

PI Checklist - Initial Applications

I. Principal Investigators (PI)/Investigators

- a. Contact information entered and up to date. Note you can edit your own contact information from the online system.
- b. Complete Initial or renew human subjects training.
Note: The PI must hold rank of Asst. Professor or higher or be granted waived - PI from IRB to submit an initial application.

II. Project specific questions

- a. Is your project externally funded? If so, submit grant application.
- b. Are any of the research sites Primary or secondary schools or an off-campus facility? If so, need to obtain and submit Letters of Permission.
- c. Are non-MSU individuals/institutions "engaged" in non-exempt research? Apply for Individual Investigator Agreement (IIA) or Institutional Authorization Agreement (IAA).
- d. Is another IRB reviewing the project? If so, you may be requested to submit approval letter from the other institutions.
- e. Is/will project be submitted to the FDA?
 - i. Submit package insert if using an FDA approved device.
 - ii. Provide IND or IDE (if applicable).
 - iii. Provide explanation as to how & where drug will be stored.
 - iv. Determine whether a data safety monitoring board is necessary.
 - v. If require a MTA, contact MSUT.
- f. Note: Charging for an investigational drug in a clinical trial under an IND is not permitted without prior written approval from the Food and Drug Administration (FDA). Associated with subjects? If so, describe safeguards in place to eliminate coercion.

III. Documents

- a. Consent form
 - i. Audio/video taping? (if optional, include yes/no option. If not, clearly state that it is required for participation)
 - ii. Compensation provided? Include description (be specific).
Note: If awarded by chance, cannot be over \$100 without lottery license. Also, if course credit provided, must have alternative that is equal in required amount of time involved in participation.

- iii. Will subject incur additional costs to participate? Describe.
 - iv. Minors enrolled? Need Parental Permission form and Assent
 - Note: 5-7 yrs. - verbal assent appropriate (submit script)
 - 8-12 yrs. - written and signed assent required
 - 13 - 17 yrs. - can sign parental permission if written as you/your child or states: When we say "you" in the consent form, we mean you or your child, "we" means the study staff. Must have signature line for both the parent and minor.
 - v. Conflict of interest must be describe if applicable
 - vi. If requesting waiver of consent or alteration of consent, you must complete the waiver criteria (4 questions).
 - vii. If enrolling subjects with diminished capacity submit a complete and standardized evaluation to test the capacity of the potential subject. When appropriate the IRB will allow legally authorized individual or family member sign proxy consent. Whenever possible the subject should be approached and give their assent. If you are enrolling subjects with diminished capacity it will be reviewed by the convened board.
 - viii. HIPAA authorization form or waiver of authorization form for protective health information (PHI).
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- b. Survey Instrument
 - Note: Submit all versions (paper/pencil or online). If online, may submit the link to the survey in place of the PDF. IRB must be able to access the survey at any time, not just once.
 - c. Interview/Focus Group Questions.
 - d. Media clips and/or visual stimuli (pictures, videos, computer tasks, etc). Note: If unable to submit all stimuli provide the reason why you are unable to submit all stimuli to the IRB. The IRB may request a representational sample of the stimuli.
 - e. Recruitment/Initial contact script (email, mail, and phone).
 - f. Debriefing form (when deception/incomplete disclosure involved).
 - g. Advertisement (flyer, email, newspaper). The IRB will need to review the actual final product (but can pre-approve the text).
 - h. Translated documents (provide name of native speaker or agency hired to do the translations in the application).

- i. Data extraction sheet or list of variables if collecting data from another source (i.e. charts, existing dataset, etc).
- j. If this is a multi trial medical study, submit the case report forms (CRF).

IV. General Information

- a) Records must be retained a minimum of 3 years following closure.
- b) IRB recommends destroying audiotapes after they are transcribed.
- c) If data is de-identified and cannot identify original subjects with data set, submit a closure application. IRB does not need to continue to review your project.
- d) Include ALL individuals who will require a copy of the IRB approval letter as additional investigators on project. If the project is being done in fulfillment of a masters or PhD the graduate student should be listed as the secondary investigator.
- f) Make sure ALL investigators have current training prior to submission. Note you can search training status of investigators from the IRB website under education.
- g) It is the PIs responsibility that all key personnel working with identifiable data are current with their human subjects training.