

## INVESTIGATOR RECORDS CHECKLIST

### SELF-ASSESSMENT TOOL

#### GENERAL INFORMATION

<b>Principal Investigator</b>		
<b>E-mail Address</b>		
<b>Sub-Investigator(s)</b>		
<b>Key Personnel/Function</b>	<b>Personnel</b>	<b>Function</b>
<b>IRB Panel</b>		
<b>IRB Protocol Number</b>		
<b>Study Title</b>		
<b>School/Center/Institution</b> <i>Please check one:</i>	<input type="checkbox"/> SOM <input type="checkbox"/> Dental <input type="checkbox"/> Pharm <input type="checkbox"/> Nursing <input type="checkbox"/> SW <input type="checkbox"/> CVD <input type="checkbox"/> MPRC <input type="checkbox"/> IHV <input type="checkbox"/> GCC <input type="checkbox"/> GCRC	
<b>Subject Population</b> <i>Please check all that apply:</i>	<input type="checkbox"/> Geriatric <input type="checkbox"/> Pregnant Women <input type="checkbox"/> Pediatric <input type="checkbox"/> Prisoner <input type="checkbox"/> Psychiatric <input type="checkbox"/> Mentally Disabled <input type="checkbox"/> Handicapped <input type="checkbox"/> Veteran <input type="checkbox"/> Employee/Student <input type="checkbox"/> Community	
<b>Sponsor</b> <i>Please check one:</i>	<input type="checkbox"/> Industry <input type="checkbox"/> Government <input type="checkbox"/> Internal/Department <input type="checkbox"/> Foundation <input type="checkbox"/> Other: _____	
<b>Funding Source</b> <i>Please check one:</i>	<input type="checkbox"/> Industry <input type="checkbox"/> Government <input type="checkbox"/> Internal/Department <input type="checkbox"/> Foundation <input type="checkbox"/> Other: _____	
<b>Person Completing Checklist</b>		
<b>Date Checklist Completed</b>		

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**1. REGULATORY DOCUMENTATION**

**Reference ICH GCP 4.9.4**

**Table 1a. REGULATORY CHRONOLOGY**

Depending on the type of study, the sponsor and IRB/R&D decisions, some studies go through numerous phases of conditional approvals & responses as well as amendments, re-approvals, and continuing reviews. This can lead to difficulty in grasping the regulatory flow of the study, especially if documents are filed by type (IRB, R&D, Sponsor, etc) and therefore require flipping back and forth through the binder to locate documents.

Review the regulatory documents and complete this section, indexing the documents in chronological order. This should make it easier to detect missing documents (for example, a “request for modification” but no approval letter). Then, if helpful or appropriate, complete the summary below (2b). See Attachment 1 for an example/guideline.

See the list in 1b for reminders on what forms to look for. Include pre-BRAAN documentation. Remember to include R&D correspondence and approvals as well as IRB.

	<b>Document*</b>	<b>Date written/sent</b>	<b>Response**</b>	<b>Date Response (from IRB/RD/etc) received</b>
1a.1				
1a.2				
1a.3				
1a.4				
1a.5				
1a.6				
1a.7				
1a.8				
1a.9				
1a.10				
1a.11				

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	Document*	Date written/sent	Response**	Date Response (from IRB/RD/etc) received
1a.12				
1a.13				
1a.14				
1a.15				

\*Include name/description of document; for example: “response to IRB letter of -/--”. If it’s an amendment, include a very brief description of the change (‘change in personnel’, change in entry criteria’, etc); if a deviation, an SAE report, etc., a brief description of the event, date; etc.

\*\* Include name/description of approval; date of letter; period of approval, etc. Including the period of approval is very important as a way of deciphering which ICFs were valid at the time of consent.

### Table 1b. REGULATORY DOCUMENTATION SUMMARY CHECKLIST

Depending on the type of study and sponsor, some studies require different regulatory documents. Review your regulatory documents and complete this section according to the requirements that apply to your study.

		YES	NO	N/A	References/Comments:
1b.1	Approved protocol on file? List: Original – _____ Amendment 1 – _____ Amendment 2 – _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 8.2.2
1b.2	Protocol Signature Page Completed? List: PI: _____ Sub-inv.: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1b.3	Signed FDA 1572 (IND study only) on file? Original – _____ Revision 1 – _____ Revision 2 – _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21 CFR 312.53(c) <a href="http://forms.psc.gov/forms/FDA/fda-1572.pdf">http://forms.psc.gov/forms/FDA/fda-1572.pdf</a>
1b.4	Signed FDA 1571 (PI is IND sponsor) on file? Original – _____ Revision 1 – _____ Revision 2 – _____	<input type="checkbox"/>	(IND # _____)	<input type="checkbox"/>	21 CFR 312.22(d) 21 CFR 312.23(a)
1b.5	CVs of PI/Co-PI and all study staff on file? Updated within the past two years? Are they signed and dated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 4.1.1 ICH GCP 8.2.10 See table on next page
1b.6	Medical Licenses of PI/Co-PI and all study staff on file? Current?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	See table on next page
1b.7	Is a copy of the Clinical Investigator Financial Disclosure form on file for each investigator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21 CFR 54 21 CFR 312.64(d) See table on next page

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1b.8	Is there a subject screening log?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 8.3.20
	Is subject screening log complete?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1b.9	Is there a subject enrollment log?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 8.3.22
	Is subject enrollment log complete?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	# of subjects screened? _____ # of subjects included? _____ # of subjects excluded? _____ Reasons specified? <input type="checkbox"/> YES <input type="checkbox"/> NO				
1b.10	Is there a Subject Identification Code List?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 8.3.21
1b.11	Is there a monitoring log?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 8.3.10
	Is monitoring log complete?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	How often is site monitored? _____				
b1.12	Is there a staff signature log?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 4.1.5 ICH GCP 8.3.24 See table on next page
	Is staff signature log complete?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the staff signature log include delegation of responsibility?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1b.13	Are all versions of the Investigator Brochure or Device Manual on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 7.1 ICH GCP 8.2.1 ICH GCP 8.3.1
	Original – _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Package insert/product info. sheet on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1b.14	Is there any study/sponsor-specific documentation? If yes, specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1b.15	All correspondence to and from sponsor and/or FDA on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 4.9.4
1b.16	Are lab tests required?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	If yes, is a copy of normal lab values on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 8.2.11
	If yes, and an outside lab is being used, is a copy of the lab certification on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 8.2.12 ICH GCP 8.3.7
	<b>Laboratory</b>	<b>License</b>	<b>Expiration Date</b>	<b>Lab Normals</b>	<b>Comments</b>
				<input type="checkbox"/> YES <input type="checkbox"/> NO	
				<input type="checkbox"/> YES <input type="checkbox"/> NO	

**Table 1c. CONFIRMATION OF MANDATORY TRAININGS**

**See Appendix B**

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Table 1d. CONFIRMATION OF REQUIRED DOCUMENTS

Principal Investigator and Sub-investigators	CV		Medical License Expiration Date	Financial Disclosure Form		Signature / Responsibility Log			
	Signed YES NO	Dated		Signed YES NO	Dated	Signed YES NO	Initials YES NO		
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:

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**2. DRUG/DEVICE DISPENSING ACCOUNTABILITY**

- Check here if this section is N/A and indicate why:  Observational study  
 Device on loan from sponsor  
 Other (specify): \_\_\_\_\_
- Check here if this is a drug/device study, and complete the following:

					<b>References/Comments:</b>	
2.1	Who is responsible for: Shipping - _____ Receiving - _____ Return - _____				ICH GCP 4.6.1 ICH GCP 4.6.2	
<b>SHIPPING</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>References/Comments:</b>	
2.2	Are shipping receipts / packing slips available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 8.2.15	
	<b>If yes, please list:</b>	<b>Date Shipped</b>	<b>Date Received</b>	<b>Signed in by Whom?</b>		
	_____	_____	_____	_____		
<b>STORAGE</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>References/Comments:</b>	
2.3	Secure?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Limited access?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Separated from other drugs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Special conditions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	If yes, specify: _____					
	Documentation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	If yes, specify: _____					
	Specifications met?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	If no, specify: _____					
	Back-up system?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If yes, specify: _____						
<b>ACCOUNTABILITY</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>References/Comments:</b>	
2.4	Is there a dispensing log?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21 CFR 312.62(a) ICH GCP 4.6.3 ICH GCP 8.4.1	
	If yes, does it include:					
	To whom dispensed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Date dispensed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Amount dispensed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Date returned?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Amount returned?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Person logging in return?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
<b>INVENTORY</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>References/Comments:</b>	
2.5	Is inventory consistent with accountability?					
<b>RETURN</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>References/Comments:</b>	
2.6	Are return shipping forms available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	<b>If yes, please list:</b>	<b>Date Shipped</b>	<b>Shipped by whom?</b>	<b>Date Received</b>		
	_____	_____	_____	_____		

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**3. RECORD KEEPING**

		YES	NO	References/Comments:
3.1	Is there a binder/folder of regulatory documents? <i>(e.g. items listed in section 1 of checklist)</i>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 2.10 ICH GCP 4.9.4
3.2	Is there a binder/folder of IRB correspondence? <i>(e.g. items listed in section 2 of checklist)</i>	<input type="checkbox"/>	<input type="checkbox"/>	
3.3	Is there a study file for each subject?	<input type="checkbox"/>	<input type="checkbox"/>	
3.4	Are there systems in place to protect subject confidentiality? Describe: _____	<input type="checkbox"/>	<input type="checkbox"/>	
3.5	Are all records/files readily available for review?	<input type="checkbox"/>	<input type="checkbox"/>	
3.6	Are records/files well organized?	<input type="checkbox"/>	<input type="checkbox"/>	

**4. ALLOCATION OF RESPONSIBILITIES**

		PI	Sub-Inv	CRC	Other	References/Comments:
4.1	Who prepares the progress reports to the IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 4.1.5 ICH GCP 4.2.4 ICH GCP 4.10.1
4.2	Who prepares the SAE/AE reports?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ICH GCP 4.10.2
4.3	How many consent forms reviewed are signed by each of the following:	_	_	_	_	

**5. SPONSOR AUDITS**

		YES	NO	N/A	References/Comments
5.1	Have there been any sponsor audits of this study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	If so, are the reports available for inspection?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	If so, were there any citations related to the protection of human subjects or compliance with human subject research regulations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	If so, is there documentation of the implementation of corrective action in response to noted deficiencies?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

If necessary, use this space to explain any items:

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Appendix A: Suggestions for completing the Regulatory Timeline

**Regulatory Timeline**  
**[Adapt to fit the study]**

	Document	Date submitted	Response	*Date received
1.1	RPN (Dr. ----- was the PI)		Queries received from the IRB from meeting of -----	
1.2	Resubmission sent to IRB by Dr. -----		IRB states that there is remaining issue:	
1.3	Response from Dr. -----		IRB approval (#-----) ICF dated ----- ([dates of approval period])	
1.4	Amendment request (change in eligibility criteria)		IRB approval ICF dated [dates of approval period]	
1.5	Amendment request (change in PI, change in eligibility criteria, addition of study event)		IRB approval ICF dated [dates of approval period]	
1.6	Amendment request (add personnel, change in eligibility criteria)		IRB approval ICF dated [dates of approval period]	
1.7	Annual Report / Continuing Review		IRB approval ICF dated [dates of approval period]	
1.8			R&D approval -----	
1.9	There are no further changes until the protocol lapses in ----- ----- because Dr. ----- did not submit a continuing review.		Protocol is temporarily suspended in -----	
1.10	Continuing review submission Study is complete except for data analysis.		Modification memo Risk class decreased to minimal	
1.11	Response from Dr. -----		Approval [dates of approval period]	
1.12				
1.13				

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### Appendix A: Suggestions for completing the Regulatory Timeline

Principal Investigator, Sub-investigators, and Research Staff	Status			VHA Privacy Policy Training		CITI Training		Good Clinical Practices (GCP) Training*		VA Cybersecurity		VA Research Data Security and Privacy		Validator's initials**
	VA Staff	WOC	UMB*	Current? Y N	Date	Current? Y N	Date	Current? Y N	Date	Current? Y N	Date	Current? Y N	Date	
				<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		
				<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		
				<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		
				<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		
				<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		
				<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		
				<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		
				<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		
				<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		
				<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		
				<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		

\* If the person is NOT VA staff AND should not be WOC, then VA trainings are not required. If the person interacts with VAMHCS patients at the VAMHCS or performs procedures at the VAMHCS, then the person MUST be WOC. CITI training is required for all staff involved in human subject research (whether UMB or VA-affiliated).