

OFFICE OF RESEARCH AND DEVELOPMENT
 VETERANS HEALTH ADMINISTRATION

**Comparison of VHA Handbook 1200.05 (November 12, 2014) vs.
 VHA Directive 1200.05 (January 7, 2019):
 Requirements for the Protection of Human Subjects in Research**

Paragraph	VHA Handbook 1200.05 November 12, 2014	Change	Paragraph	VHA Directive 1200.05 January 7, 2019	Change
1	Purpose	Updated	1	Purpose	Updated
2	Background	Updated	2	Background	Updated
3	Scope	Changed to Para 4 "Policy"	3	Definitions	Updated to reflect revised Common Rule
4	Definitions	Updated and moved Para 3	4	Policy	Previously "Scope"
5	Assuring Compliance with this Policy	Removed	5	Responsibilities	New
6	IRB Membership	Moved to Para 7	6	Applicability of 2018 Requirements	New
7	IRB Functions and Operations	Moved to Para 8	7	IRB Membership	Updated to reflect revised Common Rule
8	IRB Review of Research	Moved to Para 9	8	IRB Functions and Operations	Updated to reflect revised Common Rule
9	Expedited Review	Moved to Para 11	9	IRB Review of Research	Updated to reflect revised Common Rule
10	Criteria for IRB Approval	Moved to Para 12	10	Exempt Review	New
11	Review by Institution	Moved to Para 13	11	Expedited Review	Updated
12	Suspension or Termination of IRB Approval	Moved to Para 14	12	Criteria for IRB Approval	Updated to reflect revised Common Rule
13	Collaborative Research	Moved to Para 15	13	Review by Institution	Updated
14	IRB Records	Moved to Para 16	14	Suspension or Termination of IRB Approval	Updated
15	General Requirements for Informed Consent	Moved to Para 17	15	Collaborative Research	Updated
16	Documentation of Informed Consent	Moved to Para 18	16	IRB Records	Updated to reflect revised Common Rule

Paragraph	VHA Handbook 1200.05 November 12, 2014	Change	Paragraph	VHA Directive1200.05 January 7, 2019	Change
17	Research Involving Pregnant Women, Human Fetuses, and Neonates as Subjects	Moved to Para 19	17	General Requirements for Informed Consent	Updated to reflect revised Common Rule; inclusion of Broad Consent
18	Research Involving Prisoners as Subjects	Moved to Para 20	18	Documentation of Informed Consent	Updated to reflect revised Common Rule; removal of VA specific requirements
19	Research Involving Children as Research Subjects	Moved to Para 21	19	Research Involving Pregnant Women, Human Fetuses, and Neonates as Subjects	Signification update to allow research on IVF patients
20	Subjects Lacking Decision-Making Capacity	Removed	20	Research Involving Prisoners as Subjects	Updated to reflect revised Common Rule
21	Certificates of Confidentiality	Moved to Para 22	21	Research Involving Children as Research Subjects	Updated for VA policy
22	Privacy Officer and Information Security Officer Duties	Removed (information under "Responsibilities")	22	Certificates of Confidentiality	Updated to reflect 21 st Century Cures Act
23	HIPAA Authorization	Unchanged	23	HIPAA Authorization	Updated for VA policy
24	Participating of Non-Veterans as Research Subjects	Removed	24	Treatment of Research-Related Injuries	Unchanged
25	Treatment of Research-Related Injuries	Moved to Para 24	25	International Research	Unchanged
26	International Research	Moved to Para 25	26	Training Requirements	New
27	Accreditation of Human Research Protection Programs	Removed	27	Records Management	New
28	Student and Other Trainee Research	Removed	28	References	Updated
29	VA Investigator Responsibilities	Removed (information under "Responsibilities")			
30	References	Moved to Para 28			

Paragraph	VHA Handbook 1200.05 November 12, 2014	Change	Paragraph	VHA Directive1200.05 January 7, 2019	Change
Appendix A	Categories of Exempt Research		Appendix A	Categories of Exempt Research: Pre-2018 Requirements	Unchanged
Appendix B	Activities Appropriated for Expedited Review		Appendix B	Categories of Exempt Research: 2018 Requirements	New
			Appendix C	Documentation and Review of Human Subjects Research Conducted by VHA Program Office Employees	New
			Appendix D	Sample Format for Documentation of Program Office Research	New