Guide to completing an ethics approval request and writing informed consent

University of Szeged
Institute of Psychology

What is ethical risk analysis?

An ethical risk analysis must be carried out ***to complete the ethics request***. The steps of an ethical risk assessment are as follows:

1. Identify and enumerate potential risk factors
2. Estimating the extent of the risk and its proportionality to the value of the expected outcome
3. Determine the steps to minimize the risk.

Research with human participants must not seriously or permanently compromise the well-being of the participants physically, emotionally, or mentally. Factors that are temporarily and not excessively potentially threatening well-being are sometimes unavoidable or even necessary to carry out a particular examination. In such cases, the expected value and benefits of the research should convincingly justify the expected risks, and particular attention should be paid to minimising and managing the risks.

The sources that endanger physical or mental health can be, among others: physical pain, fatigue, stress, negative feelings, unpleasant situation, unpleasant stimuli, any possible cause of disadvantage, information management.

IMPORTANT: ***Risk that exceeds the minimum automatically occurs:***

1. **In the case of highly sensitive populations** (people under the age of 18, sick, disabled, dependent on others, belonging to minorities);
2. For sensitive topics (sexual behavior, political behavior, personal life topics, etc.);
3. **In the case of investigations involving significant misrepresentation** or withholding of information;
4. **In connection with the recording of sensitive personal data** (e.g. biological-genetic data, employer-sensitive data

Risk-reducing measures may include the elimination of unnecessary sources of risk, the provision of a slight degree of risk, the provision of subsequent information and the creation of the possibility of processing.

What should the informed consent include?

When inviting the person to participate, the researchers ***must inform the requested person orally or in writing about all the essential elements of the research that may influence him or her in making the decision to participate – this is called informed consent.*** Informed consent must therefore briefly describe the study situation, the expected tasks, the location, circumstances and expected duration of participation. During the information, the person invited must be given the opportunity to ask any questions. The name and contact details of the person conducting the research and the name and contact details of the supervising teacher must be provided.

Informed consent ***is given directly to the person participating in the study*** and gives their consent after being duly informed. Uninformed consent is e.g. Permission from the school principal to conduct the investigation (although such permission is required for institutions, see institutional consent below).

Informed consent should not contain unnecessary technical terms or foreign expressions. Describe only the purpose of the study briefly, and first of all, provide all relevant information about the study situation itself (including its expected duration, the exact task situation, etc.). It should be written in a language and style that is fully understandable and clear to the person giving their consent.

Age and informed consent:

1. If the child examined person **is under 3 years of age**, the informed consent is given by the parent.

2. If the age of the child examined is **between 3 and 14 years old**, the parent gives written consent and the examined child orally.

3. If the child **is between 14 and 18 years old**, both the child and the parent must be aware of the information and the consent of both parties is required.

Parental informed consent can be active or passive. Active ***consent*** means that we ask for the return of written informed consent (e.g. through the kindergarten teacher, by post, in person). In the case **of passive consent**, the informed consent will be sent to the parent and informed consent will be informed in the text of the informed consent that if they consent to the study, they do not need to return the sheet. You should only return the sheet with your negative consent if you do not consent to the study.

Institutional Consent:

Informed consent comes from the participants or their representatives. If the research is carried out in an institution (e.g. school) or concerns an institution, the **consent of the institution** must also be requested to start the research (from the principal, the class teacher, or both, depending on the local conditions).

Informed consent - Sample

This sample asks for so-called passive consent, i.e. the paper is only requested to be returned in case of non-consent. The text and form of the informed consent should always be agreed with the lecturer supervising the research.

Date

Dear Parent,

As a student of the Institute of Psychology of the University of Szeged, I would like to conduct a research on developmental psychology with preschool children in the kindergarten where your child also attends.

The title of the research is "Kindergarten role-playing". In the course of the research, two students spend an hour in the morning in the kindergarten for a week, where they observe the children's role-play and play individually with the participating children for about 15 minutes. We intend to make a video recording of the observations, including the individual play period. The video recordings are used anonymously for analysis purposes. If the child does not wish to participate in the individual game, of course, he or she does not have to participate, or he or she can interrupt the participation at any time.

I hereby ask for your consent so that your child can participate in the research described. If you agree to participate, you do not need to do anything. If you do not agree to your child participating, please indicate this with your signature at the bottom of the paper and send the paper to the kindergarten teacher!

If you have any questions about the research, please contact me by phone, e-mail or through the kindergarten teachers below.

The research is supervised and directed by the Institute of Psychology lecturer XY. Contact details of the instructor's email: xy@gmail.com.

Regards

XY
a Pszichológiai Intézet hallgatója
email: xy@gmail.com.
phone: mmm

1. I do not give my consent to my child's participation.

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(Signature of parent or caregiver) Date