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**Application for Ethics Approval to the Faculty of Medicine Ethics Committee for RESEARCH**

**DETAILS OF APPLICANT AND SUPERVISOR RESPONSIBLE FOR PROJECT (where applicable)**

**Please Tick (✓)**

**Undergraduate 🞏 Masters 🞏** **PhD ◼ Staff 🞏**

*NB Staff should always tick the ‘staff’ box*

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| **Applicant Title** | **MSc** | **Applicant Forename** | **Fernando** | **Applicant Surname** | | **Santos Sanchez** |
| **University Department Address**  *These MUST be current addresses as this is where correspondence will be sent.* | **PCPS Aldermoor Surgery**  **Aldermoor Cl, Southampton SO16 5ST** | | | | | |
| **e-mail** [**fss1g15@soton.ac.uk**](mailto:fss1g15@soton.ac.uk) | | | **Telephone 023 8059 1864**  **074 0557 8516** | | |
| **Current Post** | **PhD Researcher** | | | | | |
| **Signature** |  | | | | **Date 14/10/2017** | |

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| **Name of course if project forms part of a course of study** (e.g. PhD/BMedSc/BM5/BMEU) | | **iPhD in Web Science** | |
| **Supervisor**  **(name and title)** | **Prof Jeremy Wyatt** | **e-mail J.C.Wyatt@soton.ac.uk**  **Telephone 023 8059 7551** | |
| **Current post/ Division /School & institution** | | **Director of Wessex Institute**  **Professor of Digital Healthcare** | |
| **Signature** |  | | **Date** |

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| **Short Title of Study *(Maximum Six Words)***  **Developing a Computer Assisted Reviewer for Assessing PIL quality** |

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| **Full Title of Study (for which approval is sought)**  **Developing a Computer Assisted Reviewer for Assessing the Quality of Patient Information Leaflets from Randomised Controlled Trials** |

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| **Completion date:**  **NOTE – please ensure this matches the date in your IRGA form.** |

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| **Version number and date of completion of application form:** | **V5**  **01/11/2017** |

***Committee use only:***

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| *Received date and submission no:* | *Decision and date:* | *Full Approval number* |

**DETAILS OF RESEARCH PROPOSED**

**Short Title of Study *(Maximum Six Words)***

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| **A Computer Assisted Reviewer for Assessing PIL quality** |

**1. BACKGROUND TO PROJECT**

*Please use language suitable for the non-specialist reader*

**a Key research questions**

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| 1. How many reviewers are needed to review a Patient Information Leaflet (PIL)? 2. What kind of topics do public reviewer comment on PIL cover? 3. What correlation exits between PPI comments, quantitative text analytics and PIL quality? |

*Specify the key questions that your study is designed to address*

**b Background to Study/Summary of Literature**

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| Clinical trials have become a corner stone for maintaining high quality in the health-care systems of developed countries [Lovato 1997]. They enable researchers to compare the effects of new drugs and treatments against those that are currently employed, to improve the health-care of the general population by developing new guidelines and practices [NHS 2017]. On the other hand, their very nature implies a risk for the patients that choose to participate in them of either receiving a sub-optimal treatment or suffering previously undiscovered side-effects [Moore 2002]. Thus, it is of great importance the creation of regulations to ensure the patient is aware of the risks and enforce the ethical practice during recruitment [mrcNHSConsent 2016].  One of the core elements in informing the patient is the patient information leaflet (PIL) [Knapp, 2011] with all clinical research studies that involve patients in the UK being asked to develop one. The Health Research Authority (HRA) defines the role of PILs as “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” [HRA 2017] and it states that effective informing enables the participant to make appropriate decisions and that the information should be understandable by the participant and consider their own circumstances [HRA 2016, 2017].  These leaflets are usually designed by following the guidance provided by the HRA, are commonly based on templates [HRA 2017] and are reviewed by an ethics panel as part of the research procedure in the UK. To further ensure a high quality the researchers are recommended to employ Public and Patient Involvement (PPI) groups to review the PILs [HRA 2017].  However, there is no formal requirement to do so, the PPI groups are commonly below 9 people with no formal assessment of the effect of their comments on leaflet quality and the recommended £25 per hour per person pay [NIHR 2014] can be excessive for pragmatic trials. Even more, several research studies have found that we do not have a standardized method for assessing the quality of PILs [Moult 2004] and that current PILs do not communicate the information effectively [Gilles 2014, Reinert 2014, Knapp 2011]. While RCTs’ leaflets are considered essential for valid consent [Knapp 2011], in general, they lack the capability to meaningfully inform the patient [Gilles 2014] and in some cases, they may not enable valid consent [Knapp 2011]. In particular, the formal tone of the leaflets was found to hinder the readability of the text [Reinert 2014].  The Health Research Board Trials Methodology and Networks (TMRN) working with the James Lind Alliance and the TrialBank convened the Priority group to identify several priority questions including quantifying the effects that PPI groups have on PILs and RCTs [TMRN 2016]. Specifically, identifying which information should be communicated, assessing the effect of PPI collaboration on recruitment rates and finding the best methods to deliver information are among the top five questions identified by this JLA priority-setting panel [TMRN 2016]. Therefore, it is our intention to build a tool that supports PPI groups reviewing PILs for RCTs in the UK answer these questions.  *(Lovato et al, 1997) Laura C Lovato, Kristin Hill, Stephanie Hertert, Donald B Hunninghake, and Jeffrey L Probstfield. Recruitment for controlled clinical trials: literature summary and annotated bibliography. Controlled clinical trials, 18(4):328–352, 1997*  *(NHS, 2014) NHS Confederation. UK NHS named best healthcare system by the Commonwealth Fund, 2014. [http://www.nhsconfed.org/resources/2014/07/uk-nhs-named-best-healthcare-system-by-the-commonwealth-fund]*  *(NIHR 2014) NHS Confederation. Patient and Public Involvement in Health and Social Care Research. A hadbook for researchers. 2014.*  *(Moore & Savage, 2002) Moore, Lucy, and Savage, Jan. "Participant observation, informed consent and ethical approval." Nurse Researcher 9.4 (2002): 58-69.*  *(MRC, 2016) MRC. Consent and participant information sheet preparation guidance, 2016 [http://www.hra-decisiontools.org.uk/ consent/principles-general.html]*  *(HRA 2016) Health Research Authority, Consent and Participant Information Sheet Preparation Guidance [*[*http://www.hra-decisiontools.org.uk/consent/principles-general.html*](http://www.hra-decisiontools.org.uk/consent/principles-general.html)*], UK 2016.*  *(HRA 2017) Health Research Authority, Guidance on applying proportionate approach seeking consent, UK 2017.*  *(TMRN 2016) Health Research Board Trials Methodology Research Network, Final ranking of unanswered questions from PrioRiTy workshop on 1st December 2016, UK 2016.*  *(Moult 2004) Moult, Beki, Linda S. Franck, and Helen Brady. "Ensuring quality information for patients: development and preliminary validation of a new instrument to improve the quality of written health care information."* ***Health Expectations*** *7.2 (2004): 165-175.*  *(Gilles 2014) Gilles, Huang, Brehaut, and Cotton. “Patient information leaflets (PILs) for UK randomised controlled trials: a feasibility study exploring whether they contain information to support decision making about trial participation”.* ***Trials Journal*** *(2014): 15-62.*  *(Reinert 2014) Christiane Reinert, Lukas Kremmler, Susen Burock, Ulrich Bogdahn, Wolfgang Wick, Christoph H Gleiter, Michael Koller, and Peter Hau. Quantitative and qualitative analysis of study-related patient information sheets in randomised neuro-oncology phase iii-trials.* ***European Journal of Cancer****, 50(1):150–158, 2014.*  *(Nielsen 2006) Jakob Nielsen, Quantitative Studies: How Many Users to Test? [*<https://www.nngroup.com/articles/quantitative-studies-how-many-users/>*]. 2006.*  *(Nielsen 2012) Jakob Nielsen, How Many Test Users in a Usability Study? [*<https://www.nngroup.com/articles/how-many-test-users/>*]. 2012.*  *(Knapp 2011) Peter Knapp, David K Raynor, Jonathan Silcock, and Brian Parkinson. Can user testing of a clinical trial patient information sheet make it fit-for-purpose? -a randomized controlled trial. BMC medicine, 9(1): 89, 2011.*  *(Saldaña 2015) Saldaña, Johnny. The coding manual for qualitative researchers. Sage, 2015.*  *(Henry 2015) Henry, David, et al. "Clustering methods with qualitative data: a mixed-methods approach for prevention research with small samples." Prevention Science 16.7 (2015): 1007-1016.* |

*Summarise the relevant literature and explain how the idea for the study evolved (max 250 words). Please include key references*

**c Study Design**

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| This is a cross-sectional observational study of the Patient Information Leaflets (PILs) from Randomised Controlled Trials (RCTs) capacity to inform essential aspects of the trial. |

*E.g. cross-sectional observational study*

**2. SAMPLE AND SETTING**

**a Specify and justify study size**

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| The leaflets will be analysed by 20 public participants as it has been established by talking with PPI officers in the Faculty of Medicine and the Wellcome Trust Clinic that it is common to have PPI groups of less than 10 people but no formal assessment of the number of reviewers needed has been done. We anticipate that 20 participants will be sufficient to reach saturation on the comments they generate. |

*Include sample size calculation, if applicable*

**b Setting**

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| The researcher will create a Website for this project. The public participants will be asked to visit the Website where they will be informed about the project and provided the option to join the study. Once the participant has joined via the Website, the researcher will provide and retrieve the materials electronically via the Website. Also, once the participants have joined in the Website they will have the option to join a face to face group at the Millennium Third Age Centre (3AC) located at 11 Cranbury Terrace, Southampton, where they will be able to fill and submit their comments and answers in a face to face setting with the researcher. The 3AC is a charity providing community resources and delivering community activities open to the general public in Southampton. No personal or identifiable information will be gathered or stored at the face to face group. |

*Specify where the study (data collection) will be conducted*

**c Details of proposed participants/sample**

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| The participants of this study will be members of the public who participant to review PILs from previous RCTs in the UK. |

*E.g. fellow students/cohort no/year. Etc*

**d Relationship of participants/sample to researcher**

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| The researcher has no relationship with the participants for the study, contact will be made by posts in public platforms [PeopleinResearch.org, Facebook & Twitter]. |

*Outline your relationship with participants in the proposed sample and confirm that you have permission to contact the participants. Provide letters of collaboration, where applicable.*

**e How will participants/sample be identified**

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| The participants will be identified by making posts in People on Research [PeopleinResearch.org] and Millennium Third Age Centre (3AC) [ThirdAgeCentre.org.uk] social media platforms. The researcher will create a group at the 3AC located in 11 Cranbury Terrace, Southampton. Where an ad of the study will be shown to facilitate the participants’ recruitment. Also, a Website will be made for the project. The Website will be accessible by querying commonly known search engines like Google. All posts and ads of the study will be made in platforms open to the general public. |

**f How will participants be approached and recruited**

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| The participants will be approached by:   * Creating a group on the 3AC * Publishing posts in social media platforms (PeopleinResearch.org, Facebook & Twitter) * Creating a Website that can be accessed from Google   In case of insufficient recruitment, Gary Hickey from the INVOLVE group has agreed to contact public participants on the researcher’s behalf |

*If a recruitment poster is to be used, provide a copy. Please refer to the example poster.*

**g State inclusion and exclusion criteria and screening tools, if applicable**

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| No specific selection criteria will be used for the participants, only that they are adult residents of the UK as the inclusion of several segments of the population could help identify differences in how the text is perceived. In particular, the understanding of populations with low-level academic background or with English as a secondary language are hypothesized to be hindered more by the formal language of the leaflets. |

**h How will consent be obtained**

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| All the participants who wish to collaborate in the project will be referred to the project Website. To join the study a web page with the full information of the study will be given to the participant (PIS). After the participant has read the information he will be asked to fill the Joining & Consent form. In the first section of the Joining & Consent form the participant must agree to the following statements:   * I am an adult resident of the UK * I have read and understood the study information * I agree to let the researcher use my anonymous comments and answers in his project * I agree to let the researcher contact me in relation with this study   The participant will accept giving their consent by clicking the “I wish to join” check box in the first section of the Joining & Consent Form. After indicating their wish to join the study, the participant must then fill a set of non-identifying demographic questions and click the “Submit” button to send their application. There is no time limit for filling the application or deciding to submit it. |

**i Will participants be given written Yes ◼ If no, why?**

**information? No 🞏**

*(include Patient Information Sheet (PIS) in application)*

**j Will participants sign a consent form? Yes 🞏 If no, why not?**

**No ◼**

*Tick ‘yes’ or explain why not (e.g. may not be required for questionnaires). Include copy of consent form where appropriate. Include consent form in application where appropriate*

The participant can choose to participate in this study in a purely electronic form. Where the participant will register, acquire the study resources and deliver the outputs via the study Website, in this case there is no method of providing or receiving printed information.

The participants will express their consent by marking the “I wish to join” checkbox in the consent form and submitting their application either to the researcher or via the Website.

**k Explain how participant/sample anonymity and/or confidentiality will be maintained?**

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| This research is a linked anonymised study. No “personal identifiable information” (such as the name of the participant) is asked to enable the researcher to maintain the anonymity of the participants. No identifying questions will be asked at any point in either the study website or the group meeting at the 3AC.  The requests will be posted in public platforms, visible to the general public and can be accessed by any user residing in Great Britain.  All participants will be assigned a unique id after joining the study which will be employed to link the data from each participant. The participant id will not be based in any information from the participant but be a 5 character randomly generated alpha-numeric string. If the participant chooses to deliver their comments via email their email will not be associated with the participant at any point nor stored in the system. |

*Anonymity:*

*i) Unlinked anonymity - Complete anonymity can only be promised if questionnaires or other requests for information are not identifying to, or received from, individuals using their name or address or any other identifiable characteristics. For example if questionnaires are sent out with no possible identifiers when returned, or if they are picked up by respondents in a public place, then anonymity can be claimed. Research methods using interviews cannot usually claim anonymity – unless using telephone interviews when participants dial in. Unlinked data cannot be withdrawn.*

*ii) Linked anonymity - Using this method, complete anonymity cannot be promised because participants can be identified; their data may be coded so that participants are not identified by researchers, but the information provided to participants should indicate that they could be linked to their data. Linked data can sometimes be withdrawn.*

*Confidentiality – The non-disclosure of research information except to another authorised person. Confidential information can be shared with those who are already party to it, and may also be disclosed where the person providing the information provides explicit consent.*

**3. INTERVENTIONS AND MEASUREMENTS**

**a What will happen to the participants/sample?**

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| The participants will be asked to enter the study website where they will read the study information and fill a set of demographic questions in order to join (Joining & Consent Form). Then they will receive a unique participant id and be able to access the resources webpage. Afterwards, the participant will be able to download files of the leaflets to review and be presented with instructions on how to make the comments. The participant will have the option to upload the commented documents into the website, upload a scan or high-quality photo of the manual comments as instructed in the website or to deliver the comments in a collection box at the Millennium Third Age Centre (3AC).  The website will also include multiple-choice questionnaires to assess the capacity of the leaflets to inform participants about important aspects of the trial. These questionnaires will be provided at the same time as the leaflets text. The participant will have the option to answer the questionnaire directly in the website, to download the format and upload a scan of the filled form or to deliver the manually filled form into the collection box at the 3AC.  It is expected that the participants will take around 1-2 hrs to complete the revision of the leaflets and answer the questionnaires. Participants will be reimbursed £20 as compensation for their time and effort in reviewing the leaflets. No reimbursement will be made for travel expenses to the 3AC but it is expected that participants that choose to attend the face to face meeting will live locally. |

*Specify what participants will be asked to do and for how long they will be asked to do it. Ensure that demands on the participants (including time and travel) are reasonable.*

**b Explain what will be measured/explored and how**

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| The study will measure the following aspects:   1. The characteristics of the participant comments: each participant will be asked to provide comments that are linked to specific sections of the leaflet text. These comments will be coded by the researcher to obtain structural and emergent themes (Saldaña 2015). 2. The capacity to inform of the PILs: each participant will be asked to answer a series of multiple-choice questions based on the Knapp scale (Kanpp 2011) after reading the leaflet information of each trial. The participant answers will be used to objectively determine the capacity of the leaflet to inform the participant about essential aspects of the trial. 3. The participant perception of the leaflet quality: The participant will be asked to provide an overall grade of the leaflet quality after reviewing it and a direct measurement of the leaflet quality via a unipolar analogue scale after answering the questionnaire. |

*Provide copies of relevant documents (including questionnaires and interview frameworks) and confirm that permission to use them is in place. Ensure that the role of all assistants and/or collaborators is made clear. Comment on the validity and reliability of the proposed tools.*

**c Outline how the data will be analysed**

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| The participants will be asked to make comments of each leaflet. These comments will be analysed by employing Applied Thematic Analysis (ATA) in particular by coding the structural and emergent topics of each comment (Saldaña 2015). Once, the themes for each comment have been obtained the similarity of the comments will be assessed to determine the optimal number of reviewers to have a covering of all the topics. The similarity analysis will be done by employing a K-means clustering as this technique has been found to be useful in revealing groups of participants with similar profiles when employed on coded qualitative data (Henry 2015). The leaflets will be characterized by quantitative metrics employed in Web Analysis to measure the complexity of the text (Flesch-Kincaid index & SMOG) and the emotive expression patterns (Mohammad & Yang 2012). A correlation between the qualitative and quantitative characteristics of the text will be made with SPSS by employing a linear regression model which will be included in the final report. |

**4. MANAGEMENT OF THE STUDY AND RISKS INVOLVED**

**a Is this a pilot study? Yes ◼ No 🞏**

**If not, outline what pilot work has already been completed or outline the pilot work that will be carried out as part of the project, as applicable**

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*Specify the decisions to be made before the main study (e.g. procedures to be clarified)*

**b Outline the potential risks/harm to participants in the study (including the researcher/s)**

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| The participants will be presented with leaflets used to recruit into interventional phase IV RCTs for comparing the current treatments of varicose veins, knee osteoarthritis, elderly rehabilitation and constipation problems in older patients. There is an extremely low chance that this could generate psychological discomfort to some participants. |

**c How will you *attempt* *to prevent* the potential risks/harm from occurring?**

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| No preventable general risk or harm has been assessed by the researcher. The leaflets have been taken from a sample of previously employed leaflets for RCTs in the UK that have passed ethical evaluations. |

**d How will you *manage* any that do arise?**

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| The participants will be given the option to leave study by visiting the website and clicking the “I wish to leave” button. The website will ask for confirmation and give a space for the participant to optionally comment about the reasons for leaving if s/he desires to do so and provide the participant id. Additionally, I will provide my contact details for participants to call me about any other issues that arise. |

*Explain the steps taken to manage any discomfort and/or distress etc (e.g. a helpline telephone number)*

**e How will data be stored securely during and after the study?**

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| The anonymized participants’ answers will be stored in the researcher offline database in the password-protected researcher university account in order to be analysed. The records of any emails between the researcher and the participants will be deleted after the appropriate data has been linked to the participant id. The email list of the participants will be deleted after the conclusion of the project. No personal or identifiable data for the participant will be stored by the researcher. All project data will be archived in accordance to the University of Southampton policy in the researcher UoS account. |

*Please note: Faculty of Medicine research conduct guidelines require data to be stored for 15 years. Audio recordings should be deleted following transcription.*

**f Raise any ethical problems not covered elsewhere and how you will deal with them.**

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| We believe that no other ethical problems arise from this study. |

*Highlight any additional ethical issues not covered elsewhere on the form (e.g. where the topic of an interview is sensitive or may cause friction between parties).*

Acknowledgement: this document is adapted from the Application Form developed by SoHPRS