# Reid 1995

1000-word extract from a Diabetes information pamphlet for patients [26 adults with diabetes mellitus took 15-item test for previous knowledge (True/False physician developed), 20-item vocabulary test and a “Need for Cogitation” questionnaire” immediately after reading an excrept from a commonly used diabetes pamphlet]:

* Readers’ comprehension is seldom monitored (Reid 1995).
* Topics readers find important differ from topics physician thought important
* Many readers lacked reading skills
* Poor recall (recalled in average 8 /108 ideas)
* Lack of organization and clarity in the text hiders comprehension
* **Measuring readability by using readability formulas:** that consider number or words in a sentence or word familiarity can improve recall in some cases [7-9] but not help in others [10-12]. Hypo: By shortening sentences the writer may omit phrases that help organize the material or reduce redundancy.
* **Organizers that outline main themes, meaningfulness, and vividness enhance recall [13-15]**
* **Material with more elaborated detail has higher recall [16]**
* **Readers recall meaningful words more than unfamiliar words [14]**
* **Even matching readers’ reading level does not assure comprehension [17-18]**
* **Recall depends not only on text metrics like word complexity and sentence length but also text organization [19], syntax, and rhetorical structure [20].**
* **Recall depends not only on text characteristics but also the readers’ characteristics: interest, reading skills, prior knowledge, need for cognition, and experience [21-24]**
* **Gopen and Swan’s seven criteria about writing text for authors [25] AS STANDARD FOR CLEAR WRITING:**
  + Following a subject asap with its verb
  + Placing new information in the stress position
* An endocrinologist identified 12 of 73 sentences in the 1000-word excerpt as most important for patients to know.
* ***“All non-health professional authors of this paper were confused by the lack of clarity…, some questions were impossible to resolve by studying the pamphlet. Technical words like ’hyperglycemia’ frequently caused misconceptions to the reader. Nevertheless, only seven reader commented about the text’s vocabulary, organization, or lack of clarity.”***
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# Reinert Et al 2014

Analysis of 9 Patient Informed Consent Documents for neuro-oncological phase III studies running between 2011-2012 at a German Brain Tumor Centre. All informed consent documents were approved by local and central ethics committees. Multicenter trials with randomised studies with an efficacy primary end-point. 2 independent reviewers. [Evaluates: text length, formal layout, readability, ethical & legal requirements, and scientific & social evidence]

* Graduate education level is needed to read and understand five of nine consent documents
* “***A document that is intended to inform and motivate patients to participate in a study needs to be well-structured and understandable. We therefore strongly mandate to re-design patient informed consent documents in a patient-friendly way.”*** [Discussion]
* *“Standardised components with a scientific foundation should be provided that could be retrieved at various times, adapted to the mode of treatment and the patient’s knowledge, and could weigh information dependent of the stage of treatment decision.”*
* ***“In RCTs obtaining the patients’ informed consent is the first step in enabling participation in the study. Verbal and written information is required by law [1-4].”***
* ***This information is intended to enable the understanding of the risks and benefits, and study protocol so patients can make an informed decision about participating in the trial [3]***
* The reasons for poor intelligibility of patient information sheets have been investigated in numerous studies:
  + Length of document [5,6]
  + Text components and formal aspects (e.g. including insurance details increases complexity) [5,7-9]
  + Overstretching patient capacity to recall [10]
  + Maximum length of 1250 words [9]
  + Linguistics features of information [11]
  + Better formal layout, use graphics and symbols [12]
  + Visual structure with sub-headings (formal requirement in ethics committees model texts) [13]
  + Use 12-point font size and 1.5-line spacing
  + **Short, clear sentence documents are required by ethics committees [13] and preferred by patients [8]**
  + **High level of reading skill necessary to understand PILs [8-10, 15,16]**
  + **Patient satisfaction with received information is often moderate [20-22]**
* **Legal / Ethical requirements of ethics committees [17,18]**
* **Scientific evidence [14,19]**
* ***Legal framework between EU member states is comparable [3][4] but national requirements often differ [2]. CHECK list for drafting PILs [18].***
* **Qualitative assessment of scientific evidence DICERN criteria [27] validated tool for checking methodological quality of patient information texts [14,19,28]**
* ICH Topic E 6 (R1) guideline for good clinical practice note for  
  guidance on good clinical practice; 2002. Available online at:  
  http://www.emea.europa.eu/docs/en\_GB/document\_library/Scientific\_guideline/2009/09/WC500002874.pdf [reviewed 30.4.13].
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  relating to the implementation of good clinical practice in the  
  conduct of clinical trials on medicinal products for human use.  
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# Nichols Et al 2009

Quality assessment of 31 information leaflets about skin cancer.

* Readability assessed by SMOG scoring system
* 3 Consultant dermatologists reviewed the accuracy of each leaflet noting minor and major inaccuracies/inconsistencies with National Institute for Health and Clinical Excellence referral guidelines for skin cancer.
* Presentation and content reviewed by a 3 team of health professionals (3 pharmacists, 2 practice nurses, 4 GPs) by using the Ensuring Quality Information for Patients (EQIP) scale
* None of the leaflets was within the recommended readability range for health education material (SMOG <= 5) [8]
* Only 6% (2 leaflets) were in the highest quartile of EQIP score
* 17% (5 leaflets) had major inaccuracies.
* Study shows potential conflict between marketing and health messages (All leaflets with major inaccuracies had links to commercial organizations).
* 97% meet the “respectful tone” and 81% the “clear language” EQIP criteria
* 12/31 leaflets did not meet:
  + Use generic names for medicines and products
  + The purpose, benefits, side-effects and alternatives of any test, medication or product.
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# Knapp Et al 2011

RCT PILs, User testing, Qual

* “Studies looking at patients understanding at the end of a trial have found sub-optimal comprehension:
  + One in five participants not knowing the name of the drug tested [7].
  + A similar amount not knowing that they could withdraw at any time [8] [9]”
* Confirmed finding by a systematic review of communication and informed consent in cancer trials [10]
  + Treatment risks and benefits
  + Right to withdraw

# Moult Et al 2014

Pediatric PILs, Quality Metrics, EQIP

* EQIP QUESTIONNAIRE ATTACHED
* “EQIP does not rigorously assess readability or comprehension of written information. Therefore, other tools such as the FRE [32] and REALM [33] should be used in the initial development of written healthcare information.”
* “Furthermore, reading and comprehension levels of the intended audience should be periodically sampled”
* “EQIP was developed for use by patient information managers and health care professionals and requires at least some knowledge of the topics. However, the perspective of the health care consumer with no knowledge of the topic is also important in the quality assessment. The tool developed by Gibson et al [24] … might be more broadly useful for consumers evaluating the quality of written healthcare information.”

# NHS 2014

Patient and public involvement in health and social care research, A handbook for researchers.

* “*Patient and Public Involvement (PPI) in research (also known as service user/lay involvement) refers to partnership between patients and or members of the public and researchers.”*
* *“Applications that are technically excellent but have little patient or public involvement may be asked to address this before an offer of funding is made” [National Institute for Health Research (NIHR)]*
* *“The contributions of patients can be extremely valuable, providing alternative views from those of the research team or NHS staff”*
  + Make judgements based on their understanding of their condition
  + Have different aspirations and thoughts about health outcomes
* *“Research funders, such as the NIHR, now require PPI as a condition of funding.”*
* *“NIHR suggest five key stages in the research process where involvement could take place:*
  + *Design of the research*
  + *Development of the grant application*
  + *Undertaking / management of the research*
  + *Analysis of data*
  + *Dissemination of research findings.”*
* ***“You do not need to undertake all the activities described… You should try and undertake the activities of most relevance to your research and the patients / public that you will actively involve”***

# HRA 2017

Applying a proportionate approach to the process of seeking consent HRA Guidance

* “We aim to ensure that health research involving them [participants in health research] is ethically reviewed and approved, that they are provided with the information that they need to help them decide whether they wish to take part, and that their opportunity to do so is maximised by simplifying the process by which high quality research is assessed.” P4
* Application of the principle of proportionality to the provision of information to potential research participants for the purpose of seeking their consent in accordance with UK-wide legal requirements.
* Proportionate approach in **pragmatic trials** (‘simple trials, ‘comparative effectiveness trials’, ‘non-interventional trials’ or ‘low-intervention trials’, do not involve extra interventions beyond those required as part of the patients’ routine care and do not withhold effective treatment; they compare effects of accepted or licensed interventions/therapies in the context of current clinical practice). P4
* Do not address issues of research in emergency context.
* Does not constitute legal interpretation of the requirements regarding the writing information to be given set within the **EU Clinical Trials Directive and the Medicines for Human Use (Clinical Trials) Regulations (SI 2004 1031).** However it reflects the expectations of the Health Research Authority with respect to the provision of information to potential participants/legal representatives/consultees and seeking advice/consent for research in a proportionate manner.
* Should be read in conjunction with the HRA **“Consent and Participant Information Sheet Preparation Guidance”. P4** [<http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/>]
* “Seeking informed consent is central to the conduct of ethical research and, wherever possible and appropriate, potential research participants should be provided with the information they need to help them decide whether they wish to take part in research or not. Seeking informed consent properly respects a person’s right to determine what happens to them.  
  However, it has been suggested that the requirement and procedures for seeking that consent can sometimes be applied too rigidly and with too little sensitivity to the values that are at stake in connection with different kinds of research protocols [**3**]. Others have suggested that the seeking of consent has become either “routinized”, posing a threat to the protection of personal autonomy [**4**]; “cruel” [**5**] or a “ritual” hindering valuable research [**6**]. Furthermore, participant information sheets are often too long and complex and their length and complexity is increasing. Lengthy, complex information sheets covering every minor detail of the research may protect the researcher and sponsor against litigation but they do not necessarily facilitate the genuine understanding and consent of potential participants [**7**] nor facilitate recruitment. Excessively long participant information sheets can also overburden the health care professional (HCP) seeking consent and may even deter some health care professionals from taking part in the recruitment process at all.” **P5**
* “A proportionate approach to seeking consent, i.e. adopting procedures commensurate with the balance of risk and benefits, should always be adopted so that potential participants are not overwhelmed by unnecessarily lengthy, complex and inaccessible information sheets but instead are provided with succinct, relevant, truthful information in a user-friendly manner that better promotes their autonomy. Indeed, in many cases it will be the verbal exchange of information during the discussion of the proposed research that will be crucial in facilitating the potential participant’s decision [**8,9,10**], but this can often be neglected if undue emphasis is placed on the written materials to be provided.” **P5**
* **“The methods and procedures used to seek informed consent and the level of information provided should be proportionate to**:
  + The nature and the complexity of the research;
  + The risks, burdens and potential benefits (to the participants and/or society); and
  + The ethical issues at stake” **p5**
* **“The closer the research is to standard clinical practice, the less need there is to provide patients and service users with detailed and lengthy information about the research.** By the same token, the more research deviates from established clinical practice or otherwise detrimentally affects the balance between the anticipated risks and benefits, the greater the need to cover a wide range of information in detail and to convey that complexity in a way that potential participants can understand.**” P6**
* The **common law** [**11**] requires that participants be informed, in broad terms, of the nature and **purpose** [**12**] of the research and the material **risks, benefits and reasonable alternatives** [**13**].In the case of **drug trials** all participants must have been informed of the **nature, significance, implications and risks** of the trial [**14**].
* [**11**] Law developed by judges through decisions of courts and similar tribunals, as opposed to statutes adopted through the legislative process or regulations.
* **It is possible to provide this information in a succinct way which provides the core detail that participants need to know without overloading them. P6**
  + Paying attention to the way information is conveyed
  + Using language most people can understand
  + Considering layout and format (including the use of visual aids for better explanation)
  + Testing participant information with an appropriate group (PPI) [**15**]
* **Lengthy information sheets may be divided: P6**
  + **Core information:**
    - **Nature**
    - **Significance**
    - **Implications**
    - **Risks**
  + Practical aspects may not necessarily be provided upfront:
    - Timing of visits
    - Payment of travel expenses
    - Confidentiality
    - Indemnity
    - Withdrawal procedures
    - Complaint procedures
    - Who has reviewed the study
  + **Providing practical information is necessary** when it has implications on whether participants would want to participate or not (e.g. abstinence requirements)
  + ***“Practical information has been found to often confuse rather than promote genuine understanding where presented as part of an excessively lengthy information sheet.” P6***
* ***CONSENT REQUIREMENTS: P7***
  + ***In order for consent to be valid it must be:***
    - *Given freely (with no undue influence)*
    - *By a person with the necessary mental capacity*
    - *Who has been adequately informed*
  + ***Anyone asked to give their consent to taking part in a research study should:***
    - *Neither be coerced nor deceived (and can judge that they are not coerced or deceived);*
    - *Not be overwhelmed with information but able to control the amount of information they receive; and*
    - *Have the opportunity to withdraw consent previously given.18*
  + ***The layered approach [19] is supported by the HRA and can be applied to a variety of research, not just pragmatic trials. It involves providing:***
    - Potential participants initially with a short summary including sufficient, but brief, information (using any appropriate format) needed to decide whether or not to take part in the research;
    - User-friendly methods of access to further, more detailed information (e.g. additional paper information sheets, and / or online information) presented in one or more additional layers (but not provided upfront). The primary information should clearly explain how this further information may be accessed.
* PRAGMATIC TRIALS: are simple and cost effective, address relative merits of different treatments in common use [**23**] [**24**], normally do not involve interventions beyond the patient routine care [**25**], and do not withhold effective treatment. **As their levels of burden aren’t higher than standard medical care** the methods of seeking consent (including the amount of information provided upfront) can be proportionate adapted to comply with the law but not overburden the patient. **Non-drug** pragmatic trials only have to comply with “common law”, research involving medicines must comply with **“The Medicines for Human Use (Clinical Trials) Regulations 2004”** (“The Clinical Trials Regulations”).
* *The Clinical Trials Regulations will apply where the drug received by the patient is* ***decided by the protocol instead of their doctor or other healthcare professional*** *even when involving only medicines that are licensed and already in routine use.* The Medicines and Healthcare Regulatory Agency (**MHRA**) has an algorithm to determine if a trial is a CTIMP. Participation in CTIMP requires written consent [26].
* **In order to have valid consent, Clinical Trials Regulations require participants must have had explained to them*:***
  + Nature
  + Significance
  + Implications
  + Risks
  + Interview with a research member
  + **In pragmatic trials** this requirements may be achieved by the use of a short PIS provided by the Investigator or GP/HCP
  + **Supporting information** may be provided online [28] with an URL included in the short PIS. However, the participant **must be given opportunity to access and consider all relevant information** before they give their consent.
* PRAGMATIC TRIAL SEEKING CONSENT PROCESS P.12
* SHORT PIS FORM EXAMPLE FOR USE IN PRAGMATIC TRIALS P.15
* GOOD CLINICAL PRACTICE (GCP) REQUIRED TRAINING FOR SEEKING CONSENT P.17
* 1 Pragmatic trials (also referred to as ‘simple trials’, ‘comparative effectiveness trials’, ‘non-Interventional trials’ or ‘low-intervention trials’) do not normally involve any extra interventions beyond those required as part of the patient’s routine care and do not withhold effective treatment; rather they compare the effects of accepted or licensed interventions/therapies in the context of current clinical practice.
* 2 <http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/>
* 3 Hansson MO. Balancing the quality of consent. J Med Ethics 1998;24:182–7.
* 4 Ploug T, Holm S. Informed consent and routinisation. Journal of Medical Ethics 2012;39:214-218.
* 5 Tobias J, Souhami R. Fully informed consent can be needlessly cruel. BMJ 1993;307:1199-1201.
* 6 Roberts I, Prieto-Merino D, Shakur H et al. Effect of consent rituals on mortality in emergency care research. The Lancet 2011;377:1071-1072.
* 7 O'Neill O. Some limits of informed consent. Journal of Medical Ethics 2003;29:4-7.
* 8 Flory J, Emanuel E (2004) Interventions to improve research participants’ understanding in informed consent for research: a systematic review. JAMA; 292(13): 1593-1601.
* 9 Nishimura A, Carey J, Erwin P Et al. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. BMC Medical Ethics 2013;14:28
* 10 Kirkby, H. M., Calvert, M., McManus, R. J., & Draper, H. (2013). Informing potential participants about research: Observational study with an embedded randomized controlled trial. PLoS One, 8(10), e76435
* 11 Law developed by judges through decisions of courts and similar tribunals, as opposed to statutes adopted through the legislative process or regulations.
* 12 Chatterton v Gerson [1981] 1 All ER 257
* 13 Montgomery v Lanarkshire Health Board [2015] UKSC 11
* 14 The Medicines for Human Use (Clinical Trials) Regulations 2004
* 15 You do not need to obtain NHS Research Ethics Committee (REC) approval to test your information sheet with patients or other groups
* 16 http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information
* 17 http://www.ctu.mrc.ac.uk/resources/patient\_involvement/
* 18 O'Neill O. Some limits of informed consent. Journal of Medical Ethics 2003;29:4-7.
* 19 Antoniou E, Draper H, Reed K, Burls A, Southwood T et al. (2011) An empirical study on the preferred size of the participant information sheet in research. J Med Ethics; 37: 559-562.
* 20 This guidance does not address the issues surrounding research undertaken in an emergency context which presents its own set of challenges in terms of providing information about the research and obtaining consent.   
  Further guidance on this is available at: http://www.hra-decisiontools.org.uk/consent/principles-emergency.html (HRA Consent and Participant Information Sheet Preparation Guidance - Principles of consent: Emergency research)
* 21 Brosteanu et al. Risk analysis and risk adapted on-site monitoring in non-commercial clinical trials. Clinical Trials 2009: 585-596
* 22 REC members may ask the applicant to state the risk category of a clinical trial of an IMP at the REC meeting. Where the risk category is available prior to submitting an application for ethical review then the risk category may be included as part of the covering letter for the application and/or within the protocol
* 23 "Pragmatic trials measure effectiveness - the benefit the treatment produces in routine clinical practice. ...the design of a pragmatic trial reflects variations between patients that occur in real clinical practice and aims to inform choices between treatments. To ensure generalisability pragmatic trials should, so far as possible, represent the patients to whom the treatment will be applied". Roland M, Torgerson DJ. Understanding controlled trials. What are pragmatic trials? BMJ 1998;316:285.
* 24 The forthcoming **EU Clinical Trials Regulation** (expected to come into effect by **October 2018**) introduces the term ‘low-intervention trial’ (a trial with minimal additional risk compared to normal clinical practice e.g. where the investigational medicinal product is covered by a marketing authorisation or, if that product is not used in accordance with the terms of the marketing authorisation, that use is evidence-based and supported by published scientific evidence on the safety and efficacy of that product)
* 25 PRECIS-2 website: PRagmatic Explanatory Continuum Indicator Summary – is a clever acronym for a tool to help trialists designing clinical trials consider where they would like their trial to be on the pragmatic/explanatory continuum.
* 26 The exception to this is emergency research where the participant may be unable to consent for themselves and a representative is not available.
* 27 General Medical Council. Good practice in prescribing and managing medicines and devices (2013)
* 28 See HRA Consent and Participant Information Sheet Preparation Guidance: Content: Participant Information Sheet - Supporting Information.
* 29 Adapted from: Kim SY & Miller FG. Informed consent for pragmatic trials - the integrated consent model. N Engl J Med. 2014 Feb 20;370(8):769-72.; Faden et al. Informed consent, comparative effectiveness, and learning health care. N Engl J Med. 2014 Feb 20;370(8):766-8 and Weir et al. Veterans Healthcare Administration providers' attitudes and perceptions regarding pragmatic trials embedded at the point of care. Clin Trials June 2014 11: 292-  
  299, first published on March 20, 2014.
* 30 Where this has not been possible or the potential participant requires more time than is available to consider the information then this may result in their not being eligible for recruitment to the trial
* 31 See the General Medical Council’s ‘Good practice in prescribing and managing medicines and devices (2013)’ - Prescribing unlicensed medicines: http://www.gmc-uk.org/guidance/ethical\_guidance/14327.asp for further information
* 32 Required by forthcoming EU Clinical Trials Regulation
* 33 A type of research design that randomises the drugs or treatments being investigated to different groups or clusters of individuals (such as households, primary care practices, hospital wards, classrooms, neighbourhoods or communities), rather than individuals.
* 34 See HRA “Information for participants at the end of a study: Guidance for Researchers” for more information: <http://www.hra.nhs.uk/documents/2014/09/information-participants-end-study-guidance-researchers.pdf>

# HRA 2014

Consent and Participant Information Sheet Preparation Guidance

* **Principles of consent and role of Participant Information Sheets p7**  
   “For consent to be considered both legal and ethical it must be  
   +Given by a person with capacity;  
   +Voluntarily given, with no undue influence;  
   +Given by someone who has been adequately informed**;** +A fair choice.”  
  + **Informing potential participants:** **aiding understanding p7  
    “**It is known that you can improve understanding by providing information in a number of different formats (e.g. by providing a writing PIS that support conversation).”  
    “Effective informing should enable potential participants understand what is involved. Interactive questioning of potential participants within the consent process can also aid understanding and highlight areas that potential participants are misunderstanding without appearing condescending”
  + Does consent have to be in writing?  
    “Consent does have to be indicated in some way; for many studies consent can be written, oral or non-verbal. However, in Clinical Trials of Investigational Medicinal Products (CTIMPs) consent is not considered legal unless it is in writing.”
  + **The role of PIS p8  
    “**The PIS should support the consent process by helping to ensure that all those who are invited to take part in a research study have been adequately informed.”  
    *In most cases the PIS is used to support conversations with potential participants and not as a sole source of information  
    “*Effective informing should enable potential participants to make an appropriate decision that is right for them.”  
    “Potential participants must be able to understand the information given to them and consider this information in light of their own circumstances”
  + **Testing your PIS p8**“We strongly encourage testing your PIS with an appropriate group of people (patients groups or other members of the public) can be very helpful in ensuring that:  
     +The language is appropriate;  
     +The style and format of the PIS aids understanding;  
     +The PIS covers the risks and benefits that are relevant to your potential participants etc.”  
    “You do not need to obtain NHS Research Ethics Committee (REC) approval to test you PIS with patient groups or others.”  
    “Involving patient groups or the public in other ways can also be invaluable”
  + Who is the right person to seek consent?
  + **Good Clinical Practice (GCP) and consent p9  
    “**The Research Governance Framework of each UK nation identifies the principles of Good Clinical practice (GCP) as describing best practice in all health and social / community care research.” (Principles of ICH GCP)  
    “In Clinical Trials of Investigational Medicinal Products (CTIMPs), UK law requires compliance with the principles of GCP described in legislation.” (Principles in The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, No. 1928)  
    “The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Guideline for Good Clinical Practice (ICH GCP) provides further guidance on the information you may provide to potential participants as part of the consent process **but this is not mandatory.**”  
    Extract of the ICH guidance. Adapt your PIS to your specific study (one size doesn’t fit all
    - Study title and invitation to participate
    - That the trial involves research
    - Study purpose
    - Why the potential subject has been chosen?
    - Voluntary nature of participation, withdrawing from study
    - Trial treatments and probability of random treatment allocation
    - Trial procedures, including invasive procedures
    - Identify aspects of the trial that are experimental
    - Alternative procedures or treatments available to the subject and their important potential benefits and risks
    - Approximate number of subjects involved in the trial
    - The subjects’ responsibilities in the study, including expected duration of their participation
    - Reasonable foreseeable risks or inconveniences
    - Reasonable expected benefits. Where there is no clinical benefit the subject must be informed of this
    - Informing in timely manner of information that may be relevant to the subjects’ willingness to continue participating
    - Foreseeable circumstances / reasons under which the subject’s participation may be terminated
    - Care after the trial has stopped
    - Compensation and / or treatment available in the event of trial related injury
    - Contact details for further information about the trial and the rights of the subjects.
    - Contact information in the event of trial related injury.
  + **Voluntary consent p10**
  + Deception as research method
* *Clinical Trial of Investigational Medicinal Product different rules*
* **Style: What makes a good PIS p35**
  + One size does not fil all p35
  + **Proportionality:** how long should a PIS be? P35
  + Importance of **study title p36**
  + **Invitational style**
  + **Do not use passive voice**
  + **Use plain English, avoid jargon p36**
  + **Format p37**
  + **Different ways of explaining**
  + **Participant perspective p38**
  + **Clarity about expected risks and benefits**
  + Different groups – different PIS?
  + **Test with relevant people p39**
  + Adults not able to consent for themselves
  + Children and young people
  + Emergency research p40
* **Content**
  + **PIS p41**
    - **PIS title p42**
    - **Invitation and summary**
  + **What is involved p44**
    - **Explanation: purpose of and background to the research and invitation p44**
    - **What would taking part involve? P45**
    - **What are the possible benefits of taking part? P46**
    - **What are the possible disadvantages and risks of taking part? P46**
    - Adults not able to consent for themselves p48
    - Pregnancy and breast feeding
    - Young people and pregnancy p49
    - Therapeutic research – **Clinical alternatives p50**
    - **Side effects** of treatments / therapies in trials
    - **Randomisation and blinding p51**
    - **Screening and exclusion**
    - Therapeutic studies – What happens when the research stops? P52
    - Tissue samples
    - **Research databases** and tissue banks p53
    - **Expenses and payments p53**
    - **Findings p54**
    - Genetic research
    - Impact on **insurance p55**
    - Radiation: Ionising Radiation (Medical Exposure) Regulations (IRMER) p55
    - **Accessing ONS,NRS and** other **registry data p55**
    - **Generic consent p55**
  + **Supporting information**
    - **What if something goes wrong? P57**
    - **Leaving the study p58**
    - **Will my information be kept confidential? P59**
    - **What will happen to the study results? P60**
    - **Who is organising and funding the study?**
    - **How have patients and the public been involved in this study?**
    - **Who has reviewed this study? P61**
    - **Further information and contact details**
    - **Version control p62**
    - **Consent process**
    - **What if relevant information becomes available?**
    - **Involvement of GP / other healthcare practitioner p63**
    - **What will happen to the samples I give?**
    - **Commercial exploitation p64**
  + **Consent Forms**
    - **General content**
    - **Itemising specific elements**
    - **Signatories,** witnesses and legal representatives p66
    - Adults lacking capacity p67
    - Version control

# Tobias 1993

Fully informed consent can be needlessly cruel

* “Attempts to gain the “informed” participation of patients in randomised clinical trials are already doing harm in many individual cases”
* Most clinicians recognize that the anxious patient sitting opposite to them in the consulting room requires, above all, reassurance and a clear exposition of what needs to be done to provide a cure … frankness on the part of the doctor may cause considerable anxiety in those patients who prefer to be directed rather than participate as an equal partner [including highly sophisticated professionals].”
* “*I received from physicians … well intended but contradictory advice … became increasingly confused and emotional distraught.”*
* *“What you need is a doctor: forget the information I already knew and seek instead a person who would tell me what to do [and who would] assume responsibility for may care”*
* *“The move towards full disclosure of all details of diagnosis, treatments and prognosis is a major change in social perception in the United Kingdom and the United States. However, no sensible doctor makes full disclosure to every patient”*
* *The process of informed consent should be based on the doctor’s clinical judgement: Full explanation should be given to patients who want to know all aspects of the decision making but* ***a distraught patient may be unable to take in any but the most basic details****.*
* *“[Distraught patients] can hardly be expected to cope with full discussion of options to be decided at random.”*
* *“A crucial point: to disclose that this decision is based on randomisation in which the physician plays no direct part. This may be very unnerving for patients … who may feel disturbed by the thought that their doctor is not making the fundamental decision about treatment policy.”*

# Moore & Savage 2002

Consent issues in Participant Observation Qualitative Studies

* “It is naïve to assume that everyone from whom data may be collected can be informed to the same extent, or know precisely to what they are consenting” (Merrell and Williams 1994)
* Qualitative approaches to research may not be able to give clear statement to potential participants at the outset about anticipated outcomes and benefits of the study (Johnson 1992)
* Tactical decision-making makes gaining informed consent and ongoing process instead of a single event (Merrell and Williams 1994)
* ***“A prescriptive approach to ethical practice is unhelpful [for certain research approaches as ethnography], and inhibits researchers from thinking carefully about the issues raised by specific situations” (Murphy and Dingwall 2001)***
* ***“****Highly restrictive ideals will prevent researchers exploring complex social realities” (Punch 1994)*
* *“It is not always practical to gain consent from everyone tangentially involved in an ethnography study” (Gerrish 1997)*
* *“It is difficult to keep reminding colleages that the researcher is there to collect data without undermining one of the aims of participant observation, to become as much of an ‘insider’ as possible” (Merrell and Williams 1994)*
* ***“The involvement of staff had the helpful effect of increasing the acceptance of the researcher”***
* *“Members of staff were enormously helpful in enlisting patients, yet it was clear that their efforts to do so obviously disrupted the clinic and consumed time that they could not afford to lose”*
* *This involvement introduced bias into the study, they avoided approaching patients:*
  + *Due for intimate clinical examination*
  + *Known mental health problems*
  + *Patients seen as ‘difficult’*
* *“The need to gain consent from patients who agreed to be observed was downplayed by practice staff”*
  + *Lack of time*
  + *Little training in research*
  + *Unfamiliar with particulars of informed consent*
  + *Trust that practice staff placed in the researcher: Having made their own decision to become involved they assume that patients could also consent.*
* ***“Some patients became worried when asked to sign consent forms – having to sign a document suggested that something of considerable import was about to happen”***
* ***“Many found difficult to understand the formal need for an information sheet and consent form simply so that the researcher could be present during their consultation”***

# Gilles Et al 2014

20 PILS for UK RCTs sampled from registered UK Clinical Trials Unit websites. Evaluation tool for supporting decision making, 2 researchers evaluated each PIL with the tool.

“Informed consent is regarded as a cornerstone of ethical healthcare research and is a requirement for most clinical research studies. Guidelines suggest that prospective randomised controlled trial (RCT) participants should understand a basic amount of key information about the RCTs they are being asked to enrol in in order to provide valid informed consent. This information is usually provided to potential participants in a patient information leaflet (PIL). There is evidence that some trial participants fail to understand key components of trial processes or rationale. As such, the existing approach to information provision for potential RCT participants may not be optimal. Decision aids have been used for a variety of treatment and screening decisions to improve knowledge, but focus more on overall decision quality, and may be helpful to those making decisions about participating in an RCT. We investigated the feasibility of using a tool to identify which items recommended for good quality decision making are present in UK PILs.”

* Informed consent forms the cornerstone of ethical requirements in healthcare research [1] [2]
* “It means that an individual has made an informed and voluntary decision about their participation in a research study”
* “RCTs usually require all participants to sign an informed consent document indicating that they have understood the information … before they commence participation on the trial [1].”
* Potential UK trial participants are provided with a PIL to assist in making an informed decision. The **PILs’ information is guided by the Declaration of Helsinki, the International Conference on Harmonisation Good Clinical Practice (ICH GCP) and national guidance (e.g. National Research Ethics Service (NRES)) [1] [2] [3]**
* As per guidance a **PIL must contain** at least information on **[1] [3]**:
  + The trial purpose
  + Procedures
  + Interventions
  + Possible risks and benefits
  + Sources of finance
  + Potential conflicts of interest
  + And the researcher affiliation
* Guidance for informational requirements covers **mostly fact-based** information and **is standardized** at population level [1] [3]
* ***“The PIL and consent form are the only components of the decision making process that are formally regulated, through specific guidance, and reviewed by ethics committees [1].”***
* ***“Potential participants vary in the amount of information they desire when faced with a decision about trial participation [5-7]”***
* *“When the information minimum has been pre-determined by the guidance [1] [3] [4], many participants’ preferences for information may be exceeded [6]”*
* ***“There is evidence that some trial participants, both those considering participation and those actively enrolled in clinical trials, fail to understand key components of the trial process or rationale [8-10]”***
  + Misunderstanding risks [11]
  + The right to withdraw [11]
  + Confidentiality [12]
  + Side effects [13]
  + Trial purpose [14]
* “*This suggest that … existing approaches to information provision may be sub-optimal and* ***some decisions may not have been based on a full understanding or consideration of the relevant issues”***
* ***“****This may be because the information is too complex or not designed to support an informed decision but to present factual information to the potential participant”*
* Many studies have explored way of improving information, and generally **focus** on the **information** **content and structure:**
  + PIL length [10] [15]
  + Simplified vs enhanced versions of same PIL [16] [17]
  + Patient specific information vs generic information [18] [19]
  + Linguistic analysis of leaflets [20]
  + Consumer involvement in PIL development [21]
  + Audio-visual information [22]
  + Computer based information [23]
  + User testing to improve content [24]
* ***“Informed decision making for trial participation is a complex process that requires more than just greater understanding or comprehension of fact-based information”:***
  + *Established ‘good’ decision making theories [****25****]:*
    - *Considering alternatives*
    - *Making trade-offs*
    - *Evaluating potential outcomes of the decision*
  + *“Might not be presented at all during the consent discussion or in the PIL”*
* These omissions may stem from the conceptualisation of trial participation as an “act of informed consent” related to ethical and regulatory requirements rather than viewing deliberations and decisions about participation as broader and more complex [26].
* **Decision aids** have been tried **to improve “informed decisions”** [**25**]
  + The aids provide:
    - Information commonly present in PIL
    - Available options
    - Associated outcomes
    - Personalize information
    - Exercises to find what matters most to the patient
    - Communication waysto the healthcare professional to reach a decision
  + Positively influence:
    - Improving knowledge, especially when there is **clinical equipoise**
    - Providing accurate perceptions of outcomes probabilities
    - Align preferred outcomes with choice made
  + They appear to improve aspects of the decision making process [28-32]
    - Have been found acceptable and valued by potential participants [28-29]
    - Substitute PIL
    - Improve understanding about trial and interventions [28-29]
    - Produce low level decision conflict [29]
    - Not raise anxiety [28-29]
  + **Small sample populations**
  + **Hypothetical trial context [28-32]**
* ***“The traditional conceptualisation of informed consent in RCTs is as a behaviour relating to understanding rather than promoting informed decisions.”***
* *“may have led to the information contained within PILs being focussed on fact-based trial information rather than, for example, what trial participation might mean for that individual. Yet, these personal considerations do play a significant role for people when deciding whether or not to participate in a trial [****27****] and this is often the type of information contained within treatment decision aids.”*
* **Standards for encouraging good quality decision making:**
  + **International Patient Decision Aid Standards (IPDAS) [33-34]**
  + **Brehaut study (USA consent documents conform to the standards):**
    - **Set of items derived from IPDAS**
    - **Set of items derived from published guidance on informed consent [34]**
    - **Did not assess word count or readability**
    - US PILs differ from UK PILs, UK consent form is one-page document whereas US forms are longer and include much of the information contained in UK PILs.
* ***EXCLUSION CRITERIA:***
  + *PILs for RCT that was on-going or completed after 2001 (to coincide with the introduction of* ***the European Clinical Trials Directive 2001/20/EC [36])***
  + *PILs designed for a primary RCT,* ***not follow-on studies***
  + *PILs designed for competent adults making a decision about their own participation,* ***not******proxy decision makers.***
  + *Exclusions of PILs for:*
    - *Cluster RCTs*
    - *Emergency research with retrospective consent*
    - *RCTs recruiting children*
  + *PILs were sample purposively to allow for variation in intervention and CTU. Four main intervention groups were identified:*
    - *Drug*
    - *Surgical*
    - *Cognitive*
    - *Other*
* ***FINDINGS:***
  + *“We assumed that all included PILs had been reviewed by an ethics committee and had been given a favourable opinion. Despite this, we found that the majority of PILs did not perform well using the tool (based on a score of less than 50%).”*
  + *“There were four sub-sections in Section A that scored consistently poorly across all leaflets.”*
    - *Presenting probabilities*
    - *Clarifying and expressiong values*
    - *Structured guidance in deliberation and communication*
    - *Using evidence*
  + *“These concepts* ***are not currently included*** *in the informed* ***consent guidance*** *[****1,4****]. However, the items reflect standards that have been shown to be* ***important to promote high quality decisions*** *for treatment and screening [****25****] and identify items that have also been shown to be important to trial participants during their trial participation experience [****27****].”*

# Donovan Et al 2014

**Recruiters’ Perspectives** on 6 Pragmatic RCTs, a Qualitative Analysis

* “*Few studies have even considered how the process of recruitment occurs, or the influence that recruiters might have on it”*
* RCTs were experiencing severe recruiting problems or were pilot/feasibility studies expecting difficulties
* Collected data (interviews while they were actively trying to recruit) from recruiting staff:
  + Doctors
  + Nurses
  + Researchers
* Barriers identified:
  + Organizational challenges
  + Strong preference for particular intervention (Patients & Doctors)
  + Views on research
  + Their roles in research and clinical care

# Donovan Et al 2014

Intellectual Challenges and Emotional Consequences of **Equipoise** in 6 Pragmatic RCTs

* “*Approcimately 50% of initiated RCTs reach their original recruitment target [1]”*
* *“Research on RCT recruitment has focused on increasing patient participation”*
  + *Providing additional favourable information [2]*
  + *Comparing PIL lengths [3]*
* ***“Systematic reviews have identified only a small number of successful interventions directed at patients [4] and pointed to the lack of prospective research in ongoing RCTs and studies involving recruiters [5]”***

# Afolabi 2014

**Informed consent and comprehension in African research settings**

* ***“Comprehension is one of the essential elements of a truly informed consent.”***
* *“Internantional ethical guidelines stipulate* ***informed consent must be given in a comprehensible manner*** *to a competent person who freely decides to participate* ***after understanding the information****” (****NBAC 2001; CIOMS 2002; Marshall 2006****)*
* *“The amount and quality of study information required for potential participants to comprehend the study is unclear, and there are divergent opinions among researchers on the level of comprehension that must be reached to be able to freely decide****” (Ijsselmuiden & Faden 1992; Hyder & Wali 2006)***

# Knapp 2011

***Can user testing of RCT PIL made it fit for purpose?***

* ***“****The PIS is a critical part of the process of valid consent. However, there is long-standing concern that these lengthy and complex documents are not fit-for-purpose.”*
* *Recent approaches to improve PIS have included performance based testing and improving readability (user testing). This method is widely used to improve patient medicine leaflets – determining whether people can find and understand key facts.*
* This study applied a controlled desing to determine if a PIS developed through user testing had improved readability over the original, using a sheet from a UK trial in acute myloid leukemia (AML16).

# Smith 1992

Analysing 150+ financial chairman narrative samples from company pairs (failed company-surviving companies)

* “Any attempt to measure the understandability of [accouting] narrative messages must be related to the target audience”
* *“Conventional readability measures used in the analysis of narrative statements may be inappropriate, in that they are not measuring the underlying complexity of the narrative”*
* *“The understandability or comprehensibility of a narrative passage may be different to its readability and the latter might frequently be used erroneously as a proxy of the former.”*
* *“The complexity of a narrative is a function of the user of the statements, we suggest that user groups of differing [accounting] sophistication will experience different degrees of difficulty in processing text.”*
* *“This article demonstrates that the complexity of the financial narrative is such that it is understandable by only the most sophisticated accounting user group.”*
* ***Alternative measures of readability***
  + *Flesch reading ease formula and LIX measures are independent of both narrative context and target audience.*
  + *“All [readability methods] base their computation of the difficulty of the narrative on the length of the sentences and the length of the words employed. Such measures are independent of the intended audience.”*
  + *“Readability formulae have been widely adopted as alternatives to reader-feedback and comprehension tests in assessing the difficulty of narrative passages on the assumption that they generate common conclusions. They are based on two features:*
    - *Word length (W) – related to speed of recognition.*
    - *Sentence length (S) – related to a recall of words in the immediate memory.”*
  + *Different readability formulae arise from different measures of “word length” and different weightings applied to the component parts*
    - *FLESCH = 206.385 – 0.84W – 1.015S; W=number of syllables per 100 words and S=total number of words / total number of sentences. 80+ for comic jounals, less than 50 for academic literature, less than 30 for technical and scientific articles.*
    - *FOG = 0.4 (W+S); W=percentage of hard words in the passage and S=average number of words per sentence. Less than 14 for newspapers and comics, 17+ for scientific and technical literature.*
    - *LIX = W+S; W=percentage of words of seven or more letters and S=average number of words per sentence. Harrison (1980), Anderson (1983).*
* ***Differences between readability and understandability***
  + LIX and FLESCH scores are highly correlated (-0.62 p<0.005) but their correlation with CLOZE score is relatively low (r=-0.23) and (r=0.37) significant only at the 0.5 and 0.4 levels.
  + Comparison of LIX FLESCH and CLOZE scores on an undergraduate audience. It demonstrates different concepts were being measured [readability / understandability] each associated with the complexity of the narrative.
  + ***“reducing sentence length will not necessarily improve matters, since the addition of subordinate clauses often aids comprehension Klare (1974-75), Davison & Kantor (1982).”***
  + passive voice is a factor known to affect readability but reflected in the formulae only the longer sentences generated Lesikar & Lyons (1986, p.151)
  + The **CLOZE** procedure (Taylor, 1953): delete every nth word and replace by a blank space. Respondents are asked to predict the correct word. CLOZE test scores of 44 and 57 per cent on English comprehension passages have shown to be comparable with multiple-choice comprehension test results of 75 and 95 percent, Bormuth (1968). The deletion of every fifth word gives optimum results. Only exact responses are treated as valid.
    - ***57 percent minimum CLOZE score criterion to constitute understandability Bormuth (1968)***
    - Miller & Coleman (1967) exhaustive validation of CLOZE procedure. Cross-correlation greater than 0.9.
    - Stevens et al (!983) used CLOZE to measuer the understandability of Financial Accounting Standards Board Statement 33: “Financial Reporting and Changin Prices”. It identified two pontential user groups who found it incomprehensible.
    - Aquino (1969) and Nestvold (1972) have found that CLOZE procedure **scores correlate highly with readers’ perceptions of the degree of difficulty of narrative.**
    - **A minimum of 150 words is suggested by Taylor (1953) and Miller & Coleman (1967) to allow between 30 and 50 deletions in text mutilation.**
    - Delete every 5th word except for proper namesm dates and numbers.
    - Each CLOZE statement was measured on at least 9 separate occasions by different respondents. Each respondent completed 5 such statements. Tested by a 146 final-year UK undergraduate accounting students.
* ***How to measure understandability***

# Friedman & Wyatt 2006

Evaluation Methods in Biomedical Informatics, Chp 5-6

Reliability: “is the degree to which measurement is consistent or reproducible”, a reliable measurement “is measuring something.”

Validity: “is the degree to which that *something* is what the investigator wants to measure”

“We cannot even discuss the validity of a measurement process until we demonstrate it to be reasonable reliable.”

“Reliability and validity are not properties solely of the measurement but, rather, of the total measurement process.”

Archer analogy:

* Target corresponds to an object with a hidden *bulls-eye* corresponding to an exact true value [cannot be known]
* Each arrow corresponds to a single observation (the result of the measurement)
* “The irregular target shape suggests to the archer the location of the hidden bulls-eye, but does not reveal it.”
* “The differing shapes of the target correspond to differing values of the attribute for each object.”
* “For each target, the archer aims where he *thinks* the bulls-eye is.”
* “If there is enough consistency to the archer’s shooting to speak of a central point on the target around which the arrows cluster, the archer has enough reliability to prompt a meaningful discussion of validity.”
* “The smaller the distance between this central point and the actual location of the hidden bulls-eye, the grater the archer’s validity”.
* “We can **estimate the reliability** of a measurement process through the task of **measuring the scatter** of the arrows over a series of targets.”

The reliability of a measure can be improved by increasing the number of independent observations for each object and averaging the results.

Test-retest reliability: reapeat measurements over time. Does not work when studying the attributes of humans because is necessary to repeat the study at the right time and to re-create exactly the circumstances of the initial measurement.

Co-occurring observations reliability: multiple observations conducted on the same occasion. Observations cannot be carried out identically. The observations must be crafted in ways that are different enough for each observation to create a unique challenge for the object yet similar enough that they all meassure essentially the same attribute.

The reliability coefficient is defined as . The reliability coefficient shown in Appendix A is known as **Cronbach’s alpha** (α).

The estimate for the standard error of measurement (SE): SEmean=SDsqrt(1-p). SD= the standard deviation of all measurement results. For demonstration studies SEmean=SD/sqrt(N).

Decision support system performance, assess the attribute of “accuracy of advice”:

* Pat