Table 2: Content of Informed Consent Letter

____ Purpose of the research
____ Benefits of the research
____ Procedures
    ____ description of what participants are asked to do
    ____ instrument(s) to measure are identified
    ____ participation in treatment described
    ____ alternate treatment or placebo described
    ____ length of participation
    ____ ethics of control group use addressed

____ Participant characteristics
    ____ approximate number
    ____ age
    ____ gender
    ____ role status

____ Risks to participants
    ____ statement of no known or anticipated risk
    ____ statement of reasonable risks or discomforts to participant and how these are to be minimized
    ____ extent of confidentiality and methods to maintain it
    ____ location of storage of data (locked file cabinet)
    ____ time and method to destroy data (collection forms)
    ____ withdrawal statement (may withdraw from participation at any time without penalty)
    ____ voluntary participation statement
    ____ compensation (if any) or description of any costs to the participant
    ____ group, aggregate data reporting (no identifiable information)

____ Mechanics of informed consent
    ____ contact phone numbers during research (researcher; student researcher; human subjects committee chair)
    ____ written at appropriate reading level for participants
    ____ statement that each person signing the consent is given a copy
    ____ statement of understanding the informed consent letter
    ____ line for signature of participant and date

____ Age guidelines implemented
    ____ <12 years of age or participants with significant cognitive impairments; informed consent is required from parent or legal guardian (letter addressed to parent or legal guardian)
    ____ in above, assent (indication of willingness to participate) must be obtained from participant (to extent of ability) and documented
    ____ 12–17 years of age; letter of informed consent for adolescent (addressed to and signed by adolescent) AND letter of informed consent for parent or legal guardian
    ____ 18 and older; signed informed consent from participants

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Note: Rate each item on the checklist using the following scale. For any NO items, provide specific revision feedback in the comments section.

YES—yes, the item is included and clearly explained to protect human subjects
NO—no, the item is not included or is not clear to protect human subjects (comment)
N/A—the item is not applicable to this research or not needed
Comments—make comments on needed revisions