

	eResearch Section Number																																							
Change to Application	1	2	3	5	6	7	8	9	10	11	13	14	15	16	17	18	19	20	21	22	24	25	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	44		
STUDY TEAM CHANGES																																								
Change in PI or Co-I	1.3			Prot			8-1		ICD 10-6**				15-1						21-1																					
Ref. HRPP OM Part 6																																								
Add or remove research staff	1.3			5			8-1		ICD 10-6**																															
Add or remove consultants	1.3			Prot																																				
VULNERABLES																																								
Neonates				Prot 5.4 5.6	6		8.1 8-1	9-1 9-3**	10.2 10-6** ICD																					34								41		
Children				Prot 5.4 5.6 5-2* 5-4**	6		8.1 8-1	9-1 9-3**	10.2 10-6** ICD				15																									41		
Ref. IRBMED webpage - Children in Research																																								
Cognitively impaired adults				Prot 5.4	6		8-1	9-1 9-3**	10.1 10.1.3 ICD 10-6**																												39		41	
Ref. HRPP OM Part 7																																								
Women of Child-Bearing Potential				Prot 5.4	6			9-1 9-3**	10-6** ICD			14.8	15																								37		41	
Pregnant women				Prot 5.4	6		8-1	9-1 9-3**	10-6** ICD				15																								35		41	
Lactating women				Prot 5.4	6		8-1	9-1 9-3**	ICD 10-6**				15																								36		41	
Patients of the study team				Prot 5.4	6		8-1	9-1 9-3**	10.1 10-6**																														41	
Non-English speaking subjects				Prot	6		8-1	9-1 9-3**	10.1 10-6** ICD																		29		31											
Ref. IRBMED webpage on Non-English Speaking																																								
Prisoners				Prot 5.4	6			9-1 9-3**	10.1 10-6** ICD																													38		
Ref. IRBMED webpage on Prisoners in Research																																								
DRUGS, DEVICES, RADIATION, STEM CELLS, TRANSPLANTS																																								
Placebo	1.8			Prot	6	7-1 7-3**			10.1 10-6** ICD			14			17																									
Radiation				Prot	6	7-1 7-3**	8-1		10-6** ICD			14		16						21 21-1 21-2																				
Use of approved or unapproved device	1.8			Prot	6	7-2 7-3**			10-6** ICD					16																										
Use of investigational drug	1.8			Prot	6	7-1 7-3**			10-6** ICD				15																											

* Cancer Center studies only
 ** Applications Requesting Review by a non-UM IRB

