**Principal Investigator:**

<table>
<thead>
<tr>
<th>HUMAN STUDIES SUBCOMMITTEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>INVESTIGATOR AUDIT</td>
</tr>
<tr>
<td>Self Assessment Tool</td>
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</tbody>
</table>

This is where your Auditor looks first...👇 IRB Files

**A. IRB Files** *(Materials submitted by Investigator to IRB for review.)*

<table>
<thead>
<tr>
<th>Item</th>
<th>YES</th>
<th>NO</th>
<th>Partial</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Professional qualifications to do the research including a description of necessary support services and facilities (such as Division Mgr forms are signed &amp; statement of quals in protocol submission packet)</td>
<td>☐</td>
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<tr>
<td>2. Certifications of completion for GCP/HS training for all research staff</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>3. HSS approved study protocol with abstract</td>
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<tr>
<td>4. Investigator’s Brochure – current and all previous versions</td>
<td>☐</td>
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<td>5. Subject – surveys or questionnaires</td>
<td>☐</td>
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<tr>
<td>6. Reports of Adverse Events or UnAnticipated Problems (UAP/SAE/AE)</td>
<td>☐</td>
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<td>7. Approved study advertising material (and stipends if applicable)</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>8. Waivers / Exemption / Expedited determination (as applicable)</td>
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**a) Waiver of INFORMED CONSENT**

No more than minimal risk, this waiver won’t affect the rights or welfare of subject, project couldn’t be practically carried out without this waiver, whenever appropriate, subject will be provided with additional information after their participation (used for chart reviews, data collection, pathological specimens) in non FDA approved research and a WAIVER of SUBJECT AUTHORIZATION (HIPAA consent) indicating there is no more than minimal risk based at least on these elements: protect identifiers, coded data, stored on VA Server, plans to destroy identifiers, written assurances to protect PHI, no reuse or disclosure of data, couldn’t practically do the research without this waiver and there is a need for access to and use of PHI. This HIPAA waiver is signed by the IRB Chair. Full details available here for WAIVER of INFORMED CONSENT: [http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/waiveric.doc](http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/waiveric.doc) and WAIVER of SUBJECT AUTHORIZATION: [http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/waiverauth.doc](http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/waiverauth.doc)

**b) Request for Review Preparatory to Research**

A granted request will allow you to review medical records to collect data to prepare a research protocol or to determine if adequate subjects would be available to make a research study worthwhile. If identified patient data will be collected for recruitment purposes, a Request for Waiver of Subject Authorization must be completed instead of this form.

Full details are available here: [http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/revprep.doc](http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/revprep.doc)

**c) Waiver of DOCUMENTATION of Informed Consent – IMPLIED consent - that is informed consent obtained without a signed document.** Requested for protocols in which subjects are aware of their participation but they do not sign a consent form, either by choice or by study design. Examples would include studies involving some types of surveys to be completed in person or surveys sent through the mail. Full details are located here: [http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/waiverdoc.doc](http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/waiverdoc.doc)

**d) Request for Review of DECEDENT Information**

Used only if your study involves the review of medical records of deceased persons ONLY


**e) Request for EXPEDITED IRB Approval** *(allowing Expedited Review signed by IRB Chair)*

These studies present no more than minimal risk to human subjects and involve only certain procedures. No other procedures will be performed. This study does not involve procedures where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

f) Waiver of **FLAGGING** a Medical Record (FLAGGING is a Note in CPRS that alerts others to subject’s participation in a research study)
Most studies involving VA patients require that patients' charts in CPRS be flagged to indicate their participation in a research study. There are some exceptions such as, only one encounter or use of a questionnaire/chart review or use of previously collected biological specimens’ or if ID of subject in a study would present greater than minimal risk. Full details at:
http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/waiverflag.doc

g) **Determination of EXEMPTION** from IRB Approval Signed by the IRB Chair
*Exempt Studies have no further Continuing Review from our HSS (IRB) required – only Annual R&D approval
The most common reason for requesting a Determination of EXEMPTION in our setting is: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. The reviewed materials already exist at the time the research is proposed and are not prospectively collected. [38 CFR 16.101(b)(4)] [45 CFR 46.101(b)(4)]

*At our Milwaukee VA, this category will not be used if the data to be accessed is identified.* For example, the collection of de-identified data from CPRS, which contains identified data, will not be considered exempt.

Full details are available here: http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/exempt.doc

<table>
<thead>
<tr>
<th></th>
<th>9. Request for changes or protocol amendments in study after approval</th>
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<tbody>
<tr>
<td></td>
<td>11. Final report. (-----ongoing -----data analysis or ------ )</td>
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<td>12. Termination documents (letter from PI to IRB, etc.)</td>
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**PI and Research Staff: START HERE...✈ these are your Regulatory Files**

**Suggestion: Do not take apart your original approved IRB submission packet**

**B. Investigator’s Files** *(Regulatory Documents/ Essential Files)*

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>Partial</th>
<th>N/A</th>
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<tbody>
<tr>
<td></td>
<td>Applicable Regulatory Documents are readily accessible – organized and clearly labeled as needed:</td>
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<tr>
<td></td>
<td>1. Investigational Drug Information Record VA Form 10-9012.</td>
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<td>2. Report of Subcommittee on Humans Studies VA Form 10-1223</td>
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<td>3. IRB (and R&amp;D) Approval Letters &amp; Waivers (above 8a-g as applicable)</td>
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<td>4. Investigational New Drug (IND) (or IDE) application</td>
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<td>5. Safety Survey Approval VA Form 10-0398</td>
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<td>6. Financial Interests &amp; Arrangements of Human Studies Investigators local form (Local RSO (Research Service Office) Financial Disclosure Form for Sponsored Studies only)</td>
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<td>7. FDA Form 1571 if the PI is a Sponsor-Investigator</td>
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<td>8. DSMB (Board) or DSMP (Plan) reports in file and sent to IRB (as needed)</td>
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<td>9. Current, complete FDA Form 1572, if research is FDA regulated w/ all sub-investigators</td>
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<td>10. Current signed/dated CV (and licenses) for PI, Co or Sub as appropriate – update 2 yrs.</td>
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<td>11. Current protocol and /or operations manuals (older versions on file)</td>
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<td>12. Clinical laboratory certification and normal range listings (as needed).</td>
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<td>13. Current Investigator Brochure. (if a drug trial)</td>
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<td>14. IRB current approved consent VA Form 10-1086 (&amp; all older versions)</td>
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<td>15. HIPAA authorization attached to consent form</td>
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</table>
16. IRB written communication/correspondence are present

17. IRB Amendment Memos (Amendment approval letters)

18. Advertising approved for study / subjects is in Regulatory File

19. Log for Protocol Violations / Deviations

20. UAP/SAE/AE reports are on file – have been sent to IRB (as req’d) and acknowledgment has been received back from IRB

21. Consent Log/Contact List listing dates, contact information (as applicable) last 4, version(s) signed and dates of withdrawal or completion for each subject. (Could also be same as Contact List for Continuing Review)

22. Delegation/Signature Log to delineate the roles of each study staff member, listing items such as their signature, title, initials, training record and to record their dates of project involvement

23. Scopes of Practice are available for review and discussion of continued delegation for each study team member if needed

24. Copies or proof of Research VA mandated annual trainings in Regulatory Document Files for each staff member, at a minimum must include:
   - Cyber Security Awareness,  
   - VA Privacy Training,  
   - VA Data Security and Privacy Training,  
   - HIPAA Essentials for Researchers,  
   - Human Subject Protection & Good Clinical Practices replaced with  
   - Information Security for Research & Development 201 also on VA LMS as of April 24, 2008  
   - Shipping & Transporting Specimens Training – may be required 

    Suggest: PRINTING OUT CERTIFICATES and placing in Regulatory Binders/Files for ease of retrieval

   Trainings available on ANGEL – MCW Infoscope website: https://campus.mcw.edu/frames.aspx

25. When investigators hold the IND or IDE, they must comply with FDA’s requirements for sponsors. The Investigator must be able to state that they are knowledgeable / informed about the specific IND Regulations. These include:

   IND (DRUGS & BIOLOGICS)

   - 21 CFR 11 Electronic records and electronic signature  
   - 21 CFR 54 Financial Disclosure by Clinical Investigators [FDA forms3454 and 3455]  
   - 21 CFR 210 Current Good Manufacturing Practice In Manufacturing, Processing, Packing, Or Holding of Drugs; General  
   - 21 CFR 211 Current Good Manufacturing Practice for Finished Pharmaceuticals  
   - 21 CFR 312 Investigational New Drug Application  
   - 21 CFR 314 Drugs for Human Use  
   - 21 CFR 320 Bioavailability and Bioequivalence Requirements  
   - 21 CFR 330 Over-The-Counter (OTC) Human Drugs Which are Generally Recognized as Safe and Effective and Not Misbranded  
   - 21 CFR 601 Biologics Licensing

   When investigators hold the IND or IDE, they must comply with FDA’s requirements for sponsors. The Investigator must be able to state that they are knowledgeable / informed about the specific IDE Regulations. These include:

   IDE (DEVICES)

   - 21 CFR 11 Electronic records and electronic signature  
   - 21 CFR 54 Financial Disclosure by Clinical Investigators [FDA forms3454 and 3455]  
   - 21 CFR 814 Premarket Approval of Medical Devices  
   - 21 CFR 820 Quality System Regulation  
   - 21 CFR 860 Medical Device Classification Procedure

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Version dated: December 1, 2008
Printed: 2/13/2009 av
C. Medical Chart/Source Documents/CPRS

**DO you have a Waiver of Flagging* granted by the IRB**

*FLAGGING is a Note in CPRS that alerts others to subject's participation in a research study*

Most studies involving VA patients require that patients’ charts in CPRS be flagged to indicate their participation in a research study. There are some exceptions such as, only one encounter or use of a questionnaire/chart review or use of previously collected biological specimens’ or if ID of subject in a study would present greater than minimal risk. Consent Notes and Study Completion Notes are templated and found under “Postings”. Full details at: [http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/waiverflag.doc](http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/waiverflag.doc)

✓ If This Section is Not Applicable ☐ To This Review

1. Records to document subjects' involvement in study (CPRS/subject files)
2. Case histories are adequate and accurate (CPRS/subject files)
3. Procedures for protecting confidentiality/privacy are evident (e.g. use of codes to identify subjects on CRF or data work sheets/files, locking cabinets or offices)
4. Medical & study significant events are noted in CPRS, such as:
   - Enrollment (Consent) and end of participation (Completion) notes (located under POSTINGS)
   - Evidence of protocol specific Inclusion and Exclusion review – for each enrolled subject
   - Signed IC and HIPAA Authorization scanned (w abstract) into CPRS (unless waived)
   - Study drugs/ test article /devices involved
   - UAP/ SAE/AE -- study complications recorded
   - Reference Lab results in CPRS
   - Or _____ you decide
5. Clinical warning on medical chart or electronic flag placed in CPRS of records study vets (✓ Postings – CWAD) both for Consent & Completion of study templated note
to view the CPRS templated consent note: [http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/cwadnote.pdf](http://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeVAMCResearchService/cwadnote.pdf)
6. Copy of VA Form 10-9012 Investigational Drug Information Record (for Investigational Drugs Studies this is in CPRS)

D. Case Report Forms/Subject Files

✓ If This Section is Not Applicable ☐ To This Review

1. Have none (or minimal) Personally Identifiable Information (PII) or Personal Health Information (PHI) readily apparent to the untrained observer. Demonstrating sensitivity and protecting the confidentiality/privacy of the subject to the highest extent possible.
2. Case Report Forms are current – review Monitor Reports if available
3. Case Report Forms supported by source documents. (i.e.CPRS notes)
4. Protocol specific Inclusion and Exclusion criteria review are documented
5. Clinical laboratory and diagnostic test results are documented in CPRS, if from reference laboratories
6. Drop outs, withdraws and completions, dates and reason recorded (in CPRS)
E. Pharmacy Records (for Investigational New Drug studies as applicable)

☑ If This Section is Not Applicable ☐ To This Review

The following documents are currently on file in Pharmacy Service:

1. Fully executed informed consent VA Form 10-1086
2. VA Form 10-9012 Investigational Drug Information Record (CPRS)
3. Study protocol to Pharmacy with signed VA Form 10-1223
4. Signed authorization for each time the investigational drug issued
5. Informing Pharmacy Service, IRB and the R&D Committee when a study involving investigational drugs has been terminated
6. Written disposition records (aka: LOGS) for any remaining study article / drug upon termination
7. Investigational drugs are identified as study medication (CPRS)

These are questions you will need to review…. And be able to answer at the time of review. Ask each Team Member to review these items.

F. Privacy, Research Data Security and Confidentiality:

1. Informed Consents are obtained in an area offering privacy and time is allowed for the subject to think over their participation and, if appropriate, have discussion time with family or others.  
   ** Witnessed observation of your consenting process may be included in review, you should Contact Research Compliance x41445 to arrange this observation at any time...

2. Trial is registered with clinicaltrials.gov (as appropriate)

3. PI has copy of project Data Security Certification Checklist.  
   (RSO (Research Service Office has this on file – PI should retain their copy)

4. Subject has been offered additional information sources to learn about research and trials such as through brochures, fliers, discussion or www.clinicaltrials.gov as appropriate

5. Confidentiality of subject’s PII and PHI evident as outlined in VHA Handbook 1200.5, our HSS (IRB) SOP and in the Investigator Handbook, all on our Infoscope research web site, per PI
6. Laptops, thumb drives or other portable storage media (no CDs) are password protected / encrypted and issued or certified by the VA, if in use

7. Subject identifiable (sensitive) data is stored on the VA Server or other VA certified (or issued) data storage media

8. Back ups of all data is stored within a protected VA environment

9. Time outs on all computers are active

10. If there exists a code (to decode = reidentify) data, the code must be kept in a protected VA environment

11. PI (and /or SC)states having knowledge of procedures for reporting theft or loss of sensitive data or electronic equipment with sensitive data are familiar to researcher (and staff) who may store, use or transport the data

12. Any removal of sensitive research data is authorized by the appropriate signatory VA officials and this permission document is kept on file with the PI and it is renewed as stated

This is your Self Assessment Tool and a key to what is expected at audit time.... Please use this form to determine issues you need to address and identify your project’s strengths.

List items you’d like to discuss at your review:

1) 
2) 
3) 
4)