# UREC 3 Application for Research Ethics Approval FOR Higher Risk Social science type studies WITH HUMAN PARTICIPANTS UNDERTAKEN BY STUDENTS ON TAUGHT COURSES

Thisformisdesignedtohelpstudents and their supervisorstocompleteanethicalscrutinyofproposed research. TheUniversityResearchEthicsPolicy ([www.shu.ac.uk/research/excellence/ethics-and-integrity/policies](https://www.shu.ac.uk/research/excellence/ethics-and-integrity/policies)) shouldbeconsultedbeforecompletingthisform. The initial questions are there to check that completion of the UREC3 is appropriate for this study. The finalresponsibility forensuringthatethicalresearchpracticesare followedrestswiththe supervisor forstudent research.

Notethatstudentsandstaffareresponsibleformakingsuitablearrangements to ensure compliance with the General Data Protection Act (GDPR). This involves informing participants about the legal basis for the research, including a link to the University research data privacy statement and providing details of who to complain to if participants have issues about how their data was handled or how they were treated (full details in module handbooks). In addition, the act requires data to be kept securely andthe identity of participants to beanonymised. Theyare also responsiblefor followingSHU guidelinesabout dataencryption and research data management. Guidance can be found on the SHU Ethics Website [www.shu.ac.uk/research/excellence/ethics-and-integrity](https://www.shu.ac.uk/research/excellence/ethics-and-integrity)

Please note that it is mandatory for all students to only store data on their allotted networked F drive space and not on individual hard drives or memory sticks etc.

The present formalsoenablestheUniversityandCollege to keepa recordconfirmingthatresearch conductedhasbeensubjectedtoethical scrutiny.

Theformmustbecompletedbythestudentandthesupervisorand independently reviewed by a second revieweror moduleleader(additional guidance can be obtained fromyour College Research Ethics Chair[[1]](#footnote-2)).Inallcases,itshouldbecounter-signedand kept asarecord showingthat ethicalscrutinyhasoccurred. Some courses may require additional scrutiny. Studentsshouldretainacopy forinclusionintheirresearchprojects,anda copyshould be uploaded to the relevant module Blackboard site.

Pleasenote that itmaybenecessarytoconduct ahealthandsafetyriskassessmentforthe proposedresearch. Furtherinformationcanbeobtainedfrom theUniversity’s Health and Safety Websitehttps://sheffieldhallam.sharepoint.com/sites/3069/SitePages/Risk-Assessment.aspx

## Checklist Questions to ensure that External Approval for the research is not required

| **Question** | **Yes/No** |
| --- | --- |
| Does the research involve? | Yes |
| * Patientsrecruitedbecauseoftheir pastorpresentuseoftheNHS |  |
| * Relatives/carersofpatientsrecruitedbecauseof theirpastorpresentuse oftheNHS | Yes |
| * Access to NHS staff, premise or resources | Yes |
| * Accesstodata, organs,orother bodilymaterial of pastorpresent NHS patients | Yes |
| * Foetalmaterial andIVFinvolvingNHS patients | No |
| * TherecentlydeadinNHS premises | No |
| * Prisonersorotherswithin thecriminal justicesystem recruitedfor health-relatedresearch | Yes |
| * Police,court officials, prisoners,orotherswithin thecriminal justicesystem | No |
| * Participantswhoareunable toprovideinformed consentdue totheir incapacityeveniftheproject isnothealthrelated | Yes |
| * Is this an NHS research project, service evaluation or audit?   *ForNHS definitionspleaseseethefollowingwebsite*  <http://www.hra.nhs.uk/documents/2013/09/defining-research.pdf> | Yes |

Ifyouhaveanswered**YES**to any of the above questions,thenyou**MUST consult with your supervisor** to obtain research ethicsfrom the appropriate institution outside the university. This could be from theNHS or His Majesty’s Prison and Probation Service (HMPPS) under their independent Research Governanceschemes.Furtherinformationisprovidedbelow.<https://www.myresearchproject.org.uk/>

## SECTION A: Research Protocol

**1. Student Name:**

**College:**

**Department:**

**Email address:**

**2. Title of research:       CRITICALLY EVALUATING THE COUNSELLING, AS WELL AS THERAPY SERVICES TO REDUCE THE IMPACT OF POOR MENTAL HEALTH ON THE IMMUNE SYSTEM OF PREGNANT WOMEN: A CASE STUDY OF NHS**

**3. Supervisor:**

**Supervisor’s email address:**

**4. Proposed duration of project**

**Start date:      End Date:**

**5. Location of research if outside SHU:**

**6. Background to the study and scientific rationale** (500-750 words approx.)

|  |
| --- |
| Pregnant women have faced some issues of poor mental health as physical conditions were also affected. This research proposal has identified the impact of regular counselling and therapy to minimise poor mental health issues of pregnant women in the UK. NHS has taken initiative to minimise poor mental health issues among pregnant women. Depression and anxiety are the most common mental health issues faced by pregnant women. NHS has tried to mitigate the issue by conducting ***PATH (Perinatal Mental Health)*** (Ncbi.nlm.nih.gov, 2023)***.*** Using this strategy, the organisation has tried to provide a good quality of life to the patients and their families. Pregnant women have faced the issue most during this global pandemic situation for lack of mind-refreshing activities.  The problem of poor mental health of pregnant women can affect the future generation. The public health sector of the UK, NHS has taken the important initiative to provide a depression-free life to pregnant women. Based on the opinion of Filippetti, Clarke & Rigato (2022), in the covid-19 pandemic situation, the anxiety rate among women has increased and 40% of women have the symptoms of depression. Focusing on the present vulnerable situation of mental health issues of the UK pregnant women, NHS has tried to mitigate the issue with effective processes. The issues of mental health can be rectified by delivering mental support to the patient. Focusing on pregnant women, have already faced some physical problems during pregnancy. Family issues and excessive work pressure are other reasons to increase mental health issues. NHS has faced some issues to deliver counselling and relevant therapies to patients; those have also been managed by analysing risks and suggesting some mitigation strategies.  The research about poor mental health problems of pregnant women has continued focusing on the urban area as rural individuals have faced fewer mental health issues than the urban population. The actual issue of this study is to increase the poor mental health rate among pregnant women. According to the words of Ahmad & Vismara (2021), pregnant women have faced both physical and mental issues, which have increased their depression and anxiety level. It is a big issue as the poor mental health of a pregnant woman has put an impact on the future generation.  At present, NHS has taken the initiative of the PATH (Perinatal Mental Health) program to conduct therapy for poor mental health problems. The depression and anxiety issues of pregnant women can be minimised by conducting more effective solutions, such as different types of mental health programs and providing mental support to the victims. In the views of Nath et al. (2019), a significant psychological change has been found among all pregnant women. Mainly the urban population are affected by this issue mostly as excessive stress from family issues and work pressure is the main reason for depression. Minimising the challenge, the study has recommended some strategic solutions to the NHS to deliver more efficient counselling to patients. |

**7.** **Main research questions**

|  |
| --- |
| * To discuss the concept to deal with the adverse impact of poor mental health on the immune system during pregnancy * To analyse the effectiveness of counselling, as well as therapy services of NHS in developing poor mental health of pregnant women * To identify the main issues faced by NHS to deliver therapy services to pregnant women for reducing mental health issues * To evaluate some effective solutions to NHS to minimise challenges in the counselling process |

**8. Summary ofstudy design, procedures, types of data collection, and proposed data analysis.**

|  |
| --- |
| Research approach The research approach will guide the researcher to complete the process in a structural method. The researcher of this study will follow a ***deductive research approach*** to apply theory to identify results. According to the words of Pearse (2019), the deductive research approach has suggested confirming or rejecting the research hypothesis by conducting an analysis using the existing theories. The researcher of this study will follow the research approach to analyse the impact and issues of counselling faced by NHS to deliver services for reducing mental health issues during pregnancy time. This research approach will guide the researcher to analyse relevant theories relating to the topic, by which the overall quality of the study will be developed. This study will not create a theory, for which the inductive research approach will not be followed in this study. Research strategy The researcher will select the ***qualitative research*** strategy to conduct primary and secondary qualitative data collection and data analysis processes. According to the words of Malmqvist et al. (2019), the research strategy is an important factor in conducting research, by which, the researcher can designs the data collection and analysis process. Quantitative research design has not been followed by the researcher as the descriptive opinion of the medical practitioners is needed to complete the research. Applying qualitative research in this study, the researcher can conduct a brief analysis of the collected data.  The study will follow both primary and secondary research processes to conduct interview analysis and thematic analysis. As per the opinion of Newman & Gough (2020), the Primary research process has been conducted to collect recent data about the topic and secondary research has assisted to collect other information related to the topic. The study will follow the strategy to select both types of research to make the study more valuable. The researcher will conduct primary data collection and data analysis process by following the primary research process. In addition, a secondary research process has been followed to select relevant journals and analyse those with thematic analysis. Data collection The study will follow the ***primary data collection process*** by conducting an interview with 3 medical practitioners to collect relevant data about the topic. In the opinion of Agung & Darma (2019), primary data collection has assisted to collect recent data from relevant sources by conducting surveys or interviews. The researcher of this study has made a questionnaire with 3 questions to interview 3 medical practitioners of the NHS. Present issues of therapy services of NHS have been collected by conducting a survey on the medical practitioners of this medical institute. In addition, a ***secondary qualitative data collection*** process has also been followed by this study to collect relevant data from the previous era. Analysis The data analysis section will consist of primary qualitative data analysis and secondary qualitative data analysis processes. The researcher of this study will analyse the interview results by following ***narrative analysis*** to analyse collected primary data. However, the ***thematic analysis*** will be done by the researcher to analyse selected articles. Based on the opinion of Lemon & Hayes (2020), primary data analysis assists in identifying the results of recent data and secondary data analysis helps to measure previous situations. Focusing on these two factors, the researcher will follow a brief interview analysis by describing three different opinions of three medical practitioners of the NHS. |

## SECTION B: Ethics Proforma

**1. Describe the arrangements for recruiting, selecting/sampling potential participants.** This should clearly indicate if participants with a particular health condition or healthy volunteers are being recruited, the inclusion and exclusion criteria, the sample sizes with power calculations if appropriate.**You mustinclude copies of any advertisements for participants or letters/emails to individuals or organisations inviting participation.**

|  |
| --- |
| Experiment design There are two experiments, which will be done by the researcher to conduct the research successfully. The researcher will make a ***questionnaire consisting*** of ***3 questions*** related to the poor mental health issues of pregnant women. |

**2. What is the potential for participants to benefit from participation in the research?**

|  |
| --- |
| The potential participants of this study are efficient medical practitioners with sufficient knowledge about the counselling process to reduce mental health issues. |

**3. Describe any possible negative consequences of participation in the research along with the ways in which these consequences will be limited.** This includes the use of participants time, or any discomfort both physical and psychological.

|  |
| --- |
| In the case of identifying vulnerable participants, the researcher will manage the issues by changing the participants. The researcher will maintain research ethics to complete the research by maintaining its authenticity. All the participants will be provided with relevant information about the research and participants will be asked to fill up the consent form. Their personal data will not be disclosed under any circumstances. |

**4.Describe the arrangements for obtaining participants' consent.** This should include copies of the participant information sheet and the consent formsthat participants will receive. If children or vulnerable people are to be participants in the study details of the arrangements for obtaining consent from those acting in *loco parentis* or as advocates should also be provided.

*Note: Vulnerablepeopleinclude children and youngpeople,peoplewithlearning disabilities,people whomaybelimitedbyageor sickness, pregnancy, people researched because of a condition they have,etc. See full definition on ethics website in the document* [***Code of Practice for Researchers Working with Vulnerable Populations***](https://www.shu.ac.uk/research/excellence/ethics-and-integrity/guidance) *(under the Supplementary University Polices and Good Research Practice Guidance)*

|  |
| --- |
| In addition, the opinions of the medical practitioners will not be manipulated in this study. In the views of Nguyen & Dellaportas (2020), maintaining ethics in the research development process will make the research more valuable and increase its future acceptance. |

**5. Describe how participants will be made aware of their right to withdraw from the research.** This should also include information about participants' right to withhold information and a reasonable time span for withdrawal should be specified.

|  |
| --- |
| In the secondary data analysis process, the researcher will put ***authentic referencing*** in case of using actual data of the selected articles. The study will maintain authenticity in both primary and secondary research processes, which will increase its value. |

**6.** **If your project requires that you work with vulnerable participants,please describe how you will implement safeguarding procedures during data collection.**

*Note: Vulnerablepeopleinclude children and youngpeople,peoplewithlearning disabilities,people whomaybelimitedbyageor sickness, pregnancy, people researched because of a condition they have,etc. See full definition on ethics website in the document* [***Code of Practice for Researchers Working with Vulnerable Populations***](https://www.shu.ac.uk/research/excellence/ethics-and-integrity/guidance) *(under the Supplementary University Polices and Good Research Practice Guidance).*

|  |
| --- |
| In the case of identifying vulnerable participants, the researcher will manage the issues by changing the participants. The potential participants of this study are efficient medical practitioners with sufficient knowledge about the counselling process to reduce mental health issues. |

**7. If Disclosure and Barring Service (DBS) checks are required, please supply details.**

|  |
| --- |
| Not required |

**8. Describe the arrangements for debriefing the participants.** This should include copies of the information that participants will receive where appropriate.

|  |
| --- |
| The researcher will use an “interview questionnaire” to conduct the interview, which is one of the most important resources of this study. In addition, continuing the secondary data collection method, the researcher will select some relevant articles, which are measured as another resource of this study. In addition, the research needs a recorder to record the interviews of the medical practitioners. Interview browsing is an important factor for this study, for which, the researcher has to arrange the internet facility. |

**9. Describe the arrangements for ensuring participant confidentiality.** This should include details of:

* + how data will be stored to ensure compliance with data protection legislation (GDPR)
  + how results will be presented
  + exceptional circumstances where confidentiality may not be preserved
  + how and when confidential data will be disposed of

|  |
| --- |
| The researcher will not disclose the interview recording to maintain the confidentiality of the study. |

**10. Are there any conflicts of interest in you undertaking this research?** (E.g., are you undertaking research on work colleagues or in an organisation where you are a consultant?) Please supply details of how this will be addressed.

|  |
| --- |
| No |

**11.What are the expected outcomes, impacts and benefits of the research?**

|  |
| --- |
| The expected outcome can be positive to know the perception of the therapy and counselling activities that are provided by NHS organisations for pregnant women. Proper analysis has been done in the entire research by which mental health conditions of women can be understood through the interview session. Along with that, the NHS's therapy process will get to know the way they implement counselling procedures for mental health development activities. Two theories have been considered such as HBM and social cognitive theory. These theories help to improve the healthcare operations of all care seekers. This study has included primary and secondary data collection methods by which all data can be gathered from three participants. With the help of the interview session, current data can be obtained based on the mental health issues of pregnant women.  Two methodologies have been considered where the secondary method indicates online articles and websites to collect previous data. On the other hand, the primary method allows current data from 3 medical practitioners of the NHS so that the implication of therapy and counselling services can get to know based on mental health development. |

**12.Please give details of any plans for dissemination of the results of the research.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cost  | **Section** | **Cost** | | --- | --- | | Questionnaire formation | £21 | | Recording cost | £65 | | Internet cost | £47 | | Others | £20 | |  | £153 |   **Table 1: Cost of the research**  (Source: Created by author) Time line  | **Tasks** | **Week 1** | **Week 2** | **Week 3** | **Week 4** | **Week 5** | **Week 6** | **Week 7** | **Week 8** | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Establishing aims and objectives for the research** |  |  |  |  |  |  |  |  | | **Selecting appropriate design, approach and strategy for the research** |  |  |  |  |  |  |  |  | | **Designing questions for the interview** |  |  |  |  |  |  |  |  | | **Conducting interview** |  |  |  |  |  |  |  |  | | **Collecting secondary data** |  |  |  |  |  |  |  |  | | **Data analysis** |  |  |  |  |  |  |  |  | | **Deducting conclusions** |  |  |  |  |  |  |  |  | | **Documenting the results** |  |  |  |  |  |  |  |  | | **Prepare and submit the final research project** |  |  |  |  |  |  |  |  |   (Source: Created by author) |

## SECTION C

## HEALTH AND SAFETY RISK ASSESSMENT FOR THE RESEARCHER

1. **Do you have a health and safety risk analysis for the procedures to be used?**(Discuss this with your supervisor)

Yes

No

If **YES** the completed Health and Safety Risk Assessment form should be attached. A standard risk assessment form can be generated through the Awaken system (<https://shu.awaken-be.com>). Alternatively if you require more specific risk assessment, e.g. a COSHH, attach that instead.

1. **Will the data be collected fully online (no face-to-face contact with participants)?**

Yes (See the safety guidance for online research[[2]](#footnote-3) and **go to question 7b**).

No (Go to question 3)

1. **Will the proposed data collection take place on campus?**

Yes (Please answer questions 5 to 8)

No (Please complete all questions and consult with your supervisor or

HoD for current guidance and permission for face-to-face research outside the university)

1. **Where will the data collection take place?**

(Tick as many as apply if data collection will take place in multiple venues)

|  | **Location** | **Please specify** |
| --- | --- | --- |
|  | Researcher's Residence |  |
|  | Participant's Residence |  |
|  | Education Establishment |  |
|  | Other e.g. business/voluntary organisation, public venue |  |
|  | Outside UK |  |

1. **How will you travel to and from the data collection venue?**

On foot  By car  Public Transport

Other (Please specify)

Please outline how you will ensure your personal safety when travelling to and from the data collection venue.

|  |
| --- |
| Using mask and sanitizer. |

1. **How will you ensure your own personal safety whilst at the research venue?**

|  |
| --- |
| NHS premises is enough safe for the individuals. |

1. **Are there any potential risks to your health and wellbeing associated with either (a) the venue where the research will take place and/or (b) the research topic itself?**

None that I am aware of

Yes (Please outline below including steps taken to minimise risk)

|  |
| --- |
|  |

1. **If you are carrying out research off-campus, you must ensure that each time you go out to collect data you ensure that someone you trust knows where you are going (without breaching the confidentiality of your participants), how you are getting there (preferably including your travel route), when you expect to get back, and what to do should you not return at the specified time.**

Please outline here the procedure you propose using to do this.

|  |
| --- |
| The researcher will follow ethics and authenticity in the overall data process. |

**Insurance Check**

The University’s standard insurance cover will not automatically cover research involving any of the following:

i) Participants under 5 years old

ii) Pregnant women

iii) 5000 or more participants

iv) Research being conducted in an overseas country

v) Research involving aircraft and offshore oil rigs

vi) Nuclear research

vii) Any trials/medical research into Covid19

If your proposals do involve any of the above, please contact the Insurance Manager directly ([fin-insurancequeries-mb@exchange.shu.ac.uk](mailto:fin-insurancequeries-mb@exchange.shu.ac.uk)) to discuss this element of your project.

## Adherence toSHU PolicyandProcedures

| **Ethics sign-off** | |
| --- | --- |
| **Personalstatement** | |
| Icanconfirm that:   * Ihave readtheSheffieldHallamUniversity ResearchEthicsPolicyandProcedures * Iagreetoabideby itsprinciples. | |
| **Student** | |
| Name: | Date: |
| Signature: | |
| **Supervisorethicalsign-off** | |
| Icanconfirm that completionofthisform hasnot identifiedtheneedforethical approval by theTPREC/CREC oranNHS,Social Careor otherexternal REC. Theresearchwill notcommence until anyapprovals requiredunderSections4&5havebeen received and any necessary health and safety measures are in place. | |
| Name: | Date: |
| Signature: | |
| **Independent Reviewerethicalsign-off** | |
| Name: | Date: |
| Signature: | |

**Please ensure that you have attached all relevant documents. Your supervisor must approve them before you start data collection:**

| **Documents** | **Yes** | **No** | **N/A** |
| --- | --- | --- | --- |
| Research proposal if prepared previously |  |  |  |
| Any recruitment materials (e.g., posters, letters, emails, etc.) |  |  |  |
| Participant information sheet[[3]](#footnote-4) |  |  |  |
| Participant consent form[[4]](#footnote-5) |  |  |  |
| Details of measures to be used (e.g., questionnaires, etc.) |  |  |  |
| Outline interview schedule / focus group schedule |  |  |  |
| Debriefing materials |  |  |  |
| Health and Safety Risk Assessment Form |  |  |  |

1. College of Social Sciences and Arts - Dr. Antonia Ypsilanti ([a.ypsilanti@shu.ac.uk](mailto:a.ypsilanti@shu.ac.uk) )

   College of Business, Technology and Engineering- Dr. Tony Lynn ([t.lynn@shu.ac.uk](mailto:t.lynn@shu.ac.uk))

   College of Health, Wellbeing and Life Sciences- Dr. Nikki Jordan-Mahy ([n.jordan-mahy@shu.ac.uk](mailto:n.jordan-mahy@shu.ac.uk) ) [↑](#footnote-ref-2)
2. Safety guidance for online research includes information on how to set up online surveys and/or conduct online interviews/focus groups. These guidelines can be found in BB. Please check with your supervisor/module leader. [↑](#footnote-ref-3)
3. It is mandatory to attach the Participant Information Sheet (PIS) [↑](#footnote-ref-4)
4. It is mandatory to attach a Participant Consent Form, unless it is embedded in an online survey, in which case your supervisor must approve it before you start data collection [↑](#footnote-ref-5)