*This checklist is to be used as a guide for researchers when preparing a new IRB application in eProtocol. The following items are required (as applicable) prior to submitting a new IRB application in order to be accepted for review by the IRB.* ***Do not upload this checklist in eProtocol.*** *Please contact IRB Education with questions at* [*irbeducation@stanford.edu*](mailto:irbeducation@stanford.edu)*.*

**Scientific and Scholarly Validity (SSV) Review**

For IRB Panel assignment, Review of Scientific and Scholarly Validity completed by at least one of the following mechanisms *(not required for Exempt or Chart Review protocols)*.

* + Federal grant/award (eg. NIH, NSF, DOD)
  + FDA review for IND/IDE studies
  + Stanford Cancer Institute [Scientific Review Committee](https://med.stanford.edu/cancer/research/trial-support/src.html) (SRC)
  + [Clinical Research Unit](https://med.stanford.edu/spectrum/study-team-resources/clinical-research-unit-cru.html) (CRU)
  + VA R&D Scientific Review Subcommittee (*for unfunded VA research*)
  + Scientific merit review by a funding agency for a competitive award
  + [Academic Sponsor](https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs#academicsponsor)
  + [Department Chair/Division Chief or designee review](https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs#ssv) (*needed if none of the above are otherwise required*)

**eProtocol Application Submission- General**

Correct [application type](https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs#protocol-submission) used

Protocol application accurately describes research procedures versus regular medical care;

Research-related scans and imaging that employ ionizing radiation listed under Radiation/Radioisotopes (*eProtocol section 4*);

For research including children, appropriate justification provided for [child risk determinations](https://stanfordmedicine.box.com/shared/static/0dubjxalejn6hp380s6yhwf06a6erjug.pdf) (*eProtocol section 9e/9f*);

If Stanford investigator is responsible for registration on [ClinicalTrials.gov](https://stanfordmedicine.app.box.com/s/ehpld4l0jresrtbvmd3qbg7flrc78ljw), NCT# provided in the IRB application

**eProtocol Attachments**

FDA documentation for Sponsor-Investigator (investigator initiated) protocols (*e.g. Study May Proceed letter, FDA receipt acknowledgement letter*);

Surveys/Questionnaires/Interview guides/Recruitment materials;

App screenshots for App-based studies;

Investigator’s Brochures/Package Inserts/Device Manuals for drugs and devices being studied

**Ancillary Committee Reviews completed**

Administrative Panel on Biosafety (APB) for [human gene transfer](https://ehs.stanford.edu/manual/biosafety-manual/human-gene-transfer) and [basic](https://ehs.stanford.edu/manual/biosafety-manual/tissue-culture-human-and-primate-tissue) research (*application submitted*);

[Student Data Oversight Committee (SDOC)](https://irds.stanford.edu/) for research on Stanford students (*submit your protocol to* [*sdoc\_review@lists.stanford.edu*](mailto:sdoc_review@lists.stanford.edu));

[Student Athlete Research Oversight Committee (SAROC)](https://med.stanford.edu/saroc/For-Researchers/research-intake-form.html) for research on Stanford student athletes;

[STARR Data Privacy Attestation (DPA)](https://med.stanford.edu/starr-tools/data-compliance/data-privacy-attestation.html) for chart review studies;

[Conflict of Interest Committee (COIC)](https://opacs.stanford.edu/) (*OPACS disclosure submitted*);

Other [Institutional and Ancillary Reviews](https://stanfordmedicine.box.com/shared/static/2hukpmgrja5ytq5rai74jt5720ywk68f.docx) may be required as applicable

**Consent/Assent Requirements**

Current version of Stanford [consent/assent template(s)](https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates) and HIPAA Authorization used, or appropriate [Waivers](https://stanfordmedicine.box.com/shared/static/6s5bimwuqdan2k5zxr3kbzdghctjgbx8.pdf) included;

Clean copy of consent/assent forms provided in Word format (no tracked changes or comments)

**Supplemental Questionnaires**

[International Research Supplemental Questions](https://stanfordmedicine.box.com/shared/static/vrpa7sjf59zspwee5xqovl5e1y955wlp.doc) when conducting international research;

[Gene Transfer Protocol Application Supplemental Questions](https://stanfordmedicine.box.com/shared/static/zlr02afphvcwgsr0cez3px13i9igf58x.doc) when conducting gene transfer research