

## Appendix 1: General informed consent document

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### **INTRODUCTION**

You are invited to volunteer for this research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the researcher. You should not agree to take part unless you are completely happy about what is expected of you.

### **WHAT IS THE PURPOSE OF THIS STUDY?**

The purpose of this study is to develop an evidence-based practice model for the implementation of Developmentally Supportive Care (DSC) in a South African public Neonatal intensive care unit (NICU). The study is planned in six phases.

The research phases and objectives are as follows:

Phase 1: Problem analysis and project planning

- To describe a conceptual framework for implementation of DSC in a South African public NICU.

Phase 2: Information gathering and synthesis

- To identify the factors involved in the successful implementation of DSC in a South African public NICU.

Phase 3: Design

- To plan and apply the information needed for the implementation of DSC.

Phase 4: Early development and implementation

- To execute the implementation plan (from phase 2 & 3) for DSC implementation in a South African public NICU.

Phase 5: Evaluation of implementation

- To evaluate the implementation plan through monitoring progress into a public NICU.

Phase 6: Advanced development and dissemination.

- To describe an evidence-based model for the implementation of DSC in a South African context.

### **WHAT IS EXPECTED OF YOU DURING THIS STUDY?**

As a participant, you will be expected to participate during the phases 2 to 5. It is not necessary to participate during all the phases, but due to the nature of the implementation process, consistent participation would be preferred. This will include attending one or more focus groups, training on DSC principles and implementation thereof, discussion groups during DSC implementation, and environmental audits of the NICU.

The topics to be covered during these focus groups will include factors involved in successful and unsuccessful DSC implementation, as well as practices needed for successful DSC implementation. The focus group will take approximately one hour. The discussion will be recorded and transcribed. During the focus group a facilitator will lead the discussion, and an additional person or researcher might take field notes. The transcribed data will be kept in a safe place and confidentiality will be ensured at all times. No names will be mentioned in the transcribed notes and participants will remain anonymous.

Training will be provided to all members of the multidisciplinary team at a convenient time and venue. The training sessions will consist of a four hour workshop which will be presented until all members of the multidisciplinary team have had an opportunity to attend. An information document will be given to each participant on the information covered during the workshop.

The discussion groups will take place during the implementation phase which will give you, as a member of the multidisciplinary team, an opportunity to discuss problems, concerns and possible solutions that arise during the implementation of DSC. These discussions will be informal, but will still be recorded and transcribed to allow the researcher to document problems and possible solutions. These discussions will be facilitated by the researcher. Again, the principles of anonymity and confidentiality will be maintained.

The environmental audits of the NICU will be carried out during the implementation phases by the researcher and an independent observer. The environment and multidisciplinary team activities in terms of DSC principles will be observed. As a participant, you will not

have to do anything outside your daily activities during these audits. These audits will be used solely to determine the progress of implementation in the NICU.

#### **HAS THE STUDY RECEIVED ETHICAL APPROVAL?**

This study protocol (21/2004) has received ethical approval from the Research Ethics Committee of the University of Pretoria, Faculty of Health Sciences. The study is also fully supported by the Department of Nursing Science, University of Pretoria.

#### **WHAT ARE YOUR RIGHTS AS A PARTICIPANT IN THIS STUDY?**

Your participation in this study is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will involve no penalty or loss of benefits. As all data collected remains confidential and anonymous, please note that once data has been transcribed and analysed, tracing of information to a particular participant will be unattainable and recall of consent at this stage will not be possible.

#### **MAY ANY OF THESE STUDY PROCEDURES RESULT IN DISCOMFORT OR INCONVENIENCE?**

Involvement in the focus groups, training and discussions will take time for participation, which is highly appreciated. There will be no discomfort or inconvenience involved during the environmental audits as these will strictly be observational. No other discomfort or inconvenience will result from your participation.

#### **WHAT ARE THE RISKS INVOLVED IN THIS TRIAL?**

There are no risks involved in participation in this study.

#### **CONFIDENTIALITY**

All information obtained during the course of this study is strictly confidential. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study.

#### **PHOTOGRAPHY**

If consent is granted, photographs may be taken in the NICU as documentation of research findings. The photographs may also be used as examples of DSC

implementation for hospital staff, parents, training and presentation of the above mentioned research.

**SOURCE OF ADDITIONAL INFORMATION**

If you have any questions during this study, please do not hesitate to approach the researcher.

Researcher: Ms A.C. Hennessy 082 371 5104

Supervisor: Dr S.J.C. van der Walt 012 354 2125

**INFORMED CONSENT**

I hereby confirm that I have been informed by the researcher, Ms A.C. Hennessy and/or consent supporter about the nature, conduct, benefits and risks of the study. I have also received, read and understood the above written information (Participant Information Leaflet and Informed Consent) regarding the study.

I am aware that the results of the study, including personal details and photographs taken will be anonymously processed into the research report for possible publication in scientific journals and use in training programs.

I may, at any stage, without prejudice, withdraw my consent and participation in the study. I have had sufficient opportunity to ask questions and of my own free will declare myself prepared to participate in the study.

Participant's name ..... (Please print)

Participant's signature ..... Date .....

Witness's name ..... (Please print)

Witness's signature ..... Date .....

I, Ms A.C. Hennessy herewith confirm that the above participant has been informed fully about the nature, conduct and risks of the above study.

Researcher's name ..... (Please print)

Researcher's signature ..... Date .....

## Appendix 2: Questionnaire 1

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Medical Staff

Nursing Staff

Allied Health

Non-medical Support Services

This information will be kept anonymous and confidential

### Awareness meeting questions

1. Do you think that developmental care can be implemented successfully in your unit?

Yes

No

Unsure

2. Do you think that you can contribute to the success of this project?

Yes

No

Unsure

3. What are your expectations for this project?

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4. What are your concerns about this project?

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5. What resources will you need to enable the success of this project?

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Appendix 3: Commitment certificate

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**Developmental Care  
Commitment Certificate**

*I hereby commit myself*

---

*to be an active participant in the  
Developmental care implementation project*

*Hospital  
Neonatal Intensive Care Unit*

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*Staff member's signature and Date*

## Appendix 4: Environmental audit instrument

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If item is present, please mark with a tick (✓). If not present or observable, please mark with a cross (x).

### **SECTION ONE**

#### **1. HEALTH CARE FACILITY**

1.1 Name of hospital: ..... Date: .....

1.2 Unit manager's contact details: .....

1.3 Developmental care implementation date: .....

1.4 Unit's bed capacity: .....

1.5 No. of patient in the unit: .....

1.6 Estimated staff parent ratio

:  Intensive care

:  High care

:  Low care

:  Other (specify) .....

1.7 Level(s) of neonatal care provided:

Intensive care

High care

Low care

Other (specify) .....

### **SECTION TWO**

#### **2. PRINCIPLE ONE: INDIVIDUALISED CARE**

2.1 Individualised care plan

Observed (visible)

If "Yes", briefly describe:

.....  
.....

- .....
- Procedures done according to infants needs (prn suctioning, cluster care)
  - Individualise infant's space / bed (personal belongings, toy, etc...)
  - Verified from records
  - Verified other (specify) .....
  - Lack of individualised care (specify)
- .....
- .....
- .....

2.2 Physiological stress cues (PSC) (tachycardia / bradycardia, tachypnoea / bradypnoea / apnoea, hypertension / hypotension, hypothermia, skin colour changes, feeding intolerance, hyperglycemia, hypoglycaemia)

Item	Observed	Verified from records	Verified other (specify)
Staff observe PSC	<input type="checkbox"/>	<input type="checkbox"/>	
Staff respond to PSC	<input type="checkbox"/>	<input type="checkbox"/>	
Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	

- Lack of physiological stress cue recognition (specify)
- .....
- .....
- .....

2.3 Behavioural stress cues (BSC) (extension / hyperflexion / hypotonia, splaying of hands and/or feet, crying behaviours, facial expression, etc...)

Item	Observed	Verified from records	Verified other (specify)
Staff observe BSC	<input type="checkbox"/>	<input type="checkbox"/>	
Staff respond to BSC	<input type="checkbox"/>	<input type="checkbox"/>	
Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	

- Lack of behavioural stress cue recognition (specify)
- .....
- .....
- .....



**3. PRINCIPLES TWO: FAMILY-CENTERED APPROACH**

3.1 Facilities for parents, siblings and grandparents

- Comfortable chairs
- Resting area
- Refreshments facility
- Visitation policy (specify) .....

3.2 Family involvement and empowerment facilitated by staff

- Observed (visible)  
If "Yes", briefly describe:  
.....  
.....  
.....

Item	Observed	Verified from records	Verified other (specify)
Parent(s) informed about infant's condition and related aspects	<input type="checkbox"/>	<input type="checkbox"/>	
Parent(s) involved in medical decisions made involving their infant	<input type="checkbox"/>	<input type="checkbox"/>	
Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	

- Lack of family involvement and empowerment (specify)  
.....  
.....  
.....

3.3 Parent-child bonding facilitated by staff

- Observed (visible)  
If "Yes", briefly describe:  
.....  
.....  
.....

- Verified from records
  - Verified other (specify) .....
  - Lack of parent-child bonding facilitation (specify)
- .....
- .....
- .....

3.4 Informed decision making

- Observed (visible)
- If "Yes", briefly describe:
- .....
- .....
- .....

Item	Observed	Verified from records	Verified other (specify)
Written / verbal informed consent obtained for minor procedures (x-rays, blood sampling, etc...)	<input type="checkbox"/>	<input type="checkbox"/>	
Written informed consent obtained for major procedures (surgery, blood administration, etc...)	<input type="checkbox"/>	<input type="checkbox"/>	
Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	

- Lack of informed decision making (specify)
- .....
- .....
- .....

**4. PRINCIPLE THREE: POSITIONING**

4.1 No. of patients positioned: .....

- Evidence of positioning (according to principles)

- Evidence of positioning (not correct / inefficient application)
- No evidence of positioning

4.2 Flexion (curved back, rounded shoulders, knees and ankles together with head in a neutral position)

- Observed (visible)  
If "Yes", briefly describe:

.....  
.....  
.....

- Verified from records
- Verified other (specify) .....
- Lack of flexion (specify)

.....  
.....  
.....

4.3 Midline orientation (flexed arms with hands in midline close to face, flexed legs with feet in midline)

- Observed (visible)  
If "Yes", briefly describe:

.....  
.....  
.....

- Verified from records
- Verified other (specify) .....
- Lack of midline orientation (specify)

.....  
.....  
.....

4.4 Containment (firm unrestricting boundaries, swaddled bathing / weighting / procedure)

- Observed (visible)  
If "Yes", briefly describe:

.....  
.....

- .....
- Verified from records
  - Verified other (specify) .....
  - Lack of containment (specify)
- .....
- .....
- .....

4.5 Kangaroo care (skin-to-skin contact, nutrition, early discharge)

- Observed (visible)  
If "Yes", briefly describe:

.....

.....

.....

- Continuous kangaroo care (24hrs/day excl. mother's bath time)
  - Intermittent kangaroo care (20min/day minimum)
  - Verified from records
  - Verified other (specify) .....
  - Lack of kangaroo care (specify)
- .....
- .....
- .....

4.6 Positioning aids used

- None
- Linen (blankets, towels, sheets, etc...)
- Specifically designed positioning aids
- Gel wedges / gel cushions
- Sheepskin bedding / soft mattresses
- Other (specify) .....

**5. PRINCIPLE FOUR: HANDLING TECHNIQUES**

5.1 No. of patients handled: .....

- Evidence of handling - according to principles
- Evidence of handling - not correct / inefficient application

No evidence of handling

5.2 Positive touch (skin-to-skin, hands-on containment, transitional touch)

Observed (visible)

If "Yes", briefly describe:

.....  
.....  
.....

Verified from records

Verified other (specify) .....

Other positive touch (specify) .....

Lack of positive touch (specify)

.....  
.....  
.....

5.3 Correct routine touch (firm touch palmer touch,

Observed (visible)

If "Yes", briefly describe:

.....  
.....  
.....

Incorrect techniques observed (stroking, rubbing, tickling, etc...)

Verified from records

Verified other (specify) .....

Lack of correct routine touch (specify)

.....  
.....  
.....

5.4 Positional changes (containment during positional changes, slow motion, one direction at a time)

Observed (visible)

If "Yes", briefly describe:

.....  
.....  
.....

- Verified from records
  - Verified other (specify) .....
  - Lack of correct positional changes (specify eg. 'Premie-flip')
- .....
- .....
- .....

5.5 Cluster care

- Observed (visible)  
If "Yes", briefly describe:  
.....  
.....  
.....
  - Specified rest time for infants (between 12h00 and 14h00)
  - Verified from records
  - Verified other (specify) .....
  - Lack of cluster care (specify)
- .....
- .....
- .....

5.6 Day-night cycle

- Observed (visible)  
If "Yes", briefly describe:  
.....  
.....  
.....
  - Built into routine care (longer rest periods during the night)
  - Verified from records
  - Verified other (specify) .....
  - Lack of day-night cycle (specify)
- .....
- .....
- .....

**6. PRINCIPLE FIVE: ENVIRONMENTAL MANIPULATION**

6.1 Light (dimmer switches, individual lighting, protective barriers over eyes)

Observed (visible)

If "Yes", briefly describe:

.....  
.....  
.....  
.....

Verified from records

Verified other (specify) .....

Lack of reduced lighting (specify)

.....  
.....  
.....  
.....

6.2 Noise (no radio or TV, soft talking away from infant's bed, quick response to telephone and alarms, quiet shoes, music therapy, protective barriers over ears)

Observed (visible)

If "Yes", briefly describe:

.....  
.....  
.....  
.....

Verified from records

Verified other (specify) .....

Lack of reduced noise (specify)

.....  
.....  
.....  
.....

6.3 Smell (reduction of strong odours, positive olfactory stimuli)

Observed (visible)

If "Yes", briefly describe:

.....  
.....  
.....  
.....

- Verified from records
- Verified other (specify) .....
- Lack of negative smell manipulation (specify)

.....  
.....  
.....  
.....

**7. PRINCIPLE SIX: NON-NUTRITIVE SUCKING**

7.1 Non-nutritive sucking (pacifiers, thumbs, nipple, during feeding, for self-regulatory effect)

- Observed (visible)  
If "Yes", briefly describe:

.....  
.....  
.....  
.....

- Verified from records
- Verified other (specify) .....
- Lack of non-nutritive sucking (specify)

.....  
.....  
.....  
.....

**8. PRINCIPLE SEVEN: PAIN MANAGEMENT**

8.1 Pain management (syrup simplex during painful procedures or during stressful episodes)



Observed (visible)

If "Yes", briefly describe:

.....  
.....  
.....  
.....

Verified from records

Verified other (specify) .....

Lack of pain management (specify)

.....  
.....  
.....

**SECTION THREE**

**9. ORIENTATION, TRAINING AND PARTICIPATION**

9.1 How often do you get new staff in the unit (organogram)?

.....

Stays constant (specify) .....

Rotate (specify: internal / external)

Who rotates?.....

Rotation intervals? .....

9.2 Is orientation regarding developmental care given to all new staff?

Yes

No

Not applicable

9.3 If "Yes", how is the orientation conducted (copy)?

Oral orientation  Verified from in-service records

Written orientation  Verified from in-service records

Other (specify) .....

9.4 Have staff members in the unit had specific training regarding developmental care implementation?

Yes

No

Unsure

If "Yes", specify: .....  
.....  
.....  
.....

9.5 Is there a protocol / policy that ensures all staff are adequately training in developmental care principles?

Yes

No

Unsure

If "Yes", specify: .....  
.....  
.....

9.6 Which categories of staff are involved in developmental care?

Medical staff

Nursing staff

Allied health

Non-medical support services (cleaning staff, ward clerk, porter, etc...)

Other (specify) .....

9.7 What is the multidisciplinary team's level of involvement?

Much involvement and/or support

Some involvement and/or support

Impartial / little support / resistance

Other comments (specify) .....  
.....  
.....

9.8 Which managerial positions are involved in developmental care?

CEO / Superintendent

Nursing service manager (specify)  
.....  
.....

Unit manager / Sister in charge

Other (specify) .....

9.9 What is the management's level of involvement?

- Much involvement and/or support
- Some involvement and/or support
- Impartial / little support / resistance

Other comments (specify) .....

.....

.....

9.10 General impression on routine application of developmental care principles

- Good
- Average
- Poor
- Unsure

Comments:.....

**10. DEVELOPMENTAL CARE DOCUMENTATION**

10.1 Nature of unit record(s) showing proof of developmental care

- Unit register
- Nursing records / bed letter
- Medical records
- Individualised care plan form
- Other (specify) .....

10.2 Policies available in the unit

- Developmental care policy (view policy)
- Kangaroo care policy (view policy)
- Developmental care included in unit philosophy (view philosophy)
- Developmental care included in unit mission (view mission)
- Developmental care included in unit vision (view vision)
- Other (specify) .....

10.3 Guidelines and procedures for developmental care implementation

- Medical staff
- Nursing staff
- Allied health
- Non-medical support services (cleaning staff, ward clerk, porter, etc...)
- Other (specify) .....

10.4 What information is available for parents?

- Information sheet(s) / pamphlet(s)
- Oral education (verify from parents)
- Books / internet resources / poster(s) or pictures on wall
- Other (specify, eg video, audiotapes) .....

## Appendix 5: Institutional informed consent document

### **APPLICATION TO CONDUCT A RESEARCH STUDY**

Faculty of Health Sciences Research Ethics Committee  
University of Pretoria  
Pretoria Academic Hospital  
South Africa  
Tel: (012) 339 8612  
Fax: (012) 339 8587  
E Mail: [manda@med.up.ac.za](mailto:manda@med.up.ac.za) - Main Committee  
E Mail: [dbehari@med.up.ac.za](mailto:dbehari@med.up.ac.za) - Student Committee

Soutpansberg Road - MRC-Building - Level 2 - Room 19  
Private Bag x 385 – Pretoria – 0001

### **GENERAL INFORMATION AND AGREEMENT BY APPLICANT**

1. **APPLICANT:** Investigator Angie Catherina Hennessy
- 1.1 **FIRM:**
  - Name of firm : N/A
  - Telephone Number: +27 12 3464099 (H), +27 82 371 5104
  - Fax Number: +27 12 4609713
  - E.Mail address: angiech@iafrica.com
  - Postal Address: P.O.Box 1218, Groenkloof, Pretoria, SA, 0027
- 1.2 **FULL TITLE OF RESEARCH STUDY:** Facilitation of developmental care for high-risk neonates: an intervention study
- 1.3 **OUTLINE DETAILS OF PREVIOUS TRIALS/EVALUATIONS CONDUCTED IF ANY:**  
Developmentally Supportive Care: The effects of positioning on the stress levels of the preterm infant (S112/2002)
- 1.4 **REGISTRATION**
  - 1.4.1 **NON-PHARMACEUTICAL**
    - 1.4.1.1. State registration/code number : N/A
    - 1.4.1.2. What is the estimated cost of these investigations? R24 150.00
    - 1.4.1.3. Who will be responsible for these costs? The Researcher
    - 1.4.1.4. What other equipment will be required for the study? All necessary equipment will be provided by the researcher, eg linen, if the need arises during DSC implementation.

**1.5 ARE ANY SPECIAL PRECAUTIONARY MEASURES TO BE TAKEN AND BY WHOM?**

Any items needed for the research study will be provided by the researcher at no additional cost to your hospital.

**1.6 INDICATE EXPECTED DATE OF RESEARCH STUDY REPORT:**

DAY	MONTH	YEAR
30	November	2005

**1.7 INDICATE NUMBER OF PARTICIPANTS INVOLVED:**

The researcher would like to conduct in-depth interviews with members of the multidisciplinary team involved during the implementation of developmental care.

**1.8 THE NAME(S) OF THE HEAD OF THE DEPARTMENT:**

\_\_\_\_\_

**1.9 WILL SUFFICIENT RESEARCH STUDY MATERIAL BE SUPPLIED?**

Yes  No

**1.10. AGREEMENT BY APPLICANT**

1.10.1. The applicant(s) agree(s) as follows

1.10.2. To conduct the research study recorded in and under the conditions set out in this application form.

1.10.3. To conduct this research study at no additional expense to your hospital whatsoever.

1.10.4. To accept full responsibility for any or all possible harmful effects on a participant by participating in the in-depth interview.

1.10.5. To exonerate your hospital from all liability of damages, legal, financial or otherwise, including my claim instituted by a participant involved in this study.

THE APPLICANT MUST SIGN HERE

APPLICANT- INVESTIGATOR			DATE		
Signature	Initial(s)	Surname	Day	Month	Year

**Designation/ Rank:**

**2. INITIAL CONSENT BY DEPARTMENTAL HEAD**

2.1 I \_\_\_\_\_ head of \_\_\_\_\_

department of \_\_\_\_\_ hospital in consultation with the Chief Executive Officer / Superintendent of this Hospital grant permission to submit an application to conduct a research study to the Chairperson (s) of the relevant Ethics, Research and Therapeutic Committees of this Hospital.

2.2 The officer conducting the trial/evaluation will be \_\_\_\_\_

Designation / Rank \_\_\_\_\_

**THE HEAD OF THE DEPARTMENT MUST SIGN HERE!**

HEAD OF DEPARTMENT			DATE		
Signature	Initial(s)	Surname	Day	Month	Year

THE APPLICANT MUST SIGN HERE

TRIALIST-INVESTIGATOR			DATE		
Signature	Initial(s)	Surname	Day	Month	Year

2.3. APPROVAL BY HOSPITAL CHIEF EXECUTIVE OFFICER:

I \_\_\_\_\_ Chief Executive Officer / superintendent of \_\_\_\_\_ Hospital, hereby agree that this trial / evaluation be conducted in the \_\_\_\_\_ Department of this hospital. The officer conducting the trial will be: \_\_\_\_\_

The officer controlling supplies will be: \_\_\_\_\_

HOSPITAL C.E.O. / Superintendent			DATE		
Signature	Initial(s)	Surname	Day	Month	Year

3. APPROVAL BY SUPERINTENDENT GENERAL :

SUPERINTENDENT GENERAL			DATE		
Signature	Initial(s)	Surname	Day	Month	Year

## Appendix 6: In-depth interview informed consent document

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### **INTRODUCTION**

You are invited to volunteer for this research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the researcher. You should not agree to take part unless you are completely happy about what is expected of you.

### **WHAT IS THE PURPOSE OF THIS STUDY?**

The purpose of this study is to develop an evidence-based practice model for the implementation of Developmentally Supportive Care (DSC) in a South African public Neonatal intensive care unit (NICU). The study is planned in six phases.

The research phases and objectives are as follows:

Phase 1: Problem analysis and project planning

- To describe a conceptual framework for implementation of DSC in a South African public NICU.

Phase 2: Information gathering and synthesis

- To identify the factors involved in the successful implementation of DSC in a South African public NICU.

Phase 3: Design

- To plan and apply the information needed for the implementation of DSC.

Phase 4: Early development and implementation

- To execute the implementation plan (from phase 2 & 3) for DSC implementation in a South African public NICU.

Phase 5: Evaluation of implementation

- To evaluate the implementation plan through monitoring progress into a public NICU.

Phase 6: Advanced development and dissemination.

- To describe an evidence-based model for the implementation of DSC in a South African context.



### **WHAT IS EXPECTED OF YOU DURING THIS STUDY?**

As a participant, you will be expected to participate in an in-depth interview with the researcher about the implementation of DSC. The topics covered during the interview will help the researcher to determine and identify factors that promote or inhibit the successful implementation of developmental care. The interview will take approximately an hour and a half to complete. The completion of the interview will take place during a visit to your hospital. The interview will be digitally recorded on a digital voice recorder. During the interview, the researcher might take field notes. Once transcribed and analysed, the data will be kept in a safe place and confidentiality will be ensured at all times. No names will be mentioned in the analysed information and participants will remain anonymous.

### **HAS THE STUDY RECEIVED ETHICAL APPROVAL?**

This study protocol (21/2004) has received ethical approval from the Research Ethics Committee of the University of Pretoria (South Africa), Faculty of Health Sciences. The study is also fully supported by the Department of Nursing Science, University of Pretoria.

### **WHAT ARE YOUR RIGHTS AS A PARTICIPANT IN THIS STUDY?**

Your participation in this study is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will involve no penalty or loss of benefits. As all data collected remains confidential and anonymous, please note that once data has been transcribed and analysed, tracing of information to a particular participant will be unattainable and recall of consent at this stage will not be possible.

### **MAY ANY OF THESE STUDY PROCEDURES RESULT IN DISCOMFORT OR INCONVENIENCE?**

Involvement in the in-depth interviews will take time for participation, which is highly appreciated. There will be no other discomfort or inconvenience.

### **WHAT ARE THE RISKS INVOLVED IN THIS TRIAL?**

There are no risks involved in participation in this study.

### **CONFIDENTIALITY**

All information obtained during the in-depth interview is strictly confidential. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study.

#### **SOURCE OF ADDITIONAL INFORMATION**

If you have any questions during this study, please do not hesitate to approach the researcher. Researcher: Ms A.C. Hennessy +27 82 371 5104 (mobile)

[angiech@iafrica.com](mailto:angiech@iafrica.com)

Supervisor: Dr S.J.C. van der Walt +27 12 354 2125

#### **INFORMED CONSENT**

I hereby confirm that I have been informed by the researcher, Ms A.C. Hennessy about the nature, conduct, benefits and risks of the study. I have also received, read and understood the above written information (Participant Information Leaflet and Informed Consent) regarding the study. I am aware that the results of the study, including personal details will be anonymously processed into the research report for possible publication in scientific journals and use in training programs.

I may, at any stage, without prejudice, withdraw my consent and participation in the study. I have had sufficient opportunity to ask questions and of my own free will declare myself prepared to participate in the study.

Participant's name ..... (Please print)

Participant's signature ..... Date .....

Witness's name ..... (Please print)

Witness's signature ..... Date .....

I, Ms A.C. Hennessy herewith confirm that the above participant has been informed fully about the nature, conduct and risks of the above study.


Researcher's name ..... (Please print)

Researcher's signature ..... Date .....

Appendix 7: Developmental care launch pamphlet

**What are the evidence-based benefits of Developmental Care?**

- ↓ hospital costs
- ↓ hospitalisation period
- ↑ growth & weight gain
- Improved neurodevelopmental outcomes
- ↓ morbidity
- ↓ stress levels
- Improved respiratory status
- Improved physiological stability
- Faster transition from tube to oral feeds
- Improved self-calming abilities




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Developmental Care Implementation Project

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**Developmental  
Care  
Project Launch**



**Their future is in  
OUR hands!**

## What is Developmental Care?

Developmental care is an approach introduced during the 1980s abroad that altered the conventional care delivered to sick and preterm infants in order to support positive growth and development. The principles of developmental care aim at altering the neonatal intensive care unit (NICU) environment to simulate the uterine environment, hereby providing protection for the vulnerable neurological system. It allows for the stabilisation of physiological and behavioural functioning by protecting the developing neurological system, which may ultimately improve neurodevelopmental behaviour of these infants.



### Why do we need developmental care?

It is well known that the NICU is a noisy and busy environment that often causes much stress for the health professionals working there. Neonates, especially sick and preterm infants experience this stress too! Each stressful incident may alter the normal growth and development that would have taken place in all systems, especially the neurological system.

Internal stressors (e.g. pain, hypoxia, acid-base disturbances, infection, etc...) and external stressors (e.g. bright light, noise, incorrect positioning, sleep interruptions, excessive handling, etc...) result in stress for the neonate who presents with stress cues. Stress cues can present in two ways namely behavioural cues or physiological cues (e.g. blood pressure changes, tachycardia, bradycardia, feeding intolerance, etc...).

Behavioural cues are generally seen first and include the following: generalised hypotonia, flaccidity or floppiness, hyperextension of extremities or body, splaying of fingers and toes, facial expressions (grimace & frown), irritable behaviour, sleep disturbances, hiccupping, sneezing, gagging, spitting up and yawning.

Developmental care reduces external stressors which results in an improved environment for optimal growth and development.



**Behavioural Stress Cues**

### What are the principles of Developmental Care?

- Individualised infant care (incl. Cluster care)
- Family-centered care
- Specific positioning (incl. Kangaroo Care)
- Appropriate handling and touch
- Non-nutritive sucking
- Environmental manipulation (incl. noise reduction, light reduction & positive smell stimuli)
- Pain medication (use of syrup simplex solution and non-pharmacological interventions)

Appendix 8: Fundraising photographs





Appendix 9: Photographs of new positioning aids

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