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Medical Research: Forms & Consent Templates

This section contains all of the forms and consent templates that apply to investigators from:

- ? School of Medicine (SoM)
- ? Veteran's Affairs (VA) Hospital
- ? Psychology (fMRI studies)

*Please note that when creating a protocol for IRB submission, these investigators need to select the Medical eProtocol Application category.

If you have questions or are having trouble accessing these forms, please contact IRB Education ([email](#) [1] or call 650-724-7141).

The consent/assent form should be in a language that is understandable to someone without a medical or scientific background. Please use the [Microsoft Readability Statistics tool](#) [2] as needed when writing your consent form.

Consents See consent template updates [3] for recent changes	VA [rev. date]	Stanford [rev. date]
Consent (HIPAA embedded)	VA doc [4] w/HIPAA 12/2/19	doc [5] w/HIPAA 12/7/20
Consent without HIPAA Note: For separate VA HIPAA, use FORM 10-0493.	VA doc [6] no HIPAA 12/2/19	doc [7] no HIPAA 12/2/19
Minimal Risk Consent (e.g., blood draws, data collection, leftover specimens, interviews, surveys, behavioral interventions.)	VA doc [8] w/HIPAA [9] 12/2/19	doc [10] w/HIPAA 12/2/19
Minimal Risk Consent without HIPAA Note: For separate VA HIPAA, use FORM 10-0493.	VA doc [11] no HIPAA [9] 12/2/19	
Minimal Risk Consent - MRI for research (e.g., for fMRI use in behavioral research; HIPAA included)		doc [12] 12/2/19
HIPAA Authorization - VA Form 10-0493 - standalone document	VA pdf [13] 09/2015	doc [14] 02/23/16

VA Header & Footer 10-1086	VA doc [15] 11/02/11	
Short Form Consent Process & Templates		shortform [16]
Somatic Cell Donation for Stem Cell Research (HIPAA included)		doc [17] 12/2/19
Radiation Consent Language		EH&S Website [18]
NIH Certificate of Confidentiality (Spanish)		pdf [19] 02/23/16
General Data Protection Regulation (GDPR) Consent Form Language		doc [20] 10/22/18
Assents, scripts, phone screens, info sheet See consent template updates [21] for recent changes		
Assent ? under 18		doc [22] 1/07/15
Assent ? adults (18+) unable to provide consent i.e., LAR provides consent		doc [23] 1/07/15
Telephone Screening of Potential Subjects ? Sample Phone Screen Level 1a ? Sample Phone Screen Level 1b		? Guidance [24] ? Screen1a [25] ? Screen1b [26]
Research Information Sheet - Use for Waiver of Documentation & Exempt applications		doc [27] 12/19
Schedule of Procedures Table		doc [28] 10/05/17

Other Forms:

HS Research determination; IND & IDE forms; Other	
Human Subject Research (HSR) Determination Form	pdf [29]
Letter of Agreement - for research in cooperation with other organizations	doc [30]
IND Forms and Instructions: - FDA 1571 Investigational New Drug Application - FDA 1572 Statement of Investigator - Instructions for completing FDA forms 1571 and 1572	FDA/CDER website [31]
IDE application	FDA website [32]
FDA forms & submission requirements (drugs)	FDA website [33]
SIR Self-Assessment Checklist - IND/IDE	AID-58m [34]
Emergency Use of a Test Article - Notification to the IRB	pdf [35]

Scientific Review	
Review of Scientific and Scholarly Validity, and Oversight (by Academic Sponsor)	doc [37]
Review of Scientific and Scholarly Validity (by Dept Chair or School Dean)	doc [38]
Scientific Review Protocol - for projects not otherwise undergoing scientific review	doc [39]

eProtocol Forms:

Required Attachments	
Required Questions - VA Research	doc [40]
International Research Supplemental Questions ? research outside the US	doc [41]
Gene Transfer Protocol Application Supplemental Questions	doc [42]
DOE-supported research: Protection of Personally Identifiable Information (PII) [Form APP-14]	doc [43]
Blank eProtocol [44] Application Forms	
<p>Requires Stanford SUNetID Login to view</p> <p>New, Modification, Continuing Review</p> <p>(These are for informational purposes only)</p>	<p>? Medical:</p> <ul style="list-style-type: none"> -Regular [45] -Expedited [46] -Exempt [47] -Chart Review [48] -sIRB [49] -HSR [50] <p>? Mod [51]</p> <p>? Continuing Review [52]</p> <p>? Non-Medical:</p> <ul style="list-style-type: none"> -Regular [53] -Expedited [54] -Exempt [55] -sIRB [56]
<p>eProtocol [44] is used to submit:</p> <ul style="list-style-type: none"> ? New Protocol applications - see examples above. <ul style="list-style-type: none"> - Complete and attach supplemental required attachments as needed (see above) ? Modifications to approved protocols (need prior IRB approval to implement). ? Continuing Review applications. ? Reports unanticipated problems, events/information requiring prompt reporting. ? Final Reports (not required for Exempt research). 	

- [1] <mailto:IRBeducation@stanford.edu>
- [2] <https://support.office.com/en-gb/article/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2>
- [3] <https://stanfordmedicine.box.com/shared/static/09v23e108tyv0xktoyr6rihv5nv6fjc4.pdf>
- [4] https://web.stanford.edu/dept/DoR/compliance/rco.sites/va/CONSENT_VA_Reg_with_HIPAA.docx
- [5] <https://stanfordmedicine.box.com/shared/static/ad6nuqi08j7nd0y5k6khiabbvjvpkasu.doc>
- [6] https://web.stanford.edu/dept/DoR/compliance/rco.sites/va/CONSENT_VA_Regular_No_HIPAA.docx
- [7] <https://stanfordmedicine.box.com/shared/static/1o74ve7ll8535scof1wub1totmk48czb.doc>
- [8] https://web.stanford.edu/dept/DoR/compliance/rco.sites/va/CONSENT_VA_Minimal_risk_with_HIPAA.docx
- [9] <https://stanfordmedicine.box.com/shared/static/06vyhux98ep10whi5xht19ocy5isu7b9.doc>
- [10] <https://stanfordmedicine.box.com/shared/static/5zel02z8fwdjhsxtwr96l06b362dg5ob.docx>
- [11] https://web.stanford.edu/dept/DoR/compliance/rco.sites/va/CONSENT_VA_Minimal_risk_No_HIPAA.docx
- [12] <https://stanfordmedicine.box.com/shared/static/i9y5onkiie1vbzo4403k0su6yz7y4mu4.docx>
- [13] <https://web.stanford.edu/dept/DoR/compliance/rco.sites/va/hipaaVA.pdf>
- [14] <https://stanfordmedicine.box.com/shared/static/8cxasnr3yupss0f5y24isk9s9xt04wua.doc>
- [15] https://web.stanford.edu/dept/DoR/compliance/rco.sites/va/VA_10-1086_Header_and_Footer.doc
- [16] <https://researchcompliance.stanford.edu/panels/hs/consent/forms/short-form-consent-process>
- [17] <https://stanfordmedicine.box.com/shared/static/eoyksq8sh37k6yv2levo4mvrzwclp3zr.docx>
- [18] <https://ehs.stanford.edu/manual/radiation-protection-guidance-hospital-staff/guidance-preparing-research-proposals-involving>
- [19] <https://stanfordmedicine.box.com/shared/static/jacqgf7ov0ws1scgced4ejf3jat3rexh.pdf>
- [20] <https://stanfordmedicine.box.com/shared/static/1igt6tuic4mqdtgshz5umj9qd8jnv2ok.docx>
- [21] <http://stanfordmedicine.box.com/shared/static/09v23e108tyv0xktoyr6rihv5nv6fjc4.pdf>
- [22] <https://stanfordmedicine.box.com/shared/static/a18pt6haeovx8o9u4dl76pe1n06hzm23.doc>
- [23] <https://stanfordmedicine.box.com/shared/static/0mc4xsawqp3seqfmc9jfvq06qz4zot2.docx>
- [24] <https://stanfordmedicine.box.com/shared/static/lnlt88zaqxhw7dulvqx2um8grtgxmvi5.pdf>
- [25] <https://stanfordmedicine.box.com/shared/static/7lwpw0bogm2ko7nil6x5ckd336lmzve1.doc>
- [26] <https://stanfordmedicine.box.com/shared/static/e6d2olfd2c1ppmgae5d2ws08fs00uafu.doc>
- [27] <https://stanfordmedicine.box.com/shared/static/0k6mpyvad2ykjnyjo9o9fjfpj5k9quo6.docx>
- [28] <https://stanfordmedicine.box.com/shared/static/6iqpcjc42xfow50ip2b2pq1kf1bj1i2c.docx>
- [29] <https://stanfordmedicine.box.com/shared/static/jm5gac2qyhz80glrmds8uas32fwn87ce.pdf>
- [30] <https://stanfordmedicine.box.com/shared/static/c2xd0b2ub0g3biv5kzgzj87e1fpcu1cp.doc>
- [31] <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalDeviceExemptions/InvestigationalDeviceExemptions.htm>
- [32] <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptions/InvestigationalDeviceExemptions.htm>
- [33] <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/default.htm>
- [34] <https://stanfordmedicine.box.com/shared/static/ecw0rxnqx1qgrx2mfvvcdpknmg1kz4xl.docx>
- [35] <https://stanfordmedicine.box.com/shared/static/zffoz6icql3vb2ccktunhdb9lgs5z3v8.pdf>
- [36] <https://stanfordmedicine.box.com/shared/static/cdukfb1soyx1vcn1751fa8jcl6vhoova.pdf>
- [37] <https://stanfordmedicine.box.com/shared/static/j6di978rz4t46rsh60hxzc94i2rzygg4.doc>
- [38] <https://stanfordmedicine.box.com/shared/static/dn7t0l43q872ohjxc8ykrymu0xsw5pb1.doc>
- [39] <https://stanfordmedicine.box.com/shared/static/9g56g2xqj553wy0czwuhfj9z0d9q9hfw.doc>
- [40] http://web.stanford.edu/dept/DoR/compliance/rco.sites/va/APP-1m_VA_Required_Questions.docx
- [41] <https://stanfordmedicine.box.com/shared/static/vrpa7sjf59zspwee5xqovl5e1y955wlp.doc>
- [42] <https://stanfordmedicine.box.com/shared/static/zlr02afphvcwgsr0cez3px13i9igf58x.doc>

- [43] <https://stanfordmedicine.box.com/shared/static/ibb09kek42xmucngtu6zxocp08ivdbq3.docx>
- [44] <https://eprotocol.stanford.edu/>
- [45] <https://stanfordmedicine.box.com/shared/static/wynocgvviy8qu8yoz409q2j8bguwtryy.pdf>
- [46] <https://stanfordmedicine.box.com/shared/static/nzt16qkrfqk2fj9m1nh0zjpyvokzwb90.pdf>
- [47] <https://stanfordmedicine.box.com/shared/static/wljbyijvfk7jkw7v5uxhhe5eqwziadc.pdf>
- [48] <https://stanfordmedicine.box.com/shared/static/cf6jkd91mmdq3oq4p8f1j85tkiqyzzrf.pdf>
- [49] <https://stanfordmedicine.box.com/shared/static/63kxdgg38l815heavd6ymoeremnw4pyq.pdf>
- [50] <https://stanfordmedicine.box.com/shared/static/rcceklom78r3bnjdpnn2xzlb5hfdysry.pdf>
- [51] <https://stanfordmedicine.box.com/shared/static/1zgxs52y97q6txrnez91egeef7o2wso5.pdf>
- [52] <https://stanfordmedicine.box.com/shared/static/oe2tsw4j22hnd2nckcdhu3y37bgg8hpn.pdf>
- [53] <https://stanfordmedicine.box.com/shared/static/sz2ghzbi0eo66rzaie4vbq8aidqm6lws.pdf>
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- [55] <https://stanfordmedicine.box.com/shared/static/h6nafqz3mm6af923gwacdjiyuh442ro.pdf>
- [56] <https://stanfordmedicine.box.com/shared/static/1fk3iyhz0as8hodq5cczsq9h78h57vo0.pdf>