

All research involving procedures that pose greater than minimal risk (i.e., require review by the convened IRB) must undergo scientific review. Examples of such procedures are presented below.

If required and scientific review has not been conducted externally (e.g., external IRB, protocol review committee or the equivalent for federally or foundation funded research), the research must be reviewed by the UNC Scientific Review Committee (SRC) prior to IRB review. Study section or FDA IND/IDE review of investigator-initiated research is not adequate for this purpose. A single site RO-1 or similar study funded by NIH or other agency will generally require review by the UNC SRC unless it falls within a ‘minimal risk’ category as described below.

- Research conducted under the oversight of an external IRB (e.g., institution, NCI CIRB or Independent/Commercial IRB) does **not** require scientific review by the UNC SRC. This refers to those instances when the external IRB will be the IRB of record for the study and UNC provides a reliance agreement.
- Research that recruits cancer patients or has a focus on cancer or risk factors for cancer does **not** require SRC review as it will undergo scientific review by the Oncology Protocol Review Committee (PRC).
- Multi-center, industry-funded/foundation sponsored research does **not** require scientific review by the UNC SRC. However, if the UNC researcher is the regulatory Sponsor (i.e., holds the IND or IDE), UNC SRC is required.
- Research that involves the collection of blood specimens or the use of investigational devices to perform research measurement should be reviewed by the IRB to determine if the research requires SRC review.

Examples of *research procedures that REQUIRE SCIENTIFIC REVIEW, i.e., potentially greater than minimal risk	Examples of research procedures that DO NOT REQUIRE SCIENTIFIC REVIEW, i.e., generally not greater than minimal risk
Collection of additional biopsy specimens	Collection of blood from healthy adults by finger stick to evaluate blood glucose level
Collection of bone marrow aspirate	Secondary use of data or specimens or collection of <i>leftover</i> specimens
Nasal scraping or nasal swabs that go beyond the nares	Collection of data through medical chart review or extraction and analysis of EMR based data
Randomized assignment to one of two FDA-approved drugs or devices	Interviews, surveys or focus groups
MRI (with contrast)	MRI (without contrast)
Radiography (x-ray, CT)	Hearing tests
Non-FDA approved medical devices	Videotaping of subject’s performing simple tasks
Studies conducted under an IND or IDE	Behavioral observation
Administration of or additional duration time under anesthesia	Cognitive testing
Bronchoscopy procedures	VO ₂ Max testing in normal, healthy volunteers
Use of conscious sedation	Educational testing of adults (e.g., college students)
Collection of endotracheal aspirate	Ambulatory blood pressure monitoring (using a FDA-approved device)
<p>*The examples listed assume that the research procedures listed are being conducted for <i>research purposes only</i> (procedures that are being conducted as part of routine clinical care do NOT require SRC review.)</p>	

