

PI:  
Title:

MIRB # (Office Entry):

## Initial Project Submission Checklist

### All Studies

- Research & Development Information Sheet/Project Data Sheet, VA form 10-1436
- Abstract, (2nd page of form 10-1436) and on 3 ½ " diskette
- Prospectus of Research, (version *August 2006*)
- Narrative ( Investigator Initiated Protocol or  Sponsor Master Protocol) **5 copies**  
*For details on how to prepare a narrative for an investigator initiated study go to Guidelines for Narrative Description of Proposed Research. **Sponsored studies must still follow this format, but can submit the information as part of the Narrative Summary.** (include merit review or other grant applications related to the study)*
- Narrative Summary (3 page limit) – Synopsis of Narrative [A Narrative Summary is not necessary if the Investigator Initiated Protocol (Narrative) is not substantially longer than 3 pages. The intent is to provide R&D Committee with a brief description of the study; not duplication of investigator efforts. Use the same format as the Narrative.]
- Research Safety Survey, 10-0398 (Safety submission must be sent electronically to [chuck.sohaskey@med.va.gov](mailto:chuck.sohaskey@med.va.gov) for pre-review prior to submission of signed hard copy)

### Additional – Human Subjects

- Application for IRB Review (Version 8/25/06)
- Application for IRB Review Supplement (Stored human biological material or DNA) (Version 8/25/06)
- Consent Form (VA Form 10-1086) – unstamped (Version 8/25/06)
- Consent Form (VA Form 10-1086)– genetic (if applicable) (Version 8/25/06)
- HIPAA Authorization Form (Version 8/25/06)
- HIPAA Revocation Form (Version 8/25/06)
- Patient Recruitment Material (intended to be seen or heard by potential subjects)
- Investigational Drug Information Report (VA Form 10-9012) (one for each drug to be used on study, if applicable)
- Investigator's Brochure, dated \_\_\_\_\_ (if applicable) **5 copies**
- Optional: Waiver of Authorization for Pre-screening/Recruitment (for CPRS searches beyond investigator's patient population)
- If requesting – Waiver of Informed Consent/HIPPA Authorization Request
- If this is a Device Study – Investigator Device Plan/Information Form (Version 8/25/06)
- If this is an Investigational Device Study-provide Investigational Device Exemption information
- Impact Estimation Worksheets, signed and dated ( Pharmacy,  Radiology,  Laboratory)
- Proposed subject questionnaires/educational materials, subject instructions, etc.
- Other \_\_\_\_\_

### Additional – Animal Subjects

- Full ACORP
- ACORP Appendices (if appropriate)
- Consultant Veterinarian Pre-review Confirmation (attach e-mail from Dr. Jeffrey Lee, DVM confirming veterinarian review)
- Impact Estimation Worksheets, signed and dated ( Radiology,  Laboratory)

#### \*Prior to submission

Human studies – Contact Debbie Ludke at x4715 to verify that all staff listed on the Prospectus and IRB Application have met training/education requirements.  
Research Office Verification:

Animal studies – Contact Tammy Bon at x4948 to verify that all staff listed on the Prospectus and ACORP have met training requirements. Research Office Verification:

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## IRB Exempt Project Submission Checklist

1.  IRB Exempt Eligibility Determination Form (Version 8/25/06)
2.  Research & Development Information Sheet/Project Data Sheet, VA form 10-1436
3.  Abstract, (2nd page of form 10-1436) and on 3 ½ " diskette
4.  Prospectus of Research, (version *August 2006*)
5.  Narrative ( Investigator Initiated Protocol or  Sponsor Master Protocol) **5 copies**  
For details on how to prepare a narrative for an investigator initiated study go to Guidelines for Narrative Description of Proposed Research. **Sponsored studies must still follow this format, but can submit the information as part of the Narrative Summary.** Please include Merit Review or other grant applications related to the study
6.  Narrative Summary (3 page limit) – Synopsis of Narrative [A Narrative Summary is not necessary if the Investigator Initiated Protocol (Narrative) is not substantially longer than 3 pages. The intent is to provide R&D Committee with a brief description of the study; not duplication of investigator efforts. Use the same format as the Narrative.]
7.  Research Safety Survey, 10-0398 (Safety submission must be sent electronically to [chuck.sohaskey@med.va.gov](mailto:chuck.sohaskey@med.va.gov) for pre-review prior to submission of signed hard copy)
8.  Impact Estimation Worksheets, signed and dated ( Pharmacy,  Radiology,  Laboratory)
9.  Request for Waiver of Authorization to Release Medical Records or Health Information Form (if collecting Protected Health Information (PHI). A listing of PHI may be found on the last page of this form *Note: If the investigator is not collecting PHI, he/she needs to put this in writing in the form of a memorandum to the IRB.* (Version 8/25/06)
10.  Other (anything else the IRB would need to know about your study to conduct a thorough review)

### \*Prior to submission

Human studies – Contact Debbie Ludke at x4715 to verify that all staff listed on the Prospectus and IRB Application have met training/education requirements.  
Research Office Verification:

PI:  
Title:

MIRB #:

## Continuing Review Project Submission Checklist

### All Studies

- Research & Development Information Sheet/Project Data Sheet, VA form 10-1436
- Updated Abstract, (2nd page of form 10-1436) and on 3 ½ " diskette
- Research Safety Survey, 10-0398 (Safety submission must be sent electronically to [chuck.sohaskey@med.va.gov](mailto:chuck.sohaskey@med.va.gov) for pre-review prior to submission of signed hard copy)
- Listing of currently approved study staff (including PI, co-investigators and other staff):  
\_\_\_\_\_

### Additional – Human Subjects

- Application for Continuing Review (version 8/25/06)
- Application for IRB Review Supplement (originally submitted document if tissue banking) (Version 8/25/06)
- Consent Form – (currently approved stamped version) *only if still consenting or required by sponsor to have an active ICF*
- Consent Form – (unstamped version 8/25/06) *only if still consenting or required by sponsor to have an active ICF*
- HIPAA Authorization Form (currently approved stamped version) *only if still consenting or required by sponsor to have an active ICF*
- HIPAA Revocation Form (currently approved stamped version) *only if still consenting or required by sponsor to have an active ICF*
- HIPAA Authorization Form –(unstamped version 8/25/06) *only if still consenting or required by sponsor to have an active ICF*
- HIPAA Revocation Form – Unstamped version 8/25/06) *only if still consenting or required by sponsor to have an active ICF*
- Master Protocol/and or Narrative Summary, most current **3 copies**
- Investigator's Brochure (if updated) **3 copies**
- External Study Monitor Visit Reports and Follow-up Memos
- Any adverse event reports from investigators, sponsor safety reports (e.g., IND or IDE), MedWatch reports, updated Investigator Brochures and/or DSMB reports not previously submitted.
- Any newly proposed consent documents/HIPAA documents/advertisements
- Any recruitment documents or advertisements for which you are seeking approval or re-approval (for re-approvals, please submit stamped and unstamped versions)
- Completed Request for Modification Form for any changes to the protocol, consent or other documents that are being proposed at this time (Version 8/25/06)
- Documentation of protocol violations and/or deviations, unanticipated problems or non-compliance with applicable regulations that have not been previously submitted
- Other \_\_\_\_\_

### Additional – Animal Subjects

- Narrative Summary (3 page limit) – Synopsis of Narrative
- Annual Progress Report
- Copy Approved ACORP and Appendixes

### \*Prior to submission

Human studies – Contact Debbie Ludke at x4715 to verify that all staff listed on the Prospectus and IRB Application have met training/education requirements. Research Office Verification:

Animal studies – Contact Tammy Bon at x4948 to verify that all staff listed on the Prospectus and ACORP have met training requirements. Research Office Verification:

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## Modification Submission Checklist

### Animal Studies and Basic Science Protocols

1.  Research & Development Information Sheet/Project Data Sheet, VA form 10-1436
2.  Updated Abstract, (2nd page of form 10-1436) and on 3 ½ " diskette
3.  Narrative Summary (3 page limit) – Synopsis of Narrative
4.  Copy Approved ACORP and Appendixes (N/A for Basic Science Protocols)
5.  Modification Request – Go to Animal Studies [N/A for Basic Science]
6.  Research Safety Survey, 10-0398 (Safety submission must be sent electronically to [chuck.sohaskey@med.va.gov](mailto:chuck.sohaskey@med.va.gov) for pre-review prior to submission of signed hard copy)
7.  If applicable, listing of study staff being removed with this modification: \_\_\_\_\_
8.  If applicable, listing of study staff being added with this modification: \_\_\_\_\_
9.  If this modification includes any staff changes, provide a complete listing of proposed study staff. \_\_\_\_\_
10.  Other:

### Human Studies Protocols

1.  IRB Request for Modification Form (Version 8/25/06))
2.  A copy of the modified sponsor protocol and/or narrative summary, if changed
3.  If this is a sponsored study; A summary of protocol modifications – if provided by sponsor
4.  If the consent has been modified, submit a copy of the currently approved (stamped) form, a copy of modified form with the changes marked, plus an unmarked copy for stamping (Version 8/25/06).
5.  Other documents:
6.  If applicable, listing of study staff (including investigators) being removed with this modification: \_\_\_\_\_
7.  If applicable, listing of study staff being added (including investigators) with this modification: \_\_\_\_\_
8.  If this modification includes any staff changes, provide a complete listing of proposed study staff (including PI and other investigators, and other staff). \_\_\_\_\_

### For Office Use Only:

Verification of training and credentialing of listed staff.

PI:  
Title:

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## Closure Submission Checklist

### Human Studies Protocols

1.  Research & Development Information Sheet/Project Data Sheet, VA form 10-1436
2.  Updated Abstract, (2nd page of form 10-1436) and on 3 ½ " diskette
3.  Application for Continuing Review (version 8/25/06), marking "closure" on question #1a
4.  Other (including publications, etc.)

### Animal Studies Protocols

1.  Research & Development Information Sheet/Project Data Sheet, VA form 10-1436
2.  Updated Abstract, (2nd page of form 10-1436) and on 3 ½ " diskette
3.  Annual Progress Report
4.  Other (including publications, etc.)