

# Scientific Review Questions Added to IRBIS to Support Scientific Review Committee Review (9/16/2016)

As previously announced, Beginning September 19, 2016 any new study submitted for IRB review will be required to have scientific review completed and documented. All clinical research conducted at the University of North Carolina at Chapel Hill involving greater than minimal risk must undergo scientific review. Scientific review is a process that evaluates the scientific merit of a clinical trial protocol.

To facilitate this process, a new **Scientific Review** section has been added to the Initial IRB application. You will be asked a single question: “Does your research require review by the Scientific Review Committee?” Information to assist you in determining if your research requires review by the UNC Scientific Review Committee (SRC) precedes the question. Additional information is available by via the “Additional examples” link and on the [Office of Clinical Trials website](#).

If review by the UNC SRC is required, you should respond *yes*. You will then be directed to submit your protocol to the SRC prior to completion of the IRB application. Below (divided across two pages) are two screen captures, depicting outcomes of the two possible answers.

**Note:** The Scientific Review section will not display, if an application is determined (by IRBIS) to be Not human subjects research (NHSR); or is an Exemption if requested; or if you request reliance on an external IRB.

The screenshot shows the IRBIS interface for a Scientific Review application. The left sidebar contains a navigation menu with sections: General Information, Exemptions, Scientific Review (highlighted), Part A. Questions Common to All Studies, Part B. Direct Interaction, Part C. Existing Data, Records, Specimens, Part D. The Consent Process, Data Security Requirements, Consent Forms, Attachments, Approving Depts, and Cover Memo. The main content area is titled "Scientific Review" with Reference ID: 126667. It includes links for "Online Submission FAQ" and "Online Submission Guide", and options for "Quick View (HTML)", "PDF", and "Delete Submission". The text explains that biomedical research at UNC involving greater than minimal risk requires scientific review. A link "Additional examples can be found here" is circled in red. The question asks: "1. Does your research study require review by the Scientific Review Committee?" with instructions to contact the OCT if unsure. Radio buttons for "Yes" (selected) and "No" are present. Below the question, there are two sections: "IF YOU ALREADY RECEIVED APPROVAL BY THE UNC SRC" and "IF YOU HAVE NOT RECEIVED APPROVAL BY THE UNC SRC", each with specific instructions for the applicant.

If review by the SRC is not required, you should respond *no*. You will then be asked why SRC review is not required by selecting your response from a pre-populated list.

1. Does your research study require review by the Scientific Review Committee?

If you are unsure if your project requires SRC review, please contact the OCT at 919-843-2698. Failure to select the correct answer may result in significant delays.

Respond “no” if your research methods are limited to:

- the collection and/or use of existing data, documents or specimens or,
- administering surveys; conducting interviews or focus groups, or
- prospective collection of biological specimens by non-invasive means (hair and nail clippings, sweat, dental plaque and calculus, saliva, sputum).

\*

Yes  No

Select one or more of the following:

- This protocol does not involve interaction or intervention that poses greater than minimal risk to subjects.
- This protocol is not PI-initiated and the protocol/grant was peer reviewed by a Federal-funding agency (e.g., NIH, CDC, DOD)
- This protocol is not PI-initiated and the protocol/grant was peer reviewed by a national foundation (e.g., American Heart Association)
- The protocol was written and conducted by an industry sponsor (e.g. pharmaceutical or device trials)

**This research project does not require review by the UNC SRC. Please complete the remainder of the application.**