Expedited Review New Study Application

"Expedited" is a category of research that is minimal risk and will be reviewed by an IRB Chair or member; it will not go to full committee for review. “Expedited” does not relate to the length of time for review and approval.

1 copy of each of the following documents should be **delivered to our office and emailed** to **hrrc@salud.unm.edu**.

You can download each of the forms directly from this checklist.

Required for Every Submission

	Expedited Application (This document)
	Department Review Form
	Conflict of Interest forms for Every Investigator on the study Conflict of Interest form for UNM Employees or Students Conflict of Interest form for non-UNM Employees
	Make sure all of the above documents are signed and filled out!
One of these	Investigators Protocol: Guidelines for developing the Protocol NIH Grant Application (If study is supported by NIH) Cooperative Group Protocol Sponsor's Protocol (for commercially Sponsored Study)

Attachments that may be applicable

	Sponsorship Form and if applicable $2,000 Application Fee
	1. Additional Investigators List
	2. Studies Involving Minors
	3. Studies Involving Drugs, Biologics, Radiopharmaceuticals
	4. Studies Involving Biological Specimens
	5. Studies Involving Exposure to Ionizing Radiation
	8. Request for Waiver of Informed Consent
	9. Studies Involving Use of Medical Devices
	10. Studies Involving Prisoners
	11. Studies Involving Use of PCIR (formerly GCRC)
	Consent Forms
	HIPAA Forms
	All Questionnaires, surveys, etc.
	All recruitment Material and Advertisements
	Investigators Brochure or device manual (for commercially sponsored studies)
	Sponsor's non-significant risk determination (if device study and no IDE was submitted to FDA)
	VA Investigators must include the VA R&D approval letter **with** the submission

HUMAN RESEARCH REVIEW COMMITTEE (HRRC)

For HRRC Office Use Only

EXPEDITED REVIEW APPLICATION

I. BASIC INFORMATION

A. Research Project Title (also include Grant title, as applicable):

Development of an Assent Process for Children Enrolled in the NCS Vanguard Study
INF-04-A, Contract No: HHSN267200700031C

B. Principal Investigator: Robert D Annett, Ph.D. (Definition: The scientist or scholar with primary responsibility for the design and conduct of a research project.)

Faculty Appointment and title/position: Professor
Department and Division: Department of Pediatrics
Phone: 5050-272-4462 Pager/Cell:505-239-0366 Fax:505-272-6845 E-mail:rannett@salud.unm.edu
MSC#:_____ Dept: _____ Address: _____

Required CITI has been completed: Yes (Choose yes or no from drop-down list)
If training has not been completed, it must be completed prior to study approval

Additional investigators: Attached ☒ None ☐

(Note: If additional investigators are involved, all must be listed in Attachment 1)
INVESTIGATOR: An individual, whether faculty, staff, student, consultant, or collaborator, who actually conducts an investigation **or** who is responsible for tasks related to the design, conduct, or reporting of the study including obtaining informed consent.)

C. Study Contact (if different than PI): Jeanne Dalen, Ph.D.
Phone:505-842-8932 Pager/Cell: _____ Fax: 842-5091 e-mail:jdalen@ori.org
Note: If study contact has any interaction with research subjects, this person must also be listed on Attachment 1.

D. What UNM and/or VA entities listed below will be involved in research?

1. Will this research be conducted completely or partially at the VAMC, at approved VA off-site locations, facility and/or by a VA researcher while on official VA duty time?
Yes ☐ No ☒ If yes, provide a copy of the R&D Committee documentation.

2. Will this research be conducted at the CTSC (Clinical and Translational Science Center)?
Yes ☐ No ☒ If yes:
A. Provide a copy of the CTSC Advisory Committee documentation when available.
B. Complete Attachment 11

3. Will this research be conducted at the Clinical Trials Center?
Yes ☐ No ☒

4. Will this research involve a clinical trial and/or laboratory study that applies specifically to the prevention, diagnosis, treatment, or prognosis of cancer?
Yes ☐ No ☒ If yes, provide a copy of the review done by the CRTC protocol review committee (PRC)/NMCCA Medical Scientific Review Committee (MSRC)

E. Will non-UNM/VA entities or employees be involved in research (i.e. NMCCA, LRRI, HIS, other universities)?
Yes ☒ No ☐ If yes, list other entities where the research will take place, indicate if other IRB approvals are required or have been obtained and whether you are relying on that organization's IRB for oversight of the research: Subcontract is with the Oregon Research Institute: Center for Family and Adolescent Research (ORI-CFAR); 707 Broadway NE, Suite 402, Alb. NM 87102. Phone number: 505-842-8932, Fax number: 842-5091. Expedited IRB review will be required by the ORI IRB Review Board. Both UNM and ORI-CFAR IRB applications will be submitted simultaneously.

F. Is this a multi-center study (one where different PI's at different institutions are conducting the same study?
Yes ☐ No ☒
If yes, will UNMHSC function as the lead (coordinating) center?
Yes ☐ No ☒
If yes, attach a copy of the management plan describing the communication with participating sites regarding: Modifications to the study, safety information, unexpected problems, and study results. Also

include information on the administrative aspects of the study (i.e. record retention, submissions to HRRC office, review of other IRB correspondence, etc.).

G. Is this research project intended to fulfill a requirement of any student curriculum?
Yes ☐ No ☒ If yes, what is the anticipated time frame that the student will be involved in this project?
_____

REQUEST FOR EXPEDITED REVIEW

"Minimal risk" is defined in 45 CFR 46.102(i) as "the probability 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 examinations or tests" Research involving in vitro fertilization, and/or fetus/fetal tissue will not be reviewed in expedited fashion. The expedited review procedure may not be used where identification of subjects and/or their responses would reasonably place them at risk of criminal/civil liability or be damaging to financial standing, employability, insurability, reputation or be stigmatizing unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Note: In order to qualify for expedited review, research activities must (1) present no more than minimal risk to subjects, (2) Not involve classified research, and (3) involve procedures listed in one or more of the following research categories.

Research Categories

This research involves: (You **must** check yes on any **one or more** of the following **[1-7]** in order to qualify for expedited research. If not, you will need to submit a full review study application)

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

   ☐ 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.)

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

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

   ☐ From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, 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.

   ☐ From other adults and children, considering age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected and the frequency with which it will be collected. For these subjects, 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.

3. ☐ Prospective collection of biological specimens for research purposes by noninvasive means.

Examples:

1. Hair and nail clippings in a non-disfiguring manner.
2. Deciduous teeth at time of exfoliation or if routine patient care indicates need for extraction.
3. Permanent teeth if routine patient care indicates a need for extraction.
4. Excreta and external secretions (including sweat).
5. 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.
6. Placenta removed at delivery.
7. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor.
8. Supra- and sub gingival 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.
9. Mucosal/skin cells collected by buccal scraping or swab, skin swab, or mouth washing.
10. Sputum collected after saline mist nebulization.

4. ☐ Collection of data through non invasive 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:

1. 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 subjects' privacy.
2. Weighing or testing sensory acuity.
3. Magnetic resonance imaging.
4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography.
5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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).

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.

II. SPONSORSHIP/FEES

Does this study involve any arrangements with a commercial, nonprofit, or federal entity (sponsor)?
Yes ☐ No ☒
If Yes, Complete: Sponsorship Information and Fees form

III. PARTICIPANT INFORMATION

A. Does this study involve subjects of both genders?
Yes ☒ No ☐

B. Does this study involve? (Mark all that apply):
- ☒ Minors
  (if minors are to be included, complete Attachment 2)
- ☐ Fetuses/Fetal Tissue/Neonates
- ☐ In vitro Fertilization
- ☐ Pregnant Women > 18 years old
- ☐ Pregnant Women < 18 years old
- ☐ Economically/Educationally Disadvantaged
- ☐ Native American Populations
- ☐ Persons unable to give valid informed consent due to a physical or mental condition
- ☐ UNM employees
- ☒ Healthy Volunteers
- ☐ Students
- ☐ Non-English Speaking – specify language _____ (If it is anticipated that non-English speaking/reading subjects will be enrolled, submit a consent form translated in that language and provide documentation of translator's qualifications.)

C. Is study designed to target specific ethnic/cultural groups?
Yes ☐ No ☒ If yes, list groups: _____

D. Will this study involve subjects who meet the federal definition of "prisoner" (see our manual) - section 6.2.2
or who are at increased risk of meeting this definition during the course of the research?
Yes ☐ No ☒
If Yes, Complete Attachment 10

E. If any vulnerable subject populations (as indicated in Section III.B.) are to be included in this study, list additional protective measures to be taken with these subjects. For populations whose decision making capacity may be in question, include how an individual's capacity to consent is determined – both before and during the study. If requesting approval for obtaining consent from a legally authorized representative (LAR), provide clear reasoning and justification:

Participation will be voluntary and participants will have the option of leaving the study at any time. Focus group and family interview participation will not present an increased risk to parents, educators and children ages 7-8 year old as the study is minimal risk and data collection will be limited to asking/answering questions and discussion of study topic. Recruitment and consent materials will be written, as much as possible, at a 5th grade reading level and assent forms will be written in a format/language appropriate for use with a 7-8 year old.

F. For populations whose decision making capacity may be in question, include how an individual's capacity to consent is determined – both prior to enrollment and during the study

(see Guidelines)

In addition to the consent form that parents and educators will fill out, children ages 7-8 will have an additional assent form designed to talk about the study in language appropriate for this age group. The research assistant will go over this form and probe for questions or concerns that the child may have. The research assistant will emphasize the point that the study is 100% voluntary and that by signing the assent form they are not giving up their rights to terminate participation in the study at any time. All participants are told that regardless of the reason, if at any point they would like to withdraw from the study, they are free to do so.

G. If requesting approval for obtaining consent from a legally authorized representative (LAR), provide clear reasoning and justification:
Not applicable

IV. INFORMED CONSENT/HIPAA AUTHORIZATION

Individually Identifiable Health Information (Protected Health Information – PHI) is information that is a subset of health information, including demographic information collected from an individual, and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and in which it is reasonably believed the information can be used to identify the individual.

A. Does this project involve the use or disclosure of Individually Identifiable Health Information (referred to as Protected Health Information – PHI)?
- ☐ No, PHI is not being collected or HIPAA is not applicable (such as for international research)
- ☒ Yes, one of the following actions must occur:
  - ☒ Include appropriate HIPAA Privacy language in a modified consent form document
  - ☐ Waiver of HIPAA Authorization is being requested – Complete Attachment 8

B. Is standard written HRRC Informed Consent Document required?
- ☒ Yes, informed consent document(s) attached. (NOTE: Consent document language may be streamlined but must contain required elements. For more information, see our manual - and go to section 7.3.)
- ☐ No, modified informed consent document(s) attached (i.e. form does not include all required Elements and/or no signature). Complete Attachment 8
- ☐ No, waiver of informed consent is being requested. Complete Attachment 8
  Note: Waiver for informed consent is not allowable for FDA-regulated research.

V. DRUGS/DEVICES/RADIOPHARMACEUTICALS

A. Does study involve use of drugs, biologics, and/or radiopharmaceuticals?
Yes ☐ No ☒

If yes, complete Attachment 3

B. Does study involve the use of medical devices?
Yes ☐ No ☒
If yes, complete Attachment 9

C. Does this study involve exposure to ionizing radiation (x-rays, radionuclides, nuclear medicine scans, DXA scans, CT scans)?
Yes ☐ No ☒
If yes, you must complete Attachment 5

D. Does this study involve exposure to non-ionizing radiation (MRI, ultrasound)?
Yes ☐ No ☒
If yes, differentiate between procedures for standard care and research

E. Are readable MRI images being obtained through research procedures?
Yes ☐ No ☒
If yes, a) describe the images to be obtained in this study and b) explain whether all images will be reviewed by a designated radiologist. If the radiologist agrees that only certain images will need review or that none will be useful for reading, specify the recommended review plan:

F. The HRRC requires that images obtained through research be read by a qualified neuroradiologist /radiologist. Please state who will perform this evaluation: _____

VI. BIOLOGICAL SPECIMENS

A. Does this study involve use of biological specimens (these may include samples originally collected for research or non-research purposes or use of archived specimens)?
Yes ☐ No ☒
If Yes, Complete Attachment 4

VII. SUMMARY OF RESEARCH

Note: Each question must be fully addressed; a reference to the protocol or Investigator's Brochure will not be accepted.

A. Hypothesis/Study Goals (questions hoped to be answered by study):

The overall goal of this study is develop an informed assent process for children ages 7-8 years old who will be enrolled in the National Children's Study (NCS). We propose to develop a prototype for an interactive media-based assent tool and evaluate child engagement, comprehension, and parental acceptance of the assent process. The study will be conducted in two parts. In part 1, we will examine the attitudes, beliefs and concerns of educators and parents (without children present) towards the development of a media-based assent tool for children ages 7-8 years old using focus group methodology. In part 2, we will develop a prototype based on information gathered in part 1 and will

invite back the parents (with their children present) to test the prototype and provide feedback to inform the final media content. Information gathered in this study will come from qualitative data gathered in focus groups and family interviews. Specifically, this proposal will:

Aim 1: Conduct focus groups of educators and parents of children ages 7-8 to inform the development of an informed assent process based on developmentally-appropriate presentation of research concepts within the NCS to children 7 and 8 years of age.

Aim 2: Develop a prototype for a media-based assent tool for children 7 and 8 years of age participating in the NCS and gather parental and child feedback to inform the final interactive media content and evaluate efficacy before significant resources are invested in a final product.

B. Background Information

1. Summarize previous studies in the field, including previous human, laboratory, and animal studies (describe existing knowledge):

The primary goal of the Assent Vanguard pilot study is to determining the feasibility, quality and cost of developing a robust assent process for children enrolled in the NCS. Unfortunately, little empirical evidence exists about the optimal procedures to gain the voluntary assent of children for biomedical research. Children bring different developmental capacities and experiences to treatment or research participation decisions (Scherer, Annett, Brody, et al, 2007). Consequently, they are apt to differ in the depth of their understanding and appreciation of research (Brody, Annett, Scherer, et al, 2005), their perceptions of risks and benefits (Annett, Brody, Scherer, et al 2004), and their judgments about participation (Brody, Annett, Scherer, et al, 2009). For example, young children are typically less capable of understanding the research and more likely than adolescents to rely on parental opinions. Parents of younger children may also approach research participation decisions differently than parents of older children. Thus, we believe the most responsible and ethical first step for valid child assent in the NCS study is to approach this population directly, gaining first-hand knowledge and experience regarding age-appropriate assent methods.

2. What is the rationale for performing the research? For example, if a new drug is being tested, how does the drug work (mechanism of action):

The greatest need for guidance comes from the problem of how to engage children in the assent process in a way that provides the most beneficial protection, and yet assures that child participants are accorded their full rights. In addition, there have been rapid technological advances in media and interactive technologies that have provided important new opportunities for delivering programs to children and adolescent populations.

C. Experimental Design

1. Concisely describe experimental design and procedures (include optional testing and blinding/un-blinding procedures if applicable) to be used to accomplish study goals. Include a precise description of all tests and measurements and expected duration. Describe methods by which data will be managed (stored and destroyed), analyzed, and interpreted:

Aim 1 Methods.

Two separate focus groups will be conducted: (1) parents of children ages 7-8, and (2) professional educators of children ages 7-8. All focus groups will be conducted until saturation of themes has been reached. The following domains will be assessed within respective groups:

Parents of children 7 and 8 years old. (1) Presentation Medium: determine the preferences of parents for explaining the study to children (parent and child together, separate, with or without a research assistant present); what types of media are of greatest interest to their children; their child's perceived skill level with contemporary media (e.g., computer, hand held devices), and (2) Vernacular: determine how content within the consent/assent for the NCS can be presented to children; for example, we seek to understand the optimal content to characterize risks and benefits associated with an observational study such as the NCS, as well as the specific elements of the protocol and collection of samples from the children themselves.
Educators of children ages 7 and 8 years old. (1) Presentation Medium: what state-of-the-art media technologies are successfully being used in classroom and professional setting with children in this age range, and (2) Vernacular: determine how best to characterize risks and benefits associated with an observational study such as the NCS; how to provide information to children without undue influence; appropriate emphasis in consent; content information for parent-child discussion vs. media-child discussion, and appropriate length of assent administration.

Aim 2 Methods.

Information obtained in Aim 1 will be utilized to inform the development of a media-based assent tool prototype for children ages 7-8 years old who will be enrolled in the NCS. Using storyboard software such as "Toon Boom Animation" (www.toonboom.com), the prototype will consist of developmentally-appropriate footage and graphics to educate children about the protocol elements they would be asked to be involved in regarding NCS study participation. Potential domains include the purpose of the study, specific procedures, risks, benefits, and compensation. The prototype will be presented on an IPAD device and will be interactive in nature. This prototype will then be tested with healthy children of the parents involved in the Part 1 focus groups to evaluate child engagement and comprehension, and parental acceptance of assent process. The goal is to inform the final interactive media content and evaluate efficacy before significant resources are invested in a final product. Approval of the storyboard prototype will be obtained from the NCS prior to family interviews.

The following domains will be assessed: (1) appropriateness regarding length of assent administration, (2) measures of children's comprehension of basic elements of participation in the NCS, (3) children's attention to and interest in the assent protocol, and (4) parental acceptance of assent process.

Sample. Candidate participants will be drawn from the Albuquerque area and Valencia County, which is the actual recruitment site for the NCS protocol in New Mexico. It is anticipated that participants will reflect the ethnic composition of the community (45% non-Hispanic white, 44% Hispanic, 5% Native American, 3% African American and 3% Asian).

Participants for the *parent* focus groups and *parent/child* dyad interviews will be recruited from Valencia County elementary schools over a period of two months. Parent/Child Inclusion Criteria: (1) male or female parent/guardian of at least one child ages 7-8 years old, (2) child assent to participate, (3) willingness to participate in both part 1 and part 2 of the study, and (4) parent and child able to read and speak English (self-identified).

Participants for the *educator* focus groups will be recruited from the Albuquerque area from the Explora

Science Center and Children's Museum of Albuquerque and from Valencia county elementary schools over a period of two months. Educator Inclusion Criteria: (1) male or female in a professional educator role for children ages 7-8 years old, and (2) able to read and speak English (self-identified).

The following table specifies the estimated sample size for each group.

Sample Size	Participants per Group	Range	# of groups	Estimated Sample Size
Part 1				
Parent-only focus groups	8	6-11*	4-5	32-40
Educator focus groups	8	6-11*	4-5	32-40
Part 2				
Parent/child dyads	individual family interviews			32-40 dyads

*Up to 11 participants will be recruited for each group to allow for adequate group size should some people need to cancel or be absent.

Procedures. Once appropriate approval is obtained from participating schools/clinics, letters will be sent to potential participants by pre-identified school staff connected with the NCS study who will identify eligible parents/educators by the inclusion/exclusion criteria. The letter will provide preliminary information about the study and will request that participants contact research staff is they are interested in participating (Appendix A). Once contact has been made, the research assistant will ascertain eligibility for the study, provide additional information, answer any questions, and, if still interested in participating, get contact information (name, address, phone number, or email) so that the participants may be contacted to schedule a focus group appointment. Secondary procedures will also be implemented which will include advertisements through school media channels, e.g., newsletters, bulletin boards (Appendix B).

Group participants will be recruited approximately two to four weeks before the planned focus group. Final focus group times will be arranged by telephone or email with each participant. Confirmation letters will be mailed to each participant one week before the session along with a copy of the study consent/assent form (Appendix C) (although participants will not complete the consent/assent process until the actual focus group or individual family interview). The research assistant will make reminder telephone calls to each participant the evening before the focus group or interview. Informed consent will be obtained from the parents/educators prior to the start of the focus group and assent will be obtained from the child prior to the start of the individual family interview. There will be ample opportunity to ask any further questions before signing forms. Focus groups and family interviews will be held in a conference room at the University of New Mexico Valencia Campus NCS Study Office. Parking and child care will be provided. Only one focus group will be held a day to allow for adequate time for thorough debriefing of the moderator team (focus group moderator and assistant moderator specifically dedicated to this project) after each group. Individual family interviews will be scheduled in 2 hour blocks to allow adequate time for debriefing. All groups and interviews will be audio taped using a dual-taping system. Only self-chosen alias names, will be used during group and interview discussions to insure the confidentiality (on audio-tape) of participants.

Focus groups. The focus groups will be moderated by Dr. Jeanne Dalen, who has experience

conducting focus groups using techniques outlined by Morgan (1998) and Krueger (1998). The study research assistant will serve as the assistant moderator. The assistant moderator's primary responsibilities will be to draw a seating diagram, assign unique participant ID numbers for coding on the questionnaires and to link to the alias names on the audio recording (rather than using participants' names), assist with the audio-taping equipments, and take field notes during the focus group sessions. Field notes will include a speaker log—a running record of the first phrase of what each speaker says. This log will later be used when the audiotapes are transcribed to provide clear data about who (e.g. Speaker #1, #2) said what. Field notes will also include key points of the discussion, notable quotes, and important observations such as silent agreement and obvious body language (Kruger, 1998).

Initially, the moderator will adopt a directive role, restating the purpose of the group and leading introductions. The moderator will also elicit agreement from group members that what occurs in the focus group is confidential and not to be discussed outside the group. The moderator will first provide an overview of the NCS study and assent procedures. After this introductory phase, the moderator will adopt a more facilitative role. The specific open-ended questions for the focus groups have been developed using guidelines and techniques described by Krueger (1998). The focus group questions are found in Appendix D. Initial introductory questions will allow participants to relax and become familiar with the topic before key questions are. Questions will be continually explained, modified, and redirected as necessary to encourage discussion and to ensure that all aspects of attitudes, beliefs, and concerns toward the development of a media-based assent tool are discussed. Inconsistent, vague, or cryptic comments will be probed for understanding. As recommended by Krueger (1998), no push towards ensuring conformity or consensus will be made since the goal is to derive a comprehensive picture of attitudes.

Each focus group will end with a participant verification phase (Kruger, 1998). Participants will have an opportunity to summarize their thoughts and feelings and to respond to a summary of key points presented by the moderator and assistant moderator. Immediately following the group meeting, the moderator and assistant moderator will meet for a debriefing session. They will share perceptions of critical points and notable quotes that emerged from the focus group.

Family Interviews. These interviews will be moderated by Dr. Jeanne Dalen who has significant experience using semi-structured interviewing procedures with both children and adults. The moderator will first provide an overview of the purpose of the study and assent procedures. Dyads will also be reminded that though the NCS is a real study, the parent/child dyads are not in reality being asked to be a part of the study. Instead, we would like to get their opinions on how best to inform future children enrolled in the study. We will educate the dyad on how the media device works and conduct the presentation of the storyboard with them. Evaluation of the prototype will be conducted in two ways. First, comprehension questions embedded within the storyboard presentation will be given to the dyad to ascertain knowledge levels. Then, a semi-structured interview with both standardized and open/ended questions will be used to solicit the opinions of both the parent and child regarding the prototype (see Appendix E).

Evaluation. 1) The audiotapes from the focus groups/interviews will be transcribed verbatim; 2) the investigators then will begin a process of content analysis of the transcripts from the focus group sessions to describe participants' attitudes, beliefs and concerns; content analysis is a method for making replicable and valid inferences from data to their context; 3) transcriptions will be compared to audiotape recordings and field notes to verify the accuracy of the data; 4) data will be entered into the Atlas/ti software program for systematic analysis; computer-aided content analysis contributes to high reliability because rules for coding are made explicit and consistently applied to text. Strategies for

increasing the reliability and validity (trustworthiness and credibility) of the content analysis have been incorporated throughout the design. Reliability will be strengthened by the use of a consistent moderator/assistant moderator for all focus groups, including participant verification and debriefing activities; audiotapes and verbatim transcripts of focus group sessions; documentation of a clear decision trail with respect to data collection, coding, and analysis; and computer-aided content analysis.

Storage of data. Access to the data is limited to project staff. Confidentiality is maintained by using participant numbers rather than names. All paper files are stored in locked file cabinets in research assistant offices. The data entry is performed by research assistant staff. Access to the keys is limited to project staff. Data files are established only on SPSS data bases. The files are on a password protected local network drive on the Oregon Research Institute (ORI) computer system. Their local office is located at 2700 Yale S.E., Albuquerque, NM 87106. Access is limited to ORI project staff. No identifying information is stored on the computer files. Audiotapes will be made of the focus groups as a mechanism of reliable and valid data collection. Only alias names will be used by the focus group participants during the focus groups. The audiotapes will be maintained until the transcripts of the groups have been verified and will be destroyed at completion of the study. No one other than members of the research team will have access to the audiotapes. They will be stored in a locked file cabinet in the PI's office. Audiotapes will be made of the focus groups as a mechanism of reliable and valid data collection. Only alias names will be used by the focus group participants during the focus groups. The audiotapes will be maintained until the transcripts of the groups have been verified and will be destroyed at completion of the study. No one other than members of the research team will have access to the audiotapes. They will be stored in a locked file cabinet in the PI's office.

Timeline of Activities. Period of Performance: September 23, 2010 – July 31, 2011.

ACTIVITY	MONTH
Phase 1: Develop focus group protocols and submit to UNM & ORI IRB	1-2
Phase 2: Recruit parents and educators for focus group participation	2-4
Phase 3: Develop a prototype of an interactive media-based assent tool	4-6
Phase 4: Evaluation of the prototype with children and parents	6-8
Phase 5: Finalize content for development	9-10

Literature Cited.

Annett, RD, Brody, JL, Scherer, DG, Perkett, EA. (2004). Perceived risk associated with asthma research procedures among children, parents, and pediatricians. Journal of Asthma and Clinical Immunology, 114 (5), 1138-1145.

Brody, JL, Annett, RD, Scherer, DG, Perryman, ML, Coffrin, KMW. (2005). Comparisons of adolescent and parent willingness to participate in minimal and above minimal risk pediatric asthma research protocols. Journal of Adolescent Health, 37, 229-235.

Brody, JL, Annett, RD, Scherer, DG, Turner, C, Dalen, J. (2009). Adolescent asthma research participation decisions: Differential effects of investigator relationships and participation recommendations. Journal of Asthma, 46(5), 492-497.

Morgan DL. Planning focus groups. Thousand Oaks, CA: S; 1998.

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Krueger R. Analyzing and reporting focus groups results. Thousand Oaks, CA: Sage; 1998.

Scherer, DG, Annett, RD, Brody, JL. (2007). Ethical issues in adolescent and parent informed consent for pediatric asthma research participation. Journal of Asthma, 44, 489-496.

2. Provide a description of procedures, if any, that will be performed for diagnostic or treatment purposes:
Not applicable

3. Describe current standard of care for the condition being studied, if applicable:
Not applicable

4. Provide approximate number of subjects to be enrolled locally & study wide (if applicable):
32-40 parents (range: 24-44)
32-40 educators (range: 24-44)
32-40 children ages 7-8 years old (range: 24-44)

5. What characteristics (inclusion criteria) must subjects have to be in this study? (Answer for each subject group, if different):

Parent Inclusion Criteria: (1) male or female parent/guardian of at least one child ages 7-8 years old, (2) child assent to participate, (3) willingness to participate in both part 1 and part 2 of the study, and (4) parent and child able to read and speak English (self-identified).

Educator Inclusion Criteria: (1) male or female in a professional educator role for children ages 7-8 years old, and (2) able to read and speak English (self-identified).

6. What characteristics (exclusion criteria) would exclude subjects, who are otherwise eligible, from this study? (Answer for each subject group, if different).

Parent Exclusion criteria are: (1) not having at least one child age 7-8 years old, (2) child not willing to participate, (3) not willing to participate in both parts of the study, and (4) self-identified as not able to read and speak English.

Educator Inclusion Criteria: (1) not currently in professional educator role for children ages 7-8 years old, and (2) self-identified as not able to read and speak English.

7. Where will the study procedures be carried out?
Focus groups and individual family interviews will be held in a conference room at the University of

New Mexico Valencia Campus NCS Study Office.

8. Please describe how the facilities at the study site conducting the research are adequate for the research? (i.e. private room for study procedures, emergency equipment available, etc.)
The conference room(s) used will have adequate seating, be easily accessible for participants with nearby parking, and have a closed door for privacy.

D. Data Analysis

1. Who will be responsible for performing the statistical/data analysis? Note: If person conducting the data analysis has access to identifiable or coded data, he/she must be listed as an investigator on Attachment 1.
   i. ☐ Sponsor
   ii. ☒ Investigator - Provide name of person: Robert Annett, Ph.D. and Jeanne Dalen, Ph.D.
   iii. ☐ Statistician – Provide name of person: _____

2. What statistical tests are applicable and will be used in this research to analyze the data? If this is an investigator initiated study, provide the rationale for using the statistical methods you've chosen: Qualitative data will be analyzed using Atlas/ti software. Content analysis of the transcripts of the focus groups will be used to describe participants' attitudes, beliefs, and concerns related to the development of a prototype for an interactive media-based assent tool. Initial data analysis will involve several readings of the deidentified transcripts by the investigators to increase familiarity with data and to begin to identify recurring themes. Next, analysis will begin on the textual level using open coding. Codes and memos will be attached to relevant text passages. Units of analysis will be phrases or sentences reflecting attitudes toward electronic media and how this might be used with an assent process in children. Constant comparison of indicators of a given code or concept will be used. Once initial coding is completed, instances of data will be grouped into broad categories. Decisions used to guide the categorization of data will be recorded throughout the analysis process. Any text that does not fit a predefined category will be coded "unknown". "Unknown" text will be re-examined for emergent themes and new dimensions for the model. Thus, both manifest and latent content will be considered in the analysis. Coding frequencies will be examined to aid pattern detection, but unlike quantitative content analysis, interpretation will be based on contextual analysis rather than frequencies alone.

VIII. **RECRUITMENT METHODS**

Please see our manual - Section 11.2 for more information about acceptable recruitment methods.

A. Select the recruitment strategy(ies) from the list below that you will use to identify potential subjects. Check all that apply:

☒ Study investigators will recruit their own patients directly and/or nurses or staff working with researchers will approach patients. *Please explain in detail under question B.*

☐ Study investigators will send an HRRC-approved letter to colleagues asking for referrals of eligible patients interested in the study. The investigators may provide the referring physicians an HRRC-approved Information Sheet about the study to give to the patients. If interested, patient will contact the PI or with documented permission from the patient, the PI may be allowed to talk directly with patients about enrollment. *Attach documents for review.*

☐ Study investigators provide their colleagues with a "Dear Patient" letter describing the study. This letter can be signed by the treating physicians and would inform the patients how to contact the study investigators. The study investigators will not have access to patient names and addresses for mailing.
Example of "Dear Patient" letter. *Attach document for review.*

☒ Advertisements, notices, and/or media used to recruit subjects. The HRRC must first approve the text of these, and interested subjects will initiate contact with study investigators. *Attach ads, notices, or media text for review. Please explain under question B where ads will be posted.*

☒ Study investigators request a *Waiver of Consent/HIPAA Authorization* for recruitment purposes. This waiver is an exception to the policy but may be requested in circumstances such as:

- ☐ Minimal risk studies in which subjects will not be contacted (i.e. chart review only).
- ☐ Review of medical records (containing PHI) is needed to identify prospective subjects who will then be contacted. Explain in *Waiver Form*.
- ☒ Large-scale epidemiological studies and/or other population-based studies when subjects may be contacted by someone other than personal physician (Explain in *Waiver form*)

☐ Direct contact of potential subjects who have previously given consent to be contacted for participation in research. Clinic or program has developed an HRRC-approved recruitment protocol that asks patients if they agree to be contacted for research (a recruitment database) or consent for future contact was documented using the consent form for another HRRC-approved study. *Please explain in detail under question B.*

☐ Study investigators recruit potential subjects who are unknown to them. Examples include snowball sampling, use of social networks, direct approach in public situations, random digit dialing. *Please explain in detail under question B.*

B. Provide details regarding the selected methods of recruitment in the space below (i.e., how, when, where, and by whom are potential subjects approached?):

Parents will be recruited from elementary schools in Valencia County and educators will be recruited from both elementary schools in Valencia County and Explora Science Center in Albuquerque, New Mexico. Upon school approval, pre-identified school staff connected with the NCS study will identify eligible participants by the inclusion/exclusion criteria. These names will remain confidential. Once identified, the family/educator will be sent a letter providing information about the study and will be asked to contact research staff if they are interested in obtaining more information on participation. Research staff will then contact and schedule the parent for the first focus group visit. Secondary procedures will also be implemented which will include advertisements through school media channels, e.g., newsletters, bulletin boards.

C. Describe steps that will be taken to protect subject privacy throughout the research (recruitment, consenting, and research procedures, follow-up, etc.) *For a description of privacy see the HRRC Manual* - section 6.1.3

Recruitment will be conducted through private mailings. Focus groups will be conducted in a private conference room at the UNM Valencia Campus in a space that is being rented out specifically for the NCS study. All focus groups will be conducted with a closed door. Study participants may discontinue participation in the study at any time, free from pressure or coercion. All participants in the focus group will be asked to use only alias names during the focus group and participants will be directed to not

share any personal information revealed in the group. Transcripts of the focus groups will use the participants' aliases. Audiotapes, transcripts, and questionnaires will be kept in a locked file cabinet drawer in the researcher's office. The names, addresses, and phone numbers of the participants will only be used to schedule the focus groups and will not be linked to individual questionnaires or individual focus group results. These names, addresses and phone numbers will be stored in a separate file in a locked cabinet and will be destroyed at the completion of the study. Only the investigators and the research assistant will have access to the completed transcripts and questionnaires.

Data protocol. Access to the data is limited to project staff. Confidentiality is maintained by using participant numbers rather than names. All paper files are stored in locked file cabinets in research assistant offices. The data entry is performed by research assistant staff. Access to the keys is limited to project staff. Data files are established only on SPSS data bases. The files are on a password protected local network drive on the Oregon Research Institute (ORI) computer system. Their local office is located at 2700 Yale S.E., Albuquerque, NM 87106. Access is limited to ORI project staff. No identifying information is stored on the computer files. Audiotapes will be made of the focus groups as a mechanism of reliable and valid data collection. Only alias names will be used by the focus group participants during the focus groups. The audiotapes will be maintained until the transcripts of the groups have been verified and will be destroyed at completion of the study. No one other than members of the research team will have access to the audiotapes. They will be stored in a locked file cabinet in the PI's office.

D. Will you need access to subjects' medical, academic or other personal records for screening purposes or will you receive such information from a data repository?
Yes ☐ No ☒ If yes, explain answer. Specify types of records, how you will access them, what information you will take from the records and how you will use them:

IX. **RISKS/BENEFITS**

A. Describe any potential risks (including risks to an identifiable group), including physical, psychological, social, economic, or legal, as well as those that might arise due to a breach of confidentiality. Identify their seriousness and likelihood (If a placebo will be used, will the placebo arm place subjects at greater risk than the treatment arm?):
This study is minimal risk. Participants may experience some emotional discomfort related to the focus group questions. Participants may experience a loss of privacy if they chose to disclose an attitude, belief, or concern during the focus group that they later regret discussing.

B. Discuss alternatives to study participation (i.e. other treatments or interventions) where appropriate:
The only alternative is not to participate.

C. Identify circumstances for terminating the study:
Participants may choose to leave the focus group at any time during the study.

D. Describe procedures for protecting against or minimizing the likelihood of identified risks. Include any procedures that will be used to maintain confidentiality as applicable:
Recruitment will be conducted via private mailings. Names of families/educators will not be disclosed

to research staff. Initial contact to research staff is made only by those participants who are interested in the study. Focus groups will be conducted in a private conference room at the UNM Valencia Campus in a space that is being rented out specifically for the NCS study. All focus groups will be conducted with a closed door. Study participants may discontinue participation in the study at any time, free from pressure or coercion. All participants in the focus group will be asked to use only alias names during the focus group and participants will be directed to not share any personal information revealed in the group. Transcripts of the focus groups will use the participants' aliases. Audiotapes, transcripts, and questionnaires will be kept in a locked file cabinet drawer in the researcher's office. The names, addresses, and phone numbers of the participants will only be used to schedule the focus groups and will not be linked to individual questionnaires or individual focus group results. These names, addresses and phone numbers will be stored in a separate file in a locked cabinet and will be destroyed at the completion of the study. Only the investigators and the research assistant will have access to the completed transcripts and questionnaires.

E. Describe the expected benefits, including any possible direct benefit (such as alleviating a condition or providing a better understanding of a participant's condition) and any benefits to society (such as learning the answer to an important question). Note: payment to subjects is <u>not</u> a benefit:

Participants may experience satisfaction in participating in a study that contributes to our understanding of how best to educate and assent young children who are participating in the National Children's Study. The information gained in this study will assist the investigators with implementation of the National Children's Study in Valencia County, New Mexico.

F. Explain why the risks are reasonable in relation to the anticipated benefits to subjects and the importance of the knowledge that may reasonably be expected to result:

The risks of this study are minimal when compared to the satisfaction that participants may experience from voluntary cooperation in a study that will help us to understand how best to educate and assent young children who are participating in the National Children's Study. This study is of major importance for our understanding of the genetic and environmental determinants of children's health and increasing children's engagement and understanding of the research process could lead to greater satisfaction and adherence.

X. **COSTS/PAYMENTS**

A. Treatment Related Studies Only: List any costs to the subjects (or their 3rd party payers), including any charges for study drug/devices, procedures, or visits; Complete the following tables (entering procedures from the study calendar or study schedule section). Ensure that the cost section of the informed consent document reflects the costs that are covered by the sponsor and the costs for which the subject or 3rd party payer are responsible.

	Research Procedures (specimens/study visits/procedures/other, done solely for this research study)	Number of samples/procedures	Who will be billed?	
			Study	3rd Party Payer or Subject
1		<u>8</u>		

2				
3				
4				
5				
6				
7				
8				

	Standard of Care Procedures (specimens/study visits/procedures/other, done as standard care but will be used for study)	Number of samples/procedures	Who will be billed?	
			Study	3rd Party Payer or Subject
1				
2				
3				
4				
5				
6				
7				
8				

1. Will subjects/patients be charged for the costs of the investigational drug/device/intervention?

Yes ☐ No ☐ N/A ☒ If yes, please explain:

2. List any costs to subject not already described above. Explain who will be responsible for paying for treatment of adverse events:

Note: If sponsor is paying for treatment of research related injury; submit a copy of the Clinical Trial Agreement (CTA) for review.

B. Will participants receive any compensation?

Yes ☒ No ☐

If yes complete the following:

1. Dollar amount per visit and maximum amount possible: Monetary compensation will be provided for study participation time and travel. Specifically, educators will receive a $25 gift card + $5 travel money; parents will receive a $25 gift card + $5 travel money at both the focus group and the individual family interview ($60 total); and children will receive $10.
2. Schedule of payments (at each visit, after final study visit:) at completion of the focus group
3. Method of payment (Cash, check, Course Credit, Other): cash
4. Explain why the proposed, compensation is reasonable and fair and appropriate for subject's time involved. Explain why payments do not constitute (or appear to constitute) undue pressure, influence, or coercion to participate in the research study.

$30 is a minimal amount of compensation for approximately 2 hours of focus group time.

XI. **INFORMED CONSENT PROCESS**

(If you are requesting a waiver of informed consent, skip to section XII)

To assist in answering the following questions on the consent process, refer to HRRC Manual - Section 7 and the HRRC Clinical Research Working Guidelines on Obtaining and Documenting Consent.

A. Provide a detailed timeline that describes the consent process from study introduction, discussion, to signing of the consent form and beyond:

Group participants will be recruited approximately two to four weeks before the planned focus group. All group participants will be sent a copy of the consent form in the mail once they have signed up to attend a focus group. Consenting/assenting will occur when a participant arrives at the focus group or family interview and will be conducted by the investigator and research assistant. The research assistant will explain the study in detail and answer any questions. Parents and educators who agree to participate will sign an HRRC-approved consent form. In addition to the consent form that parents and educators will fill out, children ages 7-8 will have an additional assent form designed to talk about the study in language appropriate for this age group. The research assistant will go over this form and probe for questions or concerns that the child may have. The research assistant will emphasize the point that the study is 100% voluntary and that by signing the assent form they are not giving up their rights to terminate participation in the study at any time. All participants are told that regardless of the reason, if at any point they would like to withdraw from the study, they are free to do so.

B. Describe how you will provide the prospective subject or their representative sufficient opportunity and time to consider whether or not to participate:

Study participants will have a choice about whether or not they choose to respond to the information letter they receive. The focus groups will not be conducted until at least two-four weeks after recruitment. All participants will be sent a copy of the consent form and the prospective participant will have that time to consider whether or not they want to participate and will make the final decision as to whether or not they attend, initialize the consent form, and participate in a specific focus group or family interview.

C. Describe how you will minimize the possibility of coercion or undue influence:

The study participant will make the final decision as to whether or not they want to participate in the study. The participant will have the choice of getting to the focus group or not, and of participating or not once he/she is there. Payment will be explained as reimbursement for time and effort and is not excessive. The participant has the right to choose to withdraw participation at any time.

D. Describe how you will attempt to ensure the information given to the subject or their representative will be understood:

The information will be HRRC-approved and written as much as possible at a 5th grade reading level and the assent form will be written in an age-appropriate format. The research assistant will review the information about the study verbally with the potential participants and will be available to answer

any questions that he/she may have. The investigator will also conduct the final consenting at the focus groups and will be available to answer any questions. All potential participants will have contact information for both Drs. Annett and Dalen and the research assistant and will be able to call or email for additional information or clarification at any time before or after the focus groups.

E. Describe how the consent process will be documented in the research and/or medical record (timeline, discussion, questions answered, subject given a copy of the consent, etc). Include whether a copy of the consent form will be placed in the subject's medical record). *Note: For greater than minimal risk studies a copy of the informed consent documents must be placed in the medical record (except in certain instances for confidentiality reasons related to sensitive information).*

This study is minimal risk. The research team will not have access to a potential participant's or a participant's medical record and nothing about the study will be recorded there. Consent will be documented by a signed consent form completed at the focus group.

If the consent form will be placed in MR, the consent form should inform the participant of this. Does the consent form state this?
Yes ☐ No ☒ Explain Answer (where is this located in consent):

Will not be part of MR.

F. It is not general practice to file research data in a subject's medical record. If you plan to place the data collected for this study in the subject's ***medical record***, please explain why this is necessary.
N/A ☒

XII. CONFIDENTIALITY OF RESEARCH DATA

A. Will you maintain any direct identifiers (names, Social Security numbers, patient, hospital, laboratory or claim numbers, addresses, telephone numbers, locator information, etc.)
Yes ☒ No ☐ If No, skip to Section XIII
If Yes, explain why this is necessary and complete the rest of section XII:
Names, addresses, telephone numbers, and emails will be collected only to schedule the focus groups. At the completion of this study, this information will be destroyed.

1. Will you retain a link between study code numbers and direct identifiers?
Yes ☐ No ☒ If yes, explain why this is necessary, where the link will be kept, and how long the link will be kept:

2. Describe how the data will be coded to protect it against disclosure to the public or to other researchers or non-researchers. Explain who (other than members of the research team) will have access to data (e.g., sponsors, advisers, regulatory agencies, HRRC, etc.):

Focus groups and transcripts will be conducted using only alias names. Transcripts will be stored on a password protected computer at either UNM or ORI-CFAR. No one outside of the research team will have access to the data.

3. Do you plan to use any results from this study (that are identifiable or linked) for other studies in the future?
   Yes ☐ No ☒ If yes, explain answer and include this information in the consent form:

   There will not be any identifiable or linked data in this study.

XIII. **ADDITIONAL INFORMATION**

A. Will you make audio-visual tape recordings or photographs of subjects?
Yes ☒ No ☐ If yes, this information must be disclosed in the procedure section of the consent form. Explain what type of recordings you will make, how long will you keep them, and if anyone other than the members of the research team will have access to them:

Audiotapes will be made of the focus groups as a mechanism of reliable and valid data collection. Only alias names will be used by the focus group participants during the focus groups. The audiotapes will be maintained until the transcripts of the groups have been verified and will be destroyed at completion of the study. No one other than members of the research team will have access to the audiotapes. They will be stored in a locked file cabinet in the PI's office.

B. Does any "Investigator" (Principal Investigator, co-investigator, or any other person whether faculty, staff, student, consultant, or collaborator) who is responsible for tasks related to the design, conduct or reporting including obtaining informed consent of this study have a significant financial or other conflict of interest in this study?
Yes ☐ No ☒

Note: UNM's Conflicts of Interest in Research Policy requires that all "investigators" listed on Attachment 1 must complete a UNMHSC Conflict of Interest Disclosure Statement and turn it in to HSC Pre-Award or Main Campus Office of Research Services. Copies of each disclosure must accompany this application. An application will not be reviewed until a Conflict of Interest Disclosure Statement has been received for each investigator.

ACKNOWLEDGEMENT AND SIGNATURE

The signature below certifies that:

- The information provided in this application form is correct.
- The Principal Investigator (PI) and study personnel are aware of, and agree to conduct the research in accordance with state law, Good Clinical Practices and regulations presented in the Code of Federal Regulations (CFR) Title 21 Parts 50, 56, 312 and 812 / Title 45 Part 46 and Title 45 Parts160-164 (the HIPAA Privacy Rule).
- The PI agrees to conduct the research in accordance with the three basic ethical principles of the Belmont report (Respect for persons, Beneficence, and Justice)
- The PI will seek and obtain prior written approval from UNM HSC HRRC for any substantive modification in the proposal, including, changes in procedures, co-investigators, etc.
- Unanticipated problems involving risks to subjects or others in the course of this study will be promptly reported to UNM HSC HRRC in accordance with UNM HSC HRRC Policy for Reporting Unanticipated Problems.
- The PI or someone under the PI's supervision will explain the consent form to all prospective subjects before obtaining their signature (unless waiver or alteration of consent is approved).
- Any significant new findings that develop during the course of this study that may affect the risks and benefits to participation will be reported in writing to UNM HSC HRRC and to subjects.
- The research may not be initiated until final written approval from UNM HSC HRRC is received.
- This research, once approved, is subject to continuing review and approval by UNM HSC HRRC (applies unless the HRRC provides written determination that research is *exempt*).
- The PI will comply with all UNM HSC HRRC requests to report on the status of this study.
- The PI will maintain records of this research according to federal and state regulations and guidelines, including keeping copy of this application for the investigator's records. *If this application is approved, the PI must maintain copies of all HRRC correspondence for at least 3 years (5 years for VAMC research) after the completion of the study; or longer if required by study sponsor.*
- Appropriate administrative, technical and physical safeguards to protect the privacy of protected health information are in place.

Principal Investigator

Your signature on this form indicates that you will be responsible for ensuring that all investigators at this site fulfill their responsibilities as Principal or Sub-Investigators as defined in the Code of Federal Regulations, the conditions listed above as well as any additional responsibilities that may be imposed by the UNMHSC HRRC. If these conditions are not met, approval of this research could be suspended.

Signature of Principal Investigator

_____ Date _____

Printed name of principal investigator (including middle initial and highest earned degree)