IRB Protocol Application #IRB0006181, PI: Sheila K Hanson

Title: MHA Nation Drone Project Needs Assessment

Initial Approval Date	07/08/2024
Expiration Date	07/07/2025
Protocol Overall Status	Administratively Closed
Current Status	Administratively Closed
Protocol's Review Type	Expedited

Review Comments

Date	Section/Field
12/13/2024 3:06 PM	General

Section	General
Type	General Note
Status	Resolved
Comment	Expedited amendment requires member review.
Attachments	

Date	Section/Field
11/15/2024 3:31 PM	General

Section	General
Type	General Note
Status	Resolved
Comment	Expedited amendment requires member review.
Attachments	

Date	Section/Field
06/28/2024 1:13 PM	General

Section	General
Type	General Note
Status	Resolved
Comment	Expedited proposal requires member review.
Attachments	

06/27/2024 2:01 PM	General

Section	General
Type	Modifications Required
Status	Resolved
Comment	Please see the comments below for a listing of revision/clarification requests from the reviewer assigned to your IRB review. The Review Comments table is only to help you quickly identify the issues and shouldn't be used for submitting changes in the conversation option. You will need to make the changes directly to the sections/questions listed. The reviewer will be able to do a version comparison to easily see the revisions.
Attachments	

06/27/2024 1:59 PM	Privacy & Confidentiality: Describe the records retention plan for all research records (datasets, signed consent forms, etc.), and if applicable, at what point PII and/or deductive identifiers will be removed from the dataset.

Section	Privacy & Confidentiality: Describe the records retention plan for all research records (datasets, signed consent forms, etc.), and if applicable, at what point PII and/or deductive identifiers will be removed from the dataset.
Type	Required Change
Status	Resolved
Comment	Please update your response. You will no longer have hard copies of the consent forms with participant names on them. Also, as indicated in the previous comment, researchers at UNDare required to store the data for at least 3 years after the study has ended.
Attachments	

06/27/2024 11:27 AM	Informed Consent: Adult consent (Only PDF file types)

Section	Informed Consent: Adult consent (Only PDF file types)
Type	Required Change
Status	Resolved
Comment	Since you are requesting a waiver of documentation of consent, remove the line for the participant's name to be written or typed onto the consent form. In order to protect the confidentiality of the subjects, there is no need to have their name on the consent form to indicate that they participated in the research study.
Attachments	

06/14/2024 2:26 PM	General

Section	General
Type	Modifications Required
Status	Resolved
Comment	Please see the comments below for a listing of revision/clarification requests from the reviewer assigned to your IRB review. The Review Comments table is only to help you quickly identify the issues and shouldn't be used for submitting changes in the conversation option. You will need to make the changes directly to the sections/questions listed. The reviewer will be able to do a version comparison to easily see the revisions.
Attachments	

06/14/2024 2:08 PM	Protocol Description: Describe the sampling plan, the sample size or study group(s), planned data analysis, and power of any planned statistical tests (if applicable).

Section	Protocol Description: Describe the sampling plan, the sample size or study group(s), planned data analysis, and power of any planned statistical tests (if applicable).
Type	Question/Clarification
Status	Resolved
Comment	Are you doing any analysis of the interview data?
Attachments	

06/14/2024 2:04 PM	Informed Consent: Explain the process for obtaining informed consent from participants, their parent/guardian, and/or legally authorized representative.

Section	Informed Consent: Explain the process for obtaining informed consent from participants, their parent/guardian, and/or legally authorized representative.
Type	Suggested Change
Status	Resolved
Comment	It would make more sense not to have anyone sign consent forms if not everyone is signing them. Participants would be given a copy of the consent form to keep but they wouldn't have to sign anything. If you choose to go this route, be sure to update responses to any impacted questions. If the tribe is requiring participants sign consent forms, then you'll have to figure out a way to get signed consent from everyone.
Attachments	

06/14/2024 2:03 PM	Informed Consent: Adult consent (Only PDF file types)

Section	Informed Consent: Adult consent (Only PDF file types)
Type	Question/Clarification
Status	Resolved
Comment	Instead of getting written consent from some people and verbal from others, why don't you just get verbal consent from everyone? You'd need to remove the footer and signature lines from the consent form. Participants would be given a copy of it to keep, but you wouldn't collect signatures.
Attachments	

06/14/2024 1:59 PM	Privacy & Confidentiality: Are there potential ethical or legal circumstances when it would be necessary to break confidentiality?

Section	Privacy & Confidentiality: Are there potential ethical or legal circumstances when it would be necessary to break confidentiality?
Type	Required Change
Status	Resolved
Comment	On the consent form you indicate that researchers will have to report instances of suspected child abuse so this should be yes.
Attachments	

06/14/2024 1:59 PM	Privacy & Confidentiality: In what format(s) will the data be maintained during the life of the study?

Section	Privacy & Confidentiality: In what format(s) will the data be maintained during the life of the study?
Type	Required Change
Status	Resolved
Comment	The question is asking in what format the data will be kept, not where it will be kept. That's the next question.
Attachments	

06/14/2024 1:58 PM	Privacy & Confidentiality: Will any personally identifiable information (PII) be collected from or about participants?

Section	Privacy & Confidentiality: Will any personally identifiable information (PII) be collected from or about participants?
Type	Required Change
Status	Resolved
Comment	This should be yes because you're collecting names and geographic data from them.
Attachments	

06/14/2024 1:57 PM	Privacy & Confidentiality: Describe the records retention plan for all research records (datasets, signed consent forms, etc.), and if applicable, at what point PII and/or deductive identifiers will be removed from the dataset.

Section	Privacy & Confidentiality: Describe the records retention plan for all research records (datasets, signed consent forms, etc.), and if applicable, at what point PII and/or deductive identifiers will be removed from the dataset.
Type	Required Change
Status	Resolved
Comment	Please review the help text for this question and provide a more thorough response on data storage. Researchers at UND are required to store data.
Attachments	

06/14/2024 1:56 PM	Privacy & Confidentiality: Describe how personally identifiable research data will be shared among research team members, collaborators, etc.

Section	Privacy & Confidentiality: Describe how personally identifiable research data will be shared among research team members, collaborators, etc.
Type	Required Change
Status	Resolved
Comment	Above you say there is no personally identifiable research data. Here you say there is. If you are collecting or accessing PII, then you need to say yes to the question above and list the variables you'll have. Also, this question is asking how you're sharing personally identifiable information between research team members, not between participants and researchers.
Attachments	

06/14/2024 1:54 PM	Privacy & Confidentiality: Describe how you will protect the privacy of participants while they are being consented for the research (if applicable) and throughout the course of the research procedures/interventions. Examples may include a private setting for obtaining consent or conducting interviews, secure communication methods with participants, or reviewing sensitive participant data in a controlled environment (if applicable).

Section	Privacy & Confidentiality: Describe how you will protect the privacy of participants while they are being consented for the research (if applicable) and throughout the course of the research procedures/interventions. Examples may include a private setting for obtaining consent or conducting interviews, secure communication methods with participants, or reviewing sensitive participant data in a controlled environment (if applicable).
Type	Required Change
Status	Resolved
Comment	This isn't asking about data. It's asking how you're protecting the privacy of participants while they're being consented for the research and while they're being interviewed.
Attachments	

06/12/2024 4:35 PM	Protocol Description: Describe any online/electronic resources be utilized for recruitment, data collection, or storage

Section	Protocol Description: Describe any online/electronic resources be utilized for recruitment, data collection, or storage
Type	Required Change
Status	Resolved
Comment	Will any online/electronic resources be used for recruitment? You mention possibly recruiting via email. You also mention further down that zoom could be used for interviews. Please answer the question in full.
Attachments	

06/12/2024 4:33 PM	Protocol Description: Describe in detail your research design and methodology. Use nontechnical language to describe what participants will do and/or what information will be collected about them.

Section	Protocol Description: Describe in detail your research design and methodology. Use nontechnical language to describe what participants will do and/or what information will be collected about them.
Type	Required Change
Status	Resolved
Comment	Please provide more information on the research design and methodology. Where will meetings be held? How long will interviews last? What type of questions will be asked aside from demographics? The response to this question should explain the research in greater detail.
Attachments	

06/12/2024 4:26 PM	Review Type Determination: Reliance Agreement

Section	Review Type Determination: Reliance Agreement
Type	Required Change
Status	Resolved
Comment	Please attach a copy of the document indicating that the other institution will be relying on the UND IRB review.
Attachments	

Primary Info

Protocol Number	IRB0006181
IRB Protocol Title	MHA Nation Drone Project Needs Assessment
Lay Summary	This research effort is part of a larger study, the MHA Nation Drone Project: Planning & Protocol development to plan for and demonstrate the innovative use of Uncrewed Aircraft Systems (UASs) to serve historically underserved populations. The current study is a needs assessment to better understand the perceptions of and strive to address the needs of the people of MHA Nation in any potential UAS planning and development efforts.
Is this a student project?	No
Is this a continuation to an old protocol?	No

Research Team

Role	Name	Department	Business Title	Edit Permission	Responsibilities
⊖ Principal Investigator	Sheila K Hanson	Entrepreneurship & Management	Associate Professor	YES	Consent Subjects Recruit Subjects Research Design Collect Samples or Data (e.g., Surveys) Project Coordination /Management Data Analysis Oversight of Student Investigator Transcription

Training documents	N/A

⊖ Co-PI	Thomasine Lee Heitkamp	VP Research & Economic Dev	Temp Research Developer	YES	Consent Subjects Recruit Subjects Research Design Collect Samples or Data (e. g., Surveys) Project Coordination /Management Data Analysis Oversight of Student Investigator Transcription
Training documents	N/A				
⊖ Faculty	David T Flynn	Economics and Finance	Professor	NO	Consent Subjects Recruit Subjects Collect Samples or Data (e. g., Surveys) Data Analysis Transcription
Training documents	N/A				
⊖ Graduate student	Rylee S Dahlen (i)	Dean's Office CoBPA		NO	Consent Subjects Recruit Subjects Research Design Collect Samples or Data (e. g., Surveys) Data Analysis Transcription
Training documents	N/A				

⊖ Undergraduate student	Eliana Malnourie (External)			NO	Consent Subjects Recruit Subjects Collect Samples or Data (e.g., Surveys) Data Analysis Transcription
Training documents	N/A				

sIRB Contact

Review Type Determination

For any required documents, please verify that you have the latest version. You can download the latest version by clicking on the document icon:

Are you requesting determination for a project lacking immediate plans for involvement of human participants, their data, or their specimens (for grant proposals only)?	No

Collaborative Research

Will an external IRB act as the IRB of record for this study?	No
Are other institutions engaged?	Yes

Institution	IRB Contact	Email
Nueta Hidatsa Sahnish College	N/A	N/A

Is UND acting as the IRB of Record?	Yes

	Click files to view	Date Uploaded	Uploaded By
Reliance Agreement	MHA_Reliance_Agreement.pdf	06/26/2024 12:45 PM	Sheila K Hanson

Exempt Determination

Research involving any of the following categories is not eligible for exemption IRB review. Does your project involve any of the following: • Prisoners or other institutionalized individuals • Collection of biological specimens • Conducting of biomedical procedures • Recording subjects via audio, video, digital, image, or other platforms.	Yes

Expedited vs Full Board Determination

Any radiation exposure for research purposes?	No
Any FDA approved or investigational drugs requiring an IND?	No
Any investigational devices?	No
Does your study involve the use of stem cells, discarded tissue, fetal tissue, or human blood or fluids?	No
Does the study involve more than minimal risk?	No
Select Research Types View research type descriptions	7 - Research on individual or group characteristics - surveys, interviews

Vulnerable Populations

Indicate if individuals from any of the following groups will be specifically recruited:	• American Indian/Alaskan Native

Upload relevant attachments for inclusion of vulnerable populations.	Click files to view	Date Uploaded	Uploaded By
	Drone_Project_Needs_Assessment_Minute_Request_HHR_Committee_5_2_24_(1).pdf	05/20/2024 11:35 PM	Sheila K Hanson

Provide a justification for the inclusion of vulnerable populations in your study	MHA Nation is the prime grant recipient on the MHA Nation Drone Project: Planning and Protocol Development. A needs assessment is desired to help understand the needs and uses for drones at MHA Nation. Thus we plant to engage in conversations with Tribal members to ensure that their perceptions and opinions are heard.
Auto-determined Review Type Amendment Review Type	Expedited

Protocol Description

Purpose and Goals of the Research	The purpose of the mixed methods (qualitative and quantitative) research is to assess the needs of MHA Nation related to drone use. In order to reflect the needs MHA Nation, our goal is to talk to Tribal members from all MHA Nation segments.
Describe in detail your research design and methodology. Use nontechnical language to describe what participants will do and/or what information will be collected about them.	This is a mixed methods (qualitative and quantitative) research design. Participants will be interviewed individually, in pairs, or in small groups either in HIPPA-compliant Zoom room or in the homes, offices, or meeting rooms of enrolled Tribal members. In Indigenous culture, people tend to bring family or friends along to activities. All participants will be asked to do the informed consent in order to participate. We will ask basic demographic information for introductory purposes (name, occupation, community/location of residence) followed by the questions on the discussion guide. Any demographic information will be deidentified for data analysis and reporting. The researchers will answer any questions participants have about the project during the conversation. Alternatively, MHA Nation residents and enrolled members living in nearby areas will have the opportunity to provide feedback via a survey on a voluntary basis.

Describe what participants will be asked to do and/or what information or specimens will be collected from them.	
Describe any online/electronic resources be utilized for recruitment, data collection, or storage	Project staff will utilize email for recruitment of subjects an sending informed consent forms. Electronic interviews will be done using HIPPA-compliant Zoom. Research staff will type notes on a laptop computer and save to a secure drive.
Specify where the research will be conducted.	The research will be conducted in-person on MHA Tribal lands or in communities (e.g., Bismarck, ND) where enrolled members reside. Research will also be conducted virtually via a HIPAA-compliant Zoom link or over the phone.
Anticipated Start date of the research	06/03/2024
Describe the sampling plan, the sample size or study group(s), planned data analysis, and power of any planned statistical tests (if applicable).	This mixed methods (qualitative and quantitative) research project will utilize a convenience sample and provide the opportunity for the MHA Nation community to provide input in a manner most comfortable for them. The plan is for a minimum sample of n=20 for the qualitative research, but the qualitative research will continue after n=20 up to n=50 as the research team wants to include any potential participants who wish to be heard and voice their opinions about drones. Staff will type notes onto laptop in password-protected Word documents. Later, research team will code notes, finding themes, and triangulate information received in various interviews. Nvivo software may be utilized to help analyze the notes. Further, a Qualtrics link to a quantitative survey will be available to the MHA Nation to provide input. Those data will later be downloaded and descriptive statistics will be generated as well as analyses of group differences (e.g., by geographical segment).
Will the research involve use of data, documents, records or specimens that have already been collected (pre-existing) from individuals, or will be collected solely for non-research purposes?	No

Recruitment

Which of the statements describes the recruitment strategy? (If both apply, select both)	• Potential subjects will self-identify based on response to an advertisement, flyer, presentation or respondent driven sampling

Describe recruitment procedures including where/how recruitment notices will be displayed. If research involves targeted recruitment sampling, describe who will send recruitment messages and in what format:	MHA Drone Project Advisory Board members and Project Team will recruit individuals to participate in interviews. Participants will be recruited over the phone, via email, or in-person via word-of-mouth as a convenience sample. The MHA Nation will also be invited to participate in a voluntary survey to give more individuals an opportunity to provide input on the needs for drones at MHA Nation, particularly for medical uses. The survey link will be shared on the MHA Nation Drone Project Facebook page and MHA Nation Advisory Board members will share the link via email as well.

Attach a copy of any oral script, advertisement, announcement or invitation that will be used.

Click files to view	Date Uploaded	Uploaded By
QUAL_recruitment_script.docx	05/23/2024 12:57 PM	Sheila K Hanson

Indicate the total number of participants to be recruited.	50
List the inclusion criteria.	Adult (age 18 or older), MHA Nation Tribal member or affiliated with MHA
List the exclusion criteria.	Under 18 years of age, neither MHA Nation Tribal member nor affiliated with MHA
Will incentives be offered for the research?	No
Describe any alternative procedures available to those who choose not to participate, if applicable.	Participation is entirely voluntary and participants may choose to exit the study at any time.
Does any member of the research team or anyone else assisting with the research have an authority relationship with potential participants?	No

Informed Consent

Explain the process for obtaining informed consent from participants, their parent/guardian, and/or legally authorized representative.	All interview participants will be given an electronic or hard copy of an informed consent form. When recruiting participants via email, participants will be provided a consent form via email to read in advance. The interviewer will review the consent form with all participants and ask for consent verbally. Potential participants will also be given the choice not to continue. Survey participants will be provided with a consent form in Qualtrics at the beginning of the survey to review before voluntarily proceeding with the survey if they so choose.
Will all participants provide informed consent for themselves?	Yes
Will consent occur in a language other than English?	No
Are you requesting a waiver and/or alteration of informed consent?	No
Are you requesting to waive the signature requirement for informed consent?	Yes
Check the statement that applies to justify waiving documentation of consent:	The research presents no more than minimal risk and includes no procedures for which written consent is normally required outside the research context.
Provide an explanation why your research meets the stated criteria	The research is voluntary and minimal risk. Though there are guiding general questions in a discussion guide, we hope to listen to opinions and remind participants to only share what they are comfortable discussing. These are 'ordinary' conversations that individuals might have about the use of new technology. Regardless of interview format (Zoom, in-person, or phone), , the alternative would be a verbal consent. All participants will receive the consent form and provide their consent, in order to participate, regardless of modality of interview.

Adult consent
(PDF and Docx file types only)

Click files to view	Date Uploaded	Uploaded By
informed_consent_MHA_verbal.pdf	06/27/2024 2:19 PM	Sheila K Hanson
Online_consent.pdf	11/17/2024 9:37 PM	Sheila K Hanson

	Click files to view	Date Uploaded	Uploaded By	Status	Description
Approved Stamped Consent	IRB0006181_approved_consent_v12162024.pdf	12/16/2024 9:11 AM	Renee Carlson	Active	

Risks and Benefits

Indicate all potential risks of harm/discomfort to participants or others.	• Psychological/emotional distress or discomfort • Privacy/Confidentiality
Describe precautions you will take to minimize each of the potential risks identified above.	No identifying information aside from the basic demographics previously mentioned will be collected. Participants may experience some psychological or emotional distress if they have had negative experiences with drones or they may describe a distressing situation (e.g., missing person) that they experienced or others experienced where a drone could have been useful. The research team will only ask individuals to share what they are comfortable sharing and interview will last up to 90 minutes, but typically under an hour.
Describe what steps will be taken if participants experience serious injury, distress, discomfort, or decompensation during research participation.	If significant discomfort occurs beyond what is expected in a discussion about drone use, the interview will be terminated immediately. If needed, the subject will be referred to the UND Counseling or health services or other health services at MHA Nation.
Describe any potential benefits to participants and/or society in general.	Participants may gain understanding of their own beliefs and perceptions about the use of drones at MHA Nation. Understanding the perceptions of MHA Nation related to drones will inform the Tribal government and the funding agency. If the Tribe gives approval to disseminate any of the results of the research more broadly, it could inform academics and practitioners as well as benefit society in better understand the needs for and perceptions of drones on Tribal lands.

Privacy & Confidentiality

Describe how you will protect the privacy of participants while they are being consented for the research (if applicable) and throughout the course of the research procedures/interventions. Examples may include a private setting for obtaining consent or conducting interviews, secure communication methods with participants, or reviewing sensitive participant data in a controlled environment (if applicable).	Virtual interviews will be conducted using a HIPPA-compliant version of Zoom. For all interviews, the research team will plan to hold interviews in a private setting (home, office, or meeting room) where they will not be overheard by others who are not part of of the individual or group interview. Informed consent forms will also be done in the same private setting before interviews begin. Online surveys can be taken in private locations at the respondents choice. Results will be pooled for reporting and any identifying information about participants will be removed from any data files.
Will any personally identifiable information (PII) be collected from or about participants?	Yes
Identify ALL direct identifiers that will be obtained?	Email addresses Geographic data Names Telephone numbers
How long will the PII be maintained?	During the data collection phase and destroyed after data analysis complete.
Why is it necessary to maintain direct identifiers?	In order to reach participants email addresses and sometimes phone numbers will be needed during the recruitment and data collection phase. Geographic location (i.e., segment of the MHA Nation) will be collected to ensure interviewing participants in varied geographic locations amongst the six segments.
Describe the coding system (link) that will be used to protect against disclosure of these identifiers.	Data will be is collected via notes for each participant that will have a “Study ID,” and a password-protected linkage file will be maintained where the Study ID is associated with the subject’s identifiers (name, location, email, and sometimes phone numbers).
How long will the link between identifiers and code be maintained?	The password-protected linkage file will be destroyed after the data are analyzed.
Will any demographic information be collected which could lead to a deductive disclosure of participant(s) identities?	No
In what format(s) will the data originate?	Interview notes will be typed and stored on a password protected computer and drive. Online survey data will be downloaded from Qualtrics and also saved on password protected computer and drive.

Describe how personally identifiable research data will be shared among research team members, collaborators, etc.	Research team members will be working from de-identified research notes that contain only a study ID# during data analysis. PII will only exist in a password-protected linkage file for use during the recruitment and interview phases. No PII will be shared beyond the research team. No PII will be shared will other project members or DOT.
In what format(s) will the data be maintained during the life of the study?	Data will be stored in password-protected Word, SPSS, and Excel files on a password protected computer and drive.
Where will the data be stored?	Data will be stored on a password protected computer and drive.
What security provisions will be taken to protect the data?	• Paper records accessible only by research personnel and locked/secure storage • Computer files accessible only by research personnel and protected by passwords and encryption • Data transfer electronically through secure email and encrypted external storage
Are there potential ethical or legal circumstances when it would be necessary to break confidentiality?	Yes
Describe	For the qualitative research, as stated on the informed consent form, the "law may require us to show your information to a court or to tell authorities if we believe you have abused a child, or you pose a danger to yourself or someone else."
Describe the records retention plan for all research records (datasets, signed consent forms, etc.), and if applicable, at what point PII and/or deductive identifiers will be removed from the dataset.	All research data, including a record of who obtained verbal consent by study ID#, will be stored in password-protected computers which only the research team will have access to and be able to login. Any hard copies of handwritten notes taken during the interviews will be stored and locked in a file cabinet. Only the PI and the research team will have access to these files. The researchers at UND will continue to store the data for at least 3 years after the study has ended. After that time, long-term records retention will reside with NHS College, if so desired, or may be destroyed three years after study completion.
Indicate ALL proposed forms of dissemination.	Journal article Academic paper Conference presentation Other Report to funding agency (DOT)
Describe:	

Connected Projects

Indicate if any part of your project is funded by an external sponsor	Funded/Pending Proposal

Sponsored Research Records

Project ID	Title	PI	Dept	Stage	Status
⊖ UND0028542 (ERAC0005692)	MHA Nation Drone Project : Planning and Protocol Development	Thomasine Lee Heitkamp	VP Research & Economic Dev	Award Amendment	Award Finalized

Sponsor Type	Non-Profit
Sponsor (Prime/Direct)	U.S. Department of Transportation / MHA Nation
Combined Research Files	MHA_FullProposal_v2.pdf MHA_FullProposal_v2.pdf MHA_FullProposal_v2.pdf MHA_Nation_Drone_Project_Proposal.pdf MHA_Nation_Drone_Project_Proposal.pdf
Budget justification	SMART_PROJECT_BUDGET_NARRATIVE.docx SMART_PROJECT_BUDGET_NARRATIVE.docx SMART_PROJECT_BUDGET_NARRATIVE.docx

IRB Protocol Connections

Additional Documents

	Click files to view	Date Uploaded	Uploaded By
Survey, Questionnaire, Data Collection Tool	Discussion_Guide_for_MHA_Interviews.docx	05/22/2024 4:40 PM	Sheila K Hanson
	MHA_Drone_Project_Perceptions_11.15.2024.docx	11/17/2024 9:37 PM	Sheila K Hanson

Grant Application (minus the appendices & budget information, for federally-funded studies, e.g. NIH, CDC, DOD)
Additional Forms or Documents Related to External Study Sites
Product Information
Participant Education Material
Additional Research Protocol Documents
Data Use Agreement
Data Safety Monitoring Plan (More than Minimal Risk) - Submit 'Data Safety Monitoring Plan' if Not included in Protocol
Lead Multi-Center Study - Submit 'Lead Multi-Center Study'
Investigator Brochure
Other Documents (Please appropriately name files)

Adverse Events

Protocol Deviations

IRB Correspondence

Date/Time Sent	Sender	Subject Line	Email Status	Attachments
07/08/2024 3:23 PM	Renee Carlson	IRB Approval Letter and Stamped Consent Form	Sent	IRB0006181_approved_consent_form_v07082024.pdf
11/15/2024 4:30 PM	Renee Carlson	UND IRB Amendment Approval Letter and Stamped Consent Form	Sent	IRB0006181_approved_consent_form_v11152024.pdf
12/16/2024 9:16 AM	Renee Carlson	UND IRB Amendment Approval Letter and Stamped Consent Form	Sent	IRB0006181_approved_consent_v12162024.pdf
09/02/2025 2:44 PM	Michelle Bowles	IRB Protocol IRB0006181 Administratively Closed	Sent	

Requirements

Stage - Revision #	Created	Current Status	Status Date	Approval Date	Submission Review Type	Requested modifications	Notes
Amendment - revision #3.2 **Viewing**	12/13/2024 3:06 PM	Administratively Closed	09/02/2025 2:43 PM	12/16/2024		Study Design, Methods, or Procedures	In order to gather perceptions of community needs, research team plans to add a quantitative component to the study within the same topics as the research themes on the previously approved qualitative research discussion guide. At the MHA Advisory Board meeting on Wednesday, 11/13, at which the PI from NHS College participated, the Advisory Board approved a short survey to be added to the study. Automatically created after "Ready for Member Review" specified.

Amendment - revision #2.2	11/15/2024 3:30 PM	Approved	11/15/2024 4:12 PM	11/15/2024		Updating Research Personnel Team	The following are research personnel to be added to the IRB: Eliana Malnourie and David Flynn. There are both at UND and both have completed their CITI training. Automatically created after "Ready for Member Review" specified.
Initial Protocol Application - revision #1.4	06/28/2024 1:13 PM	Approved	07/08/2024 3:21 PM	07/08/2024			Automatically created after "Ready for Member Review" specified.

Status	Requirement	Completion State	Revision	Completed by	Completed Date
Draft Submission Pending	Submit protocol	Completed	#3.1	Hanson, Sheila K	12/05/2024 11:59 AM
PI Certification Pending	Certify Protocol (PI)	Completed	#3.1	Hanson, Sheila K	12/05/2024 11:59 AM
Training Completion Pending	Complete Human Subjects training on Citi: Sheila K Hanson	Completed	#3.1	System	11/17/2024 9:18 PM
	Complete Human Subjects training on Citi: Thomasine Lee Heitkamp	Completed	#3.1	System	11/17/2024 9:18 PM
	Complete Human Subjects training on Citi: Rylee S Dahlen (i)	Completed	#3.1	System	11/17/2024 9:18 PM
	Complete Human Subjects training on Citi: Eliana Malnourie	Completed	#3.1	System	11/17/2024 9:18 PM
	Complete Human Subjects training on Citi: David T Flynn	Completed	#3.1	System	11/17/2024 9:18 PM

IRB Review Pending	IRB Admin Processing	Completed - Ready for Member Review	#3.1	Carlson, Renee	12/13/2024 3:06 PM
	IRB Admin Processing	Completed - Review Complete	#3.2	Carlson, Renee	12/16/2024 8:58 AM
Approved	*No requirements*		#3.2	Carlson, Renee	12/16/2024 8:58 AM
Administratively Closed	*No requirements*		#3.2	Bowles, Michelle	09/02/2025 2:43 PM

THE UNIVERSITY OF NORTH DAKOTA
CONSENT TO PARTICIPATE IN RESEARCH

Project Title:	**MHA Drone Project Needs Assessment**
Principal Investigator:	**Sheila K. Hanson** **Thomasine L. Heitkamp**
Phone/Email Address:	*701-777-5507* sheila.hanson@und.edu, thomasine.heitkamp@und.edu
Department:	Nistler College of Business & Public Administration

What should I know about this research?
- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?
We expect that your taking part in this research will last approximately 60 minutes.

Why is this research being done?
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MANDAN, HIDATSA & ARIKARA NATION

Three Affiliated Tribes * Fort Berthold Indian Reservation

404 Frontage Road * New Town, North Dakota 58763-9402

TO: Sheila Hanson

FROM: Crystal Taylor,
Recording Secretary, I

DATE: May 20, 2024
RE: Minutes Request

THREE AFFILIATED TRIBES
TRIBAL BUSINESS COUNCIL
HEALTH & HUMAN RESOURCES COMMITTEE MEETING
MAY 2nd, 2024

D. Drone Project – *Rylee Dahlen*

Rylee Dahlen introduced herself and Prairie Rose Seminole, both are TAT tribal members. Ms. Dahlen discussed the needs assessment. Would like to do one on one interviews with tribal members. Already created an advisory board for this project. Councilwoman Monica Mayer states, we already approved the Drone Project. Councilwoman Monica Mayer asked for a motion to approve.

Motion: Councilman Robert White moved to approve the Drone Project (Needs Assessment). Councilman Fred Fox seconded the motion. Vote: 3-0-0. Motion carried.

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THE UNIVERSITY OF NORTH DAKOTA
CONSENT TO PARTICIPATE IN RESEARCH

Title: MHA Drone Project

Project Directors: Sheila Hanson, Thomasine Heitkamp
Assessment Staff: Rylee Dahlen, Eliana Malnourie

School/Department: Institute of Policy & Business Analytics

Purpose of Study:
Given that there is only 1 bridge connecting 6 segments at MHA Nation, the MHA Drone Project, has been working on delivering

life-saving meds using drones to serve the citizens of MHA Nation. The purpose of this survey is to determine community perceptions and needs for future use of drones. We appreciate you taking the time to tell us what you think! You will be asked to fill out an online questionnaire related to drone use. You will also be asked to answer a series of demographic questions as well. Participation will take about 5-10 minutes and you can complete the online survey all at once or stop and return to finish as you have time.

Risks:

There are no foreseeable risks to participating beyond what you encounter in daily life.

Benefits:

You might learn more about your perceptions of drones by participating in this study.

You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to

which you are otherwise entitled. Your decision whether or not to participate will not affect your current or future relations with the University of North Dakota.

Project Information:

The project staff are Rylee Dahlen, Eliana Malnourie, Thomasine Heitkamp, and Sheila Hanson. This project is funded by the United States Department of Transportation. If you have questions, concerns, or complaints about the research please contact Sheila Hanson by email: sheila.hanson@und.edu or by phone at 701.777.5507. If you have questions regarding your rights as a research subject, or if you have any concerns or complaints about the research, you may contact the University of North Dakota Institutional Review Board at (701) 777-4279. Please also call this number if you cannot reach research staff or if you wish to talk with someone else. General information about being a research subject can be found on the Institutional Review Board website "Information for Research Participants" http://und.edu/research/resources/human-subjects/research-participants.cfm

Statement of Confidentiality:

We will not be collecting your name and so your responses will be completely anonymous. In any sort of report that might be published, responses will be pooled. All survey responses that we receive will be treated confidentially and stored on a secure server. However, given that the surveys can be completed from any computer (e.g., personal, work, school), we are unable to guarantee the security of the computer on which you choose to enter your responses. As a participant in our study, we want you to be aware that certain software programs exist that may track or capture data that you enter and/or websites that you visit.

Time:

Most people complete the study in around 5-10 minutes.

Compensation:

There is no compensation for your completion of this survey.

Voluntary Participation:

You do not have to participate in this research. You can stop your participation at any time. You may refuse to participate or choose to discontinue participation at any time without losing any benefits to which you are otherwise entitled. You must be 18 years of age older to consent to participate in this research study. Completion and return of the survey implies that you have read the information in this form and consent to participate in the research. Please keep this information for your records or future reference.

By clicking the circle labeled "I consent" you are indicating that you agree to take part in this research study.

○ I consent

Survey

1. You may have heard about the work of the team on the MHA

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Dr. Kerry Hartman
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220 8th Ave., N
P. O. Box 490
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June 26, 2024

Michelle Bowles, Director of Research Assurance & Ethics
Institutional Review Board
Tech Accelerator, Suite 2050
4201 James Ray Dr Stop 7134
Grand Forks, ND 58202

Dear Ms. Bowles:

I am pleased to confirm that Nueta Hidatsa Sahnish (NHS) College has established an Institutional Review Board (IRB) reliance agreement with the University of North Dakota for the DOT SMART Grant MHA Nation Drone Project: Planning and Protocol supported by a United States Department of Transportation (DOT) Grant (SMARTFY22N1P1G38). I serve as a Principle Investigator on the grant.

MHA Nation Drone Project staff presented the research plan for an assessment of Tribal needs to the Health and Human Resource Committee meeting on May 2, 2024. At that meeting the research was approved by that Tribal Committee. Meeting minutes were also provided in the IRB submission to UND. As part of the grant, there is an approved data management plan in place with DOT covering data sovereignty and privacy. Presently neither NHS College nor the MHA Nation has an IRB. However, NHS College is relying upon the expertise of University of North Dakota's IRB for the ethical review, approval, and management of research involving human subjects.

For any questions regarding this IRB reliance agreement, please contact me by phone at (701) 627-8053 or email.

Sincerely,

Dr. Kerry Hartman
khartm@nhsc.edu

Note: Only .pdf file attachments are merged into this document. All attachments of this project (including: .pdf, .docx, ...etc) are attached to this PDF document. You can access them using the attachments section of your PDF reader.

Here is a list of all the included attachments:

1 IRB0006181_approved_consent_v12162024.pdf
2 Discussion_Guide_for_MHA_Interviews.docx
3 IRB0006181_approved_consent_v12162024.pdf
4 informed_consent_MHA_verbal.pdf
5 Drone_Project_Needs_Assessment_Minute_Request_HHR_Committee_5_2_24_(1).pdf
6 IRB0006181_approved_consent_form_v11152024.pdf
7 Online_consent.pdf
8 QUAL_recruitment_script.docx
9 MHA_Drone_Project_Perceptions_11.15.2024.docx
10 IRB0006181_approved_consent_form_v07082024.pdf
11 MHA_Reliance_Agreement.pdf