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| Title of PhD project         | <b>Improving informed consent for clinical vaccine trials in pregnant women in Uganda</b>  |       |
| Supervisor                   | <a href="#">Professor Kirsty Le Doare</a>  | SGUL  |
| Co-Supervisor                | <a href="#">Professor Janet Seeley</a>   | LSHTM |
| Brief description of project | <p>Most studies examining the relationship between health literacy and informed consent conclude that patients with low health literacy are less likely to participate in decision making concerning their health care. Much of the written material related to the informed consent is too difficult for health care users to understand, thus disabling individual choice to join a clinical trial.</p> <p>Traditionally the quality of the informed consent process and its effects have been assessed in three important dimensions: information, comprehension, and voluntariness. Yet many factors can influence a research participant’s understanding and experience of the information provided, such as the type of study, its cultural setting, local beliefs and customs, as well as the participant’s language, religion, level of education, and socio-economic status. Whilst it is ultimately the pregnant woman who signs the informed consent form, in sub-Saharan Africa, the engagement of third parties, who are important in the decision-making processes of individuals – husbands, mothers-in-law, community leaders are key to the informed consent process. Moreover, discussions, opinions, and statements that are easily available on the internet or within communities can include misinformation about immunisation that can lead to lack of trust in vaccination, unwarranted fear, or even refusal to be vaccinated. While care should be taken to ensure that this decision making does not undermine the autonomy of pregnant women, not planning for third-party consent could be a major encumbrance for research conducted in sub-Saharan Africa. Therefore, a dialogue is necessary to take into account the wider community concerned with consenting in this setting.</p> <p>This project aims to answer research questions related to informed consent in low-literacy populations, including what the drivers and barriers to informed consent are and who is involved in weighing up information and in consenting decisions. The candidate will also work with communities to</p> |       |

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|   | develop and test a toolkit of interventions based these findings to improve consent and retention of information. The successful candidate will develop skills in qualitative research, community engagement and translational science to improve the equal inclusion of women into clinical trials. |
| Skills we expect a student to develop/acquire whilst pursuing this project              | The project will provide training in quantitative and qualitative data collection and analysis, qualitative skills, translational research and interdisciplinary working with social scientists and clinical trialists.  |
| Particular <u>prior</u> educational requirements for a student undertaking this project | MSc in social sciences/qualitative research training   |
| Project key words   | Vaccination<br>Pregnancy<br>Children<br>Hesitancy<br>Clinical trial  |
| Possible under 1+4 route? Master's options identified.                                  | Yes<br>SGUL – MRes Clinical Research<br>SGUL – MSc Global Health   |
| MRC Core Skills developed through this project  | Quantitative skills<br>Interdisciplinary skills  |
| MRC LID themes  | Global Health<br>Translational and Implementation Research   |
| Further reading   | <a href="#">Maternal Vaccination in Uganda: Exploring Pregnant Women, Community Leaders and Healthcare Workers' Perceptions</a><br><br><a href="#">Exploring informed consent in HIV clinical trials: A case study in Uganda</a><br><br><a href="#">Vaccination in Pregnancy—Recent Developments</a> |