

# CONSENT FORM CHECK LIST (Human Research)

Requirements from Calif. H & S Code § 24173 et. Seq and Title 45 CFR Part 46

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<u>Informed Consent Element</u>	<u>Page-Line</u>
The consent form <i>should</i> provide:	
1. A copy of the California Experimental Subject's Bill of Rights.	_____
2. Language requirements:	
a. California law requires that the consent form and the Experimental Subject's Bill of Rights be written in a language in which the subject is fluent. The consent form should include a statement such as " <u><i>I have read this information, which is printed in *name of language*. This is a language that you read and understand.</i></u> " in the beginning or at the end of the consent form.	_____
b. Understandable to lay person (avoid or explain technical terms)	_____
c. No exculpatory phrases	_____
d. Clearly written, no ambiguous phrases	_____
3. Fair explanation of procedures	
a. Purpose of experiment	_____
b. Identification of experimental aspects For example, "My standard medication will be replaced by:..."	_____
c. Nature of drugs and dosages, route of administration	_____
d. Extent of experience with investigational drug	_____
4. DNA testing (if applicable)	
a. Purpose of the DNA testing	_____
b. Whether DNA testing is mandatory or optional	_____
c. Separate DNA informed consent form required	_____
5. Name, affiliation & address of person responsible for experiment	_____

80' P co g"qh'r tpekr cnlpxguki cvqt."hwpf lpi "uqwteg."o cpwlcwewtgt.  
"cwj qt k lpi "qti cp k cvkqp" aaaaaaaaaa"

90' Kpxguki cvqt)u'qhht 'v'cpuy gt"cp{ 's wguvkqpu" aaaaaaaaaa"

: 0' P co g."cf f tguu"( 'r j qpg"pwo dgt"qh'ko r ctvkn'y kf "r ctv{ 'hqt  
""cf f tguukpi 'eqo r rckpw<y g'Rcpgn'tgs wktgu'y g'pco g."cf f tguu'cpf 'r j qpg"  
""pwo dgt"qh'c's wcnkkgf "qh'kg"qt"kp f kxk' wcn'y cv'j cu'dggp'f guki pcv'gf "d{ ""  
y g'tgugctej "kpukwkg"qt"ur qpuqt"v'j cxg'tgur qpukdkk{ "cpf "cwj qt k{ "v"  
""hqmjy "w'qp'eqo r rckpw0" aaaaaaaaaa"

; 0' Tkumi"v'uwdlgev"

c0 F lueqo hqtu" aaaaaaaaaa"

d0 F twi "ukf g"ghgewu" aaaaaaaaaa"

e0 Wpf lueqxtgf "f twi "vzlek{ " aaaaaaaaaa"

f0 Nqpi /vgt0 "ghgewu'y cv'ecppqv'dg'npqy p" aaaaaaaaaa"

g0 Ur gekn'tkumi'kp"ecug"qh'r tgi pcpe{ "\*"qt'r quukdn'g'r tgi pcpe{ +" aaaaaaaaaa"

320' Rquukdn'gdpghku"

c0 Vj gtr gwke" aaaaaaaaaa

d0 Dgpghk\*"qt"pqp g+"v'uwdlgev" aaaaaaaaaa

e0 Vq'uqekgv "g0 0'uelpv'khe"npqy r'f i g+" aaaaaaaaaa

f0' Vq'c'r tpekr cnlpxguki cvqt"qh'y g'tgugctej ."y g'tgugctej  
""kpukwkqp"qt"o cpwlcwewtgt" aaaaaaaaaa

330' Xqmpvct{ 'r ctvkr cvkqp"

c0 Engctn{ "ucv'gf " aaaaaaaaaa"

d0 Ur gekn'tkum'r qr wrcv'kqpu" aaaaaaaaaa"

e0 O c{ 'y kj f tcy "htqo "gzr gtko gpv'y kj qw'r gpcn{ " aaaaaaaaaa"

12. Disclosure of Financial Compensation

a. To investigator by study sponsor (if applicable) \_\_\_\_\_

b. To subject for participation in study (if applicable) \_\_\_\_\_

13. Alternative procedures (drugs) for therapy \_\_\_\_\_

14. Policy regarding treatment and compensation provisions for injured research subjects: the Panel requires the following:

a. Should any complication derive from the procedures, the research subject will receive medical treatment. \_\_\_\_\_

b. If the sponsor/institute fails to offer to pay for the costs of the treatment, the consent form must state that a participant in the study always has the right of suit to recover compensation for damages directly caused by research procedures. \_\_\_\_\_

15. Confidentiality statement: \_\_\_\_\_

The Panel requires that a statement be included in the consent advising potential research subjects that their records may be inspected by the Research Advisory Panel; or , "State or Federal Regulatory Agencies".

16. Signature by subject \_\_\_\_\_

17. Signature by person administering consent to attest to adhering to informed consent procedures \_\_\_\_\_

18. Subject's receiving a copy right: \_\_\_\_\_

The consent form should include a statement such as "You will receive a copy of this signed informed consent form as well as a copy of the Experimental Subject's Bill of Rights." in the beginning or at the end of the consent form.

19. Authorization to use and disclose protected health information (PHI) \_\_\_\_\_