This checklist aims to cover the essential aspects of an IRB protocol to ensure both ethical and procedural rigor.

**Administrative Details:**

* Protocol title aligns with rational and purpose of study
* Principal Investigator (PI) information is completed and accurate
* Student PIs application has been reviewed and approved by faculty sponsor
* Co-Investigator(s) Information is included when there is one
* Funding Source(s), if applicable

**Protocol Overview:**

* Brief summary of the study objectives
* Estimated start and end dates

**Ethical Review:**

* Statement on the necessity of human subjects
* Explanation of expected benefits and potential risks
* Ethical considerations, particularly for vulnerable populations
* Inclusion of appropriate referral resource information (if potential risks are identified)

**Participant Details:**

* Target population description
* Sample size is stated and matches what is in the informed consent
* Inclusion and exclusion criteria
* Recruitment procedures (attach script for all communications)
* Withdrawal procedures for participants
* Informed consent process (attach consent forms)

**Study Procedures:**

* Description of what participants will do (e.g., surveys, interviews)
* Description of the time commitment for participants
* Description of data to be collected
* Steps taken to minimize risks or discomfort
* Contingency plans for adverse events

**Data Management:**

* Data storage methods
* Data access controls
* Data backup and recovery procedures
* Data destruction timelines and methods
* Anonymization procedures

**Additional Requirements:**

* CITI Training Certificates for all research team members are up to date
* Any necessary external approvals (e.g., other institutions, organizations, letters of support for recruitment, etc.)
* Copies of all data collection instruments (e.g., survey questions, interview guides)

**Reviewer Section:**

* Check for completeness of all sections
* Assess ethical considerations and potential risks
* Verify that all investigators have completed CITI Training- This should be updated automatically on Mentor
* Confirm that data management plans are secure and compliant with regulations