

*Building Intrapartum Research through Health- a whole system approach to understanding and contextualising physiological labour and birth (BIRTH) (COST Action IS1405)*

*Report of an STSM:*

*Home birth in Denmark: knowledge translation and research to inform Homebirth Guidelines in Northern Ireland*



*DATE OF STSM: 3rd -9th September 2017*

*HOST: Dr Jette Clausen, Metropol University College, Copenhagen Denmark*

*Chief Investigator (CI): Dr Patricia Gillen, Southern Health and Social Care Trust/ Ulster University, Northern Ireland*

*Co-Investigator (CO): Dr Jette Clausen, Metropol University College, Copenhagen Denmark*

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## Abstract

In Northern Ireland, home birth accounts for approximately 1% of all 26,500 births per annum. This is set against a backdrop of a regional maternity care strategy (DHSSPS 2012) which promotes choice and the normalisation of birth; particularly for those women with a straightforward pregnancy. However, service users and providers acknowledge that when women request a homebirth, responses range from supportive, to some resistance, to refusal to 'allow' the woman to plan to birth at home. In contrast, Danish legislation requires that a woman is supported to have a homebirth and has a system ensures that homebirth are facilitated as part of mainstream maternity care with recent years evidencing a steady increase in the percentage of homebirths.

The aim of the STSM was to explore the context and culture of homebirth service provision in Denmark to inform the development of Homebirth guidelines in Northern Ireland.

This was a two phase study involving a documentation analysis and interviews with Homebirth midwives, academics and researchers in different regions in Denmark.

Ethical approval for the study was obtained from Ulster University. Access to participants was facilitated by by Dr Jette Clausen, Metropol University, Copehagen.

Interviews revealed a context and culture in Denmark that is supportive of homebirth with a range of service provision models that are designed to meet the needs of women planning birth at home. In one of the regions where interviews took place, the growing numbers of homebirths has led to an increase in the numbers of homebirth midwives to meet demand. There is an expectation that all women who request a homebirth should be facilitated to have one. Transfer to hospital from home during labour is not seen to be problematic but indicative of good decision- making by the mother and midwife and includes transfer via taxi or own car. Ambulance transfer is available if required for an emergency transfer through a specific telephone number for healthcare professionals. Good relationships between hospital midwives and Home birth midwives are valued and see Homebirth Midwives accompany women into hospital and stay with her promoting continuity of care. This information has been fed back to the Homebirth Guideline Development Group and has helped to shape the thinking around transfer during labour; the arrangements for transfer and the perception of transfer as a positive reflection of good decision-making.

**Key words:** Homebirth, Culture, Guidelines

## Introduction:

Where a woman gives birth impacts not only on the type of birth that she has and experiences, but also the number of interventions that the woman and baby are exposed to during labour and birth (Hutton *et al.* 2016; Halfdensdottir *et al.* 2015; Blix *et al.* 2012, Brocklehurst *et al.* 2011; Davis *et al.* 2011; Hollowell *et al.* 2011). A Cochrane review by Olsen & Clausen (2012, p 2) concluded that there was '*no strong evidence...to favour either planned hospital birth or planned home birth for low-risk pregnant women*'. However, there is evidence to support the assertion that women who plan to give birth in a midwife-led unit or at home have lower numbers of interventions than if they gave birth in an obstetric unit. Good practice evidence based guidelines including NICE Intrapartum guideline (CG190, 2014) recommend that low-risk nulliparous women be advised that if birthing at home, there is a '*small increase in the risk of an adverse outcome for the baby*' (p.6). However, the perinatal outcomes from home birth are considered to be as low and not significantly different (Offerhaus *et al.* 2012, Van der Kooy *et al.* 2011) from those in obstetric units.

In a survey undertaken by the Royal College of Midwives (RCM) in 2011, only 58% of the survey participants indicated that a home birth service was available through their maternity services. On-call demands and lack of midwives confidence in their skills were highlighted as reasons for homebirth not being made available, in addition to a perceived lack of support from obstetric colleagues and hospital midwives (RCM, 2011).

In Northern Ireland, home birth accounts for approximately 1% of all 26,500 births per annum. This is set against a backdrop of the most recent regional maternity care strategy (DHSSPS 2012) which promotes choice and the normalisation of birth and encourages the provision of balanced information about maternity care provision including homebirth; particularly for those women with a straightforward pregnancy. This has seen the development of 8 midwife-led units (5 alongside and 3 freestanding) since 2001. However, even with a proactive strategy implementation group which has progressed the objectives of the strategy, discussion on a recent home birth association social media site highlighted that women who are exploring the option of homebirth receive a variety of responses from maternity care providers. These responses range from supportive, to some resistance, to refusal to 'allow' the woman to plan to birth at home (NI Homebirth Facebook Group, 22 September, 2016). During the development of the Guideline and Audit Implementation Network (GAIN) Guideline for Admission to Midwife-led Units in Northern Ireland and Northern Ireland

Labour and Birth Care Pathway (GAIN, 2016), co-produced with key stakeholders, the need for regional guidelines for home birth was identified.

In Denmark, homebirth is considered part of normal maternity care with all regions in Denmark being obliged to offer homebirth services to women (Clausen & Hresanova, 2013). The Health Care legislation requires antenatal consultations with a midwife and if a woman requests a homebirth; attendance by midwives is mandatory (Sundhedsstyrelsen, 2009). Therefore, Denmark is an ideal location for this STSM as it provided the opportunity to observe, discuss and understand the context and culture which sees homebirth service provision as a normal part of maternity care provision. This would allow for knowledge exchange to inform the co-design, co-production and implementation of Homebirth Guidelines and care pathway with key stakeholders.

### *Aim of the Mission*

To explore the context and culture that support homebirth service provision in Denmark to inform the development of Homebirth guidelines in Northern Ireland.

### *Objectives:*

1. To seek an understanding of the health policy and legislation which supports homebirth provision in Denmark;
2. To explore with homebirth midwives and other stakeholders including women, academics and student midwives, the culture and context of homebirth provision and the economic differential that a less interventionist birth brings;
3. To identify key learning and knowledge translation that may be used to inform the development of Homebirth guidelines and midwifery curriculum in Northern Ireland

### *Ethical Considerations:*

In preparation for the STSM, the STSM researcher liaised with Dr Jette Clausen in order to seek agreement that Metropol University College and Dr Clausen would host the STSM. It was agreed that this STSM would be undertaken as a research study. This required a detailed work plan in order that an application for ethical approval could be submitted to the Research Ethics Filter Committee in the University of Ulster. A six page proposal with detailed Consent forms and Participant Information Sheets were designed. Further ethical approval application was not required in Denmark, but potential participants had to be advised of what the project was about and confidentiality assured. The proposed project was peer reviewed and received approval from the Research Ethics Filter Committee at Ulster University on 24<sup>th</sup> Aug 2017 (see Appendix 1). Dr Clausen facilitated initial access to participants and written consent was obtained prior to all interviews.

Confidentiality of participants was maintained with no identifying characteristics being used and pseudonyms assigned to all participants who were interviewed. All information held electronically is stored anonymously on a password protected computer in a locked room on Ulster University premises for 10 years and then confidentially destroyed in line with Ulster University policy: <https://internal.ulster.ac.uk/research/rg/0613%20data%20handling%20procedure%20V1.pdf>

### ***Methodology:***

This STSM provided the opportunity for an exploration of the context and culture within key areas of Denmark that has led to the growth of Homebirth services (see Table 1). This was a two phased study:

#### ***Phase 1:***

**Aim:** To further understand the health policy and legislation which supports homebirth provision in Denmark.

**Approach:** This included an overview of the legislation, policy and guidelines that support the provision of homebirth in Denmark through a review of documents written in English. Some of this work was undertaken prior to the visit to Denmark but additional material was acquired from experts in Homebirth while in Denmark. This ensured that as much of the relevant documentation was accessed as possible.

#### ***Phase 2:***

**Aim:** To explore the culture and context of homebirth provision with stakeholders

**Approach:** This involved interviewing a researcher with expertise in homebirth provision, homebirth midwives, student midwives and women who have had homebirth to find out the key learning from Homebirth service provision in Denmark.

**Participants:** Researcher with expertise in the area of Homebirth

#### ***Access:***

The research host in Denmark had already received preliminary agreement from an experienced researcher into Homebirth to participate in the study who agreed to being interviewed about the

context and culture of Homebirth in Denmark. A Participant Information Sheet, consent form were sent to the participant in advance of the interview.

***Participants: Midwives***

*Midwives* in two of the surrounding areas of Denmark who currently provide homebirth services for women.

***Access:***

The research host in Denmark is a midwife academic with links to midwives who provide a homebirth services. Participant Information Sheets and consent forms were sent to the host for distribution to potential participants in advance of the proposed study taking place.

***Inclusion criteria:***

*Midwives* who provide homebirth services for women in Denmark, who are able to read and speak English and are available and willing to speak to the researcher during the STSM timeframe of 4th-9th September 2017.

***Exclusion criteria:***

*Midwives* who do not provide Homebirth services in Denmark.

***Participants: Women***

Women who have had a homebirth in Denmark

***Access:***

The Host (Dr Jette Clausen) asked Homebirth midwives to ask women who have had a positive homebirth experience (i.e. one that has not been traumatic birth experience or in which there have been poor neonatal outcomes) if they were willing to participate in the study and be interviewed by the lead researcher. **No** women were available for interview during the STSM; however a Homebirth Openhouse which included women was observed during the visit; although no recording of the conversations took place.

***Participants: Student Midwives:***

*Student Midwives* in the Metropol University who currently are being educated to acquire the knowledge and skills necessary to provide homebirth services for women.

***Access:***

The research host in Denmark is a midwife academic and she invited student midwives to take part in a group interview about their education in relation to homebirth. Participant Information Sheets and consent forms were sent to the host for distribution to potential participants in advance of the proposed study taking place. Three student midwives agreed to take part.

***Inclusion criteria:***

*Student Midwives* educated in Metropol University who were available during the STSM timeframe of 4th-9th September 2017, and were able to read and have a conversation in English.

***Exclusion criteria:***

Student Midwives who are not being educated in Metropol University.

***Data Collection:***

Data collection took place from 6th September 2017. The interviews with participants were audio recorded following consent and field notes by the researcher captured specific issues of context.

***Data analysis:***

The audio recordings from the interviews with participants were transcribed verbatim and content analysed using Newell and Burnard’s (2011) pragmatic seven step approach to qualitative data analysis.

In order to meet the aim and objectives of the STSM, the following work was undertaken:

***Table 1: Summary of STSM activity (only names of participants who were not interviewed as part of the research are included)***

<b>Day/Date</b>	<b>Activities</b>	<b>Expected Outcomes</b>
<b>Day 1 3<sup>rd</sup> September 2017</b>	Travel to Copenhagen, familiarise self with travel links Telephone call with Dr Jette Clausen to confirm arrival and discuss arrangements for next day/ remainder of week overview	Orientation to Copenhagen; confirmation of plan for week including travel arrangements for next day
Day 2 4 <sup>th</sup> September 2017	Met 3 private homebirth midwives who collaborate closely with the public hospital and the region; 1 hr 15 minutes train journey from Copenhagen; Interviewed 2 homebirth midwives re homebirth practice in this region. Observed Homebirth Open House for parents and their family/friends interested in Homebirth; Women with experience of Homebirth <i>Review of day and write up diary/notes &amp; plan for next day</i>	Begin to gain understanding of culture and context of Homebirth Service provision in one region of Denmark; observation of interaction between women, midwives, partners and some of their family members; consider learning that can be brought to Northern Ireland
<b>Day 3 5<sup>th</sup> September</b>	Meet with Jette Clausen and colleagues in Metropol University.	Further understanding of challenges with health care

2017	Met with Ole Olsen, Research Unit for General Practice & Section of General Practice, Department of Public Health, University of Copenhagen; discussed approaches to data collection, the use of clinical guidelines and other relevant research <i>Review of day and write up diary/notes &amp; plan for next day</i>	research including homebirth; discussions re evidence based guidelines and their use in practice; keen learning for guideline development in Northern Ireland
<b>Day 4</b> 6 <sup>th</sup> September 2017	Met and interviewed midwife from hospital-homebirth service Met and interviewed, former midwifery educationalist, homebirth midwife and advocate  <i>Review of day and write up diary/notes &amp; plan for next day</i>	Exploration and understanding of homebirth policy in practice from the perspective of a hospital-homebirth midwife and midwife educationalist, homebirth midwife and advocate; also some historical context of homebirth
<b>Day 5</b> 7 <sup>th</sup> September 2017	Skype interview with Midwifery Researcher with expertise in Homebirth  Met with the President of the Danish Midwives Association (Jordemoderforeningen), Ms. Lilian Bondo and Anne-Mette Schrell, Consultant Midwife to discuss licensing, scope of practice and professional issues relating to homebirth care provision  Met and interviewed three student midwives about their perceptions of preparedness for caring for women having a Homebirth  <i>Review of day and write up diary/notes &amp; plan for next day</i>	Context and culture including research and evidence based practice by midwives in Denmark Further clarity around legislation and midwives scope of practice; also work related interests of Danish Midwives  Better understanding of Danish student midwives perceptions of their preparedness for Homebirth including their practical experience of Homebirth
<b>Day 6</b> 8 <sup>th</sup> September 2017	Met and interviewed 2 private homebirth midwives from a town about 1 hr 15 minutes train journey from Copenhagen;  <i>Review of STSM and writing up of notes from day</i>	Exploration and understanding of homebirth policy in practice from the perspective of home birth midwives in another region of Denmark
<b>Day 7</b> 9 <sup>th</sup> September	Return journey from Copenhagen to Northern Ireland	Time to reflect on key learning for Northern Ireland

**Main findings:**

The midwives in Denmark have a strong professional identity which is supported by the Danish Midwives Association (DMA) (Jordemoderforeningen) which was founded in 1902 and provides both professional and trade union support for its members (DMA 2016).

During this STSM, the researcher met with a range of stakeholders who have an interest in homebirth including women, midwives, researchers, midwives from the Professional Association and academics. This was facilitated through Dr Jette Clausen, who made initial contact with all participants to determine their interest in taking part.

### **Maternity care legislation**

Prior to the visit, the STSM researcher was able to access a number of papers that provided background information about homebirth in Denmark including an oral history of homebirth in Denmark (Santos 2016a; Santos 2016b). The key piece of legislation which supports homebirth in Denmark is the Danish Health Act (Sundhedsstyrelsen, 2009). This stipulates that women can have the 'help of a midwife at home' and these services are free of charge. In Northern Ireland, a woman's access to Homebirth services is promoted within the Maternity Strategy (2012) but not embedded in legislation. This in effect means that homebirth although part of mainstream maternity care is often seen as additional 'burden' to a system which has an already pressurised workforce. In Denmark, there is an expectation that each of the five regions organise their homebirth services as a standard part of their maternity care provision.

### **The Homebirth experience**

The researcher spoke with midwives who were private homebirth midwives funded by the Government and who worked in large teams but mostly offered continuity of carer. It was clear that they loved the work that they do, with one midwives reporting *'I only see smiles after a delivery'*(MW2S), when compared to her experience of caring for women in hospital, who had been *induced...had a tough birth and different midwives, not the same. So they were stone-faced sometimes'* (MW2S).

Within the hospital homebirth teams, there was an acceptance that skills from homebirth and hospitals births were used to enhance care provision in both settings.

The student midwives were supportive of homebirth but recognised that not all women or indeed all midwives were keen to access or provide these services. However, this was not seen as problematic but rather that there should be consideration given to ensuring the best fit for midwives and women.

### **Economic cost of Homebirth provision**

Homebirth is provided as a normal part of service delivery in Denmark with models of care designed in order that home birth is available to all women who request it. Further analysis of costs of hospital versus homebirth in both Denmark and Northern Ireland is underway.

### **Summary:**

This STSM provided an opportunity to talk with and interview key informants for homebirth in Denmark. The interviews provided rich personal and professional accounts from homebirth midwives both current and retired about their experiences of providing homebirth services. There was a clear understanding and pride that the provision of care by a midwife for women planning homebirth is part of the legislation and therefore required in law. This has seen the development of service models that encompass homebirth as a part of the system of care, not an addition. Models of homebirth provision in Denmark have largely established good relationships between hospital staff including midwives and obstetricians and home birth midwives which for example, see homebirth midwives accompany the women into hospital and stay with her (in a doula type role which provides continuity of carer). Continuity of care is high on the agenda in maternity services in Northern Ireland, with discussions around how best continuity of carer can be a reality without being an unsustainable system for midwives working within them. Transfer to hospital from home during labour is not seen to be problematic but indicative of good decision- making by the mother and midwife and includes transfer via taxi or own car. Ambulance transfer is available if required for an emergency transfer through a specific telephone number for healthcare professionals. These key findings have been fed back to the Homebirth Guideline Development Group, have informed the discussions and will continue to inform the development of guidelines for homebirth that are woman-centred and focus on homebirth being seen as a normal part of maternity models of care.

### **Future Collaboration with Host Institution**

Dr Jette Clausen and the STSM researcher are collaborating on a paper based on the findings of this STSM.

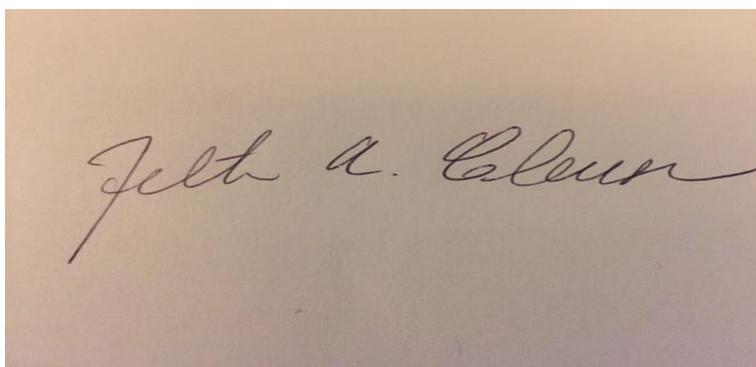
### **Future Publications**

Dr Clausen and Gillen are members of the same work group and hope to continue to work together on research and publications.

**Confirmation by the Host Institution of the successful execution of the STSM**

It was a delight to welcome Patricia Gillen to Metropolitan University College for a 7 day STSM to the midwifery department. Patricia Gillen engaged in a busy program and managed to interview home birth midwives, researcher on homebirth, women and midwifery students. Throughout the week we continually had opportunities to discuss similarities and differences in home birth organisation and legislation between Denmark, Ireland and the wider world. The material that was collected will be used for a research publication that focus on the importance of legislation.

Sincerely

A photograph of a handwritten signature in cursive script on a light-colored background. The signature reads "Jette A. Clausen".

Jette Aaroe Clausen

Metropolitan University College

Department of Midwifery

Copenhagen Denmark

**Other Comments**

A special note of thanks goes to Dr Jette Clausen, the Co-Investigator who undertook a lot of preparatory work at the Host Institution in order to ensure that the STSM researcher would have the opportunity to meet as many stakeholders with personal or professional interest in homebirth as possible. In addition, Dr Clausen provided ongoing guidance and support throughout the STSM facilitating access to premises, participants, academic staff and travel arrangements.

Thank you to COST for providing the opportunity to undertake this STSM and my employers Southern Health and Social Care Trust and Ulster University for supporting this work.

Special thanks to the all of the participants and for the hospitality shown to me by all I met.

## REFERENCES:

- Blix E, Huitfeldt AS, Øian P, Straume B, Kumle M. (2012) Outcomes of planned home births and planned hospital births in low-risk women in Norway between 1990 and 2007: A retrospective cohort study. *Sexual and Reproductive Health* 3 (4), 147–53. DOI: 10.1016/j.srhc.2012.10.001
- Brocklehurst P, Hardy P, Hollowell J, Linsell L, Macfarlane A, McCourt C, Marlow N, Miller A, Newburn M, Petrou S, Puddicombe D, Redshaw M, Rowe R, Sandall J, Silverton L, Stewart M. Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study. *BMJ* 2011 23 343:d7400. doi: 10.1136/bmj.d7400
- Clausen JA, Hresanova E. (2013) Midwifery competencies in home birth in Denmark and the Czech Republic *STSM, Cost Action Childbirth, Culture and Consequences* [accessed 11/12/2016]
- Davis D, Baddock S, Pairman S, Hunter M, Benn C, Wilson D, Dixon L, Herbison P (2011) Planned place of birth in New Zealand: does it affect mode of birth and intervention rates among low-risk women? *Birth* 38 (2): 111–119.
- Department of Health, Social Services and Public Safety (DHSSPSNI), (2012) A Strategy for Maternity Care in Northern Ireland 2012-2018. Belfast: DHSSPSNI.
- Danish Midwives Association ( Jordemoderforeningen) (2016) Midwives in Denmark (Jordemodre I Danmark) Denmark: Eks-Skolens Trykkeri Aps
- GAIN (2016) *GAIN Guideline for admission to midwife-led units in Northern Ireland*, Guideline Audit Implementation Network, RQIA: Belfast [www.gain-ni.org](http://www.gain-ni.org)
- Halfdansdottir B, Smarason A Kr, Olafsdottir O A, Hildingsson I and Sveinsdottir H (2015) Outcome of planned home and hospital births among low-risk women in Iceland in 2005–2009: A retrospective cohort study. *Birth* 42 (1), pp. 16–26.
- Hollowell J, Puddicombe D, Rowe R, Linsell L, Hardy P, Stewart M, Newburn M, McCourt C, Sandall J, Macfarlane AJ, Silverton L and Brocklehurst P (2011) *The Birthplace national prospective cohort study: perinatal and maternal outcomes by planned place of birth Birthplace in England research programme (Report No. Final report part 4)* Southampton: HMSO.
- Hutton EK, Cappelletti A, Reitsma AH, Simioni J, Horne J, McGregor C, Ahmed RJ (2016) Outcomes associated with planned place of birth among women with low-risk pregnancies. *Canadian Medical Association Journal* 188(5):E80-90. doi: 10.1503/cmaj.150564.
- National Institute for Healthcare Excellence (NICE) (2014) Intrapartum Care for healthy women and babies, Oxford: NICE Available at: <http://www.nice.org.uk/guidance/cg190>
- Newell R. and Burnard P (2013) *Research for Evidence-Based Practice* 2nd Ed Oxford: Wiley-Blackwell
- Offerhaus P, Rijnders M, De Jonge A, De Miranda E. (2012) Planned home compared with planned hospital births in the Netherlands: intrapartum and early neonatal death in low-risk pregnancies. *Obstetrics & Gynaecology*, 119 (2 Pt 1):387-8.

Olsen O, Clausen JA. Planned hospital birth versus planned home birth. Cochrane Database of Systematic Reviews 2012, Issue 9. Art. No.: CD000352.  
DOI: 10.1002/14651858.CD000352.pub2

Royal College of Midwives (RCM) (2011) *The Royal College of Midwives survey of midwives' current thinking about home birth* London: RCM.

Santos M. (2016) Where the thread of homebirths never broke- An interview with Suzanne Houd  
*Women and Birth* 30(2) 159-165

Santos MJ (2014) Private and public homebirths: comparing access, options and inequalities in Portugal and Denmark IN Padilla B., Hernandez Plaza S., Rodrigues, E., Ortiz A., Saude e Cidadania: Equidade nos cuidados de saude materno-infantil em tempos de crise, Braga, CICS-UM

Sundhedsstyrelsen (2009) *Anbefalinger for Svangreomsorg* (Recommendation for Maternity Care). Sundhedsstyrelsen. Copenhagen.  
[http://www.sst.dk/Nyhedscenter/Nyheder/2009/svangreomsorg\\_24apr.aspx](http://www.sst.dk/Nyhedscenter/Nyheder/2009/svangreomsorg_24apr.aspx)

Van der Kooy J, Poeran J, De Graaf JP, Birnie E, Denktass S, Steegers EA, et al (2011) Planned home compared with planned hospital births in the Netherlands: intrapartum and early neonatal death in low-risk pregnancies. *Obstetrics & Gynaecology*, 118:1037-46.

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RESEARCH GOVERNANCE

RG3 Filter Committee Report Form

Project Title	Home Birth in Denmark: knowledge translation and research to inform Homebirth Guidelines in Northern Ireland.
Chief Investigator	Dr Patricia Gillen
Filter Committee	Professor Omar Escalona

This form should be completed by Filter Committees for all research project applications in categories A to D (\*for categories A, B, and D the University's own application form – RG1a and RG1b – will have been submitted; for category C, the national, or ORECNI, application form will have been submitted).

Where substantial changes are required the Filter Committee should return an application to the Chief Investigator for clarification/amendment; the Filter Committee can reject an application if it is thought to be unethical, inappropriate, incomplete or not valid/viable.

Only when satisfied that its requirements have been met in full and any amendments are complete, the Filter Committee should make one of the following recommendations:

The research proposal is complete, of an appropriate standard and is in

- category A and the study may proceed\*
- category B and the study must be submitted to the University's Research Ethics Committee\*\* Please indicate briefly the reason(s) for this categorisation
- category C and the study must be submitted to ORECNI along with the necessary supporting materials from the Research Governance Section\*\*\*
- category D and the study must be submitted to the University's Research Ethics Committee\*\*

Signed:		Co-Chair Ethics Committee 24 <sup>th</sup> August 2017
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\*The application form and this assessment should now be returned to the Chief Investigator. The Filter Committee should retain a copy of the complete set of forms.

\*\* The application form and this assessment should now be returned to the Chief Investigator so that he/she can submit the application to the UUREC via the Research Governance section. The Filter Committee should retain a copy of the complete set of forms for their own records.

\*\*\* The application form and this assessment should now be returned to the Chief Investigator so that he/she can prepare for application to a NRES/ORECNI committee. The Filter Committee should retain a copy of the complete set of forms for their own records.

For all categories, details of the application and review outcome should be minuted using the agreed format and forwarded to the Research Governance section