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| VCU IRBContinuing Review Form | | | | | | | | | | | | | | | | | | | | |
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| **Principal Investigator:** | | | |  | | | | | | | | | | | | | | | | |
| **VCU Email:** | | | |  | | | | | | | | | | | | | | | | |
| **P.O. Box #:** | | | |  | | | | | | | | | | | | | | | | |
| **Research Coordinator:** | | | |  | | | | | | | | | | | | | | | | |
| **Email:** | | | |  | | | | | | | | | | | | | | | | |
| **VCU IRB #:** | |  | | **IRB Panel:** | | |  | **Type of IRB Review:** | | |  | | | | | | | | | |
| **IRB Approval Expiration Date:** | | | | | |  | | | | | | | | | | | | | | |
| **Title of Project:** | | | | | | | | | | | | | | | | | | | | |
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| **Answer all questions** | | | | | | | | | | | | | | | | | | | | |
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| **1.** If you have planned for inclusion of data on any of the following Vulnerable Populations, check all of the categories that apply: | | | | | | | | | | | | | | | | | | | | |
| Prisoners | | | Children | | Pregnant Women | | | | Fetuses (or Fetal Tissue) | | | | | | | Neonates | | | | |
|  | | | | |  | | | |  | | | | | | |  | | | | |
| cognitively impaired  adults | | | | | military personnel | | | | students or employees | | | | | | |  | | | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **2. Is your study currently or in the future utilizing investigational drugs and/or biologic agents / drugs?**  \* If YES, continue to 2A below. If NO, proceed to Question #3 | | | | | | | | | | | | | | YES\* | | | | NO | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **2A. Are you or will you use the Investigational Drug Service Pharmacy for investigational drugs or biologics?** | | | | | | | | | | YES | | | NO\* | | | | N/A\*\* | | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **\***If NO, you must submit a descriptive plan regarding appropriate drug storage and dispensing for an investigational drugs or biologic agents/drugs used in the research to the Investigational Drug Service (IDS) Pharmacy. Guidance and the form for describing the management plan is located at <http://www.investigationaldrugs.vcu.edu>. Submit the form to the IDS. Upon IDS’s receipt of the plan, an email response containing the plan is generated. Include the IDS confirmation or receipt with this submission. For assistance, please call the Investigational Drug Pharmacy at 828-7901.  \*\*Submitting a plan to the IDS is not required if: 1) the drug used in the study is FDA-approved, considered standard of care and is a patient-charge item, 2) off-label use of such a drug is not being studied and 3) there is no protocol requirement for specific management of the drug. | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **3. Is this project FDA Regulated Research?** | | | | | | | | | | | | | | Yes | | | | No | | |
| **\*** FDA regulated research includes:   1. any research involving a drug or biologic intended for human use (other than the use of an approved drug in the course of medical practice); 2. any research designed to test the safety and effectiveness of a device ; or 3. research involving ANY FDA regulated product where the intent is to submit data to the FDA in support of a research or marketing application. Regulated products include foods & dietary supplements, infant formulas, food & color additives, and electronic products. | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **4 HIPAA Regulatory Compliance** | | | | | | | | | | | | | | | | | | | | |
| **4-A. Does this study use or access protected health information (PHI)?** | | | | | | | | | | | | | | | Yes\* | | | | No\*\* | |
| See Decision Tree 1: Determining when HIPAA Applies to Research and other HIPAA guidance  at <http://www.research.vcu.edu/irb/hipaa-guidance.htm>  \*If YES, go to 4-B  \*\*If NO, go to question #5 | | | | | | | | | | | | | | | | | | | | |
| **4-B. Since the last review (initial or continuing), have there been any changes to the study that would affect the way PHI is accessed or used?**  \*If YES, update and submit Appendix A: HIPAA for Research | | | | | | | | | | | | | | | Yes\* | | | | No | |
|  | | | | | | | | | | | | | | | | | | | | |
| **5. Is your project: (1) involving human subject activities conducted by Navy and Marine Corps personnel; (2) involving naval military personnel and Department of Navy (DoN) employees as research subjects; (3) supported by naval activities through any agreement (e.g., contract, grant cooperative agreement, development agreement [CRADSs], or other arrangement), regardless of the source of funding, funding appropriation, nature of support, performance site, or security classification; or (4) using DoN property, facilities or assets?**  \* If YES, you must ensure that your project meets the additional Department of Defense (DoD)-Department of the Navy (DoN) requirements for human subject protection. Guidance on additional requirements can be found at [<http://www.research.vcu.edu/irb/wpp/flash/XVII-12.htm>] | | | | | | | | | | | | | Yes \* | | | | No | | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **6.** List all research funding proposal(s) submitted to the VCU Office of Sponsored Programs (OSP) that are associated with this research project **(include the name of the funding source and the PT/PD# for each related proposal**).  Name(s) of funding source(s) **and** PT/PD#(s):  N/A – There is no funding associated with this research project | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **7.** Has your project begun? (If yes, proceed to question #9. If No, proceed to next question.) | | | | | | | | | | | | | | | | Yes | | No | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **8.** If your project has Not begun, do you want to Close your project?  **If Yes, complete Study Closure Form.** If No, proceed to Question #18. | | | | | | | | | | | | | | | | Yes | | No | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **9.** Since initiation of your project: | | | | | | | | | | | | | | | | | | | | |
| **A.** If your research involves an Intervention: | | | | | | | | | | | | | | | | | | | | |
| * How many subjects have been enrolled? | | | | | | | | | | | |  | | | | | | | | |
| **B.** If your research involves Surveys or Interviews: | | | | | | | | | | | | | | | | | | | | |
| * How many subjects provided information? | | | | | | | | | | | |  | | | | | | | | |
| **C.** If your research involves only Analysis of Data, Documents or Specimens: | | | | | | | | | | | | | | | | | | | | |
| * How many subjects are referenced by your project? | | | | | | | | | | | |  | | | | | | | | |
| **D.** If your project involves more than one of the above categories, please estimate  the total number of subjects involved: | | | | | | | | | | | |  | | | | | | | | |
|  | | | | | | | | | | | | | | | |  | | | |  |
| **10.** Based upon the subjects involved since initiation of your study, do these individuals represent the subject population as described in your original IRB application?  If *No*, attach an Explanation and: (a) include steps that you plan to take to ensure that the original population is represented including a timeframe for achieving this representation, or (b) submit an amendment to the protocol to change the subject population. [Refer to this Question # in your response.] | | | | | | | | | | | | | | | | Yes | | | | No |
|  | | | | | | | | | | | | | | | | | | | | |
| **11.** Is your project Completed? | | | | | | | | | | | | | | | | Yes | | | | No |
| **Note:** The circumstances or conditions under which VCU IRB oversight may end and therefore, a project may close as well as additional guidance on Study Closure that must be followed, are provided in the VCU IRB Written Policies and Procedures, (specifically WPP#: X-4) available at [**http://www.research.vcu.edu/irb/wpp/flash/X-4.htm**](http://www.research.vcu.edu/irb/wpp/flash/X-4.htm).  **If Yes, complete Study Closure Form.** If No, proceed to next question. | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | |
| **12.** Do you plan to continue to enroll subjects? | | | | | | | | | | | | | | | | Yes | | | | No |
|  | | | | | | | | | | | | | | | | | | | | |
| **13.** Do you plan to continue research interventions or research interactions with subjects? | | | | | | | | | | | | | | | | Yes | | | | No |
|  | | | | | | | | | | | | | | | | | | | | |
| **14.** Since the last IRB review (initial or continuing), has the profile of adverse events (in terms of frequency, severity, or specificity) changed?  If Yes, attach a Summary of the changes. [Refer to this Question # in your response.] | | | | | | | | | | | | | | | | Yes | | | | No |
|  | | | | | | | | | | | | | | | |  | | | |  |
| **15.** Since the last IRB review (initial or continuing), have there been any unanticipated problems involving risks to participants or others? If Yes, attach a Summary describing the unanticipated problems involving risks to participants or others. [Refer to this Question # in your response.] | | | | | | | | | | | | | | | | Yes | | | | No |

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| --- | --- | --- |
| **16.** Since the last IRB review (initial or continuing), have any participants withdrawn from the research? If Yes, attach a Summary describing the numbers of withdrawals and their reasons.  [Refer to this Question # in your response.] | Yes | No |
|  |  |  |
| **17.** Since the last IRB review (initial or continuing), have any participants or others complained about the research? If Yes, attach a Summary describing the number and nature of the complaints. [Refer to this Question # in your response.] | Yes | No |
|  | | |
| **18.** Since the last IRB review (initial or continuing), have there been any publications in the literature relevant to this research?  If Yes, attach a Summary of that recent literature. [Refer to this Question # in your response.] | Yes | No |
|  | | |
| **19.**  Since the last IRB review (initial or continuing), have there been any interim findings?  If Yes, attach a Summary of the interim findings. [Refer to this Question # in your response.] | Yes | No |
|  | | |
| **20.** Since the last IRB review (initial or continuing), have there been any multi-center trial reports?  If Yes, attach a Copy of all multi-center trial reports. | Yes | No |
|  |  |  |
| **21.**  Since the last IRB review (initial or continuing), have there been any data and safety monitoring board reports? If Yes, attach a Copy of ALL data and safety monitoring board reports. If the approved Research Plan stipulates a DSMB will meet but has not, provide an explanation. | Yes | No |
|  | | |
| **22.** Since the last IRB review (initial or continuing), has there been any other relevant information regarding this research, especially information about risks associated with the research?  If Yes, attach a summary of this information. [Refer to this Question # in your response.] | Yes | No |
|  | | |
| **23.**  Since the last IRB review (initial or continuing), have participants experienced any benefits?  If Yes, attach a Summary of participant benefits. [Refer to this Question # in your response.] | Yes | No |
|  | | |
| **24.** In the opinion of the principal investigator, have the risks or potential benefits of this research changed?  If Yes, attach a Summary description of those changes. [Refer to this Question # in your response.] | Yes | No |
|  | | |
| **25.** In the opinion of the principal investigator, is adequate progress being made toward the accrual goals for this study?  If No, attach an Explanation. [Refer to this Question # in your response.] | Yes | No |
|  | | |
| **26.** Since the last IRB review (initial or continuing), have there been any amendments to the research?  If Yes, attach a Summary description of those amendments. [Refer to this Question # in your response.] | Yes | No |
|  | | |
| **27.** Has a *VCU IRB Study Personnel Roster* containing *COI* Investigator\* determination(s) been previously submitted to the IRB? | Yes | No\*\* |
| **\*NOTE:** Beginning with Continuing Review submissions received **on or after 10/1/12**, investigators must convert the previously existing Personnel Roster to the updated format which includes *COI Investigator* designations (updated form contains an *IRB Template Rev. Date* header of 9/1/12 or later) and submit with the continuing review. Following conversion, subsequent continuing review submissions are to include this document. | | |
| \*\*If NO, please convert your *VCU IRB Study Personnel Roster* to the updated version, available at <http://www.research.vcu.edu/forms/vcuirb.htm>, and submit with your continuing review (include updated version date in footer). All designated *COI Investigators*’ reported financial interests (FI) and research relatedness, if relevant, must be up to date in the Activity and Interest Reporting system (AIRS) at the time of submission. The continuing review will not be approved until an updated *Personnel Roster* containing *COI Investigator* designations is on file and financial interest reports and COI reviews are completed for all designated *COI Investigators*. | | |

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| **28.** Since the last submission of the *VCU IRB Study Personnel Roster*, have there been any changes in study personnel? | | | | Yes\* | | No |
| \*If YES, submit a *VCU IRB Study Personnel Information and Change Form*, available at <http://www.research.vcu.edu/forms/vcuirb.htm>, as well as a revised *VCU IRB Study Personnel Roster* reflecting these changes. | | | | | | |
|  | | | |  | |  |
| **29.** If this project is FDA regulated, address the following two questions:  **29A.** Does the Principal Investigator remain good standing with the FDA?  If No, attach an Explanation.  See <http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/default.htm>  **29B.** Have you been audited by the FDA for this project since your last report?  If Yes, attach a Copy of the FDA Audit Report. | | | | N/A to this study | | |
| Yes | | No\* |
| Yes\* | | No |
|  | | | | | | |
| **30.** Since the last IRB review (initial or continuing), if the conduct of this study requires any study personnel to maintain medical licensure and/or hospital privileges (at VCUHS or non-VCU facility), have such requirements been maintained?  If *No*, attach a Detailed Explanation [Refer to this Question # in your response.] | | | | Yes | | No |
| N/A to this study | | |
|  | | | | | | |
| **31.** Since the last IRB review (initial or continuing), have there been any changes that affect the ability to conduct the study (e.g. adequate human or fiscal resources or adequacy of the facility)?  If *YES*, attach an Explanation of these changes [Refer to this Question # in your response.] | | | | Yes | | No |
|  | | |
|  | | | | | | |
| **32.** In the opinion of the principal investigator, have the steps that you outlined in the original IRB application to protect the confidentiality of data been adequate?  If no, attach an Amendment to change these steps. [Refer to this Question # in your response] | | | | Yes | | No |
|  | | | | | | |
| **33.** If you are submitting any of the following changes with your continuing review report, check all that apply: | | | | | | |
| **NUMBER OF COPIES REQUIRED**  **Expedited – 4 copies**  **Full Board – 25 copies** | | | | | | |
|  | | | | | | |
| Research Plan/ Protocol Amendment1 | | | | | | |
| Includes **Non-VCU Institutions/ Sites** (domestic/foreign)2 | | | | | | |
| Study Personnel Roster Amendment**3** | | | | | | |
| Amendment to Consent/Assent document(s)**4** | | | | | | |
|  | | | | | | |
| Advertisement or amendment to advertisement(s)5 | | | | | | |
| Investigational Drug Service Pharmacy receipt of management plan (see 2A above) | | | | | | |
| Investigational Drug Brochure Amendment6 | | | | | | |
|  | | | | | | |
| Package Insert/Prescribing information6 | | | | | | |
| Research Funding Proposal7  PT/PD #:  New  Resubmission  Competing Continuation | | | | | | |
| New Principal Investigator8  Provide a CV (not to exceed 5-6 pages) or a Biosketch (2-3 pages) using the NIH Biosketch Form 398 [form is available at <http://grants.nih.gov/grants/funding/phs398/biosketch.pdf> with additional instructions at <http://grants1.nih.gov/grants/funding/phs398/phs398.html>]. | | | | | | |
|  | | | | | | |
| Other9 (please specify): | |  | | | | |
|  |  | |  | |  | |
| **Signature of Principal Investigator or Designee:** |  | | **Date of Signature:** | |  | |

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| **CHANGES IN RESEARCH INSTRUCTIONS**  THE FOLLOWING INSTRUCTIONS DO NOT NEED TO BE SUBMITTED TO THE IRB  **(1) RESEARCH PLAN / PROTOCOL AMENDMENT**   * **Submit the revised Research Plan AND revised Protocol (if applicable).** NOTE: For studies originally submitted for initial review prior to 7/1/08, revisions to the Research Plan or Synopsis are not required. * Submit documents as follows:   + - Explanation of why the changes are being made     - Clean copies of the **revised** Research Plan **and revised** Protocol     - Redline/strikeout copies of the revised Research Plan **and** Protocol, OR a detailed description of the proposed changes to each document, **and**     - 4 copies of the most recent IRB-approved Research Plan **and** Protocol (regardless of the type of review [i.e. expedited, full board]).   + **NOTE:** If the change to the Protocol does not necessitate a change to the Research Plan, or visa-versa, still provide both documents and include a note to reflect this.     - If unable to revise the Protocol, explain why the document cannot be revised. * **NOTE:** Following the implementation of the *VCU IRB Study Personnel Roster* (effective 6/1/11), investigators are reminded to, at the time of the next Research Plan amendment, update section *II. Research Personnel* of the Research Plan to reflect only the Principal Investigator. The complete list of *engaged* personnel is to be maintained within the *Study Personnel Roster*. |
|  |
| **(2) NON-VCU INSTITUTIONS/SITES**  If an amendment involves the addition of Non-VCU Institutions/Sites (Domestic and Foreign), you must follow submission instructions for the addition of Non-VCU Institutions/Sites (Domestic and Foreign) available at <http://www.research.vcu.edu/forms/vcuirb.htm>. |
|  |
| **(3) AMENDMENT TO STUDY PERSONNEL ROSTER**  Submit: (a) clean copies of the revised *VCU IRB Study Personnel Roster*, noting personnel who are being added and/or removed (update version date in footer), (b) 4 copies of the most recent IRB approved Study Personnel Roster, (c) copies of the *VCU IRB Study Personnel Information and Change Form(s)* indicating personnel who are being added and/or removed, (d) Curriculum Vitae for addition of Principal Investigator, Medically Responsible Investigator, and/or Trainee (Doctoral Student, Postdoctoral Scholar, Fellow, or Resident (if trainee project)). If this change involves the Principal Investigator, see #8 below. |
| **(4) AMENDMENT TO CONSENT/ASSENT DOCUMENT(S)**  Submit: (a) copies of red-line/strike-out version(s) of the Consent/Assent Form(s) or Detailed Description of Your Proposed Changes, (b) clean copies of the revised consent/assent form(s), (c) explanation of why the changes are being made, and (d) 4 copies of the most recent IRB approved stamped consent/assent form(s). [Version number or Date, and Page numbers MUST be included]. **NOTE**: Investigators are reminded to consider whether the protocol/research plan needs to be revised to reflect this change. |
|  |
| **(5) ADVERTISEMENT OR AMENDMENT TO ADVERTISEMENT**  Submit: (a) copies of red-line/strike-out version of the Advertisementwhen changes are proposed or Detailed Description of Your Proposed Changes, (b) clean copies of the revised advertisement, (c) explanation of why the changes are being made, **and** (d) 4 copies of the most recent IRB-approved stamped advertisement. [Version number or Date, and Page numbers MUST be included]. **NOTE:** Investigators are reminded to consider whether the protocol/research plan needs to be revised to reflect this change. |
|  |
| **(6) INVESTIGATIONAL DRUG BROCHURE, PACKAGE INSERT/PRESCRIBING INFORMATION AMENDMENT**  In addition to the investigational drug brochure amendment or package insert/prescribing information, submit a list of the changes made and indicate whether after considering the risk/benefit ratio, any changes are proposed in the conduct of the project (i.e., an amendment to the protocol and/or consent/assent document(s)). See instructions for number of copies to submit in Number of Copies section of this form. |
|  |
| **(7) RESEARCH FUNDING PROPOSAL**  Federal regulations require IRB approval ofNew, Resubmission, or Competing Continuation Federal Research Funding Proposals. If there is a new, resubmission, or competing continuation VCU federal research funding proposal associated with this research project, you must include a copy of your **ENTIRE** proposal (exclusive of appendices) and the VCU Office of Sponsored Programs (OSP) Internal Approval Form with this submission. Failure to do so may delay your research award start date. Other sponsors also may require IRB approval of research proposals. It is the investigator’s responsibility to determine whether this review is needed. If the sponsor does not require IRB approval of research proposals, do not submit them to the IRB for review. If you have questions about whether your sponsor requires IRB approval of your research funding proposal, please contact the Office of Sponsored Programs (OSP). **Submit 4 copies.** |
|  |
| **(8) NEW PRINCIPAL INVESTIGATOR**  If requesting a change in the principal investigator, the Continuing Review Form must be signed by the currently approved Principal Investigator, Department/Division Chairperson, or Dean. **Note:** Any documents which reference the current Principal Investigator should also be revised to reflect the new Principal Investigator and be included in this submission to the IRB for review and approval, e.g. protocol/research plan, informed consent form(s), advertisement(s), etc. Check appropriate boxes on this form.  In addition to the above also submit a *VCU IRB Study Personnel Information and Change Form* and revised *IRB Study Personnel Roster*, reflecting this PI change. |
|  |
| **(9) OTHER**  Also provide 4 copies of the most recent IRB-approved protocol and research plan (if applicable). **NOTE**: Investigators are reminded to consider whether the protocol/research plan needs to be revised to reflect this change. |

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| **SUBMISSION INSTRUCTIONS** |
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| Please ensure all requested information is provided and in the order requested below. Multi-page documents should be individually stapled or clipped. If a submission package is incomplete or difficult to interpret, your review may be delayed. If some of the information requested is not applicable to your project, Do list the Heading on your continuing review report and simply indicate “N/A”. If your review is delayed past the deadline date noted in the continuing review notice sent to you, your project may be administratively suspended, and ultimately, administratively closed. NOTE: Double-sided documents are encouraged; but it is recommended that one copy of consent/assent forms and recruitment documents (if applicable) be submitted as single sided to ensure that legible IRB approved stamped documents are returned to the investigator . |
|  |
| **I. Project Not Begun And Not Submitting Changes** |
|  |
| Submit **(4) Collated Sets** containing the following documents in the order indicated: |
| 1. Completed Continuing Review Form and attachments 2. Most recent IRB-approved protocol [For studies that were submitted for “Initial Review” ***prior to July 1, 2008***] |
| 1. VCU Research Plan (formerly known as Research Synopsis) **AND** Sponsor’s Protocol (if applicable) [For studies that were submitted for “Initial Review” ***on or after July 1, 2008***] |
| 1. VCU IRB Study Personnel Roster. [Personnel Roster is to include *COI Investigator* determination(s) (see Question 27)] |
| 1. Updated Appendix A: HIPAA (only if response to Question 4-B is YES) 2. List of protocol amendments approved by the IRB since the project’s last continuing review |
| 1. Most recent IRB date-stamped Consent Form(s) and Assent Form(s) (if applicable) and HIPAA Authorization form (if applicable). If legibility of the consent is in question, attach both approved, stamped version and a legible copy for a new stamp. |
| 1. Summary of all Unanticipated Problems Involving Risks to Subjects and Others. (**Note:** Copies of adverse event reports will not be accepted in lieu of a summary.) Also a copy of ALL Data Safety Monitoring Board (DSMB) reports (if applicable) or results of the investigator’s ongoing Data and Safety Monitoring Plan (if applicable) since the last IRB review. If a DSMB report is applicable but not available, please explain why. 2. Investigational Drug Service Pharmacy Receipt of Management Plan (see Question 2A). |
|  |
| **II. All other approved studies**  Submit the appropriate # of copies of all of the below documents for the type of review:   * Expedited Review: 4 COLLATED SETS of all documents (in the order listed below) * Full Board Review: 25 COLLATED SETS of all documents (in the order listed below) |
| 1. Completed Continuing Review Form and attachments. |
| 1. Summary of Progress To Date including an explanation of what happened to subjects enrolled who are no longer in the project. **Note:** This document should not exceed five double-spaced pages, and should be labeled “Summary of Progress to Date”. 2. Most recent IRB-approved protocol [For studies that were submitted for “Initial Review” ***prior to July 1, 2008***] |
| 1. VCU Research Plan (formerly known as Research Synopsis) **AND** Sponsor’s Protocol (if applicable) [For studies that were submitted for “Initial Review” ***on or after July 1, 2008***] |
| 1. VCU IRB Study Personnel Roster. [Personnel Roster is to include *COI Investigator* determination(s) (see Question 27)] |
| 1. Updated Appendix A: HIPAA (only if response to Question 4-B is YES) 2. List of protocol amendments approved by the IRB since the project’s last continuing review |
| 1. Most recent IRB date-stamped Consent Form(s) and Assent Form(s) (if applicable) and HIPAA Authorization form (if applicable). If legibility of the consent is in question, attach both approved, stamped version and a legible copy for a new stamp. **Note:** If the research is permanently closed to the enrollment of new subjects, note this in your summary of progress to date and do not submit consent/assent forms. 2. Summary of all Unanticipated Problems Involving Risks to Subjects and Others. (**Note:** Copies of adverse event reports will not be accepted in lieu of a summary.) Also a copy of ALL Data Safety Monitoring Board (DSMB) reports (if applicable) or results of the investigator’s ongoing Data and Safety Monitoring Plan (if applicable) since the last IRB review. If a DSMB report is applicable but not available, please explain why. 3. Investigational Drug Service Pharmacy Receipt of Management Plan (see Question 2A). |
| **Please Note:**   * **If you are submitting amendments to your study, you must submit the documents outlined in the footnotes to ITEM #33 on the Continuing Review Form, in addition to the documents outlined above.** * **As noted in the footnotes to ITEM #33, when submitting amended document(s), only 4 copies of the most recent IRB-approved version of the document being amended are required.** |