Instructions for Form: Continuing Review Progress Report

Under the older version of the federal regulations at 45 CFR 46, an IRB must conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. Under the revised Federal regulations, which have a compliance date of January 21, 2019, continuing review is now only required for protocols that require convened review (45 CFR 46.109 (e)), unless the IRB specifically requires ongoing continuing review for a protocol. Under the revised regulations 45 CFR 46.109 (f)(1): Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

(i) Research eligible for expedited review in accordance with §__.110;

(ii) Research reviewed by the IRB in accordance with the limited IRB review described in §__.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), or (d)(8);

(iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

What this change means is that all minimal risk, expedited review protocols that are reviewed and approved under the revised regulations will not require continuing review, unless the IRB specifically determines at the time of initial approval (or later due to changes or problems) that the protocol will still require continuing review. Protocols that were initially reviewed and approved under the older version of the regulations may stay under the older regulations or may be transitioned to the new regulations. The decision to transition a protocol to the new regulations must be made carefully and will be made on a protocol per protocol basis by ORS/IRB. More than likely, protocols that meet the older expedited categories for continuing review of 8 a and 8 c will be transitioned to the new regulations, and therefore future continuing review would not be required. It is important to note that any changes to the research still need to be submitted as amendments before they are implemented.

When required, investigators are responsible for fulfilling the requirement for continuing review prior to the expiration date of the current IRB approval period. If a lapse of approval occurs, all research activities must stop until ongoing approval is obtained. The IRB cannot extend the approval period beyond the expiration date without completing the full continuing review process.

At the time of initial review and continuing review the IRB must make the determination that the research meets the approval criteria as outlined in 45CFR 46.111:

- Risks to subjects are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

- Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonable be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.;
- Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.;
- Informed consent will be sought from each perspective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, §__.116.
- Informed consent will be appropriately documented or appropriately waived in accordance with §__.117.;
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;
- For purposes of conducting the limited IRB review required by §__.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

  (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §__.116(a)(1)-(4), (a)(6), and (d);

  (ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §__.117; and

  (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects; and
- When the research involves women, fetuses, or neonates; prisoners; or children, the research satisfies the additional requirements for IRB approval under HHS regulations subpart B, C, or D, respectively.

When conducting the continuing review and evaluating whether the research continues to satisfy the criteria for IRB approval, the IRB pays particular attention to the following aspects of the research:

- Risk assessment and monitoring;
- Adequacy of the process for obtaining informed consent;
- Investigator and institutional issues; and
- Research progress.

The IRB focuses on whether there is any new information that would alter the IRB's previous determination that the research meets the approval criteria, particularly that the risks are acceptable in relation to the anticipated benefits. In addition, the IRB assesses whether any new information would require a protocol revision or revision to the informed consent document(s). The IRB will review the current consent documents to ensure that the documents continue to meet the content requirements outlined in 45 CFR 46.116, that they contain the most accurate and up-to-date information about the research, and that the investigator is utilizing the currently approved version.

Also at the time of continuing review, the IRB must consider whether there are any issues regarding the investigator(s) or the institution where the research is being conducted, such as:

- Changes in the investigator's situation or qualification, such as an increase in the number of research studies conducted by that investigator;
- Evaluation, investigation, and resolution of any complaints related to the investigator's conduct of the research;
- Changes in the acceptability of the proposed researcher in terms of institutional commitments and applicable regulations, State and local laws, or standards of professional conduct or practice; and
- Reports from any third party observations of the research, such as IRB observation of the consent process.

Continuing review is required as long as the investigator(s) conducting the research continue to obtain: 1) data about subjects of the research through intervention or interaction with them; or 2) identifiable private information about the subjects of the research for protocols involving greater than minimal risk. Note: Under the revised regulations, continuing review will no longer be required even if you ae working with individually identifiable data, such as conducting data analysis. Simply maintaining (i.e., storing) individually identifiable private information **without** using, studying, or analyzing the information is not human subject research and would not require ongoing IRB continuing approval. When a study is completed, the investigator should complete a Final Study Closure Report that closes out the study file with the DePaul's Office of Research Services.

Check list for Continuing Review Materials

	Document or Materials
	Form: Continuing Review Progress Report signed by PI, and if applicable the Faculty Sponsor
	One copy of each consent, parent/legal guardian permission, or assent document or script that will be used moving forward with the study.
	One copy of each recruitment item or script that will be used moving forward with the study.

	If applicable, revised Co-Investigators and Key Research Personnel form indicating new personnel or personnel being deleted.
	If applicable, any attached lists of complaints, withdrawals, unanticipated problems or adverse events, or amendments that do not fit on the Continuing Review Progress report form.
	If applicable, one copy of an amendment form and revised materials that are being submitted for approval at the same time as the continuing review.
	If applicable, copies of current collaborative IRB approvals, DSMB/DSMC reports

Completing the Continuing Review Progress Report Form

Indicate the date the form was completed or revised and complete the PI and Faculty Sponsor information. The PI and Faculty Sponsor information should reflect what is currently approved on the protocol. If you have staff who complete the form for you, and whom you would like the Office of Research Services to contact with questions about the Continuing Review Progress Report, indicate the name and contact information for this person in the Additional Contact Person section.

Section I, Project Information: Provide the protocol number, title and the level of review for the research protocol at the time of initial review.

- Indicate the level of review which you are requesting at this time. Please note that should the IRB transition your protocol such that you no longer require continuing review, this decision will be documented in a letter to you.
- Indicate whether the current approval period has or will lapse before IRB re-approval can reasonably be provided.
- Indicate whether there will be changes in personnel submitted at the same time as the Continuing Review Report. Personnel may be removed from a study without submission of an amendment by simply revising the Co-investigator and Key Research Personnel form and submitting it with the Continuing Review Progress Report. Personnel being added must be added via an amendment since training must be verified.
- Indicate whether there are any amendments you are submitting at the same time as the Continuing Review Progress Report.

Section II, Project Summary:

- Provide a summary of the purpose of the project and the type of research procedures involved in conducting the research. This can be a very short and simple summary.
- Summarize the progress of the research thus far, being sure to indicate the status of new subject recruitment and enrollment, data collection, or whether the study has moved to data analysis only at this point.
- Indicate and summarize the new significant findings or other information and describe how they may impact the risks, benefits, alternatives, or the subject's willingness to continue participation, if any. If there is new information which should be provided to subjects (either those currently enrolled or previously enrolled) indicate how the subjects will be provided with this new information.

Section III, Subject Enrollment and Demographics:

- Indicate the total number of subjects enrolled in the study.
- If you enrolled more subjects than you were approved for, indicate the reason for the over enrollment in the item requesting this information (item III 1. A).
- Using the tables included in the form, provide a breakdown of the number and type of subjects enrolled in the research.

Section IV, Conflict of Interest:

If the personnel has remained the same and there are no new conflicts of interest to declare, indicate that. If there are new personnel or there are new conflicts of interest to declare, complete the conflict disclosure portion of the form. Conflicts of interest can arise at any time during the conduct of the research and the potential for conflicts must be evaluated on an ongoing basis.

Section V, Subjects Declining to Participate, including Parents, Legal Guardians, Legally Authorized Representatives declining on behalf of the Subject:

- Indicate the number of subjects or parent/legal guardian's declining on behalf of the subject and the reasons they offered for declining to participate. In every study it is expected that not all the people approached to be in a study will decide to participate. Just because someone declines to participate in your research, it does not mean there is a problem. However, if you have a high refusal rate, it may mean that you may wish to evaluate your recruitment and enrollment procedures to determine if changes need to be made that would enhance your enrollment rate.

Section VI, Subject Withdrawals:

- Indicate the number of subjects who withdrew themselves from the research and if they indicated a reason, note the reasons for withdrawal. It is expected that some subjects might provide consent to be in the research and then later change their minds and withdraw, especially when studies run for long periods of time (e.g. 12 months or more). That is part of the voluntary nature of research. Just because subjects withdraw from the research does not mean that there is a problem. However, if there is a high withdrawal rate, you may wish to re-evaluate the study to see if changes may be needed to decrease the withdrawal rate.
- Indicate whether you as the PI has withdrawn any subjects from the research and the reasons for your withdrawal of subjects. Sometimes, the PI has to withdraw subjects from the research. For example, the subject fails to return calls, misses study appointments, does not follow study instructions, has had changes to their personal life or health that no longer make them eligible for the study.

Section VII, Subject Complaints:

- Indicate whether or not you have received any subject complaints. If so, summarize the complaints and how they were resolved.

Section VIII, Informed Consent:

- Indicate whether or not new subject recruitment and enrollment is ongoing. If yes, use the table in the form to provide a list of all consent, parent/legal guardian permissions, assent forms and scripts, and

recruitment materials which you will continue to utilize in the research moving forward. You should also attach one copy of each of the listed items with your submission to the IRB.
- Indicate whether or not any persons were consented or provided permission using documents or scripts in other languages. If yes, describe the procedure, the number of people, and the language.

Section IX, Unanticipated Problems or Adverse Events:

- Indicate whether or not there have been any unanticipated problems or adverse events that have occurred. If yes, use the table in the form to provide information about the events. If additional room is needed, you may attach a separate document listing the events.
- When thinking about the listed events, indicate whether the events occurred at a higher frequency than expected or at a higher severity level than expected, or whether the risk-benefit assessment for the research is altered by the events that have occurred. If so, it is possible that changes to the research may need to occur, such as changes to inclusion/exclusion criteria, or revisions to the consent document to reflect altered risks.
- If the research has a Data and Safety Monitoring Board or Committee, indicate that fact and attach the most recent report provided by this board or committee.

Section X, Literature and New Information:

- After conducting a literature search on your research topic, indicate whether or not there is any new published literature that may reflect upon your research, especially any new or previously unidentified risks.
- If there is new information or risks that should be provided to subjects, indicate whether or not an amendment is attached to address this concern.

Section XI, Presentation or Publication:

- Indicate whether or not you have presented or published based upon the research and list the presentations and publications that have resulted from the research.

Section XII, Plan for Data Disposition:

- Indicate the current status of the data collected for the research
- Keep in mind that there is no requirement that you destroy data. Rather the requirement is that you have measures to protect the confidentiality of the data. Ways to protect the confidentiality of the data include de-identifying it as soon as possible during the conduct of the research or to code the data. However, it is not necessary to de-identify the data and some research designs include keeping data identifiable in the long-term.

Section XIII, Assurances:

- Provide your electronic signature and, if applicable, the electronic signature of the faculty sponsor.