# The PACIFY Study

Positive Attitudes Concerning Infant Feeding- a questionnaire for women living with HIV.

Version 2.0

MAIN SPONSOR: Imperial College London/Imperial College Healthcare NHS Trust
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STUDY COORDINATION CENTRE: Imperial College NHS Healthcare Trust, St Mary's Hospital
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## Clinical Queries

Clinical queries should be directed to individual participant's clinician who will direct the query to the appropriate person.

## Sponsor

Imperial College London/Imperial College Healthcare NHS Trust (delete as applicable) is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Joint Research Compliance Office
Imperial College London & Imperial College Healthcare NHS Trust
2nd Floor Medical School Building
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This protocol describes the PACIFY study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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# STUDY SUMMARY

| | |
|---|---|
| **TITLE** | Positive Attitudes Concerning Infant Feeding (PACIFY) – a questionnaire for women living with HIV. |
| **DESIGN** | Questionnaires will be completed by eligible volunteers from London HIV Pregnancy research group and analysed. Maternal CD4 and viral load nearest to time of questionnaire will be recorded. |
| **AIMS** | To explore attitudes towards breastfeeding amongst HIV positive women, who are either pregnant or post-partum. |
| **OUTCOME MEASURES** | Assessment of attitudes towards breastfeeding amongst HIV positive women, who are either pregnant (third trimester) or post-partum (three months post-delivery). |
| **POPULATION** | HIV positive women in the third trimester or up to 3 months post-partum. |
| **ELIGIBILITY** | Age >18 years; able to give written consent; post-natal and antenatal HIV positive women. |
| **DURATION** | 6 months. |

# 1. INTRODUCTION

## 1.1 INTRODUCTION

Every year in the UK, over 1,000 children are born to women who are positive for Human Immunodeficiency Virus (HIV). Current UK guidelines advise complete avoidance of breastfeeding for all HIV-infected women to reduce rates of mother to child transmission (MCT)[4]. However, the World Health Organisation (WHO) now recommends breastfeeding in resource-poor areas due to increasing evidence that the risk of MCT from breastfeeding is outweighed by the increased morbidity and mortality of non-breastfed infants in these settings [16]. The British HIV Association (BHIVA) guidelines are due to be reviewed in 2017 and the relevance of the WHO guidelines to women on antiretroviral treatment (ART) in resource-rich settings will be reconsidered [4]. However, there is very little information about the views about breastfeeding amongst women living with HIV in the UK. The PACIFY study (**P**ositive **A**ttitudes **C**oncerning **I**nfant **F**eeding) is an observational study that will explore these views, concerns and issues surrounding breastfeeding with HIV. We will recruit around 100 HIV-positive women who are pregnant or have recently given birth from several healthcare trusts around London. We will administer self-completed questionnaires to participants at antenatal and postnatal clinics and perform descriptive statistical analysis on the data collected. We aim to gain a greater depth of knowledge about the attitudes towards breastfeeding amongst HIV-positive women that will provide an important, and currently missing, factor to the debate about HIV and infant feeding in resource-rich settings.

## 1.2 BACKGROUND

In the UK, 1.5 per 1,000 pregnant women are infected with HIV, amounting to 1,018 women testing positive for HIV during routine antenatal screening in 2014 [1]. This has resulted in 11,000 children being born to HIV-infected mothers between 2006 and 2014[1, 2]. The primary concern for women with HIV infection in pregnancy is mother to child transmission (MCT) of HIV, the rate of which has been shown to be 30-40% without any interventions. Current UK

practice has achieved a reduction in this rate to below 0.5 %[3], through a combination of maternal antiretroviral therapy, elective Caesarean section and avoidance of breastfeeding[4].

However, world-wide, encouragement of breastfeeding is accepted as vital public health strategy due to its numerous benefits to the infant, both in the short-term and long-term, as well as the reduction breast and ovarian cancers in the mother [5, 6]. Breastfeeding results in significant reductions in morbidity, hospital admissions and mortality of infants from many conditions including gastroenteritis, respiratory infections, otitis media and atopic diseases [7, 8] . Though these reductions are pronounced in low resource settings with high rates of infant mortality, they also occur in more economically developed countries[7, 8], with correlations being found between prevalence of breastfeeding and reductions in infant admissions due to these causes at a Primary Care and Secondary Care level in the UK[9]. Similarly, the long-term risk of hypertension, type 2 diabetes mellitus and obesity is significantly lower in people who were breastfed in infancy [10, 11, 12, 13]. The evidence in support of the benefits of breastfeeding led to the WHO recommendation for infants born to mothers not infected with HIV to be exclusively breastfed for the first 6 months of life, with supplemental breastfeeding for up to 2 years and beyond[14, 15].

However, the traditional advice for HIV-positive mothers has been to exclusively formula feed infants from birth in settings where this is acceptable, feasible, affordable, sustainable and safe (AFASS), in order to remove the risk of MCT [16,18] . Meta-analysis of 9 randomised control trials in Africa, carried out in the era before use of ART during breastfeeding, showed the cumulative risk of MCT from breastfeeding was 9.3% at 18 months, accounting for overall 42% of the cases of MCT [17]. In similar settings, complete avoidance of breastfeeding eliminates the risk of MCT through breastfeeding, but the 2-year mortality rate is not significantly different. However results on HIV-free survival have been shown to be varied with studies showing either a decrease or increase in the breast feeding arm [18, 19, 20]. In randomised controlled trials (RCTs) and cohort studies, where women in resource poor settings have breastfed on ART, MCT rates have been reduced to 3% or less [21, 22, 23]. Studies have also shown suppressed levels of HIV RNA in breast milk, although cells that may contain integrated virus are still present [24]. RCTs assessing these outcomes in HIV-positive mothers are not possible in resource-rich settings due to formula feeding that meets AFASS criteria. In view of this most resource rich settings still advocate exclusive formula feeding.

The evidence of increased mortality in formula fed infants born to mothers with HIV, in resource-poor settings, as well as improved availability of ART and its efficacy of reducing MCT through breastfeeding, has led to a gradual shift in the WHO guidelines towards encouraging breastfeeding in HIV-positive mothers in countries where ART is available and infant mortality rates are high. The current WHO guidance advises women in this setting, who are adhering to ART, to exclusively breastfeed for the first 6 months of the infant's life and continue supplemental breastfeeding for at least 12 months, and even up to 2 years or beyond [25]. Recent changes in WHO guidelines also suggest lifelong ART from diagnosis of chronic HIV infection irrespective of CD4 count or clinical status and in line with this, women receiving lifelong ART should have no restrictions in the duration of breastfeeding [25, 26, 27] . They suggest that this guidance may be relevant to resource-rich countries, depending on the causes and rates of infant mortality, as well as the culture and practices of the population [25]. In such settings, adherence to ART is good and the provision of intensive support and monitoring of HIV-positive women and their child during breastfeeding is possible.

Although, to date BHIVA guidelines advise all mothers known to be HIV-positive to exclusively formula feed from birth, regardless of ART[4], if a mother decides to breastfeed, when fully supressed on ART, it is no longer considered a child safeguarding issue. There is also BHIVA guidance in place to support women who decide to breastfeed: maternal ART should be monitored and continued until at least 1 week after breastfeeding ceases; breastfeeding should be exclusive, other than during the weaning period; and breastfeeding should ideally end by 6 months after birth. The rationale for this advice is that engagement with healthcare services during breastfeeding will be increased, and the rate of MCT during

breastfeeding is significantly reduced by adherence to ART and increased by mixed feeding[21, 22, 23, 4, 28].

Several issues may arise from the current BHIVA recommendation for HIV positive women to avoid breastfeeding. Confusion amongst mothers with HIV stemming from the contradiction between the WHO and BHIVA guidelines, can cause mistrust in the medical professionals and a reduced uptake in the guidelines. In addition to this, there are a variety of social and cultural pressures for women to breastfeed which can cause difficulties for HIV-positive women who are advised not to breastfeed. These pressures may cause personal distress and difficult questions about their reasons for not breastfeeding, and may result in occasional breastfeeding against medical advice in certain circumstances. In addition to this, there are many practical or financial reasons why women may choose to breastfeed their infant against the recommendations, either on an occasional basis or as a primary means of infant feeding. One unifying issue with these situations, in a setting where breastfeeding in HIV positive mothers is frowned upon by the medical profession, is breastfeeding without the extra support and precautions recommended by the WHO and BHIVA and potential disengagement from healthcare services[4, 25]. This may occur without the knowledge of the medical profession due to shame or fear of judgement. Breastfeeding in this situation would have an increased risk of MCT as well as delayed diagnosis of HIV infection in the infant if transmission occurred.

There has been very little research into these issues, or the prevalence of unreported breastfeeding in HIV-positive mothers in the UK. There has also been limited exploration into the views of women with HIV about breastfeeding; the cultural and social pressures they may be experiencing to breastfeed; and their understanding of the current recommendations. With the changing evidence from African countries, and the increasing recognition that fully suppressed HIV significantly reduces all types of transmission, it is time to better understand the views of women with HIV about infant feeding.

## 2. STUDY OBJECTIVES

**Primary aim:**

- To explore attitudes towards breastfeeding amongst HIV positive women, who are either pregnant or post-partum.

**Secondary objectives:**

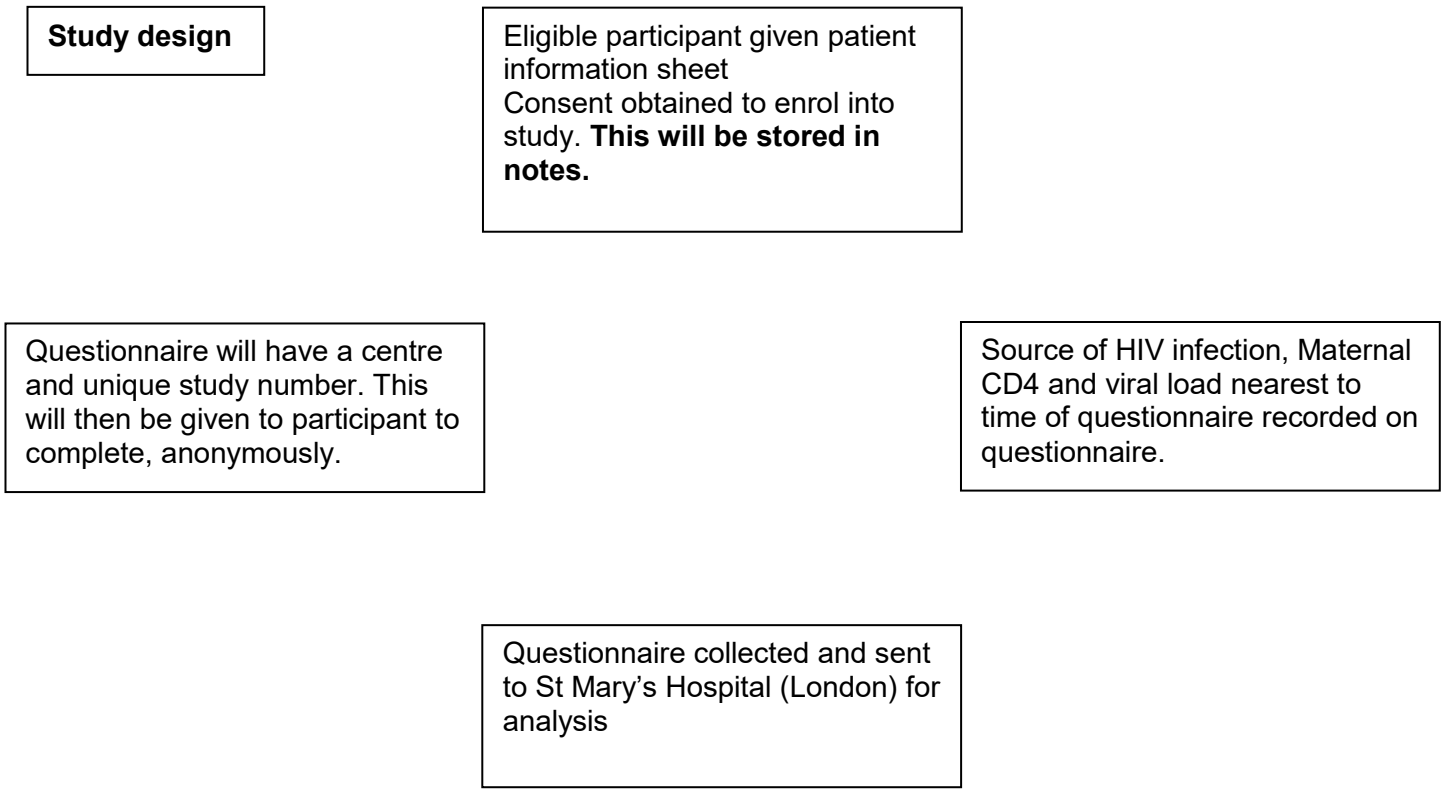
- To assess the understanding of current infant feeding guidance amongst HIV positive women.
- To assess reported non-compliance to current infant feeding guidance for HIV positive women.
- To assess whether HIV positive mothers would be willing and able to comply with special monitoring and guidance whilst breastfeeding.
- To assess the link between maternal views on breast feeding and their current CD4 and viral load measurements.

## 3. STUDY DESIGN

**Setting:**

HIV (antenatal and postnatal) clinics in and around London participating in the “London HIV Pregnancy Research Group”.

**Study Design and Methods:**
All female patients attending who are eligible to join the study will be invited to participate and a participant information sheet will be given. For those eligible women, who have consented to join the study, they will then be given a short participant questionnaire to complete. During the collection period, women with HIV attending either antenatal (third trimester) or postnatal (within three months of delivery) care will be eligible to participate, but they will only be asked once, either before or after delivery. Ideally equivalent numbers of pre and postnatal participants will be enrolled.




**Material/Sample storage**
None required.

**Peer and regulatory review**
The study was deemed to require regulatory approval from NHS Research Ethics Committees. This approval will be obtained before the study commences. The study has been reviewed and approved by an HIV women's user group. The study has been peer reviewed and approved by the Research Review Committee of the HIV Team at Imperial College.

**Assessment and management of risk**
Participants will be informed that they are free to withdraw from the study at any time, without giving a reason, and without prejudicing their medical care.
The study comprises a structured questionnaire that contains sensitive questions. Participants will be informed that they are not obliged to answer any questions they find difficult. A space in clinic will be offered to participants who wish to complete the questionnaire in private. We will strongly encourage all participants to complete the questionnaire on site at their clinical centre to avoid any inadvertent disclosure of HIV status

### 3.1 STUDY OUTCOME MEASURES

**Primary outcome measure:**
Assessment of attitudes towards breastfeeding amongst HIV positive women, who are either pregnant (third trimester) or post-partum (three months post-delivery).

# 4. PARTICIPANT ENTRY

### 4.1 PRE-REGISTRATION EVALUATIONS
Patients should meet criteria below. No other pre-registration evaluations required.

### 4.2 INCLUSION CRITERIA
Age > 18 years
Able to give written informed consent
Post-natal and antenatal HIV positive women

### 4.3 EXCLUSION CRITERIA

Age <18 years
Patients who are unable to consent.
Women with HIV who have not been pregnant.

### 4.4 WITHDRAWAL CRITERIA
Participants will be required to fill in questionnaire after consenting. Questionnaires will not have any identifiable information; therefore participants cannot withdraw once questionnaire has been completed.

# 5. ADVERSE EVENTS

### 5.1 DEFINITIONS
**Adverse Event (AE):** any untoward medical occurrence in a patient or clinical study subject.

**Serious Adverse Event (SAE):** any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*

- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

### 5.3 REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

#### 5.3.1 Non serious AEs

All such events, whether expected or not, should be recorded.

#### 5.3.2 Serious AEs

An SAE form should be completed and faxed to the Chief Investigator within 24 hours. However, relapse, death and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the Imperial College HIV research Ethics Committee where in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and
- 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

**Contact details for reporting SAEs**
**Attention:Dr Hermoine Lyall**
**Please send SAE forms to: Imperial College Healthcare Trust St Mary's Hospital, Paediatric Services, London, W2 1NY**
**Telephone: 0203 3126965**

## 6. ASSESSMENT AND FOLLOW-UP

They will be no follow up once questionnaires are completed by participants.

## 7. STATISTICS AND DATA ANALYSIS

**Analysis plan**

Data will be collected via the questionnaire from around 100 HIV positive participants over a 3 -6 month period. The questionnaires will then be analysed using descriptive statistical methods.

**Data Handling and management**

Participants will complete paper questionnaires. The questionnaires themselves will contain a study / site number only, with no identifying information. The patient's name and clinic number will not be recorded on the questionnaire. Participants will be able to place their completed paper questionnaires in a sealed envelope in a box in the clinic. Participants will be informed that their questionnaire responses will not be seen by clinical staff (unless participants request staff support in completion of the questionnaire) or recorded in their clinical notes. In the clinics the study log will be the only document linking study number with

hospital ID number and Soundex. Completed questionnaires will be stored securely in local sites prior to transfer to St Mary's Hospital (by the study team). The study log will be maintained securely along with the delegation log by the site lead investigator. Maternal CD4 and viral load nearest to time of questionnaire will be recorded on the questionnaire and sent with the questionnaire to St Mary's Hospital (London) with for analysis.

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

# 8. REGULATORY ISSUES

## 8.1 ETHICS APPROVAL

The Chief Investigator has obtained approval from the Imperial College Healthcare NHS trust HIV Research Ethics Committee. The study must be submitted for Site Specific Assessment (SSA) at each participating NHS Trust. The Chief Investigator will require a copy of the Trust R&D approval letter before accepting participants into the study. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

## 8.2 CONSENT

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so should be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

## 8.3 CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

## 8.4 INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study/ Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Litigation Authority for NHS Trusts in England, which apply to this study (delete as applicable)

## 8.5 SPONSOR

Imperial College London/Imperial College Healthcare NHS Trust (delete as applicable) will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

## 8.6 FUNDING

Funding applications are currently in progress.

## 8.7 AUDITS

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care (2nd edition).

# 9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through Dr Hermione Lyall.

# 10. PUBLICATION POLICY

This study will be presented at international conferences and be published in an international journal.

# 11. REFERENCES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**Appendix 1. Patient Information Leaflet**

Imperial College Healthcare NHS
NHS Trust

## Patient Information Leaflet

## Study Title: Positive Attitudes Concerning Infant Feeding (PACIFY) study

Ethics Ref:
Date and Version No 1.0

**1. Invitation**

You are invited to take part in a research study which will involve you answering a questionnaire on what you think about breastfeeding for women with HIV. The information we obtain from this study will help us to understand HIV positive women's views on breastfeeding in resource rich settings.

**2. What is the purpose of this study?**

We want to understand more about the views of HIV positive women on breastfeeding, by asking women with HIV who are either pregnant (in the third trimester) or have recently given birth (within the last 3 months) to complete a questionnaire. This information may help us to shape national guidelines for other women with HIV in future.

**3. Why have I been chosen?**

You have been invited to take part because you are attending the clinic today and are either pregnant or have recently given birth. Taking part in this study will not alter in any way the care and treatment that your medical team are recommending for you.

**4. Do I have to take part?**

No. Taking part in this study is completely voluntary which means it is entirely up to you to decide whether or not to take part. Your decision will not affect your medical care or treatment in any way. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you change your mind, you can, withdraw at any time, or if you decide not to take part, this will not affect the quality of care you receive.

**5. What would happen to me if I take part?**

We will ask you to complete a 10 minute anonymous questionnaire. Once you have completed the questionnaire we will ask you to place it in the envelope and box provided. If you agree, we would also like to ask your local team to fill in your latest CD4 and viral load results on the questionnaire.

**6. What would happen to questionnaires after?**

The questionnaires will then be reviewed and analysed by the research staff.

**7. What are the possible disadvantages and risks?**

The risks involved in this research are very few and no personal identifiable information will be collected with the questionnaire. We will **not** include your information your name or address. The information that you give will be stored with a code (a number) not your name, on a secure computer system, which will only be accessible by the few individuals who are working closely on this research project that are specifically named in this study.

**8. What are the possible benefits?**

This research will improve our understanding of HIV positive women's views on breastfeeding. This information may help us to shape national guidelines in future.

**9. What happens when the research study stops?**

We aim to feed back our findings to HIV user groups and to the scientific community.

**10. What will happen if I don't want to carry on?**

You are free to withdraw from with this research at any time, without giving a reason and without any effect on your future care or treatment

**11. What if something goes wrong?**

Imperial College Healthcare NHS Trust has arrangements in place to provide for harm arising from participation in the study for which the Imperial College Healthcare NHS Trust Joint Research Compliance Office, 2nd Floor Medical School Building, St Mary's Hospital Praed Street, London, W2 1NY is the Research Sponsor.

**12. Would my taking part in this study be kept confidential?**

Confidentiality and keeping your records securely are very important parts of this research. You will be allocated a unique study number that will be used for the questionnaire. All the information necessary for the research will be used through your unique research number. The researchers using this information are aware of the importance of security and confidentiality.

**13. What will happen to the results of the research study?**

The results of this research study may be presented at medical, scientific, and user group meetings or in publications. You will not be personally identified in any presentations or publications, but if you agree, we may use anonymised quotes from what you have written down on your response. These can be very powerful at getting messages across to the scientific community.

**14. Who is organising and funding the research?**

The research is supported by Imperial College NHS Trust.

**15. Who has reviewed the study?**

This research study has been peer reviewed by the research committee of the HIV team at Imperial College. It has also been reviewed by appropriate ethical committees in accordance with local and national regulations.

**16. Complaints procedure**

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the Joint Research Office of Imperial College and Imperial College Healthcare NHS Trust

**18. Contact for further information**

If you would like more information, or if you have any problems, concerns or questions about the study, please contact the doctor looking after you, or the Imperial College Healthcare NHS Trust Joint Research Compliance Office, 2nd Floor Medical School Building, St Mary's Hospital, Praed Street, London, W2 1NY and Imperial College Healthcare NHS Trust or Dr Hermione Lyall, Imperial College Healthcare NHS Trust, St Mary's Hospital, Paediatric Services, London, W21NY.

**Appendix 2. Questionnaire consent form**

Imperial College Healthcare NHS
NHS Trust

## Questionnaire consent form

Title of project: **The PACIFY Study**
**Positive Attitudes Concerning Infant Feeding**

Researcher: **Dr Hermione Lyall**

Please initial all boxes

| | |
|---|---|
| I confirm that I have read and understood the information sheet dated _____ for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | ☐ |
| I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. | ☐ |
| I agree that the anonymous information that I provide can be used for the purposes of this research. | ☐ |
| I agree to have my viral load and CD4 count recorded anonymously for the study | ☐ |
| I agree to take part in the above study. | ☐ |

| | | |
|---|---|---|
| _____ | _____ | _____ |
| Name of participant | Date | Signature |
| _____ | _____ | _____ |
| Name of person taking consent | Date | Signature |

## Appendix 3. Delegation log

### Staff signature log and site delegation tasks

| Study Title: The PACIFY Study: Positive Attitudes Concerning Infant Feeding | Protocol No: |
|---|---|
| Chief/Principal Investigator: Dr Hermione Lyall | |

**Staff signature and site delegation of tasks**

| Name | Initials | Study Role | Key Delegated study Task(s)* | Duration | | Signature | CI/PI Signature |
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