The research problem and motivation section is a detailed analysis of 1) what is informed consent and why does the world generally, and academia specifically, care about it,

Informed consent (IC) is one of the keystones of medical applications and takes its source from the autonomy principle. It is a process which consists of informing the patient about the medical interventions planned to be applied to their body and making the patient active in the decision making process ([1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4115924/#b1-bmj-31-2-132)). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4115924/>

2) what research has been done on informed consent so far and what were the general findings,

Balkan Medical Journal performed a study on consent where they brought in 522 patients, “mean age: 38.1 years; 63.8% male, 36.2% female” and found gave a questionnaire after patients signed a consent document

3) what research gap exists: what problem with the informed consent process can we see that has not yet been studied,

4) our personal motivation for pursuing this line of research.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4115924/>

* Medical article where subjects were given a questionnaire after signing a consent document for a pre-anaesthetic visit.
* 522 patients
* 2 month study
* Mean age 38
* 63.8% male
* 36.2% female
* 54% reported not reading the consent form
* 514 were literate
* Contains overview of ratios for who read the consent form (age, gender, etc)
* Contains in the questionnaire reasoning for not reading the informed consent

Issues

* Does not include the questionnaire

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5290300/>

From the Patient Perspective, Consent Forms Fall Short of Providing Information to Guide Decision Making

* 60 interviews (from wairing rooms at 2 hospitals)
* 68% had education beyond highschool
* Consent forms used: Consent for Procedure, Consent for Procedures in the Intensive Care Unit (ICU), Consent for Gastrointestinal Endoscopy, Consent for Peripherally Inserted Central Catheter (PICC) and Neonatal Intensive Care Unit (NICU) Consent for Admission, Medical Treatment and Procedures.
* readability was assessed using the SMOG Readability Test and the Fry Readability Scale, which were completed manually and by the Health Literacy Advisor Microsoft Word Add-In.
* randomly given consent forms

structure of obtaining information:

* Demographic survey: age, race, gender, education
* Literacy Assessment using REALM-SF(Rapid Estimate of Adult Literacy in Medicine Short Form)
* Numeracy Assessment: SNS or Subjective Numeracy Scale used to assess patient numerical ability and preferences
* Comprehension Quiz: 1 of five consent forms given and 3 questions asked
* Open ended questions: words of confusion, easier to read areas of the form, preference for receiving information

Open ended questions list:

* + Was it too long?
  + Was it scary?
  + Did the medical team lack time to fully explain information?
  + Was the information too general?
  + Has it hard to read?
  + Did you not expect to read?
  + Were the words too small?
  + Were the words too long?
  + Did you trust the medical team to explain fully?
  + What about the legal purposes?
  + How was the information?
  + Did you understand it, was it easy to read?
* 45% were age 50-59
* Mostly high school literacy level
* Numeracy test: 22% total score below average, 35% ability score below average, 27% preferred words over numbers

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**Informed Consent—Uninformed Participants: Shortcomings of Online Social Science Consent Forms and Recommendations for Improvement**

<https://journals.sagepub.com/doi/pdf/10.1177/1556264616654610>

Method

To have the greatest level of ecological validity, this study utilized a quasi-experimental design where students at two small liberal arts universities—institutions where teaching is prioritized over research—were exposed to the actual informed consent forms used at those schools (one long, and one short). The students were recruited from introductory communication courses at both institutions in exchange for extra credit.

* 130 undergraduates (73 long form, 57 short form)
* Mean age 19.39
* 34% male
* 65% female
* 1 transgender
* 1 no answer
* 90% Caucasian
* 47% freshman
* 7 point Likert type scales were used
* Used IRB form from the university (long form 463 words, short is about half the length)

Questions:

what is this study about?;

how old must a person be to participate?;

who is the primary investigator?;

who is the chair of the IRB at their institution?;

how many minutes maximum is the study supposed to take to complete?;

what risks may they encounter by completing the study?;

and what are the benefits to participating in the study?

Could use I don’t know, and more than half did

Evaluated:

* + Ease of reading (with Likert type scale)
  + Length of the form with one closed-ended question with 3 response options
  + Amount of detail (one closed-ended question with three response options
  + Improvements for the forms (one closed-ended question with 11 response options)
* 47% agreed to participate in the study without reading the consent form
* 43% said they skimmed it
* 9.3% said the read the entire form

|  |  |  |
| --- | --- | --- |
|  | Too long | Short form |
| Too short | 2.8% | 3.5% |
| About right | 48.6% | 66.7% |
| Too long | 48.6% | 29.8% |
| Too detailed | 23.9% | 19.3% |
|  | 74.6% | 75.4% |
|  | 1.4% | 5.3% |

**Informed Consent for Clinical Trials: a Comparative Study of Standard Versus Simplified Forms**

From 1998 so maybe too old