Informed Consent Elements & Suggested Language - IRB Health Sciences & Behavioral Sciences

Elements highlighted in yellow are required.
See 45 CFR 46.116 for regulatory information concerning informed consent.

Element and Suggested Language	***Comments***
1. Title of the project	For most projects, the title of the study should appear at the beginning of the document.
2. Researcher name, credentials, institutional affiliation	The Principal Investigator and Co-investigator(s) must be listed. For stud projects, include faculty advisor(s). Other key personnel who engage in substantial interactions with subjects should be listed.
3. Invitation to participate in a research study [PI name] invites you to participate in a research study about [topic/purpose]. The study is funded by [sponsor, if any].	See recommended language in the highlighted area. Include the followin information: *description of how/why the potential participant was selected. *description of study objectives in lay terms, no more than 1-2 sentence *statement of purpose, clearly articulating that the activity is research. *identification of study sponsor, if any. *if the study is a student project, a statement that the study is being conducted to fulfill an academic requirement (such as a thesis or dissertation). *estimate of the total number of subjects expected to enroll (not required but helpful for clinical research studies or when the research topic is sensitive).
4. Description of subject involvement If you agree to be part of the research study, you will be asked to [select] *complete a survey *participate in an interview *participate in a focus group This will take about _____ minutes/hours/days	Select the appropriate option(s) provided in the highlighted area, or modify as needed. Clearly describe research activities. Provide a realistic estimate of time required to participate. If the study involves multiple activities, describe each, in the order they will be performed. Include time estimates for each phase, well as an estimate of the total time commitment.

Revised 5/13/2009

	A	B	C	D	E	F	G	H	I	J	K	L
39												
40	**5. Benefits**						Select the appropriate option provided in the highlighted area, or modify as needed. Keep in mind that compensation is not a research benefit to the participant.					
41	[select]											
42	*You will directly benefit from being in this study because [detail]											
43	*Although you may not directly benefit from being in this study,											
44	others may benefit because [details]											
45												
46												
47	**6. Risks and discomforts**											
48												
49	[select]											
50	There are no risks associated with this study because the data						If the study is entirely free of risk, select the first option. Keep in mind tha					
51	collection is completely anonymous and the topic is not						only studies with anonymous data collection on topics that are not sensiti					
52	sensitive.						meet this definition.					
53												
54	The researchers have taken steps to minimize the risks of this						If the study is classified as more than minimal risk or it is clinical, the					
55	study. Even so, you may still experience some risks related to						language to the left is required. Select from the list of risks or modify to fi					
56	your participation, even when the researchers are careful to						your study. Be sure to include a description of the steps taken to mitigate					
57	avoid them. These risks may include the following [select]						the risks.					
58	*The questions are sensitive and may make you feel											
59	uncomfortable or embarrassed. You may remember or think											
60	about things that bother you. To reduce this risk [complete]											
61	* The researchers have taken steps to minimize the risks of this											
62	study. Even so, there is a small chance that the information you											
63	provide could be unintentionally disclosed. To reduce this											
64	risk [complete]											
65	*Some other risk specific to the study											
66	**********											
67	Clinical injury language:											
68	Please tell the researchers about any concerns or problems you						If the study is clinical, the language to the left is required.					
69	have during the study. You should also tell your regular health											
70	care provider. The study will pay for research-related items or											
71	services that are provided only because you are in the study.						"The study will pay for" means the internal or external sponsor, or the PI.					
72	By signing this form, you do not give up your right to seek						The University of Michigan will <u>not</u> pay for research-related injuries.					
73	payment if you are harmed as a result of being in this study.											
74	**********											

	A	B	C	D	E	F	G	H	I	J	K	L
75	Non-clinical injury language:											
76	Please tell the researchers about any concerns or problems you						If the study is more than minimal risk but is not clinical, the language to th					
77	have during the study. The study will pay for research-related						left is required.					
78	items or services that are provided only because you are in the											
79	study. By signing this form, you do not give up your right to											
80	seek payment if you are harmed as a result of being in this											
81	study.											
82												
83	**7. Compensation**						Select the appropriate option provided in the highlighted area, or modify					
84	[select]						as needed. If compensation will not be offered, do not include this sectio					
85	*You will not receive any payment for being in the study						Explain how compensation will be affected if the subject withdraws before					
86	*You will be reimbursed for your parking expenses						the end of the study. The IRB recommends that compensation is prorate					
87	*You will be reimbursed for your child care expenses						based upon the portion of the research that was completed.					
88	*You will be given $___ for being in the study											
89	*You will be given _____ for being in the study						Include a description of any costs that might be incurred by participants,					
90	*You will receive ____ hours of psychology/other unit subject pool						such as transportation or parking.					
91	credit											
92	*You will not be expected to pay any costs related to the study											
93	*You will be expected to pay for your own transportation, parking,											
94	or child care, if needed											
95												
96	By agreeing to be in this study, you do not give up your right to						This statement is required if the study poses greater than minimal risk to					
97	seek compensation if you are harmed as a result of participation.						subjects.					
98												
99												
100	**8. Confidentiality**						The first paragraph in the highlighted area contains recommended					
101	We plan to publish the results of this study, but will not include						language for all studies. If the study involves protected health informatio					
102	any information that would identify you. There are some reasons						(PHI), see page 6 of this document.					
103	why people other than the researchers may need to see											
104	information you provided as part of the study. This includes											
105	organizations responsible for making sure the research is done						If you have a sponsor, insert the name; if not, remove the reference to					
106	safely and properly, including the University of Michigan,						sponsorship.					
107	government offices or the study sponsor [name, if any].											
108												

	A	B	C	D	E	F	G	H	I	J	K	L
109	To keep your information safe, the researchers will [select]						Include the bracketed material if appropriate to your study.					
110	*Your name will not be attached to any data, but a study number											
111	will be used instead.											
112	*The data will be kept on a password-protected computer using						Describe how you will protect research data. Select the					
113	special software that scrambles the information so that no one						appropriate option(s) or modify, as needed.					
114	can read it.											
115												
116	If you tell us something that makes us believe that you or others						Language regarding abuse should be used only if the research might be					
117	have been or may be physically harmed, we may report that						conducted with participants or in situations in which physical abuse might					
118	information to the appropriate agencies.						be a possibility. Some research topics present the possibility that a					
119							participant might disclose information about the abuse of children or					
120							vulnerable adults. Some professions are required to report abuse.					
121							The State of Michigan has statutes about the reporting of abuse.					
122							The following document provides information about abuse reporting					
123							requirements in other states:					
124							http://www.ndaa.org/pdf/mandatory_reporting_state_statutes.pdf					
125							In such situations, reporting suspected abuse supercedes the promise					
126							of confidentiality in research and must be disclosed in the consent docum					
127												
128	The data or specimens you provide will be stored [describe]						Describe how/where data or specimens will be stored, such as on a					
129	The researchers will retain the data/specimens for [duration]						password-protected, encrypted laptop, in a locked file cabinet, on a					
130	The researchers will dispose of your data/specimens by [date]						university-maintained server, and the like. Indicate how long you expect					
131	The data/specimens will/will not [select] be made available						retain the data and when you will dispose of the data, and by what means					
132	to other researchers for related studies following the completion						If you plan to retain the data for future research or to share it with other					
133	of this research study and will/will not [select] contain						researchers, disclose those details here.					
134	information that could identify you.						For more information on safe computing, visit					
135							http://www.safecomputing.umich.edu/					
136	**10. Voluntary nature of the study**						The highlighted area contains recommended language for all studies.					
137	Participating in this study is completely voluntary. Even if you											
138	decide to participate now, you may change your mind and											
139	stop at any time.											
140												
141	If you decide to withdraw early [select]						Select the appropriate option, or modify as needed. Be clear about					
142	*the information or data you provided will be destroyed						what will happen to the participant's data if they choose to withdraw					
143	*the information or data you provided cannot be destroyed						early.					
144	because it is not linked to you either directly or by a code											
145	*You may also want to discuss it with your health care provider						Include if the study is clinical					
146	[details]											

147		See recommended language in highlighted area. Provide contact information for the PI, including phone, mailing and email address. If the is a student, provide contact information for the faculty advisor. Clearly state that participants should contact the study team for questions about research.
148	**11. Contact information**	
149	If you have questions about the study, including scheduling or	
150	your compensation for participating, you may contact [PI (and	
151	faculty advisor, if PI is a student)]	
152		
153	If you have questions about your rights as a research participant,	
154	please contact the University of Michigan Institutional Review	The highlighted area contains required language for all non-exempt studi
155	Board Health Sciences and Behavioral Sciences, 2800 Plymouth Road,	If the project is primarily managed by another institution, that institution's
156	Building 520, Rm. 1169 Ann Arbor, MI 48109-2800, (734) 936-0933	IRB contact information may need to be provided.
157	[or toll free, (866) 936-0933], irbhsbs@umich.edu	Use the toll-free number if appropriate.
158		
159	**12. Consent**	
160	By signing this document, you are agreeing to be in the study.	See highlighted area for recommended language for studies utilizing
161	You will be given a copy of this document for your records and	written informed consent. Do not include a signature line if you are
162	one copy will be kept with the study records. Be sure that	requesting a waiver of documentation of informed consent, such as for a
163	questions you have about the study have been answered and that	a web-based survey or telephone interview. There is no regulatory
164	you understand what you are being asked to do. You may	requirement for a study team member or witness to also sign the
165	contact the researcher if you think of a question later.	consent document.
166		
167	*I agree to participate in the study.*	
168		
169	Signature	
170	Date	
171		
172		
173	**THE FOLLOWING ELEMENTS MAY NEED TO BE INCLUDED**	
174	**IN THE INFORMED CONSENT DOCUMENT**	
175		
176		
177	**Signature of legal representative**	This element is used only in the case of research involving individuals ag
178	Printed name	18 or over who are legally unable to give their consent. It is not used for
179	Signature	parental permission of research involving minors.
180	Relationship to subject	
181	Date	
182		

183		
184	**Audio/visual recording of subjects**	
185		Consent to conduct audio/visual recording does not require a separate
186	Select/modify as appropriate:	signature line, but may instead be part of the overall consent to participat
187	*Audio/visual recording will be done as part of study procedures.	Such recording should be described in the Description of Subject Involve
188	*Upon completion of the study, these recordings will be	and subjects should be told explicitly whether recording is a requirement
189	*Please sign below if you are willing to be recorded	participation. The consent statement should indicate that the participant
190	*You may/may not participate in this study if you are not willing to	agrees to be recorded. In the section on confidentiality, describe the
191	be recorded	disposition of the recordings (e.g., they will be destroyed, archived, etc.).
192	*Signature	Be sure to specify whether you will conduct audio or visual recordings,
193	*Date	or both.
194		
195		
196	**Certificate of Confidentiality**	
197	To protect your privacy, the researchers have obtained a	For studies involving disclosure of sensitive or illegal information, the IRB
198	Certificate of Confidentiality from the National Institutes of Health.	may require the study team to obtain a Certificate of Confidentiality
199	With this Certificate, the researchers cannot be forced to disclose	(granted by the NIH). This protects the data from compelled disclosure,
200	information that may identify you, even by a court subpoena, in	such as through a subpoena. The language to the left is recommended
201	any federal, state, or local civil, criminal, administrative, legislative,	language from the CoC Kiosk at:
202	or other proceedings. The researchers will use the Certificate to	http://grants2.nih.gov/grants/policy/coc/appl_intramural.htm
203	resist any demands for information that would identify you,	
204	except as explained below.	
205		
206	A Certificate of Confidentiality does not prevent you or a member	As stated in the last line of the CoC language to the left, researchers
207	of your family from voluntarily releasing information about yourself	must describe the conditions under which they would disclose informatior
208	or your involvement in this research. If an insurer, employer, or	about a participant, such as in the case of child abuse. If no voluntary
209	other person obtains your written consent to receive research	disclosures will be made, state this.
210	information, then the researchers may not use the Certificate to	
211	withhold that information. The Certificate of Confidentiality does	
212	not prevent the researchers from disclosing voluntarily, without	
213	your consent, information that would identify you as a participant	
214	in the research project under the following circumstances:	
215	[describe]	

216		
217	A new Federal law, called the Genetic Information	If you are collecting genetic information in a repository, the language to th
218	Nondiscrimination Act (GINA), makes it illegal for health	left is required.
219	insurance companies, group health plans, and most employers	
220	to discriminate against you based on your genetic information.	
221	This law will protect you in the following ways:	
222	* Health insurance companies and group health plans may not	
223	request your genetic information that we get from this research.	
224	* Health insurance companies and group health plans may not	
225	use your genetic information when making decisions regarding	
226	your eligibility or premiums.	
227	* Employers with 15 or more employees may not use your	
228	genetic information that we get from this research when making	
229	a decision to hire, promote, or fire you or when setting the terms	
230	of your employment.	
231	All health insurance companies and group health plans must	
232	follow this law by May 21, 2010. All employers with 15 or more	
233	employees must follow this law as of November 21, 2009.	
234	Be aware that this new Federal law does not protect you	
235	against genetic discrimination by companies that sell life	
236	insurance, disability insurance, or long-term care insurance.	
237		
238	**Availability of further information**	
239	If significant new knowledge is obtained through the course of the	The language to the left is typically included for clinical research.
240	research which may relate to your willingness to continue	Include it in Section 10, Voluntary nature of the study.
241	participation, you will be informed of this knowledge.	
242		
243		
244	**Protected health information/HIPAA**	
245	Agreeing to be in this study gives the researchers your permission	The language to the left is required if your project involves protected heal
246	to obtain, use, and share information about you for this study, and	information (PHI) obtained through a covered entity. You should modify t
247	is required in order for you to take part in the study. Information	list of PHI you will obtain to fit your study. This should be included in the
248	about you may be obtained from any hospital, doctor, and other	confidentiality section. Covered entities include:
249	health care provider involved in your care, including:	*University of Michigan Health System (including hospitals and health
250	*Hospital/doctor's office records, including test results (X-rays,	centers, medical school, Michigan Visiting Nurses, Michigan Health
251	blood tests, urine tests, etc.)	Corporation, joint ventures)
252	*Mental health care records (except psychotherapy notes not	*School of Dentistry
253	kept with your medical records)	*School of Nursing (Nurse-Managed Centers ONLY)
254	*Alcohol/substance abuse treatment records	*UM-Flint Urban Health and Wellness Center

*Your AIDS/HIV status
*All records relating to your condition, the treatment you have received, and your response to the treatment
*Billing information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:
*The researchers may need the information to make sure you can take part in the study.
*The researchers may need the information to check your test results or look for side effects.
*University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
*Study sponsors or funders, or safety monitors or committees, may need the information to:
Make sure the study is done safely and properly
Learn more about side effects
Analyze the results of the study
*Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study
*The researchers may need to use the information to create a databank of information about your condition or its treatment.
*Information about your study participation may be included in your regular medical or dental records (as applicable).

As a rule, researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have cancelled your permission or the study is over. Examples of reasons for this include:
*To avoid losing study results that have already included your
*To provide limited information for research, education, or other activities (this information would not include your name,

*University Health Service
*Institute for Human Adjustment
*UM Autism and Communication Disorders Center
*UM Employee Benefits (only those units that manage UM health benef plans, including medical, dental, vision, and healthcare Flexible Spending Accounts)

The language to the left should be included to accurately describe who will have access to the subject's PHI that you collect as part of your study

Use the first sentence, and then select the appropriate option that best fit your study, or modify as needed.

You might want to define PHI for participants:
Protected health information (PHI) is defined as current, past or future information created or received by the University through its health care providers, health plans and contractors. It relates to the physical or ment condition of a patient or plan member, the provision of health care to that person, or payment for the provision of health care to that person. The te PHI does not generally include publicly available information, or informati available or reported in a summarized or grouped manner.
(University of Michigan Notice of Privacy Practices, effective 4/14/2003)

The language to the left describes the ongoing management of PHI. Modify the list to fit your study.

	A	B	C	D	E	F	G	H	I	J	K	L
294	social security number, or anything else that could let others											
295	know who you are).											
296	*To help University and government officials make sure that the											
297	study was conducted properly.											
298												
299	As long as your information is kept within the [covered entity], it						The language to the left is only applicable for PHI obtained through					
300	is protected by the University of Michigan's privacy policies. For						the covered entities described previously.					
301	more information about these policies, ask for a copy of the											
302	University of Michigan Notice of Privacy Practices. Note that											
303	once your information has been shared with others, it may no											
304	longer be protected by the privacy regulations of the federal											
305	Health Insurance Portability and Accountability Act of 1996											
306	(HIPAA).											