

Checklist for IRB Application and Informed Consent Document
La Salle University Institutional Review Board for the Protection of Human Subjects in Research

Principal Investigator: _____

Type of IRB review requested: Full panel review
 Expedited review (Paragraph # _____)
 Exemption (Paragraph # _____)

APPLICATION (put X if “yes” and NA if “not applicable”)

- Summary of study in non-technical language
- Indication of study dates (beginning, ending)
- Description of foreseeable risks or discomforts to the participant, their likelihood, and steps that will be taken to prevent or minimize them
- Description of any benefits to the participant or others (monetary compensation is not a benefit)
- Indication of study site(s) and plans to obtain permission from the site(s) to conduct the research
- Description of inclusion/exclusion criteria
- Funding source(s), if any, is specified
- Statement describing to what extent records will be kept confidential and who has access to research records
- Statement describing plans for disposal of data and time of disposal
- Names and locations of all investigators, with contact information for the principal investigator
- Signatures of principal investigator(s) and advisor’s signature if applicant is a student

Attachments:

- Informed Consent form
- All instruments (e.g., questionnaires, interview schedules, standardized tests)
- Approval letters from ALL relevant off-campus sites (e.g., other IRBs, school principal, corporate office) when received
- Advertisement for recruitment of participants (if relevant)

INFORMED CONSENT DOCUMENT

- Written in non-technical terms, understandable to the participant or her/his representative
- Statement that the study involves research
- Explanation of the purpose of the research and the expected duration of participation
- Clear description of what will be done to AND required of the participant
- Description of any benefits to the participant or others (monetary compensation is not a benefit)
- Description of foreseeable risks or discomforts to the participant, their likelihood, and steps that will be taken to prevent or minimize them
- Description of plans and criteria for counseling participants, if adversely affected
- Payment/compensation to participants if they take part in the study (if applicable)
- Statement that participation is voluntary, and participant is free to refuse or discontinue participation at any time without penalty
- Disclosure of any appropriate alternative procedures or treatment courses that might be beneficial to participants (if relevant)
- Explanation of whom to contact for answers to pertinent questions about the research and the participant’s rights. Include names, phone numbers, addresses of contact persons for investigators (for questions about the research) and for the La Salle IRB chairperson (for questions about participant’s rights).
- Statement of whether research findings (individual, group) will be provided to participant
- Clear assurance of participant’s confidentiality or anonymity in records and in reports of the findings.
- Statement describing to what extent records will be kept confidential and who has access to research records

Derived from NIH OHSR site (DPFM, October 4, 2004)