Columbia
COLLEGE CHICAGO

Institutional Review Board

IRB Checklist Cover Sheet for Social and Behavioral Research Application

Note: The IRB is the final authority as to which research level will be assigned to any protocol. You will be notified if the research level is changed from your original submittal.

Check the appropriate box to indicate level of review requested:

☐ Full ☐ Expedited

REQUIRED DOCUMENTS FOR IRB REVIEW

Please check all appropriate boxes. Collate and attach documents in the following order.
*Required for all submittals.

- ☐ *IRB Required Documents Checklist
- ☐ *Signed IRB Research Application (form IRB-1)
- ☐ *Informed Consent/Assent Forms
- ☐ *Completion Certificates from HHS Training (Lesson 1: When HHS Regulations Apply and Lesson 2: What is Human Subjects Research?)

Support Documents:

- ☐ Finalized version of all recruitment materials including flyers, advertisements, brochures, letters to volunteers, oral scripts, etc.
- ☐ Finalized version of interview questions/guides, questionnaires, inventories, surveys, personality tests, volunteer data collection forms, interview & focus group scripts, etc.
- ☐ Supplemental documentation for research involving Vulnerable Populations:
- ☐ Debriefing information, if applicable
- ☐ Letter of collaboration, if applicable
- ☐ Copy of funding proposal, if applicable *(minus appendices & budget information)*

Address: Institutional Review Board (IRB), Suite 201,
600 S. Michigan Ave., Chicago, IL 60605
email: IRB@colum.edu

Request for Expedited Review

(Note: This section must accompany all expedited requests)

Please check the reason for the request for expedited review and submit along with the *IRB Application*:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

   a. ☐ Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   b. ☐ Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. 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, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

   b. ☐ From other adults and children, considering the age, weight, and health of the subjects, 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 per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3. ☐ Prospective collection of biological specimens for research purposes by noninvasive means.

4. ☐ 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.

5. ☐ 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

7. ☐ 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: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

   a. ☐ where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

   b. ☐ where no subjects have been enrolled and no additional risks have been identified; or

   c. ☐ where the remaining research activities are limited to data analysis.

9. ☐ Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

10. ☐ Other Basis (specify):