KABARAK UNIVERSITY
DIRECTORATE OF RESEARCH, INNOVATION AND OUTREACH

SCIENTIFIC AND ETHICS REVIEW COMMITTEE

ETHICS REVIEW APPLICATION GUIDELINE

	Item	
1.	Participant Population	The **population** refers to the entire collection of individuals, objects, or events that meet specific criteria and hold potential interest to the researcher. It's essentially the whole group from which a smaller sample is drawn for further investigation. **Guideline:** If applicable, the population should be defined in the proposal, and its involvement in the study should be justified.
2.	Vulnerable Populations	A **vulnerable population** is a group with a higher risk of experiencing negative health, social, or economic outcomes. These groups often have limitations or barriers that make them more susceptible to problems. Vulnerability can stem from various factors, including: ● **Socioeconomic factors:** Poverty, lack of education, unemployment, homelessness, ● **Age:** Children, elderly ● **Health factors:** People with chronic illnesses, disabilities, mental health conditions ● **Social factors:** Racial and ethnic minorities, refugees, immigrants ● **Geographic factors:** People living in remote areas, disaster-prone areas **Guideline:** If a vulnerable population is included, justify why they should be included i.e., they should be included only if all other available options for the study are not forthcoming or relevant. The **'Inclusion of Vulnerable Population's form'** must be comprehensively completed. Any untruths regarding their inclusion would lead to the rejection of the proposal.
3.	Recruitment	A **recruitment strategy** in research outlines the methods you'll use to find and enroll participants in your study.

		Common recruitment approaches include 1. **Traditional methods,** such as flyers in relevant locations, posters, and newspaper ads (for local studies). 2. **Online methods** include social media groups, online forums catering to your target audience, and research recruitment websites. 3. **Organizational partnerships** include collaborations with hospitals, clinics, or community organizations serving your target population. 4. **Direct contact,** such as identifying potential participants through databases or referrals and contacting them directly via email or phone. 5. **Snowball sampling** is where existing participants refer others who might be interested. **Guideline:** In the proposal, if applicable, the specific approach/es should be clearly articulated
4.	Study Procedures	**Study procedures** refer to researchers' specific steps and methods to collect and analyze data. They include; 1. **Participant recruitment:** How participants will be identified, contacted, and enrolled in the study. 2. **Data collection methods:** The specific methods used to gather information, such as surveys, interviews, experiments, or focus groups. These methods should align with the research question and the data types needed. 3. **Data collection tools:** The specific tools used to gather data, like questionnaires, interview schedules, or observation checklists. These tools should be standardized and piloted for effectiveness. 4. **Data management plan:** How the collected data will be stored, organized, and protected to ensure confidentiality and security. 5. **Data analysis plan:** The statistical techniques or qualitative analysis methods used to interpret and draw conclusions from the collected data. **Guideline:** The proposal should provide clear procedures for conducting the study.
5.	Potential Risks	**Risks** are adverse events or circumstances that may hinder its successful conduct or cause harm and loss to the research subjects, the investigators, the environment, and the society. Risks may be physical, psychological, social risks, economic or legal. **Guideline:** All risks should be documented

6.	Protection Procedures	**Protection procedures** in research encompass a set of safeguards designed to minimize the risks of research participation for both participants and the wider community. These procedures ensure ethical research practices and responsible conduct throughout the research process. They may include informed consent, ethical review, data protection and confidentiality measures, risk mitigation strategies, and community engagement. **Guideline:** Protection procedures for the risks identified should be provided.
7.	Data Safety Monitoring Plan	A **Data Safety Monitoring Plan** (DSMP) outlines how the researchers will protect the data collected during a research study. It's a proactive plan outlining procedures to ensure data integrity, accuracy, and security throughout the research process. **Guideline:** Provide the DSMP
8.	Confidentiality and Safeguards	**Confidentiality** refers to the obligation of researchers to protect the privacy of participants and the information they disclose during the study. This means ensuring that data identifying a specific participant is kept confidential and not shared with unauthorized individuals or entities. This is achieved through informed consent, data anonymization, security, and limited data sharing. **Safeguards** encompass broader practices and procedures to minimize risks and ensure ethical research conduct. These safeguards protect not only the confidentiality of data but also the well-being of participants and the integrity of the research process. They include ethics review processes, data safety monitoring plans, informed consent procedures, risk mitigation strategies, and community engagement. **Guideline:** Confidentiality and Safeguards need to be provided in the proposal
9.	Study Benefits	**Benefits** refer to the positive outcomes or advantages that can result from participation in the study. These benefits can be experienced by individual participants, the broader scientific community, or even society. They may include improved health or well-being, increased knowledge or awareness, compensation and incentives, and contribution to knowledge or science. **Guideline:** Study benefits need to be provided in the proposal.
10.	Payment for Participation	**Payment for participation** refers to any form of compensation or incentive offered to individuals who volunteer their time and effort to be part of the research process. It's a way to acknowledge the burden participants take on and potentially encourage recruitment for the study. If payment is to be made, it should not be used to coerce participants; it should be fair and transparent and not excessive such that in

		clouds sound judgment of the participants. **Guideline:** The proposal needs to indicate payment, or lack thereof, for participation.
11.	Risk-Benefit Ratio	**The risk-benefit ratio** (also called the benefit-risk ratio) weighs the potential benefits of an action against the potential risks. **Guideline:** A risk-benefit ratio needs to be provided in the proposal. A guideline is available on Thiga, M. M. (2024). Methodology for Risk-Benefit Analysis in Research. *Kabarak Journal of Research & Innovation*, *14*(01), 1–15. https://doi.org/10.58216/kjri.v14i01.2
12.	Informed Consent Process	**The informed consent process i**s a fundamental ethical requirement in research that ensures participants understand and voluntarily agree to participate in a study. It's an ongoing conversation between researchers and potential participants, not just a single form to sign. **Guideline:** A sample form is available on the university website.
13.	Investigational Drugs / Devices	**Investigational drugs and devices** are still undergoing testing and evaluation to determine their safety and effectiveness. They haven't yet been fully approved by regulatory bodies like the Food and Drug Administration (FDA) in the United States for widespread use in the general population. **Guideline:** If applicable, these need to be indicated, and safeguards for their use must be provided.
14.	Investigator qualifications and competence	**Investigator qualifications and competence** refer to researchers' knowledge, skills, and experience in effectively designing, conducting, and overseeing a study. **Guideline:** Provide brief Curriculum Vitae (CV) for all investigators highlighting relevant education, training, and experience for the study.
15.	Conflict of Interest	**A conflict of interest** (COI) arises when an individual or organization has competing interests that could undermine their judgment or actions. In the research context, this typically refers to situations where a researcher's interests could influence their research decisions in a way that compromises the research's objectivity, integrity, or credibility. COI can be related to financial, personal, institutional affiliation, or intellectual property. **Guideline:** The proposal should contain a declaration of conflict of interest in the affirmative if present or none if there is no conflict of interest.