

## US Affiliated Studies

**If a study is required to comply with United States regulations** e.g., if a study is sponsored or monitored by any of the agencies below, the Principal Investigator is responsible for ensuring that the study complies with all applicable US regulations.

- [US Department of Health & Human Service \(HHS\) - Office for Human Research Protections \(OHRP\)](#)
- [US Food and Drug Administration](#)
- [US Code of Federal Regulations, Part 46 Protection of Human Subjects \(45 CFR 46\)](#)
- [National Cancer Institute of United States \(NCI-US\)](#)
- [National Institutes of Health of the United States \(NIH-US\)](#)
- A complete list of HHS Agencies and Offices are posted on their website: <http://www.hhs.gov/about/>

**US FWA and IRB Assurance numbers & expiry dates for the BC Cancer Agency and the BCCA REB** are posted on our web page <http://www.bccancer.bc.ca/RES/REB/FWA.htm>

***For US affiliated studies, the REB Certificate of Approval will not be released until the following are completed in the RISE on-line ethics application:***

1. **Section 7.12:** Ensure the response is marked "yes", if US affiliated.
2. **Section 7.12A:** Enter the FDA number i.e.; the (Investigational New Drug) IND or FDA (Investigational Device Exception) IDE number.
3. **Section 9.1C:** Documentation validating the IND/IDE number is also required to be attached to section 9.1C. If the sponsor has provided the number on the cover of the protocol no additional documentation is required (simply indicate that this is on the protocol when entering the number), otherwise, a letter from the FDA, or a letter from the sponsor confirming the number, or explaining the exemption status, is required.
4. **Section 9.8.:** **Research Projects Funded by US Department of Human & Health Services (HHS)** must also have a copy of the applicable grant application attached to the REB submission if supported/funded by any [HHS Agency or Office](#).

The US Department of Human & Health Services (HHS) requires Research Ethics Boards to review the actual application or proposal for HHS support (funding/grant) to ensure that all research described in the HHS application or proposal is entirely consistent with any corresponding protocol(s) submitted to the REB. A memo from HHS describing this requirement is located on the HHS webpage: <http://www.hhs.gov/ohrp/humansubjects/guidance/aplrev.htm>

**Note:** Investigators are responsible for ensuring compliance with US requirements for ongoing review and for reporting protocol deviations or unanticipated events to the applicable US agency.