

Department	Activity	Topic
Research & Development	Experimental Research	Protection of Research Participants; Ethical Procedures

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Ethical Procedures for Research with Human Participants

This document outlines the approval process that will ensure that INSEAD research with human participants meets the requirements of the INSEAD Policy for Protection of Research Participants (RD-003). Research is defined as systematic investigation designed to develop or to contribute to generalised knowledge and hence does not cover activities conducted for teaching purposes. However, research conducted in the classroom, with students, should go through the ethical review. Human participants are defined as living individuals, including INSEAD students and executive education participants, from or about whom an investigator conducting research obtains data through intervention or interaction, or identifiable private information. The approval process applies to INSEAD Faculty and PhD students, visiting faculty, and faculty from institutions with access to the ISSRC (e.g. HEC).

1. INSEAD Policy for the Protection of Research Participants

All INSEAD faculty and PhD students must indicate if they intend to carry out research involving human participants. Faculty and PhD students who intend to do so are asked to acknowledge that they have read and accept the INSEAD Policy for Protection of Research Participants. This is administered by the Department of Faculty & Research (for INSEAD faculty, visitors, and research staff), by the PhD program (for PhD students) and by the ISSRC (for HEC faculty).

2. Human Research Training and Certification

In order to conduct research with human participants at INSEAD, all persons working on the research project (including people who are responsible for the design, conduct, data analysis or reporting) must take the NIH Human Research Participant Training and obtain a certification. This online training is free and takes around 1 hour. It is available at:
<http://phrp.nihtraining.com/users/login.php>.

The ISSRC Manager, long-term research staff and the Academic Director must take the more comprehensive online course offered by CITI in responsible conduct of research

(www.citiprogram.org) and obtain the certificate. This training takes 4-8 hours and costs \$80. Faculty and PhD students who have the CITI certification do not need to obtain the NIH certification.

3. Ethical Review

The goal of the ethical review is to ascertain that the research program does not involve more than minimal risk for the participants or the researchers. Minimal risk is defined in the INSEAD Policy for the Protection of Research Participants.

When to apply for an ethical review

An ethical review must take place for all new research programs involving human participants, regardless of whether it is conducted online, at the ISSRC, on campus, or elsewhere. A research program entails all the studies (including pre-tests) conducted to examine a research topic using the same research method and personnel. It is not necessary to go through an ethical review for all the single studies or a particular research program as long as they remain within the perimeter of that research program. It is the responsibility of the principal investigator to determine whether a study is part of a new or old research program. By way of guideline, we would expect that a study that requires a new R&D project to be funded (as opposed to an extension of an existing R&D project), is likely to be part of a different research program. The ethical review does not apply retroactively to research programs that were started before the new ethical processes were introduced. In case of doubt about whether a new study belongs or not to an existing research program, it is recommended to contact the ISSRC Manager for advice and to err on the side of caution by applying for a new ethical check.

Application process

To apply for ethical review, researchers must fill out the online Ethical Review Questionnaire (<http://tinyurl.com/ethicalcheck>). Filling out the survey will take no more than 10 minutes. Responses to this questionnaire will determine which level of ethical review will apply. Researchers will be informed immediately upon completion of the questionnaire which one of the below levels apply to the study.

Level 1: Exempt.

This covers research that involves human participants or personal data, but does not involve interventions, deception, or questions about sensitive issues that may create more than minimal risk (e.g., a simple survey). No other action is required and the researcher will be informed upon completion of questionnaire that the study can start immediately. Exempt studies do not require informed consent form or debriefing.

Level 2: Standard Ethical Review.

This level covers studies that involve deception, interventions, or questions about sensitive issues, and may therefore create “more than minimal risk”. Level 2 studies will require an informed consent form and a debriefing form (see below). It will also not be possible to force participants to answer the questions about the sensitive issues included in the study (if any).

Research that falls under Level 2 will be reviewed by the ISSRC Manager or Senior Researcher against the requirements of the INSEAD Policy for Protection of Research Participants. The following outcomes are possible:

1. **Approval** by the ISSRC – The ISSRC Manager and Senior Researcher assess the proposed research as having no significant ethical implications and involving minimal risk. If necessary, they will consult with the ISSRC Academic Director, who can ask for input from the ISSRC Academic Committee.
2. **Proposal referred back to the researcher for changes**, so that ethical concerns are addressed and the research plan is amended. It is the responsibility of the researcher to amend the application.
3. **Proposal rejected by the ISSRC Committee**. This will happen in the rare cases when the research poses serious ethical implications and the potential harm to participants outweighs the potential benefits of the research, or the research is not in line with the INSEAD Policy for Protection of Research Participants.

The ISSRC Manager will aim to make decisions within one week of the submission.

Subsequent modification of proposed research

Once ethical approval has been granted, it is the responsibility of the researcher to ensure that the research does not deviate significantly from the original proposal. If significant changes are made to the research design, methodology, protocol, named personnel, or environment, re-application for ethical review will be required. Any changes to the proposed work should be sent to ethicalreview@insead.edu. Researchers will be informed if a new ethical review is needed or not.

TEMPLATES

Informed Consent Form

Many thanks for participating in a study [AT THE INSEAD SOCIAL SCIENCE RESEARCH CENTER /ONLINE /DESCRIBE LOCATION]. The principal researcher for today's study is: [NAME AND E-MAIL ADDRESS OF PRINCIPAL INVESTIGATOR].

In this study, you will [BRIEF DESCRIPTION OF WHAT THE PARTICIPANT WILL EXPERIENCE AND WILL BE ASKED TO DO]. Your participation will take approximately [AMOUNT OF TIME].

Our studies are purely for academic purposes. The results will be made available to the public in scientific journals. Responses are only shared in aggregate form. We do not conduct studies on behalf of private companies

There are no risks involved in this study other than what you would encounter in daily life. If you complete this study, you will receive [WRITE PARTICIPANT PAYMENT HERE AND OTHER BENEFITS THE PARTICIPANT WILL RECEIVE, IF ANY. For example: Potential benefits to you include: receiving information about the outcomes of the study as well as references to related research if you are interested. However, because your responses are anonymous, we can only tell you general outcomes and are unable to report specific outcomes regarding your performance].

[IF APPLICABLE, AND ONLY FOR OFF-LINE STUDIES WHERE THERE IS AN ACTUAL COST FOR THE PARTICIPANT OF SHOWING UP: It is possible that NOT everybody will be able to participate in the study because of logistical issues or because we are looking for participants with certain characteristics only. If you are turned away from the study, you will still receive [INDICATE AMOUNT OF SHOW UP FEE] and will not be required to stay for the study.]

[IF APPLICABLE]: We would like your permission to audiotape/videotape this interview. If we are interested in using quotes or identifiable information, we will obtain your permission in advance.

Your participation in this study is voluntary. You are free to withdraw from the study without any penalty to you.

Your data will remain completely confidential and will not be released in any way that can be linked to you. Data from this study [INCLUDING AUDIOTAPES/VIDEOTAPES] will be kept locked or password-protected, and will be destroyed when no longer needed for research purposes

I declare being of age and accept of free will, after having read and fully understood the above paragraphs, to participate in the study

[IF STUDY IS OFFLINE] DATE, NAME AND SIGNATURE:

[IF STUDY IS ONLINE] By clicking the "next" arrow below, I give my consent to participate.

INSEAD has a Committee overseeing the use of human participants in research to which complaints or problems concerning any research project may, and should, be reported if they arise. If you have concerns about this project, please contact Liselott Pettersson at ethicalcheck@insead.edu.

Debrief Form

Explanation of the general research field of study

[EXPLAIN IN LAY TERMS THE GENERAL FIELD OF RESEARCH AND WHY IT IS INTERESTING].

Detailed description of the study

[EXPLAIN IN LAY TERMS TODAY'S STUDY AND WHY IT IS WORTHWILE TO PARTICIPATE. UNLESS YOU THINK THAT DOING SO WOULD COMPROMISE THE RESPONSES OF OTHER PARTICIPANTS (E.G., IF PARTICIPANTS CAN EASILY COMMUNICATE THIS INFORMATION TO FUTURE PARTICIPANTS) DESCRIBE THE DIFFERENT CONDITIONS, WHETHER THERE WAS DECEPTION AND OR MANIPULATION, AND THE KIND OF RESULTS THAT YOU EXPECT]

You can find more information about the study here: [MENTION ONE OR TWO PUBLICATIONS ABOUT THIS KIND OF RESEARCH]

If you have further questions, you can contact: [YOUR NAME AND E-MAIL ADDRESS IN CASE OF QUESTIONS]

[FOR STUDIES AT ISSRC] About INSEAD Social Science Research Centre (ISSRC)

The ISSRC is a centre for behavioural research. Since its opening in 2002, over 50,000 persons have participated in studies at the centre. The centre's research has resulted in articles in academic and non-academic journals and students successfully obtaining their PhD. INSEAD researchers and INSEAD PhD students have been invited to conferences all over the world to present the results of their research at ISSRC. Typical research methods include questionnaires, computer tasks or observations of group behavior

[FOR ALL STUDIES] ABOUT INSEAD

As one of the world's leading and largest graduate business schools, INSEAD brings together people, culture and ideas from around the world to change lives and transform organisations. One of INSEAD's defining strengths is its commitment to excellence in teaching and research. We are consistently ranked among the world's leading research institutions

Short bio of the researcher [COPY AND PASTE INFORMATION ABOUT RESEARCHER]