IRB

Cosmetics Research and IRB Review

What You Need to Know

Institutional review board (IRB) review of cosmetics research is not always required, but it is considered best practice when human participants are involved.

What does the IRB do?

IRB review includes (but is not limited to) an assessment of the protocol, informed consent form (ICF), site and principal investigator (PI) qualifications, and other study materials to make sure risks to participants are minimized and participants' rights and welfare are appropriately protected.

The IRB may suggest revisions to the protocol, informed consent, and/or other study materials to improve participant protections and meet regulatory requirements.

While the IRB oversees the cosmetics study, the PI/sponsor may be required to submit periodic reports so that the IRB can continue to ensure the rights and welfare of participants are protected.

To learn more about IRBs, watch this brief explainer video.

Why should an IRB review my study?

- IRB review is an additional level of oversight to ensure participants are properly protected and that the study complies with applicable regulatory requirements.
- IRB review helps ensure that the testing methods employed in your study are properly regulated and that the research-related risks are appropriate in relation to the potential benefits.
- FDA will require IRB review of sun protection factor (SPF) products in the future, so including IRB review in your study planning now will set you up for long-term success.

What else do I need to know about the regulations governing cosmetics research?

For an overview of FDA's regulatory framework for cosmetics, read our blog Research Involving Cosmetics: What You Need to Know.

Need more information?

For free answers to your most pressing research questions, submit an inquiry to Ask the Experts: Ask Advarra.