



RESEARCH INVOLVING HUMAN SUBJECTS
NEW PROJECT
APPLICATION INSTRUCTIONS

Submit application materials to:
OFFICE OF RESEARCH AFFAIRS
544 Academic Facility
312-942-5498

Read the instructions carefully.

Answer all questions as completely as possible.

Improper submissions can result in delayed reviews.

All submissions must be typewritten or word-processed.

No Handwritten applications will be accepted.

- 1) Submit the following materials: For a study that requires full board review and consideration you will need: An original signed and dated submission form, the protocol, consent documents, advertisements or recruitment materials, along with **thirteen** copies of the original signed and dated submission form, the protocol, consent documents, advertisements or recruitment materials. (The protocol may be a research proposal, grant, a pharmaceutical protocol or another similar document.) For studies that may be expedited or exempt from continuing IRB review, please submit an original signed and dated submission form, the protocol, consent documents, advertisements or recruitment materials, along with **one** copy of the previously mentioned materials.
- 2) For studies involving investigational drugs or devices, submit **thirteen** copies of the investigational drug or device brochure and **thirteen** copies of a completed drug data or device form. For projects requiring investigational drug services (IDS), contact IDS at 312-942-3018.
- 3) **Thirteen** copies of any scripts, letters, questionnaires or survey instruments and advertisements to be used in this study unless it is an expedited or exempt study. In that case only one copy is needed.

New Project
Rush-Presbyterian-St. Luke's Medical Center Human Subject Review Form

Principal Investigator: _____ Department: _____ Department Address: _____ Email Address: _____ Telephone/Pager #/Fax Number: _____ Study Coordinator/Additional contact person for this study: _____ Study Coordinator/Additional contact phone and email address: _____
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Project Title: _____

Expedited IRB Review
 Exemption from Continuing IRB Review
 Full IRB Review

Total human subjects to be enrolled in this study:	Gender Breakdown (if known)	M:	F:	
If your project plans include any of the following study subjects, indicate below and include the proposed number of subjects:	If you are using any of the following, please indicate below:			
<input type="checkbox"/> Minors (under 18)		<input type="checkbox"/> Existing Data/Records:		
<input type="checkbox"/> Pregnant Women/Fetuses		<input type="checkbox"/> Pathology/Diagnostic Specimens:		
<input type="checkbox"/> Cognitively Impaired				
<input type="checkbox"/> Prisoners				
<input type="checkbox"/> Other				

FUNDING INFORMATION:

Project Sponsor(s): _____	<input type="checkbox"/> Departmental Funding _____
Grant/Contract Application Date(s): _____	
Funding Agency Number(s): _____	Other ORA numbers related to this project: _____
<input type="checkbox"/> Part of a Training, Center or Program Project Grant	Project Director: _____

Assurance

The undersigned assures that the protocols involving human subjects described in this application are complete and accurate, and are consistent with applicable protocols submitted to external funding agencies. All protocol activities will be performed in accordance with Rush-Presbyterian-St. Luke's Medical Center, and State and Federal regulations. No activities involving the use of human subjects will be initiated without prior review and approval by the Rush Institutional Review Boards.

 Signature of Principal Investigator Date Signature of Department Chair Date

***If Student Project: Signature of Supervising Faculty/Date:** _____

FOR IRB USE ONLY: EXPEDITED PER 45 CFR 46.110 PART _____ EXEMPT PER 45 CFR 46.101 PART _____ WAIVER OF ANY/SOME OF THE ELEMENTS OF CONSENT PER 45 CFR 46.116 C OR D _____ WAIVER OF DOCUMENTATION OF CONSENT PER 45 CFR 46.117 C _____
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Approved by IRB Chair or Designated Reviewer/Date

FDA INFORMATION: (applies to drug/device/biologic studies requiring FDA approval)

INVESTIGATIONAL NEW DRUG: IND Number and Name: _____

INVESTIGATIONAL DEVICE EXEMPTION: IDE Number and Name: _____

BIOLOGIC PRODUCT Number and Name: _____

If you have completed any of the above information, submit one copy of the drug brochure or device information with this proposal.

Investigators and other key personnel involved with human subjects on this project, include responsibilities and the names of those who will obtain consent. Include site(s) where the study will be conducted.

ABSTRACT: Provide a non-technical summary of this project. Do not provide extensive experimental details.

RESEARCH PLAN: The research plan should include sufficient information needed for evaluation of this project independent of any other document. When appropriate include inclusion and exclusion criteria, and plans for monitoring the safety of subjects. In treatment protocols, clearly state which procedures are considered standard treatment and which are research procedures.

Does this study have an independent Data Safety Monitoring Group? Yes No
If yes, provide the name of the DSMG and their location.

RECRUITING AND CONSENT PROCESS: The process for obtaining informed consent must be considered by the IRB. This includes who, when, how, and any special circumstances pertinent to the process. The Principal Investigator of the project is responsible for all aspects of the consent process regardless of any delegation of duty. Please provide detailed information regarding how subjects will be identified, who will approach them regarding potential research participation, and in cases of subjects lacking decisional capacity, when and how the Illinois Health Care Surrogate Act will be used.

RISKS: The IRB must review and find that research risks are reasonable in relation to anticipated benefits to subjects or others. **Consideration should be given to all risks.** For example: physical risks, psychological risks, emotional risks, legal risks, social risks or financial risks, risks related to privacy and confidentiality.

PROCEDURES TAKEN TO MINIMIZE RISKS:

BENEFITS: Describe potential benefits to study participants and/or mankind. **Note: Compensation is not a benefit.**

ALTERNATIVES TO PARTICIPATION: (include currently accepted treatments or practices, in some cases it may be appropriate to include non-participation as an alternative)

CRITERIA FOR EXEMPTION FROM CONTINUING IRB REVIEW

No more than minimal risk and one or more of the following:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the among instructional techniques, curricula, or classroom management methods.

- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
 - (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- (5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: The IRB, at its discretion, retains the right to require continuing review when warranted by the nature of the research and/or inclusion of vulnerable subject populations.

CRITERIA FOR EXPEDITED HUMAN SUBJECTS REVIEW

Research Activities involving:

- a) No more than minimal risk
- b) the categories in this list apply regardless of age of subjects, except as noted
- c) standard requirements for informed consent (or waiver, alteration or exception) apply

Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows: (a) from healthy, non-pregnant adults, who weigh at least 110 pounds. For these subjects, amounts drawn may not exceed 550 ml in an 8 weeks period and no more than 2 times per week; or (b) from other adults and children, considering age, weight, and health, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml/kg in an 8-week period and no more than 2 times per week.

Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings, in a non-disfiguring manner; (b) deciduous teeth at the time of exfoliation; (c) permanent teeth if patient care indicates a need for extraction; (d) collection of excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) collection of both supra- and subgingival dental plaque and calculus, provided the collection procedure is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed they must be cleared/approved for marketing. Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, ultrasound, infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

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

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

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.

Note: The IRB, at its discretion, retains the right to require full committee review when warranted by the nature of the research and/or inclusion of vulnerable subject populations.

Investigator Agreement

1. I agree to conduct the study in accordance with the relevant, current protocol and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights or welfare of subjects.
2. I agree to personally conduct or supervise the described investigation.
3. In studies involving drugs or devices, I agree to inform any subjects or any persons used as controls, that the drugs or devices being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent and IRB review and approval are met.
4. I agree to report to the sponsor and the IRB adverse experiences that occur in the course of the investigation.
5. In studies involving drugs or devices, I have read and understand the information in the investigator's drug or device brochure, including potential side effects and risks of the drug or device.
6. I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
7. I agree to maintain adequate and accurate records in accordance with the regulations and to make those records available for inspection in accordance with the regulations.
8. I ensure that I will submit this project for initial and continuing review and approval of the investigation.
9. I agree to report promptly to the IRB any and all changes in the research activity and all unanticipated problems involving risk to human subject or others.
10. Additionally, I will not make any changes to the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
11. I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements found in the regulations.

The IRB and/or the Office of Research Affairs may make audit any or all IRB approved protocols to inquire about study progress, inspect accrued consent documents, inspect accrued data, and/or observe the consent process that is used. The Principal Investigator must cooperate fully with the IRB or Office of Research Affairs staff making such visits.

Signature of Principal Investigator

Date