

Institutional Review Board Proposal Elmhurst University

Necessary Components for Informed Consent Forms

The following information needs to be included in informed consent forms. All informed consent forms should be in clear, non-technical language that is appropriate to the participant. An informed consent form must be completed by each participant; for minors, an informed consent must be signed by the legal representative and the minor must also complete an assent form. The informed consent or assent forms must be kept for a minimum of three years following completion of data collection.

1. The title of the research and the researchers. An invitation to contact these researchers should the participant have any questions should be made.
2. The purposes and/or objectives of the research.
3. A brief explanation of the experimental procedures and their likely duration for each participant.
4. Any reasonable foreseeable risks to the participant. In the case of “at-risk” research, a brief description of how these risks will be managed and what provisions have been taken to ensure this should be included.
5. Any reasonable benefit to the participant or others that might be expected to occur with participation.
6. How participants’ confidentiality and/or anonymity will be ensured.
7. A clear statement that participation is voluntary and participants can withdraw at any time without penalty.
8. Whom to contact with further questions and/or complaints about participation in the study. This should be the current Chair of the IRB.
9. A signed and dated statement indicating the above have been explained and that they agree to participate. For online surveys, this should state that by clicking through, they are agreeing to participate.

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Example of Informed Consent Form for Adults

This example is provided to assist investigators in preparation of informed consent forms. This format does not necessarily need to be precisely followed, as long as the information below is included. For online surveys, this should appear before the survey begins and should include a statement verifying that participants understand that by clicking through, they are agreeing to participate.

1. Project Title

Patient and Professional Relationships

2. Introduction of Researcher(s)

I am Professor Mary Smith of the Department of Sociology at Elmhurst University. Should you have any questions about this project at any time, feel free to contact me (us) at Name, Department of Sociology, Elmhurst University, 190 Prospect Ave. Elmhurst, IL 60126, (630) 617-xxxx, email: .

3. Purpose of Research

My colleague, Joseph Hernandez and I are conducting a study of how medical professionals relate to patients. We would appreciate your participation in this study, as it will assist us in making recommendations for improving the teaching of health professionals and the way they treat you.

4. Explanation of Procedures

You will be completing a questionnaire that takes approximately 15 minutes to complete. Our study will run for three months and there will be 100 people filling out the questionnaire.

5. Risks and Benefits

We do not anticipate any foreseeable risks or discomfort other than the inconvenience to you in completing the questionnaire. Although this study may not directly benefit you, it potentially will benefit our understanding of the doctor-patient relationship.

6. Safeguards of Data

We will use no code numbers to identify you. Data will be published in aggregate form and may be presented at professional meetings or in professional journals. Data will be kept in a locked file in the investigator's office. The data will be destroyed at the conclusion of the study.

7. Freedom to withdraw from the study

Your participation is completely voluntary. If you choose to withdraw from the study, the information gathered at that point will be destroyed and you will not be penalized (i.e., you will still receive course credit).

8. Third Party Referral

If you have any complaints about your treatment as a participant in this study, please contact the chair of the Institutional Review Board at irb@elmhurst.edu. Although the chair will ask your name, all complaints are kept in confidence.

9. **Closing**

I have received an explanation of the study and agree to participate. I understand that my participation in this study is strictly voluntary.

Name

Date

This research project has been approved by the Elmhurst University Institutional Review Board.

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Example of Assent Form for Child/Minor

This example is provided to assist investigators in preparation of informed consent forms. This format does not necessarily need to be precisely followed, as long as the information below is included.

I, _____, understand that my parents (Mom and Dad) have given permission (said it's okay) for me to take part in a project about memory formation being done by Dr. Smith. I am taking part because I want to. I have been told that I can stop at any time I want to and nothing will happen to me if I want to stop.

Signature of participant and date