

EXPEDITED REVIEW CHECKLIST [Updated Spring-2021]

Study Title:

Principal Investigator (PI):

Faculty Sponsor:

Section A: Eligibility

Indicate which of the following are True or False (T or F) in the appropriate column (P.I. or IRB Reviewer):

(for IRB use only)

P.I. IRB

Subjects DO NOT include protected groups such as children, prisoners, pregnant women, mentally disabled, or economically or educationally disadvantaged persons.

The study does not qualify for an EXEMPT review.

Any ONE or more of the following are true.

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.

Collection of data from voice, video, digital, or image recordings made for research purposes.

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

Clinical studies of medical devices when the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (limits exist).

Prospective collection of biological specimens for research purposes by noninvasive means (i.e., hair and nail clippings, excreta and external secretions (including sweat), mucosal and skin cells collected by buccal scraping or swab, or skin swab).

Section B: Data Collection, Informed Consent, Disclosures

Indicate which of the following are True or False (T or F) in the appropriate column (P.I. or IRB Reviewer): (All items need to be true for approval)

(for IRB use only)

P.I. IRB

None of the investigator's serve in a dual role that may pose a conflict of interest

Selection of participants is equitable

Risk is not greater than encountered in daily life

There are adequate provisions to maintain the privacy and confidentiality of participants

Participants expect that any information collected will be kept private

The study involves generally healthy adults without physical or mental impairments

Informed Consent indicates: Activity involves research

Informed Consent indicates: Description of procedures with opportunity to ask questions

Informed Consent indicates: Participation is voluntary (without undue coercion)

Informed Consent indicates: Participants can withdraw at any time without repercussions

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- _____ Informed Consent indicates: Information about potential risks and benefits to participants
- _____ Informed Consent indicates: All the information a reasonable person would want to know
- _____ Informed Consent indicates: Participants are given information on how to file a complaint
- _____ Informed Consent indicates: Participants must be at least 18 years old.

Section C: IRB proposal (Items not addressed above)

Indicate if each item is present and adequately explained in the IRB Proposal Document as described in the Instructions for Applicants, True or False (T or F) in the appropriate column (P.I. or IRB Reviewer): (All items need to be true for approval).

		(for IRB use only)
P.I.	IRB	
_____	<input type="checkbox"/>	Title
_____	<input type="checkbox"/>	Name and Role
_____	<input type="checkbox"/>	Faculty Sponsor
_____	<input type="checkbox"/>	Purpose
_____	<input type="checkbox"/>	Subjects
_____	<input type="checkbox"/>	Recruitment
_____	<input type="checkbox"/>	Protecting Subjects' Rights
_____	<input type="checkbox"/>	Time Frame
_____	<input type="checkbox"/>	Methods/Procedures
_____	<input type="checkbox"/>	Informed Consent
_____	<input type="checkbox"/>	Other Appropriate Documents, as needed

By signing this document, you are agreeing that ALL items in the Research Proposal are ready for submission to the IRB.

Digital Signature of PI:

Date:

Digital Signature of Faculty Sponsor:

Date:

FOR IRB USE ONLY:

Approved

Not Approved

Approved pending Revisions (revisions need to be sent back to the IRB)

Feedback Comments: