approval Date	Initial Review Type
Jan 10, 2025	**Jan 11, 2022**	**Expedited**

Feedback

Approval Comment

Initial review has been completed on January 11, 2022. Approval has been approved to recruit minors with the approved recruitment and consent procedures. Review was conducted under expedited review category 7. Continuing review is not required in accordance with 45 CFR 46.109(f)(1)(i). The study was assessed as being in accordance with 45 CFR 46.111.
Risk Level: MINIMAL
Funding: USDA-NIFA-National Institute of Food and Agriculture

General Information

Principal Investigator

Riggs, Nathaniel

Lead Unit

Human Development + Family Studies (CO-1570)

Title

EXCITE Program Evaluation

People

People

Person

Riggs, Nathaniel

Home Unit

Human Development + Family Studies (CO-1570)

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nathaniel.riggs@colostate.edu

Phone

970-491-2684

CSU Status

Faculty

Researcher Role

Principal Investigator

Contact Roles

Admin

Permissions

Full Access

People Attachments

Person

Hansen, Alexis Rachelle

Home Unit

Human Development + Family Studies (CO-1570)

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alexis.hansen@colostate.edu

Phone

7195802671

CSU Status

Staff

Researcher Role

Co-Investigator

Contact Roles

Permissions

Full Access

People Attachments

Person

Christensen, Elizabeth O'Sullivan

Home Unit

CSU Extension (CO-XT)

Email Address

libby.christensen@colostate.edu

Phone

CSU Status

Staff

Researcher Role

Co-Investigator

Contact Roles

Permissions

Full Access

People Attachments

Attachment

LIBBY CITI TRAINING.PDF

Name

CITI Certificate

Attachment Type

Other

Comments

No

Legacy eProtocol ID number

If applicable, enter the ID number this study was previously assigned in eProtocol.

General Questionnaire

Application Type

Expedited

Does this study include use of existing data or biospecimens?

No

Does this study include use of student educational records and data?

No

Does this study include the use of human blood, cells, tissues or body fluids?

No

Does this study include evaluation of medical equipment or devices?

No

Does this study include evaluation of drugs, biologics, reagents or chemicals?

No

Is this study a clinical trial?

No

Does this study include the use of Protected Health Information (PHI)?

No

Is this study a Graduate Level Thesis or Dissertation Project?

No

Is this study another type of class project?

No

Is the project funded?
Yes

Study Participants

Subjects Checklist (Select All that Apply)
Children/Minors (<18 yrs)

Collaborators

Will Colorado State serve as the Single IRB for other collaborating institutions on this study?
No, Colorado State University is the only participating institution in this study.

Funding

Funding Sources

Funding Type
Federal Government

USDA-NIFA-National Institute of Food and Agriculture

KP Proposal Number or OSP Reference Number
EXC2-2021-2104

Title of Grant (if different from protocol title)
CO CSU One Health 4-H Immunization Curriculum

Period of Funding

June 1, 2021-May 31, 2023

Is the study occurring at CSU?

Yes

Prime or Subawardee?

Prime

Funding was secured by:

CSU Office of Sponsored Programs

Please provide your IRB Approval documentation to Sponsored Programs upon receipt.

Expedited Review Category

For research to qualify for an expedited category, all aspects of the study must present no more than minimal risk to participants and fit into one or more of the categories below. Using your judgment, please self-categorize the research activities. If you are unsure or none of the categories apply, you can leave this section blank. The IRB will make the final determination during the review.

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

Expedited 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

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

Summary and Purpose

Proposed Start Date

January 10, 2022

Proposed End Date

January 31, 2023

Provide a brief summary or abstract of the project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.

This pilot project will test an innovative, experiential 4-H based immunization curriculum (i.e., the EXCITE One Health program) to educate youth about vaccines and encourage them to take a proactive role in their own and their family's immunization. The educational campaign will be delivered to fifty 4-H youth ages 11 to 18 in Routt and Larimer County, using the structure and familiarity of the existing National 4-H Veterinary Science Project curriculum. Our goal is to link vaccination to critical issues such as the human-animal bond and zoonotic disease, framing it as an issue that affects human and animal health. With the addition of animal health and vaccination, the educational campaign will be more approachable, particularly in rural settings where livestock immunization is the norm. This curriculum thus utilizes the trans-disciplinary expertise of human and animal health practitioners (including companion animals and livestock) to highlight the safety, effectiveness, and importance of vaccination in animal health and further links this to the importance of vaccination for individual and community health. As a result of this program, we expect youth to experience a greater understanding of how vaccines work, higher vaccine confidence, and an increase in youth vaccine uptake.

Describe the purpose for the proposed project.

Efforts to reach and educate vaccine-hesitant populations in Colorado have largely targeted adult urban residents and communities of color. In early 2021, Caring for Colorado Foundation provided over $2.5 million to locally-based initiatives, and the Colorado Department of Public Health and Environment launched a statewide mass-media campaign. There are a number of initiatives in our state that are targeting parents of youth; however, none identified that they were targeting youth directly. The Colorado Department of Public Health and Environment developed an online vaccine education module to help parents feel confident in vaccines. Immunize Colorado is a statewide 501(c)3 nonprofit and works to protect Colorado families, schools, and communities from preventable diseases. They currently work with health care providers, public health departments, businesses, policymakers, and community organizations to achieve their goals. The Colorado Immunization Advocates is another nonprofit organization for parents and concerned citizens who support vaccination. Despite numerous calls in the literature for immunization education directed at middle and high school students, examples within Colorado and beyond are limited. While Colorado efforts to increase youth uptake of vaccinations have primarily targeted parents, this project seeks to directly increase positive youth attitudes towards vaccines, greater confidence in immunization, and increase the likelihood of youth immunization.

What do the investigators hope to learn from the project?

The investigators seek to assess the initial efficacy of the EXCITE One Health program curriculum in increasing youth's trust in vaccines, feelings that vaccines are safe and important for disease prevention, and increase uptake. More specifically, we would like to understand if a program that teaches students how vaccines and other health topics interact with animals (with direct ties to how vaccines work in humans) can increase youth's confidence in vaccination and intention to get vaccinated.

Describe how sharing results of this study could influence behavior, practice, theory, future research designs. Specifically, how will study results apply to a larger population than the studied participants?

Results of this study contribute to a growing body of literature on increasing vaccine confidence using interventions, with a novel approach of working with harder-to-reach populations of youth (e.g., homeschooled students, students from rural settings). Rural youth consistently experience lower rates of

from rural settings). Rural youth consistently experience lower rates of vaccination compared to youth in urban areas (Elam-Evans et al., 2020; Pingali et al., 2021; Walker et al., 2019). This disparity is particularly significant when considering differences in the rates of urban vs. youth who are up-to-date on their HPV vaccinations (Pingali et al., 2021). While most interventions in this area target parents to improve uptake, this innovative approach instead encourages adolescents to advocate for their own health to friends and family members through increased understanding of health information instead of solely relying only on parents' access, knowledge, and opinions of health information. This study thus provides an alternative approach to increasing vaccination rates for youth in rural communities through the access of health information via a program they are often already involved in: 4-H. As 4-H has a national reach, leveraging the program as a standard delivery system for this curriculum could provide systemic education for harder-to-reach vaccine-hesitant populations across the U.S., thereby helping them better understand and advocate for immunization and other health topics. Provided this innovative approach works as intended, the researchers anticipate its role in improving vaccine uptake in rural youth across Colorado and beyond. Lastly, as involving youth in vaccination advocacy is relatively new to the literature, previous scales adapted for youth/adolescents have not always performed well psychometrically. As such, this study will pilot a new psychometric scale based on the "Increasing Vaccination Model" championed by the World Health Organization's BeSD Working Group (Brewer et al., 2017). Therefore, the information the investigators learn from this pilot will thus add to a growing literature of youth vaccine confidence/advocacy while simultaneously informing the curriculum's future adaptation processes. References Brewer, N. T., Chapman, G. B., Rothman, A. J., Leask, J., & Kempe, A. (2017). Increasing vaccination: Putting psychological science into action. Psychologicial Science Public Interest, 18(3), 149-207. https://doi.org/10.1177/1529100618760521 Elam-Evans L. D., Yankey, D., Singleton, J.A., et al.(2020). National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2019. MMWR Morb Mortal Wkly Rep 2020, 69, 1109–1116. http://doi.org/10.15585/mmwr.mm6933a1 Pingali, C., Yankey, D., Elam-Evans, L. D., et al. (2021). National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2020. MMWR Morb Mortal Wkly Rep 2021, 70, 1183–1190. http://doi.org/10.15585/mmwr.mm7035a1 Walker, T. Y., Elam-Evans, L. D., Yankey, D., et al. (2019). National, Regional, State, and Selected Local Area

Yankey, D., et al. (2019). National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2018. MMWR Morb Mortal Wkly Rep 2019, 68, 718–723. http://dx.doi.org/10.15585/mmwr.mm6833a2

Background

Provide a brief overview of the relevant background. Discuss the present knowledge, appropriate literature and rationale for conducting the research.

In the midst of the international COVID-19 pandemic and the consistently low rate of youth up-to-date on the HPV vaccine (e.g., 63.5% in Colorado; Pingali et al., 2021) it is important that researchers and practitioners act to improve and sustain youth vaccination rates. Historical efforts for programs to

increase vaccine uptake have primarily targeted parents as the sole decision-makers on their children's immunization; however, recent research has shown that youth have the ability to understand, form opinions on, and advocate for vaccination (Pennella, Ayers, & Brandt, 2020; Brandt et al., 2021). With this understanding came a call for youth programs to help engage youth in the decision-making process for vaccination and to consider them as potential activists to increase vaccine uptake (Penella, Ayers, & Brandt, 2020; Zimet et al., 2021; Brandt et al., 2021). Further, recent mixed-methodology literature has indicated that the primary facilitators of youth intention to vaccinate include feelings that vaccines are recommended by trusted sources as safe, effective, and important for disease prevention. Common barriers include misinformation, mistrust of government and/or health practitioners, etc. These barriers and facilitators align strongly with theories emphasizing the behavioral and social drivers of vaccination (Penella, Ayers, & Brandt, 2020; Brandt et al., 2021). Thus, CSU Extension saw an opportunity in leveraging its role in the 4-H program to implement a program to support youth in taking a more proactive role in the immunization process, with considerations of the factors influencing uptake. Brewer and colleagues' (2017) "Increasing Vaccination Model" posits that cognitive (e.g., understanding vaccines), affective (e.g., having positive/negative perceptions of vaccines), and social (e.g., having proximal peers/adults who support vaccination) factors all influence the likelihood of the youth's intention to uptake--not just the barriers/facilitators to access vaccines (WHO, June 2020). While many of

barriers, facilitators to access vaccines (WHO, June 2020). While many of Colorado's interventions seek to increase access to vaccines via practical concerns or via informing parents, these methods have not always proven as effective for the most vaccine-hesitant populations. As such, the EXCITE One Health curriculum would provide avenues to increase youth's understanding of vaccines (i.e., cognitive), perceptions of vaccines as safe and important (i.e., affective), and would create a space with proximal peers/adults who support vaccination (i.e., social). References Brewer, N. T., Chapman, G. B., Rothman, A. J., Leask, J., & Kempe, A. (2017). Increasing vaccination: Putting psychological science into action. Psychologicial Science Public Interest, 18(3), 149-207. https://doi.org/10.1177/1529100618760521 Brandt, E. J., Rosenberg, J., Waselewski, M. E., Amaro, X., Wasag, J., & Chang, T. (2021). National study of youth opinions on vaccination in the U.S. Journal of Adolescent Health, 869-872. https://doi.org/10.1016/j.jadohealth.2021.02.013 Penella, R. A., Ayers, K. A., & Brandt, H. (2020). Understanding how adolescents think about the HPV vaccine. Vaccines, 8, 693. https://doi.org/10.3390/vaccines8040693 Pingali, C., Yankey, D., Elam-Evans, L. D., et al. (2021). National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2020. MMWR Morb Mortal Wkly Rep 2021, 70, 1183–1190. http://doi.org/10.15585/mmwr.mm7035a1 World Health Organization (2020). Development of tools to measure behavioural and social drivers of vaccination: Progress report.

Please describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, and training).

Dr. Riggs is the Executive Director of the CSU Prevention Research Center (PRC) with expertise in curriculum development for youth social-emotional learning, substance use prevention, and obesity prevention that includes mapping content onto logic models, etc. He has over 20 years of experience implementing and testing preventive interventions. He has also conducted several 3rd party evaluations in partnership with community agencies. Much of Dr. Riggs' current and past work has been conducted with rural communities in Colorado and Pennsylvania. Dr. Libby Christensen has a Ph.D. from the University of California at Davis in Geography where she received formal training in quantitative and qualitative data collection and analysis. Dr. Christensen also completed the Evaluation, Assessment, and Policy Connections training with Dr. O'Sullivan. She has extensive experience

Connections training with Dr. O'Sullivan. She has extensive experience conducting social science research through the development and implementation of survey instruments. For the last three and a half years, Libby has served as an Extension Agent in Routt County. She has delivered and supported the county's 4-H program to support youth. One of her roles has been the creation of evaluation tools for the county 4-H program. Alex Hansen is a Research Associate at the PRC with two Bachelor of Science Degrees in Psychology and Human Development & Family Studies with a Concentration in Prevention & Intervention Science. Alex has over 4 years of experience conducting social science research. Over the last 2 years working at the PRC, Alex has both supported and led in the development, distribution, and analysis of over 20 evaluation surveys for community partners such as the Colorado Department of Education. In addition to their program evaluation role, they have supported the PRC's translational science efforts through the development of research-based tools on prevention science topics for K-12 schools and districts across Colorado.

Explain your knowledge of local community attitudes and cultural norms and cultural sensitivities necessary to carry out the research.

Vaccination has been politicized. Despite scientific evidence supporting the fact that vaccines are fundamental tools for preventing infectious diseases, a large portion of the population refuses some or all of them. In 2019, the World Health Organization identified vaccine hesitancy as one of the top ten threats to global health. The COVID-19 pandemic, and subsequent COVID-19 vaccination campaign, have only further demonstrated this deadly divide, particularly along the rural-urban continuum. According to the Kaiser Foundation Vaccine Monitor Dashboard, three in ten rural residents say they will either "definitely not" get vaccinated against COVID-19 or will only do so if required. So far efforts to reach and engage the "definitely not" populations have not been very effective. The CEO of the Colorado Rural Health Center summarizes that rural residents are concerned about the safety of the vaccine, lack of trust in vaccines, personal choice, and existing health conditions (Daley, 2021). Youth are disproportionately impacted by vaccine hesitancy; prior to COVID-19, the anti-vax movement was largely associated with parents (Hussain et al. 2018). Even for parents who chose to vaccinate their very young children, many parents are unaware that many childhood vaccine protection wears off and adolescents may need booster vaccinations. Further, adolescents and youth may be at higher risk for contracting certain diseases such as meningitis or other STIs. Yet, research

contracting certain diseases such as meningitis or other STIs. Yet, research into youth concerns, frustrations, and access issues with vaccines is still very limited. Over the past 15 years, several vaccines have been added to the recommended immunization schedule for adolescents in the United States. Despite these factors, youth are often overlooked in efforts to address barriers and concerns and increase the acceptability of vaccines in rural communities. Arede et al. (2018) proposed a novel long-term approach to address vaccine hesitancy involving the education of children and adolescents on the basics of immunization and critical thinking. While most assume communication about healthcare management primarily flows from parent to child, evidence exists that youth can also act as effective behavior change agents regarding health-related issues including smoking and healthy eating habits (Arede et al., 2018). Similarly, it is expected that providing information about vaccine safety to youth might lead to pro-vaccination behaviors in parents. 4-H is one of the nation's largest youth development

organizations. The goal of 4-H is to develop citizenship, leadership, responsibility, and life skills of youth through experiential science-based learning programs. One popular program for Colorado 4-H youth is veterinary science with over 200 youth enrolled. The existing curriculum briefly explores the topic of animal immunity; youth are asked to chart their animal's immunization history. This project seeks to develop and prototype a supplemental vet science curriculum using a One Health theoretical framework to educate youth about vaccines and encourage them to take a proactive role in their own and their family's immunization. This will be an innovative approach to deliver immunization education in a non-school setting, reaching rural and in some cases homeschooled youth, with the potential to overcome vaccine hesitancy with an end result of increasing vaccination rates. This project will be implemented in Routt and Larimer counties. These two counties have the largest participation in the Vet Sciences Program. The current 4-H Agents for the different counties have been identified as key project personnel. The agents live and work in these communities. They communicate with the youth and their families on a nearly weekly basis. This regular communication requires a high level of awareness of community attitudes and cultural norms. Programming must be offered with appropriate cultural sensitives for successful 4-H program implementation. References Arede, M., Bravo-Araya, M., Bouchard, E., Gill, G. S., Plajer, V., Shehraj, A., & Shuaib, Y. A. (2019). Combating vaccine hesitancy: Teaching the next generation to navigate through the post truth era. Front.

Public Health. 6, 381. https://doi.org/10.3389/fpubh.2018.00381 Daley, J. (2021). Is Colorado seeing more COVID vaccine hesitancy? The number of appointments available says yes. CPR News. https://www.cpr.org/2021/05/04/colorado-covid-vaccine-hesitancy/ Hussain, A., Ali, S., Ahmed, M., & Hussain, S. (2018). The anti-vaccination movement: A regression in modern medicine. Cureus, 10(7), e2919. https://doi.org/10.7759/cureus.2919

Procedures

List all research activity procedures in which a participant will be involved, including follow-up procedures. Please provide details.

Procedure Description

Pre- and Post- Survey Completion This pilot will utilize a cross-over randomized field trial to evaluate the effectiveness of the educational intervention. To execute this, the curriculum delivery in Larimer County will be delayed. Pre-test data will be collected from 4-H youth enrolled in the Veterinary Science Project in both counties (n = 50). In Routt County, 4-H youth will then participate in the curriculum. Post-tests will be administered at both sites after the curriculum completion in Routt County. Following the administration of the first post-test, participants in Larimer County will receive the One Health 4-H Immunization curriculum. A final post-test will be collected in Larimer County after completion of the curriculum. During survey administration, CSU 4-H Extension Personnel will deliver verbal study instructions, share the Qualtrics link with youth, and will manage questions that come up about the survey as needed. 4-H youth will then complete surveys online using Qualtrics Survey Software using their personal devices.

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:
Experimental

Where and when will this procedure take place?
Students will complete surveys prior to the beginning of the One Health curriculum and after its completion during their regular meetings for 4-H.

Who will conduct this procedure?

Personnel
Christensen, Elizabeth O'Sullivan

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.
Youth will complete one 5-10 minute pre-test and one 5-10 minute post-test. This will total approximately 10-20 minutes of the youth's time.

Describe how the data will be collected (i.e. in person or online).
Data will be collected using Qualtrics Survey Software online. Youth will be invited to use their personal devices to complete the surveys.

Will any video, photography, or audio be recorded as part of this procedure?
No

Will data be collected anonymously?
Yes

Procedure Description
Follow-up Survey Completion 1-2 months after completion of the One Health curriculum, 4-H youth from both counties will complete a follow-up survey with repeated measures. During survey administration, CSU 4-H Extension Personnel will deliver verbal study instructions, share the Qualtrics link with youth, and will manage questions that come up about the

survey as needed. 4-H Youth will then complete surveys online using Qualtrics Survey Software using their personal devices.

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:
Experimental

Where and when will this procedure take place?
Students will complete the follow-up survey during their regular meeting for 4-H 1-2 months after Larimer county completes the curriculum.

Who will conduct this procedure?

Personnel
Christensen, Elizabeth O'Sullivan

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.
Youth will complete one 5-10 minute follow-up survey.

Describe how the data will be collected (i.e. in person or online).
Data will be collected using Qualtrics Survey Software online. Youth will be invited to use their personal devices to complete the surveys.

Will any video, photography, or audio be recorded as part of this procedure?
No

Will data be collected anonymously?
Yes

Privacy and Confidentiality

Explain how the established data management plan along with consent processes and other elements of the research design address the following.

Privacy is considered from the perspective of the participant and is a right to be protected. Privacy refers to an individual's interest in controlling others' access to themselves. Based on their privacy interests, participants may want to control:

- **The time and place where they give information**
- **The nature of the information they give**
- **Who receives and can use the information**

For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy-counseling center identified as such by signs on the front of the building.

Describe how you will protect subject's privacy.

The researchers will conduct data collection using Qualtrics Survey Software, allowing youth to input their responses without the access of other youth or the curriculum facilitators. Participants will complete the survey during their normal hours for 4-H. Participants will be informed that their participation is on a voluntary basis and that they can end their participation at any time.

Confidentiality is about data. Confidentiality pertains to protecting information from disclosure based on an agreement between the participant and the researcher. When an individual shares information in a relationship of trust and expects it to be kept private or will be disclosed only with specific permissions, researchers must uphold this agreement and maintain data appropriately.

Describe how you will maintain the confidentiality of subjects' information.

The research team will assign subjects an identification number using three questions that ask for the participants': 1) first letter of their first name; 2) the day within their date of birth (i.e., if their birthday is January 11th, 2013, they would enter '11'); 3) the last letter of their last name. These items will utilize dropdowns to ensure participants do not supply more information than necessary. Personal identifiable information will only be recorded on assent/consent documents (i.e., name and age) and will not be connected to participant data at any point in the study. Additionally, data collection will occur via Qualtrics, which limits the access of participant data to only the researchers. Participant data will be stored in a password-protected research folder on a secured research drive accessible only to the research team. The research team will aggregate data for analysis and publication.

Participant Population

Are you interacting or intervening with participants?
Yes

Provide an estimate of the anticipated participant total.
4-H Extension Personnel's research interactions with participants (including time for assent/consent/survey administration) will total approximately 40-50 minutes across the duration of the study.

Are you analyzing existing data records or biospecimens?
No

Inclusion and Exclusion Criteria (e.g., Participants must have 20/20 vision, Participants must be 30-45 years of age, etc.) This should match your screening, consent, and recruitment materials.

Please list all inclusion criteria
Researchers will recruit youth ages 11-18 who are involved in the Larimer and Routt County 4-H program to participate.

Please list all exclusion criteria
Individuals must be fluent in English to participate in the surveys. Additional exclusion criterion is that they are either under 11 or older than 18 years of age and not participating in the 4-H Veterinary Science program.

What is the rationale for studying the requested group(s) of participants?
4-H Program participants are more likely to include harder-to-reach vaccine-hesitant populations (e.g., rural and homeschooled youth) who are often interested in animal science. Thus, the already-existing 4-H curriculum synergizes with the One Health EXCITE Curriculum, as both address the animal-human connection in immunization procedures. As youth would

already be experiencing this curriculum for the upcoming semester as part of their program participation, these surveys would simply serve as an addendum to assess how effective the material is in helping increase youth's trust in vaccination and uptake.

Will you use a screening procedure, instruments, tools, questionnaires etc.?
No

No

Recruitment Process

Describe the procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials.

Participant Group Descriptor

4-H Youth

Please describe the recruitment process:

4-H Personnel will describe the next section of their OneHealth curriculum. At this point, students will be invited to participate in the study on a voluntary basis. 4-H Personnel will then hand out consent/assent forms to the students.

Planned Subject Identification Methods

Class participants

Will a specific agency or institution provide access to prospective subjects?

Yes

Identify Agency

CSU Extension - 4-H Personnel

Please select the recruitment personnel

Christensen, Elizabeth O'Sullivan

No

Planned Recruitment Materials/Methods
***(All advertising must be submitted for review in its final printed/recorded form)**
Note: Attach copies of ALL recruitment materials in the attachment Section

Oral Scripts

Face to face interactions

Is there any possibility that potential participants may feel coerced to participate?
No

Is there any possibility that potential participants may feel undue influence to participate?
Yes

How will researchers mitigate this risk?
Individuals distributing the surveys will be instructed to let students know that completing the survey is voluntary and that youth can decide whether or not they participate.

Participant Compensation/Costs

Will participants be compensated?
No

Will participants incur any costs to participate in this research?
No

Risks and Benefits

Minimal risk "means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." [Department of Health and Human Services 45 CFR 46.102(j)]

Please indicate the researchers' evaluation of the overall risk level, and describe all known risks or discomforts associated with the study procedures, as prompted below. Note that any risks identified here should be consistent with risks you will disclose to participants in the consent process.
Minimal Risk

Are there risks associated with physical well-being?
No

Are there risks associated with psychological well-being?

Yes

Please describe.

There is potential that youth may experience distress in answering questions related to vaccination status.

Are there risks associated with economic well-being, including employability?

No

Are there risks associated with social well-being, including reputational risks?

No

Describe how the benefits of the research justify the likely risks to participants.

While we do not anticipate any direct research benefits to participants from completing the surveys, we also do not anticipate any substantive risks above possible discomfort answering questions on vaccination status.

Describe direct research benefits to the participants, if any.

We do not anticipate any direct research benefits to participants from completing the surveys.

Describe the indirect research benefits to society.

Assessing the initial effectiveness of the EXCITE curriculum may open the possibility of expansion of vaccination interventions for youth in additional counties across Colorado. The investigators anticipate that this would increase positive and accurate perceptions of vaccines, youth intention to vaccinate and, by proxy, youth uptake of vaccines (especially in vaccine-hesitant populations). Additionally, this research will help the investigators better understand the effectiveness of the EXCITE Curriculum; if this program is successful, the investigators anticipate that it will increase positive and accurate perceptions of vaccines in Larimer and Routt County. This would also open the possibility of expansion of vaccination interventions for youth in additional counties across Colorado through integration of EXCITE One Health curriculum into standard 4-H curriculum on animal immunization.

Data Management

Data management plans, including plans for data sharing, are integral to project development. How you decide to collect, store, share and/or destroy data impacts your consent process, research procedures, data analysis, and publication.

Responses in this section constitute your plan. For guidance on how to answer these questions and plan for the data lifecycle, reference the resources and tools listed here.

Data Management Services at CSU Libraries
General guidance and unfunded projects (DMPTool)
Funder-specific guidance and templates (DMPTool)

If you choose to create a standalone data management plan (DMP) for your own purposes or at the direction of a funding agency, please attach that document to your protocol, also.
A DMP fillable template is available from CSU Libraries.

How will the data be stored and backed up during the research?

Data will be stored in a password-protected computer folder on a secure, limited-access research drive accessible only to the research team.

Who will be responsible for data and access management, and security?

Data Access Responsibility

Hansen, Alexis Rachelle

Data Access Responsibility

Riggs, Nathaniel

Who will have access to study records or specimens?

Personnel

Hansen, Alexis Rachelle

Personnel

Riggs, Nathaniel

Will any external personnel have access to study records or specimens?

No

How will you share the data?

Data will be de-identified, aggregated, and then disseminated in its aggregated and statistically analyzed form with CSU Extension and funders.

Will identifiable data collected as part of the research be released in identifiable form? (e.g., pictures, recordings, responses to research questions, quotes)

No

Will the identifying information be destroyed at a specific date? For guidance, please reference any associated contract or grant (if applicable) and/or the CSU Research Data Policy.

No

What is the long-term preservation plan for the dataset?

Data will be stored in a CSU password-protected research drive available only to the PI and Co-investigator. Data will be de-identified and preserved for at least 3 years after collection is completed.

Do you intend to deposit your research data/specimens into a repository for future use?

No

Consent/Assent

Consent

The informed consent process involves presenting potential research participants with the key elements of a research study and what their participation will involve before they decide whether to participate. Please visit the IRB website for templates and guidelines on what information to include.

The default process for gaining consent is to use a signed form. Knowing that this does not always make sense, the IRB can approve alterations to what information is included, waive the requirement to get a signature or waive the requirement to obtain consent altogether when the request meets specific criteria.

Follow the prompts below to describe all consent processes and provide justification for any requested alterations or waivers.

Will informed consent be obtained from all research subjects (and/or their parents or legally authorized representatives)?

Yes

CSU Consent Personnel

Christensen, Elizabeth O'Sullivan

Christensen, Elizabeth O'Sullivan

No

Are you requesting a waiver of documentation of consent?

No

Consent

You do not have any procedures that include deception. If you are going to deceive or incompletely inform any subjects about any aspect of this study describe in the procedures section.

List each consent process

Who will obtain subjects consent?

Personnel

Christensen, Elizabeth O'Sullivan

Which participant group is this consent process for?
Parents of 4-H Youth in Larimer County

How is consent being obtained?
The consent personnel will describe the study in an age-appropriate manner (see Permission Script) and provide written copies of consent/assent forms to 4-H Youth to take home to their parents and return at the following meeting.

Will non-English speaking participants be enrolled?
No

Translated versions of the survey do not yet exist.

Are any subjects unable to legally provide consent?
No

Who will obtain subjects consent?

Personnel

Christensen, Elizabeth O'Sullivan

Which participant group is this consent process for?
Parents of 4-H Youth in Routt County

How is consent being obtained?
The consent personnel will describe the study in an age-appropriate manner (see Permission Script) and provide written copies of consent/assent forms to 4-H Youth to take home to their parents and return at the following meeting.

Will non-English speaking participants be enrolled?
No

Surveys are written in English. Translated versions do not yet exist.

Are any subjects unable to legally provide consent?

No

Assent

Assent is a process of soliciting affirmative acknowledgment from minors (or populations unable to give adequate consent) to participate in your research. Assent can be obtained by various methods like assent forms or verbal scripts about the study. As you develop an assent procedure, consider the participants' ages, maturity, and psychological state.

Assent processes should be appropriate for the intended population. For example, assent language should be at a level understandable to the participant and be accompanied with adequate discussion. If the study includes a broad range of capacity to consent (whether age or cognition), more than one assent procedure may be needed (i.e., an assent form suitable for a 17-year-old is not usually suitable for a 7-year-old child). Unlike the required regulatory elements of consent, assent elements are not defined by regulation and should be developed and assessed on a case-by-case basis. Check out the IRB website for templates and guidelines on what information to include.

In some cases, all or some of your participants may be incapable of providing affirmative assent to participate (based on age or diminished intellectual capacity). In such cases, the IRB may waive the requirement for assent. Even when the IRB determines that the subjects are capable of providing assent, the IRB may still waive the assent requirement if justifiable.

Follow the prompts below to describe all assent processes and provide justification for any requested alterations or waivers.

Will assent be obtained from all research subjects who are minors or individuals unable to give adequate consent?

Yes

Collection of Assent

List each Assent process

Who is obtaining child assent and parent consent? The person obtaining consent must be knowledgeable about the study and appointed by the PI to perform this function of the research.

Personnel

Christensen, Elizabeth O'Sullivan

Christensen, Elizabeth O'Sullivan

No

Which participant group is this assent for?
4-H Youth in Larimer County

How is assent being obtained?
Assent will be obtained in written form.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
Youth will first read the assent forms designated to their age group. Afterward, the Assent Personnel will verbally describe the contents of the study and informed consent form, and share that participation in the surveys is voluntary in an age-appropriate manner. After reviewing the assent forms, the assent personnel will check in with youth to verify that they comprehend what the study is about and gauge their comfort.

How will assent be obtained from minor participants along with parent/guardian consent.
Before collecting assent, 4-H Extension Personnel will read the permission script and invite youth to take the consent/permission slip home for their parents to review. After collecting consent from parents, Assent personnel will collect written assent from minor participants during their regular 4-H meeting.

Who is obtaining child assent and parent consent? The person obtaining consent must be knowledgeable about the study and appointed by the PI to perform this function of the research.

Personnel

Christensen, Elizabeth O'Sullivan

No

Which participant group is this assent for?
4-H Youth in Routt County

How is assent being obtained?

Assent will be obtained in written form.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

Youth will first read the assent forms designated to their age group. Afterward, the Assent Personnel will verbally describe the contents of the study and informed consent form, and share that participation in the surveys is voluntary in an age-appropriate manner. After reviewing the assent forms, the assent personnel will check in with youth to verify that they comprehend what the study is about and gauge their comfort.

How will assent be obtained from minor participants along with parent/guardian consent.

Before collecting assent, 4-H Extension Personnel will read the permission script and invite youth to take the consent/permission slip home for their parents to review. After collecting consent from parents, Assent personnel will collect written assent from minor participants during their regular 4-H meeting.

Conflict of Interests

For guidance on how to answer these questions and information please visit the CSU Conflict of Interest page.

Does the research involve a drug, device, or biological invented by you, an immediate family member or other Research Personnel?

No

Is the research sponsored by an entity with which you, an immediate family member, or other Research Personnel have a paid consulting or advising relationship?

No

Will you, members of your immediate family, or other Research Personnel receive special compensation or increased compensation if the research generates a favorable outcome?

No

Will you, members of your immediate family, or other Research Personnel receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, and an enrollment bonus for reaching an accrual goal or similar types of payments?

No

Do you, members of your immediate family or other Research Personnel have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

No

Will the payment you receive for services provided during the conduct of the research (e.g., investigator and Research Personnel time and tests) be inconsistent with fair market value for those services?

No

Significant Financial Interest: Please check Yes or No for each item below.

Will you, your immediate family members or other Research Personnel receive salaries, royalties and/or other payments for services (e.g., consulting fees, honoraria, research design, management position, independent contractor, service on advisory or review committees, board membership seminars, lectures or teaching engagements when totaled together exceeded $5,000 during the previous 12 months or are expected to exceed $5,000 over the next 12 months)? This excludes reasonable costs of conducting the research, as specified in the research agreement.

No

Do you, your immediate family members, or other Research Personnel hold any ownership interests including stocks, bonds, or stock options that exceed $5,000 and/or that constitute more than a five percent (5%) ownership interest in the sponsoring organization? This does not include any interests held solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the investigator and/or his or her immediate family do not exercise day-to-day control of investment decisions.

No

Minimizing Risks and Disclosure to Subjects

Have you disclosed any actual, potential or perceived conflicts of interest in the consent form? Research Personnel are required to disclose all such conflicts to all research participants in the research consent form.

No

By submitting this form, you are attesting that you have read Colorado State University's policy on Conflict of Interest and agree to abide by its terms. You will update this disclosure form when new or changes in conflict of interest arise, and that you will comply with any conflict management plan required by the Institutional Review Board (IRB) to manage, reduce, or eliminate any actual or potential conflict of interest for the duration of the research.

Attachments

Attach all relevant documentation to your research in this section. Please label each item appropriately, so your IRB reviewers understand the purpose and population each document aims to address. Please delete the existing attachment and upload the Tracked Changes version and Clean revised document for review to update or revise any existing attachments.

Any documentation that a participant will see must be reviewed and approved by the IRB, including consent, recruitment, communications, tools, instruments, etc. Additional documents required for review include funding proposals, contracts, letters of agreement, methodology, related approvals, etc. For more information and guidance on what documentation to attach, please visit the IRB website.

Answers within your application indicate that the following documentation is required:

Attachment Type

Data Management Plan

Attachment

DATA MANAGEMENT PLAN.PDF

Name

Data Management Plan

Attachment Type

Assent

Attachment

IRB ASSENT FOR YOUTH AGES 11-13 12.01.21.PDF

Name

Youth 11-13 Assent Form

Attachment Type

Assent

Attachment

IRB PARENT CONSENT FOR YOUTH 14-18 12.01.21.PDF

Name

Youth 14-18 Assent & Parent Consent Form

Attachment Type

Recruitment Materials

Attachment

PERMISSION SCRIPT.PDF

Name

Permission Script

Attachment Type

Consent

Attachment

IRB PARENT CONSENT FOR YOUTH 11-13 12.01.21.PDF

Name

Parent Consent Form/Permission Slip for Youth 11-13

Attachment Type

Other

Attachment

IRB EXCITE VACCINE CONFIDENCE ITEMS FOR YOUTH 12.01.21.PDF

Name

Youth Survey

Attachment Type

Grant or Contract

Attachment

EXCITE ACTIVITY 2.PDF

Name

Grant

Obligations

The Principal Investigator is ultimately responsible for the conduct of this project. Obligations of the Principal Investigator include the following:

· Receive IRB approval or determination prior to enrolling any subjects or collecting any data intended for research use.
· Manage and maintain all research records, including consent retention, for at least three (3) years after the close of the study, or longer per sponsor requirement.

· Ensure that personnel training status remains current.
· Provide all subjects a copy of the signed consent form, when applicable.
· Keep protocol up to date by submitting amendments for review and approval before instituting changes in any aspect of the study.
· Maintain current protocol approval by submitting renewals, as required

- Maintain current protocol approval by submitting renewals, as required.
- Promptly report any violations, deviations, unanticipated problems or adverse events to the IRB.
- Notify the IRB when the study is complete and take steps to close the protocol.

I understand that as the Principal Investigator I am fully responsible for the execution and management of this study and that I am responsible for the performance of any sub-investigators or key personnel including their adherence to all applicable policies and regulations. I understand and agree to the obligations listed above.

I certify that I have reviewed this application, including attachments and that all information contained herein is accurate to the best of my knowledge.