**CARDIFF UNIVERSITY**

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| **DENTAL SCHOOL ETHICAL APPROVAL FORM** |

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| For Office Use: Ref Meeting |

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| Tick one box: STAFF Project POSTGRADUATE Project UNDERGRADUATE ProjectTitle of Project \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name of researcher(s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name of supervisor (for student research) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| Does your research project involve: | YES | NO |
| 1 | Patients and users of the NHS. This is intended to mean all potential research participants recruited by virtue of the patient or user’s past or present treatment by, or use of the NHS. It includes NHS patients treated under contracts with private sector institutions. |  |  |
| 2 | Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined in 1. |  |  |
| 3 | Access to data, organs or other bodily material of past and present NHS patients |  |  |
| 4 | Fetal material and IVF involving NHS patients |  |  |
| 5 | The recently dead in NHS premises |  |  |
| 6 | The use of, or potential access to, NHS premises or facilities |  |  |

If you have answered **yes** to any of the above, then your project is not of relevance to the Dental School Research Ethics Committee and under NRES regulations; ethical approval **must** instead be sought from the appropriate NHS Local/Multi-centre Research Ethics Committee.

PLEASE PROVIDE AS A SEPARATE ATTACHMENT THE FOLLOWING DETAILS IN SUPPORT OF YOUR APPLICATION.

Protocol

1. Title of project.

*Please state the title of your project*

1. Purpose of project and its academic rationale.

*This section should state the aims and objectives of your study.*

*For example:*

*The aim of this study is to explore dental students' perceptions of professionalism in dentistry*

*You should also provide a brief background to the study. This should be brief and succinct. References can be used if needed. This section justifies your study so you may wish to briefly highlight.*

1. *what your topic is*
2. *Why your topic is important*
3. *Why you are doing this study (Any key studies which have been done before and where the gaps are)*

1. Description of methods and measurements (**Maximum 4 A4 pages**).

*This section should clearly outline the methods/ study design you are planning (like a basic recipe)*

*E.g.*

*"A cross sectional study of dental students"*

*"using survey methods"*

*"based on a previous validated questionnaire (please ensure questionnaire is in the appendix)"*

1. Participants: recruitment methods, number, age, gender, exclusion/inclusion criteria.

***Sample***

*Explain your study sample (e.g. a convenience sample all students registered as dental students during 2015/16). The expected sample size is: ... a sample size calculation has/ has not been carried out/ the sample is based on previous studies (reference).*

***Inclusion/exclusion criteria***

*Describe any criteria for inclusion/exclusion e.g. All students (year 1,2,3,4 and 5 BDS undergraduate student cohorts at Cardiff University in 2015/16) will be eligible to participate and there are no exclusion criteria.*

***Recruitment***

*Explain step by step how you will recruit your participants e.g. An email (attach the intended email to the appendix) will be sent to all registered undergraduate students via learning central to inform them of the study. Participant information will be sent with the email (attach the participant information to the appendix). Lectures will be identified which include the year 1,2,3,4 and 5 BDS undergraduate student cohorts.*

***Data collection***

*Specify the process for data collection e.g. Paper questionnaires (appendix x) will be delivered to lectures, with the permission of the lecturer during April 2016. Each cohort will be approached on two occasions. Participation will be optional. Students who wish to participate will complete the questionnaire at the beginning or end of the lectures and will be asked to return the information to a box at the front of the lecture theatre which will be collected by the student researcher at the end of the lecture.*

***Data management***

*Explain how you will deal with the data in a step by step manner. E.g. Data will be entered into SPSS for analysis by the student researcher. Data will be anonymous and no identifiable data will be collected. Explain how data will be stored and kept safe and when it will be destroyed. Data will stored in a secure, password-protected file within the University system. Data will be stored for X years in accordance with Cardiff University procedures for research data. Data will be destroyed by X in accordance with Cardiff University procedures.*

***Analysis***

*Explain your planned analysis:*

* *If your data is qualitative (i.e., it does not involve numerical data, such as from an unstructured interview) then explain what qualitative method of analysis you will use (e.g., thematic analysis).*
* *If your data is quantitative (i.e., it does involve numerical data) then explain what quantitative methods of analysis you will use (e.g., descriptive statistics and graphs and / or t-tests or ANOVA to look at differences between groups for a continuous outcome and / or chi-squared analyses for contingency table data and / or correlation/regression to explore the relationships between variables, etc.).*
* *Also if the data is quantitative, has a sample-size calculation been carried out and, if so, by whom? (A sample-size calculation tell you how large your sample size needs to be in order to obtain “good” results.) If a sample-size calculation has NOT been carried out, explain why not (e.g., overall sample sizes are capped at some limit that is outside your control).*
* *If your study involves mixed data (both qualitative and quantitative) then carry out ALL of the steps above AND also explain how you will combine the analyses of the qualitative and quantitative data (i.e., “triangulation” e.g. by informally comparing and contrasting the results of both to see if they agree or not).*
1. Consent and participant information arrangements, debriefing (*Please attach intended information and consent forms).*

*Explain your consent process. E.g. Participants will be asked to indicate that they have read the participant information and that they agree to participate. Participants will be able to omit questions that they do not wish to answer/ participants will be able to indicate that they do not wish to answer a question.*

*Participants will be informed that data collection is anonymous (participant information appendix x) and that they will not be able to withdraw information once it has been submitted.*

*Explain any debrief and attach it as an appendix if needed. This may include simple statements for example, if you have any concerns, you can contact the student wellbeing centre for advice (contact number/email)*

*Remember to carry out a final spell check of all documents relating to your application (e.g., information sheets, debrief documents, emails of invitation, questionnaires, etc.).*

*If you are an undergraduate or postgraduate student, remember to show your supervisor the entire application involving all documentation and to get their final approval* ***before*** *you submit your application to the DSREC.*

1. A clear but concise statement of the ethical considerations raised by the project and how you intend to deal with them.

Issues can include the management of data, anonymisation, any questions which would cause distress or concerns.

Remember to include:

Estimated start date and duration of project.

Put a version number and date at the bottom of the protocol (v0.01. Date)

**About your project**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Yes | No | N/A |
| 1 | Will you describe the main experimental procedures to participants in advance, so that they are informed about what to expect? |  |  |  |
| 2 | Will you tell participants that their participation is voluntary? |  |  |  |
| 3 | Will you obtain written consent for participation? |  |  |  |
| 4 | If the research is observational, will you ask participants for their consent to being observed? |  |  |  |
| 5 | Will you tell participants that they may withdraw from the research at any time and for any reason? |  |  |  |
| 6 | With questionnaires, will you give participants the option of omitting questions they do not want to answer? |  |  |  |
| 7 | Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs? |  |  |  |
| 8 | Will you debrief participants at the end of their participation (i.e. give them a brief explanation of the study)? |  |  |  |

If you have ticked **No** to any of Q1-8, please give an explanation on a separate sheet.

(Note: N/A = not applicable)

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| --- | --- | --- | --- | --- |
|  |  | Yes | No | N/A |
| 9 | Will you project involve deliberately misleading participants in any way? |  |  |  |
| 10 | Is there any realistic risk of any participants experiencing either physical or psychological distress or comfort? If **Yes**, give details on a separate sheet and state what you will tell them to do if they should experience any problems (e.g. who they can contact for help). |  |  |  |

If you have ticked **Yes** to Q9 or 10 please give a full explanation on a separate sheet.

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| --- | --- | --- | --- | --- |
|  |  | Yes | No | N/A |
| 11 | Do participants in your research fall into any of the following special groups?  |  |  |  |
|  | **Please note that you may also need to obtain satisfactory CRB clearance (or equivalent for overseas students).** | School children (under 18 years of age) |  |  |  |
| People with learning or communication difficulties, or vulnerable adults |  |  |  |
|  |  |  |
| People in custody |  |  |  |
| People engaged in illegal activities (e.g. drug-taking) |  |  |  |

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|  |  | Yes |
| 12 | I confirm that the relevant health and safety measures, in accordance with University policy and School requirements, have been taken into account for the proposed research.<http://www.cf.ac.uk/osheu/index.html> |  |
| 13 | I confirm that the relevant equality and diversity considerations, in accordance with University policy and School requirements, have been taken into account for the proposed research.[http://www.cardiff.ac.uk/govrn/cocom/equalityanddiversity/2011%20October%20Equality%20&%20Diversity%20Policy%20FINAL.doc](http://www.cardiff.ac.uk/govrn/cocom/equalityanddiversity/2011%2520October%2520Equality%2520%26%2520Diversity%2520Policy%2520FINAL.doc) |  |
| 14 | I confirm that where appropriate, I have read and understood CU's Interim Guidance for researchers Working With Children and Young People which forms part of the Safeguarding Children and Vulnerable Adults Policy. The Interim Guidance is at Appendix 4, Page 28 of this Policy.[http://www.cardiff.ac.uk/govrn/cocom/resources/2010%20November%20Safeguarding%20Children%20&%20VA's.doc](http://www.cardiff.ac.uk/govrn/cocom/resources/2010%2520November%2520Safeguarding%2520Children%2520%26%2520VA%27s.doc) |  |

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|  |  | Yes | No |
| 15 | Does the study involve the collection or use of human tissue (including, but not limited to blood, saliva and bodily waste fluids)? |  |  |
|  | If yes, has a copy of the submitted application form and any supporting documentation been emailed to the Human Tissue Act Compliance Team (HTA@cf.ac.uk)? A decision by the Dental School Research Ethics Committee will only be made once the documents have been received back from the HTA Team. |  |  |
|  |  | Yes | No |  |
| 16  | Has your protocol been subject to external peer review?  |  |  |  |
|  | If no, has your protocol been reviewed via the school internal peer review mechanism (or by your project supervisor in the case of FYPs)? (Cardiff University requires that peer review be undertaken of all projects prior to research ethics scrutiny – you are required to have your project reviewed before submission to DSREC)Name of reviewer ………………… Signature of reviewer ……………………NB FINAL YEAR PROJECTS do not need external peer review but your protocol needs to be approved by your Supervisor. By entering your supervisors name in the above box you are declaring that your supervisor has seen and approved your protocol. |  |  |  |

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|  |  | *Yes* | *No* |
| 17 | Does your study include the use of a drug?Is yes, you will need to contact Research Governance before submission (resgov@cf.ac.uk) |  |  |

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|  |  | *Yes* | *No* |
| 18 | Had due regard be given to the ‘prevent duty’ in particular to prevent anyone being drawn into terrorism?<https://www.gov.uk/government/.../Prevent_Duty_Guidance_For_Higher_Education><http://www.cardiff.ac.uk/public-information/policies-and-procedures/freedom-of-speech> |  |  |

*IF ANY OF THE ABOVE INFORMATION IS MISSING, YOUR APPLICATION WILL BE RETURNED.*

There is an obligation on the lead researcher to bring to the attention of the Dental School Research Ethics Committee any issues with ethical implications not clearly covered by the above checklist. In signing this form the applicant confirms that he/she has taken into account health and safety measures, in accordance with University policy and School requirements, for the proposed research. The applicant should consider any specific risks (a) to the CU employee (e.g. if the research is conducted off site and/or where the project involves a lone fieldworker) and (b) to the research participant.

***THREE copies of this form, your proposal, information, consent sheet, and (debrief sheet if any) should be submitted to Beverley Jones, Secretary, Dental School’s Research Ethics Committee, Rm128, First Floor, Dental School, Heath Park, Cardiff - Email:*** jonesB5@cardiff.ac.uk***.***

***Please ensure that all documentation contains a footnote, a version number and date.***

**E-MAIL APPLICATIONS IN THE ABSENCE OF HARD COPIES CANNOT BE ACCEPTED.**

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Print Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(*UG or PG Researcher(s), if applicable)*

*NOTE TO SUPERVISORs: by signing this form you are confirming that you have read and are happy with the accompanying protocol for this study.*

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Print Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(*Lead Researcher or Supervisor)*

**STATEMENT OF ETHICAL APPROVAL**

This project has been considered using agreed School procedures and is now approved.

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Print Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(*Chair, School Ethics Committee)*

*v 09/15*

*Submission checklist*

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| --- | --- |
| Ethics Form Completed |  |
| Ethics form signed by student |  |
| Ethics form signed by supervisor |  |
| Protocol all sections complete(Including a plan for data analysis and statements about data protection, storage and destruction)Version number |  |
| Protocol signed and dated  |  |
| Appendices Questionnaires/ question guidesParticipant information (with version number)Invitation Announcements/emails textDebrief information |  |