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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**  **14/11/2018** | |

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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 13-11-18** |

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| **Short Title of Study *(Maximum Six Words)***  **Web Analytics to Complement PIL Feedback** |

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| **Full Title of Study (for which approval is sought)**  **Assessing the effect of employing Web analysis techniques to complement the public feedback received by researchers when developing Patient Information Leaflets (PILs) for low-risk Randomized Controlled Trials (RCTs).** |

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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:** | **V8**  **14/11/2018** |

***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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| **Web Analytics to Complement PIL Feedback** |

**1. BACKGROUND TO PROJECT**

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

**a Key research questions**

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| 1. Can Web text analytics enhance public feedback on Patient Information Leaflets (PILS)? (When given as reports to Principal Investigators for low-risk trials)    1. Can sentiment analysis help the principal investigators find PIL sections with issues by finding which sections produced highly emotive comments?    2. Can the objective content analysis of the PILs provide a helpful frame on the document difficulty to the principal investigators?    3. Can the use of a knowledge model help the principal investigators by finding the PIL sections that are similar to previously commented PILs? |
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*Specify the key questions that your study is designed to address*

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

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| Our previous research has found PILs are quite different from what the texts average people read on their day to day (Master Thesis). We also found that current PILs do not provide the reader with information that is easy to understand (Moult 2004) and Principal Investigators (clinical researcher) generally do not evaluate the patient comprehend the essential aspects of the trial before signing consent (NHS 2014)(NIHR 2014). Several independent studies have implicated that the current PILs are badly written and cannot meaningfully inform the patient (Moore & Savage 2002) (Reinert 2014) (Giles 2014) (Knapp 2011) (Saldaña 2015).  This is not to say, that no interest is given in to the design of PILs: UK regulation (MRC 2016) (HRA 2016-17) stablishes they purpose 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 ensures that every trial which recruit patients should create patient information that is understandable by the patients and take into account their circumstances. Furthermore, several of UK principal funding centres would ask the principal investigator to collaborate with a Patient and Public Involvement (PPI) group in a review process to ensure the information quality before granting the research funds.  Even with the previous steps recent research like the Health Research Board Trials Methodology and Networks (TMRN) collaboration with the James Lind Alliance and the TrialBank have identified several priority questions relating to the effects PPI groups have on PILs and RCTs (TMRN 2016). In particular, focus has been given to identifying which information should be given, finding the best designs to deliver the information and asses the effect of PPI collaboration on recruitment.  With this in mind, this research seeks to evaluate several techniques employed in analysing Web text and linking information based on relationship models. We propose to evaluate the use of sentiment and content analysis in conjunction with relationship database model and clustering to provide a Web platform in which clinical researcher and public reviewers could interact as a form to measure the quality of the text, identification of issues and easy of visualising the effects of PPI.  *(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 study is an exploratory randomised experiment comprising 5 non-medical online interventions with principal investigators in independent groups. The groups will be formed by principal investigators who will be presented feedback and Web analytic reports on one of their PILs for a low-risk trial and asked to revise it. The study will recruit principal investigators in the period between 26 Nov 2018 to 31 March 2019 as described below. |

*E.g. cross-sectional observational study*

**2. SAMPLE AND SETTING**

**a Specify and justify study size**

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| 30 principal investigators who have developed at least one PIL for a low-risk trial in the last 2 years. This will allocate 5 principal investigators in each group, which will be sufficient to uncover challenges and benefits of each Web Analytic technique, by reducing the systematic differences in the study while being in the scope of the research funding. |

*Include sample size calculation, if applicable*

**b Setting**

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| A request will be made to institutions associated to the University of Southampton that are closely related to clinical research: NIHR Southampton Clinical Research Facility, Southampton NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) and the Southampton Clinical Trial Unit to contact potential principal investigators in behalf of the student and present the study PIL and an invitation to participate. In addition, invitation emails will be sent to clinical researchers who have published a clinical trial in the UK Clinical Trials Gateway. The clinical researchers will be selected in base to their trial characteristics from a set of trials with interventions in the Southampton and which focus on adult patients.  An invitation to participate will be sent to the selected principal investigators, presenting the study and providing the project Website. The project Website will provide the interface for principal investigators to join the study by filling a joining form after reading the project information and accepting the research terms.  To join the study, the principal investigators will be asked to provide details about their current position, experience and demographics when filling the application form in the website as detailed in the joining and consent forms. This information will be used to assign the investigators into groups by employing a stratified randomization procedure, which will ensure systematic differences given by a difference of experience in creating PILs are minimised.  The principal investigators who join the study will be asked to provide a PIL for a low risk clinical trial who they have designed in the last 2 years, information about the recruitment/retention rates on their trial, and general information about their jobs and experience. This information will be collected in electronic format by a survey form and an upload webpage or by attaching PDF formats to the researcher university email account.  The principal investigators will be randomized into independent groups and presented feedback on their PILs. Depending on the intervention an additional report based on a Web analytic technique will be also given to the researchers. This information will be made available to the principal investigators participating in the study in the Website and as a PDF attachment to the clinical researcher email account.  The principal investigators will be asked to revise their leaflets based on the received feedback. The revised versions of the PILs will be collected via an upload Webpage or by having the clinical researcher to attach a PDF version of the file to the student university account. The divergences on readability and understandability between the original and final versions will be assessed to determine the effect of each Web Analytic technique in complementing the normal feedback received when developing a PIL. The results of the research will be used to present a conference paper and a brief will be uploaded to the Website. |

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

**c Details of proposed participants/sample**

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| *Principal investigators associated with the University of Southampton who have developed a PIL for a low-risk RCT study in the UK in the last 2 years.* |

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

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

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| None |

*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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| Clinical research institutions associated to the University of Southampton will be requested to contact potential principal investigators on behalf of the student. These institutions include: NIHR Southampton Clinical Research Facility, Southampton NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) and the Southampton Clinical Trial Unit. Additionally, the UK Clinical Trials Gateway website will be used to identify clinical researchers who are carrying out interventions in Southampton which have similar characteristics. |

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

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| An email on behalf of the student will be sent to local principal investigators by the clinical research institutions previously mentioned. This email will present the study and provide a link to the project Website were the clinical researcher may join the study. Also, An invitation email will be sent to the clinical researcher in the UK Clinical Trials Gateway Website. |

*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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| Principal investigators must have developed a PIL for a low-risk RCT in the UK in the last 2 years. The PIL must be in UK English and focus on informing adults with capacity of procedures focused on themselves, and must have a similar sample population to be grouped with the leaflets from the other principal investigators. |

**h How will consent be obtained**

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| Informed consent will be asked as part of the joining form in the Website. |

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

**information? No 🞏**

*(include Patient Information Sheet (PRINCIPAL INVESTIGATORS) 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 principal investigators will join by employing the Website interface in a purely electronic format. The principal investigators will express their consent by marking the “I wish to join” check box in the joining form prior to sending their information.

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

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| This study does not employ or request targeted information. The clinical researcher will join electronically by filling the joining form in the Website after having read the study information, the joining form ask for an email. This email is used to only to convey the feedback on the researcher’s PIL, and should the researcher decide so to receive the original and revised versions of the PIL in a PDF format. The researcher’s email will not be linked to the participant information or used as a participant identifier. Participants will be identified by randomly generated usernames. All further data-linking will be done by employing these usernames.  As part of the study the principal investigators will be asked to provide one of their PILs for a low-risk trial. This documents will be anonymised by deleting all references to persons, organizations, places or entities.  Information on the PILs’ trials recruitment/retention rates and sample characteristics will be requested as part of the analysis for this study. This information will be stored offline and will be used for comparative analysis by the researcher. No access to this data will be given to external parties, all results produced from this data will be made in an agglomerative format. |

*Anonymity:*

*i) Unlinked anonymity - Complete anonymity can only be promised if questionnaires or other requests for information are not targeted 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 principal investigators who choose to participate will be asked to provide a PIL for a low-risk trial they developed during the previous 2 years, information about the trial recruitment/retention rates, sample characteristics, and general information on their job and experience. They will be given feedback on their leaflets and asked to revise them and submit their final versions. As part of joining they will be asked to fill a demographics questionnaire and after concluding the study they will be asked to give feedback on the Web platform and the study. The expected required time for these tasks is ~ 1hr. |

*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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| We will measure the effect of Web analytics on enhancing the feedback commonly given to principal investigators when developing PILs for low-risk RCTs:   1. Measure the effect of employing sentiment analysis to find PIL sections which generated highly emotive responses. The principal investigators in one of the interventions will be given a report highlighting these sections in addition to the normal feedback. The quality will be assessed in both the original and final version of the PIL by employing the EQIP scale, and compared with the reported differences in both control interventions. 2. Measure the effect of reporting quantitative metrics on the PIL content. This report will objectively measure the readability difficulty of the document by employing common metrics in the analysis of Web text, and give recommendations on sentence structure for specific sections of the PIL. The improvement on PIL readability made by the principal investigators on this intervention will be compared with the results obtained in the control cases. 3. Measure the effect of employing a knowledge database to find sections of the PIL that are similar to previously commented PILs. Storing and reusing knowledge is one of the core process of the Web. The improvement of principal investigators who receive additional feedback from reviews of previous PILs will be compared with the results attained by the control cases. 4. Measuring the effect of employing a Web platform to structure and present the PIL feedback. The PIL readability improvement of one of the control groups will receive only the normal feedback given to the principal investigators when reviewing the PILs. This will be compared to the results attained in the other control group were the information will be given in traditional writing format. |

*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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| This study will assess the effect of employing Web analysis techniques in the revision process of PILs for low-risk RCTs in the UK. To do this, we will employ linear regression and clustering models to find if sentiment analysis, content analysis or knowledge modelling are significant factors in improving the readability of the PILs when compared to just employing PPI comments given either in a Web platform or in a traditional setting. |

**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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| In a previous pilot study, we assessed the types of comments given to the PILs, and found comments given to specific sections of the PILs text had significant correlations with the percentage of correct answers about the trial features given by the reviewers. Also, these comments were found suitable to be used in a relational database to automatically review other leaflets. |

*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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| No particular risk or harm to the principal investigators has been assessed by the researcher. They will be conducting tasks inherent to their work when developing new PILs for low risk clinical trials and thus they will not receive any further risk than normally expected. |

**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. |

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

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| The principal investigators will be given the researcher contact details in the Website to contact me on any issues that arise from this study. |

*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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| All project data will be archived in accordance to the University of Southampton policy in the researcher UoS account. Also, a digital copy of all the research data will be stored in a usb and given to the primary supervisor. Potential loss of information will be minimised by also delivering a printed version of the data to the primary supervisor. No personal or identifiable information will be stored or printed at any point during the study. |

*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