Migrant Clinicians Network IRB Checklist

This checklist is utilized by IRB reviewers to determine the project's eligibility status (full board review, exempt, or expedited), and verify the research proposal is consistent with Belmont ethical principles.

Reviewer: _____ Date: _____

Title: _____

_____

Principal Investigator(s): _____

(Proposed) Project Dates: _____

☐ Yes ☐ No Investigator, co-investigator(s), and all research team members have completed initial or refresher training in the protection of research participants.

☐ Yes ☐ No Documentation is on file with the MCN IRB.

Research team member	Current training date (within 3 years)

Is this a funded study? ☐ Yes ☐ No

If yes, what agency is funding the study? _____

Check or NA (not applicable to the proposal)

	PROPOSAL COMPONENTS:	COMMENTS:
	1. Principal Investigator(s): Identified on cover sheet and in consent form. Phone Number and Email Included.	
	2. Type of Project Indicated:	
	3. Cooperating Institution: (e.g., school, clinic, tribe, hospital, etc.) Letter Indicating Willingness to Cooperate Attached	
	4. Special cases: Children: (<18 yrs.) (45CFR 46) a) Informed Assent: Normally obtained from children third (3rd) grade or older b) Informed Consent (parent/guardian) Prisoners, Fetuses, Pregnant Women, Human in vitro fertilization, Cognitively/Intellectually Disabled, Students (>18 yrs.) Research activities conducted outside of the United States Letter of institution abroad indicating willingness to work with researcher	
	5. Proposed Project Characteristics: Check to see if this proposal involves the use of New Drugs, Non-Approved Drugs, Investigational Device Exemption, human tissue, body fluids, pathological specimens, donated organs, fetal material or placental materials use indicated. If yes, verify that the valid IND or IDE number is documented on the Human Subjects Review Form.	

	6. Project Overview: Readability (minimal technical jargon) Purpose of Study, Sponsor of Study, justification for use of human subjects/special populations. The importance of the knowledge reasonably expected to result from the research.	
	7. Protocol Description: Clearly describes: Recruitment Procedures described (how, who, where, when, how long) Access to a population that would allow recruitment of the required number of participants Is a subject selection/exclusion criteria included with an estimated number of subjects? Is this a vulnerable group? Are there anticipated problems in recruiting adequate numbers of participants? Procedures to obtain "Informed Consent" Is a waiver of Documentation of Informed consent OR a waiver of Informed Consent requested? (If yes, does the study involve no more than minimal risk? Are the primary risks associated with a breach of confidentiality concerning the participation in the research?) Is the research not viable without the waiver? Description of procedures to be performed and time required to complete them Includes: research setting and persons who will carry our procedures with their qualifications? Provisions for managing adverse reactions, risks Compensation procedures (payment, etc.) Attachments: Copies of instruments, survey/interview questions, flyers, advertisements, diary, brochures, letters, telephone scripts, and data collection forms to be completed by participants, or used to recruit participants.	
	8. Risks: Anticipated risks to subject/others; physical, emotional, financial Described in: Protocol Description and Consent form Are the risks (including physical, psychological, legal, social, and economic risks) reasonable in consideration of the anticipated benefits? Methods to ensure *confidentiality* described (coding, reporting in aggregate form, no links) Methods to ensure *privacy* described (not violating a participant's space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public). Described record retention (locked *separate* locations, disposal of data, who has access) Retention of data for a period of time sufficient to meet federal, state, and local regulations; sponsor requirements; and organizational policies and procedures following study completion. Additional Risk Considerations Will participants be unnecessarily exposed to risks that could be avoided? Do the researchers identify a process in place in the event a possible risk should occur?	
	9. Vulnerable Populations (if applicable): Is a vulnerable population included? Who is the vulnerable group? (children; prisoners; pregnant women; fetuses; neonates; decisionally impaired adults)? Is use of this group justified?	
	10. Benefits: To subject and others described clearly (payment is not a benefit).	
	11. Explanation of Financial Interest (if applicable): If there is potential financial conflict? (e.g. Does the researcher have a vested financial interest in the intervention?)	
	12. Participants: Consider whether the selection of participants is equitable and whether the research plan has made adequate provisions to protect the *privacy* interests and *confidentiality* of participants (when appropriate).	
	13. Data Monitoring (if applicable): Consider whether data monitoring is appropriate. If so, determine whether research plan made adequate provisions for monitoring the data collected to ensure the safety of participants.	

	14. Resources: Is there sufficient time for the PI to conduct and complete the research? Adequate numbers of qualified staff? Adequate facilities (e.g., secure for data protection). A process to ensure that persons assisting with the research were adequately informed about the protocol and their research-related duties and functions? Availability of medical or psychological resources that participants might require as a consequence of the research? Do research personnel have appropriate training and experience to successfully and safely complete the study?	
	15. Multi-Site Research: Has the PI adequately indicated how information obtained in the multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications would be managed across sites? Is the coordinating center identified with a formal agreement that describes each site's roles and responsibilities? Are obligations of the sponsor and institution clearly described? Are there adequate safeguards in place to guarantee that proper research procedures and participant protections are guaranteed across all research sites?	
	16. Signatures: PI, Grant Director (if applicable)	
	17. Release of Educational Record signed by student	
	18. List of key personnel for the team	

CONSENT FORM:	
Does this consent form include? (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; (2) A description of any reasonably foreseeable risks or discomforts to the subject; (3) A description of any benefits to the subject or to others which may reasonably be expected from the research; (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; (7) An explanation of whom to contact for answers to pertinent questions about the research (PI) and research subjects' rights (IRB), and whom to contact in the event of a research-related injury to the subject; and (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. The regulations further provide that the following additional information be provided to subjects, where appropriate: (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable; (2) Anticipated circumstances under which the subject's participation may be terminated by	

	the investigator without regard to the subject's consent; (3) Any additional costs to the subject that may result from participation in the research; (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and (6) the approximate number of subjects involved in the study. Also consider: Is the consent/permission form in a language understandable to the participant/LAR? Will the person obtaining informed consent or explaining the study to the participant or LAR do so in a language that is understandable?	

Belmont Ethical Principles		
Procedures are described in the protocol in sufficient detail to determine that:		**COMMENTS:**
	Subject selection procedures will be equitable	
	Subjects will have the opportunity to make their own choice regarding participation in the study, free from coercion or undue influence	
	Participants will be able to decline at any time without penalty	
	Participants will be adequately informed of research	
	Available alternatives will not be coercive, or unduly influence participants	
	Compensation schemes will not be coercive, or unduly influence participants. Is compensation appropriate for what is asked of the participants?	
	If voluntary consent of participants will not be sought, justification is appropriate (in the opinion of the IRB Reviewer)	
	Participant's privacy, and the confidentially of their data will be respected.	

This information will help the reviewer <u>determine</u> the appropriate review category. Please *check the category (categories) that are involved*.		
EXEMPT REVIEW: 1) Research involves no more than minimal risk to participants <u>AND</u> 2). involves human subjects in one or more of the following categories. *No exemption is available if the research* children are involved in survey or interview procedures; children are involved in observation of public behavior <u>and</u> the observers participate in the activities observed. *Research that includes audio, video, digital, and image recordings of subjects does not qualify for any of the exempt review categories (no recording of identifiable information and adequate provision of confidentiality of the data is maintained)*		**COMMENTS:**
	Category #1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: a) Research on regular and special educational instructional strategies, or b) Research on the effectiveness of our comparison among instructional techniques, curricula, or classroom management methods.	
	Category #2: a) Research involves educational tests (e.g., cognitive, diagnostic, aptitude, achievement), surveys, interviews or observation of public behavior. b) Data are recorded to prevent identification of subjects. c) Any disclosure of human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.	
	Category #3: Research involves use of educational test(s) (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior not exempt under category 2 but involves: a) human subjects who are elected/appointed public officials, candidates for public office; or b) federal statute(s) require(s), without exception, that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?	
	Category #4: a) Involves collection/study of existing archival data, specimens, or diagnostic specimens (publicly available or recorded to protect identity of subjects).	
	Category #5: Research and/or demonstration project, subject to approval of department/agency head, designed to study, evaluate: a) public benefit or service programs b) procedures to obtain benefits/services c) changes/alternatives to programs/procedures d) changes in methods/levels of payment for benefits/services	
	Category #6: Involves taste and food quality evaluation; consumer acceptance studies a) wholesome foods without additives are consumed b) food consumed is at or below safe level; agricultural chemical, environmental contaminant at or below safe levels (established by FDA, EPA or USDA)	

EXPEDITED REVIEW: This research involves: 1) no more than minimal risk (minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests) AND 2) only involves subjects in one or more of the following categories.

	Category #1: Clinical studies of drugs and medical devices only when condition a) or b) is met. a. 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 risks or decreases acceptability of risks associated with use of the product is not eligible for expedited review.) OR b. 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.	
.	**Category #2: Collection of blood samples by finger, heel, or ear stick/venipuncture as follows:** a. from healthy, non-pregnant adults who weigh at least 110 pounds; amounts drawn may not exceed 550 ml in 8 weeks; collection may not occur more frequently than 2 times per week; or b. from other adults and children,[2] considering age, weight, and health of the subjects, the collection procedure, amount of blood to be collected, and frequency with which it will be collected; amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in 8 weeks; collection may not occur more frequently than 2 times per week.	
.	**Category #3: Prospective collection of biological specimens for research purposes by noninvasive means.** Examples: a. hair and nail clippings in a non-disfiguring manner; b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; c. permanent teeth if routine patient care indicates a need for extraction; d. excreta and external secretions (including sweat); e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; f. placenta removed at delivery; g. amniotic fluid obtained at time of rupture of membrane prior to/during labor; h. supra- and sub gingival dental plaque and calculus, if collection procedure is not more invasive than routine prophylactic scaling of teeth and process is accomplished in accordance with accepted prophylactic techniques; i. mucosal and skin cells collected by oral scraping or swab, skin swab, or mouth washings; j. sputum collected after saline mist nebulization.	
.	**Category #4: Collection of data through noninvasive procedures** (not involving general anesthesia/sedation) routinely employed in clinical practice, excluding procedures involving x-rays/microwaves. If medical devices are employed, they must be cleared/approved for marketing. (Studies to evaluate safety and effectiveness of medical devices are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: a. Physical sensors applied to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or invasion of subject's privacy; b. weighing or testing sensory acuity; c. magnetic resonance imaging;	

	d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.	
	Category #5: Research involving materials (data, documents, records, or specimens) collected or to be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from HHS regulations 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)	
	Category #6: Collection of data from voice, video, digital, or image recordings made for research purposes.	
	Category #7:Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.	