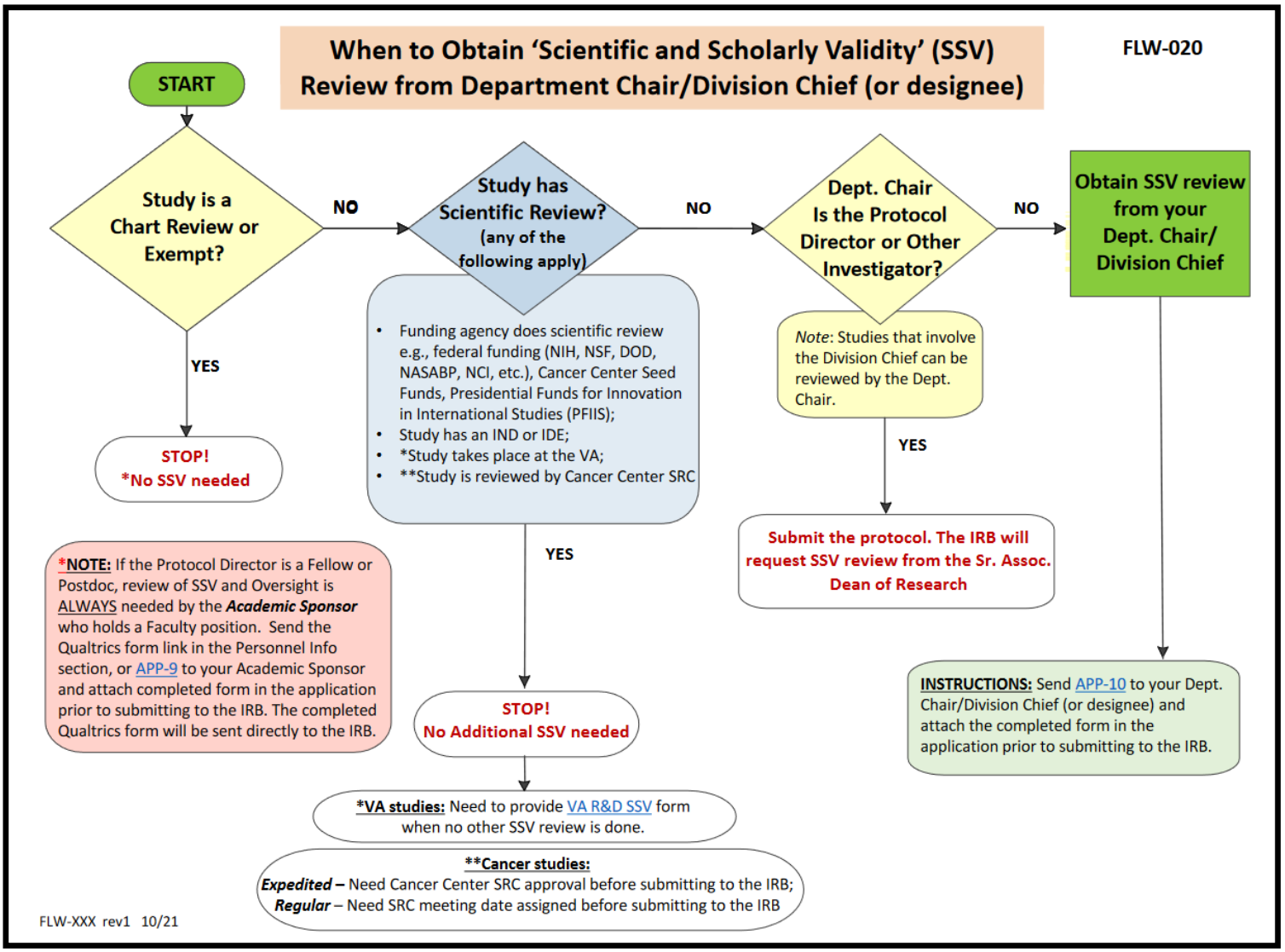
| Stanford MEDICINE \| Research Office | **Scientific & Scholarly Validity Review**<br>**Frequently Asked Questions** |
|---|---|
| **A Clinical Research Unit (CRU) Document** | |

**Background:** The requirements for Scientific and Scholarly Validity (SSV) review are specified in section 1.7 of the HRPP Manual and in the recently created Workflow from the IRB, which can be accessed from the IRB's FAQ page, under Before Submitting a Protocol (see also screen capture below). The FAQs provided here are meant to complement these two documents and clarify the requirements and submission process.




*Please note that the above workflow may be updated by the IRB overtime. Use this link to review the latest version on the IRB website.*

# A Clinical Research Unit (CRU) Document

**Q1: Could my industry sponsored study still require an SSV review?**

**A:** Yes. Industry sponsored studies that do not require an IND or IDE have not gone through FDA's review, and if no other federal agency has reviewed the protocol they would be required to undergo an SSV. Examples might be IND-exempt, Nonsignificant Risk or IDE-exempt clinical trials, or other types of clinical research.

*Note: If such a study is reviewed by Stanford's Cancer Institute's Scientific Review Committee (SRC) no further SSV will be required.*

**Q2: Do I need to wait until Stanford's IRB sends the link to the Qualtrics survey in order to complete and submit the SSV review?**

**A:** No. The Protocol Director or another member of the study team can proactively initiate the required review and attach the completed form (APP-10) to the initial eProtocol submission.

*Note: as of October 2021 Stanford's IRB requires that SSV review be submitted before initial eProtocol application is accepted for review and assigned to a panel.*

**Q3: Will Stanford's IRB accept the completed APP_10 form in place of of a completed Qualtrics survey?**

**A:** Yes. The PD/study team may submit a completed scientific review form attached in eProtocol instead of using the Qualtrics survey.

*Note: The IRB expects to include the Qualtrics survey within the eProtocol application in the future.*

**Q4: The IRB names the Department Chair, Division Chief, or Designee as the required reviewer. Can the "designee" to department chair or division chief be the CRU?**

**A:** Yes. If the CRU is conducting the scientific review for the protocol, the Faculty Lead, Operations Lead or Reviewer for the CRU can complete the SSV information on behalf of the department chair or division chief.

**Q5: What if the assigned CRU Reviewer has a conflict of interest (COI) with the study under review (e.g., the reviewer is also a named investigator in the study)?**

**A:** If the CRU reviewer is also an investigator on the protocol being evaluated, an alternate CRU reviewer must be assigned.

**Q6. Are the IRB review requirements for sIRB eProtocol submission the same as they are for Regular or Expedited eProtocol submission?**

**A:** Stanford IRB still confirms SSV, when required, when they are relying on another IRB for review. For sIRB, though, the SSV will not be a condition for initial eProtocol intake but required prior to IRB approval.