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| **VCU IRB**  **Change in Research Submission Form** | | | | |
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| **Principal Investigator:** |  | | | |
| **VCU Email:** |  | | | |
| **P.O. Box #:** |  | | | |
| **Research Coordinator:** |  | | | |
| **Email:** |  | | | |
| **VCU IRB #:** |  | | | |
| **IRB Panel:** |  | | | |
| **Title of Project:** | | | | |
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| Documentation Submitted | | Number of Copies | | Additional Guidance |
| **Changes Requested by the VCU IRB**  Notes: | | Refer to correspondence from the IRB | Refer to correspondence from the IRB | Include the front page of this form with each copy submitted. |
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| **Research Plan / Protocol Amendment 1** | | If **Exempt or Expedited Study, submit 4 Copies** | If **Full Board Study, submit 25 Copies**  The IRB requests 25 copies regardless of whether a sponsor indicates a change may qualify for expedited review. | Include the front page of this form with each copy submitted.  Note: Double-sided documents are encouraged; but it is recommended that one copy of consent/assent forms and recruitment documents be submitted as single sided to ensure that IRB approved stamped documents to be returned to investigator are legible. |
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| Includes **Non-VCU Institutions/ Sites** (domestic/foreign)2 | |  |  |  |
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| **Amendment to Consent/Assent Document(s) 3** | |  |  |  |
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| **Advertisement or Amendment to Advertisement 4**  Notes: | |  |  |  |
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| **Investigational Drug Brochure Amendment 5** | | If **Exempt or Expedited Study, submit 4** **Copies** | **Full Board Study, submit 4** **Copies** | Include the front page of this form with each copy submitted. |
| **Package Insert /prescribing information5**  Notes: | |  |  |  |
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| **Research Funding Proposal6**  **PT/PD #:**        **New**  **Resubmission**  **Competing Continuation** | | **Exempt or Expedited Study, submit 4** **Copies** | **Full Board Study, submit 4 Copies** | Include the front page of this form with each copy submitted. |

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| **New Principal Investigator** **7**  Provide CV (not to exceed 5-6 pages) or Biosketch (2-3 pages). If submitting Biosketch, the NIH Biosketch form 398 must be used. | | **Exempt or Expedited Study, submit 4** **Copies** | **Full Board Study, submit 4 Copies** | Include the front page of this form with each copy submitted. | | |
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| **Other 8:** | | | Contact the Office of Research Subjects Protection for guidance at 827-1735 | | | |
| (please specify) | | |
| **Signature of Principal Investigator or Designee:** |  | | | | **Date of Signature:** |  |

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| *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     - (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.     - See instructions for number of copies of revised documents to submit on front page of this form.   + **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*. |
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| (2) NON-VCU INSTITUTIONS/SITES  If adding Non-VCU Institutions/Sites (Domestic and Foreign), follow submission instructions for the addition of Non-VCU Institutions/Sites (Domestic and Foreign) available at <http://www.research.vcu.edu/forms/vcuirb.htm>. |
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| (3) AMENDMENT TO CONSENT/ASSENT DOCUMENT(S)  Submit: (a) clean copies of the revised consent/assent form(s), (b) copies of red-line/strike-out version(s) of the Consent/Assent Form(s) or Detailed Description of Your Proposed Changes, (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 on all revised documents.] See instructions in Number of Copies section of this form for number of copies to submit. 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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| **(4) ADVERTISEMENT OR AMENDMENT TO ADVERTISEMENT**  Submit: (a) clean copies of the revised advertisement, (b) copies of red-line/strike-out version of the Advertisementwhen changes are proposed or Detailed Description of Your Proposed Changes, (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 on all revised documents.] **See instructions in Number of Copies section of this form for number of copies to submit.** 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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| **(5) INVESTIGATIONAL DRUG BROCHURE 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., a change to the protocol or consent form). **See instructions in Number of Copies section of this form for number of copies to submit.** |
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| **(6) 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 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). **See instructions in Number of Copies section of this form for number of copies to submit.** |
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| **(7) NEW PRINCIPAL INVESTIGATOR**  If requesting a Change in the Principal Investigator, this form must be signed by the currently approved Principal Investigator or Department/Division Chairperson or Dean. **Please 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, informed consent form(s), advertisement(s), etc. Check appropriate boxes on this form. **See instructions in Number of Copies section of this form for number of copies to submit.**  In addition to the above, if requesting a Change in the Principal Investigator, also submit a *VCU IRB Study Personnel Information and Change Form* and revised *IRB Study Personnel Roster\**, reflecting this change. These forms are available at <http://www.research.vcu.edu/forms/vcuirb.htm>.  \*NOTE: As of 10/1/12, the VCU IRB will begin conversion of the existing Personnel Roster to an updated format to capture *COI Investigator* designations necessary to comply with the revised VCU Conflict of Interests in Research Policy. For existing studies, this conversion process will be implemented with Continuing Review submissions received on or after 10/1/12. If the change in Principal Investigator is being requested prior to the scheduled conversion to the updated Personnel Roster, utilize the existing Personnel Roster to reflect the PI change. However, upon submission of the change in PI, the new PI, who is considered a *COI Investigator*, will need to ensure that his/her reported financial interests (FI) and research relatedness, if relevant, are up to date in the Activity and Interest Reporting System (AIRS). A COI review in AIRS will be conducted for the new PI. |
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| **(8) 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.  If requesting a change to study personnel **other than** the Principal Investigator, do not use this *Change in Research Submission Form*. Use a *VCU IRB Study Personnel Information and Change Form* and revised *IRB Study Personnel Roster* reflecting this change. These forms are available at <http://www.research.vcu.edu/forms/vcuirb.htm>. If the change involves the Principal Investigator, see #7 above. |
| **GENERAL SUBMISSION INSTRUCTIONS** |
| * Please ensure all requested information is included and the correct number of copies provided. Multi-page documents should be individually stapled or clipped. If documents are missing, or multi-page documents are not individually stapled or clipped, your review may be delayed. * It is recommended that you not submit documents containing hole punches. If hole punched documents are submitted, please ensure that the holes are not in text areas. |