# **Kathmandu University School of Medical Sciences**

# **Institutional Review Committee**

### **Contact: KUSMS, Dhulikhel, P.O. Box: 11008, Nepal**

##### Tel: 977-11-490497, Fax: 977-11-490707

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**Application for Ethical Approval of Research Proposal**

**(KUSMS/IRC)**



Title: Skin changes of the newborn born in Dhulikhel hospital

***NOTE:***

* *Please read the instructions carefully and complete all the sections (that implies to your research)*
* *Type all the entries in English- Times New Roman Font, size 12 without bold/ Italics.*
* *Submit the completed application at IRC office, Dhulikhel Hospital.*

**Research Proposal Description**

#### Do you have funding for your project? (Encircle the answer)

a. Yes b. No c. Applied for funding but not approved

**Do you have any collaboration for this research project?**

a. None b. National c. International

#### 1. Summary of the Proposed Research Protocol (Up to 200 words)

The newborn or neonatal period is the first 4 weeks of extrauterine life. The skin of the neonate differs from adult in several ways. The thickness of newborn skin is 40% to 60% of that of adult skin. It has weaker intercellular attachment and produces lesser amount of sweat.[1](#_ENREF_1) About 96% to 99.3% of all newborn babies suffer from one or the other dermatosis if skin examination is carried out as discussed by Moosavi Z[2](#_ENREF_2) and Rivers JK[3](#_ENREF_3) but pathological skin changes were observed in 41.2% neonates only by Nobbay et al[4](#_ENREF_4).

It is necessary for those who provide neonatal care to differentiate physiological skin lesions from other more serious skin conditions which will help avoid unnecessary therapy to neonates.The parents can be assured of good prognosis of these skin manifestations.

#### 2. INTRODUCTION:

***2.1. Background:***

*(Relevant to the topic, preferably recent evidences to drive the need of the study)*

A number of innocent rashes occur in neonates. They are usually transient and self- limited and thus require no therapy.[5](#_ENREF_5) In a study conducted by Lorenz S et al[6](#_ENREF_6) in Germany, 59.7% of the skin lesions were transient, with vascular lesions as nevus flammeus and hemangioma as the most common skin lesions. In a study conducted by Zagne V et al[7](#_ENREF_7) in Brazil, mongolian spot and epidermal hyperpigmentation were common with the non-white newborns; erythema toxicum and cutis marmorata with the white newborns; salmon patch with the female sex; physiologic desquamation with the cesarean section. Similary Ferahbas et al[8](#_ENREF_8) in Turkey reported xerosis/desquamation as the most common skin finding followed by sebaceous hyperplasia, transient toxic erythema, salmon patch, Mongolian spot, cutis marmorata, suction bulla, miliaria, hypertrichosis, and dermatitis. Only 4.3% of neonates has no skin change. Odeyegi et al[9](#_ENREF_9) in Nigeria noted Mongolian spots, malaria, salmon patch, erythema toxicum, nevus, milia, café au lait spots and sebaceous gland hyperplasia as the common skin condtion in descending order. Sachdeva et al[10](#_ENREF_10) in India reported epstein pearls as the commonest skin change followed by  Mongolian spot, superficial cutaneous desquamation, icterus, milia, sebaceous gland hyperplasia, occipital alopecia, lanugo, peripheral cyanosis, breast hypertrophy and miniature puberty.

We can see different skin changes are more common in different countries. There is paucity of data regarding the study on neonatal skin conditions in Nepal. Hence this study is planned to see the incidences of different skin condition and their maternal-neonatal association.

***2.2. Statement of the Problem/ Rationale/ Need of the study:***

Physiological skin lesions is a common neonatal skin condition. This study is carried out to see the incidences of different common neonatal skin conditions to help differentiate it from pathological skin condition.

***2.3. Research Hypothesis:***

Physiological skin condition is more common than pathological skin condition.

***2.4. Objectives of the Research:***

***Primary Objective:***

To see the incidence of common neonatal skin conditions.

***Secondary Objective(s):***

To see the relationship of skin lesions with maternal-neonatal factors

***3*. METHODS/ METHODOLOGY:**

***3.1. Study design:***

*(Elaborate if it is a qualitative or a quantitative research. If quantitative, Experimental or observational- cohort, case control or a cross sectional study)*

It is a quantitative, observational and cross sectional study.

***3.2. Participants/ Study population:***

*(Describe the participant characteristics if it is healthy individuals, or patients from outpatient department or hospital wards or community)*

All the healthy neonates born by vaginal or caesarian section in Dhulikhel hospital will be included in the study.

***3.3. Selection Criteria:*** *(list out the criteria in bullets)*

***Inclusion Criteria:***

* Live neonates within the first 3 days of life

***Exclusion Criteria:***

* Neonates kept in neonatal intensive care unit(NICU) or neonatal unit.
* Outborn babies

***3.4. Study Site and justification:***

*(Explain where will the research be conducted for example: hospital ward, outpatient department or community with reasons of selecting the site)*

The research will be conducted in the obstetric ward of the hospital where the newborns will be with the mother.

***3.5.a. Sampling method/ technique:***

All the live neonates born from December 2016 to May 2017 will be included in the study

***3.5.b. Sample Size:*** *(including the calculation of sample size using appropriate formula if applicable)*

All the live neonates born from December 2016 to May 2017 will be included in the study

***3.6. Data Collection Tools/ Measures:***

*(Include the list of data collection tools that will be used in the research including the clinimetrics/ psychometric properties/ reliability and validity of the tools. If the tool is self- designed, explain in brief how it was designed, and if pre-testing was done)*

Thorough dermatological examination of the newborn babies will be done. The variables of each case will be age, ethnicity, parity of mother, blood group of mother, mode of delivery, the sex, birth weight and gestational age at the time of examination. Dermatological consultation will be done whenever required. The newborn will be examined till discharge. The lesions will be studied to assess the relationship between their occurrence and the various maternal/ neonatal aspects and finally the results will be tabulated.

***3.7. Procedure:***

*(Explain the steps in the data collection, including how the participants will be screened, how consent will be obtained. In case the research involves invasive techniques or intervention, explain the procedure in detail. In experimental design, include how randomization, allocation concealment etc will be done).*

Consent will be taken from the parent. All the babies born and beside the mother will be examined thoroughly by removing their clothes to see for the skin changes. Oral cavity will be examined for Epstein pearls.

***3.8. Plan for data analysis:***

*3.8.a. Software that will be used for data analysis:*

Data will be entered in Microsoft word and analysis will be done with SPSS 20

*3.8.b. Statistical tests: (Specify the most probable statistical tests that will be used to analyse the data depending on the predicted nature of data)*

Descriptive analysis will be presented as table, charts or percentage

***4. Limitations of the Study*** *(if any):*

***5. Significance of the Study:***

This study will help us know common physiological skin changes in newborn and no medical intervention is warranted for them. It will also help us know if there is association between common skin changes and maternal-neonatal factors.

***6. Plan for Supervision and Monitoring:***

All the newborns will be examined in the daily morning rounds. Dermatological consultation will be done if required. Any skin changes will be noted.

***7. Plan for Data Management:***

*(Explain how the data will be managed, where will be the data be stored, how will be the confidentiality of the data maintained)*

The skin changes will be noted in the proforma and the filled proforma will be kept in a separate cupboard.

***8. Plan for dissemination of the research:***

The research is planned to publish in one of the index journal of Nepal.

The research will be presented in national or international conference in the future.

***9. Work Plan*** *(should include duration of study, tentative date of starting the project and work schedule)*

|  |  |  |
| --- | --- | --- |
| **Work** | **Duration/ Date** | **Remarks** |
| *Protocol writing* | 15/10/2016 to 30/10/2016  ( 2weeks ) |  |
| *Anticipated time of protocol approval* | 30/10/2016 to 15/11/2016  ( 2 weeks) |  |
| *Clinical trial registry (in case of clinical trial)* |  |  |
| *Data collection and data entry* | 1/12/2016 to 31/5/2017  (6 months) |  |
| *Data analysis* | 1/3/2017 to 1/4/2017  (4 weeks) |  |
| *Manuscript/ Thesis book preparation* | 1/5/2017 to 1/6/2017  (4 weeks) |  |
| *Submission to journal/ Dissemination* | 01/7/2017 |  |

**10. ETHICAL CONSIDERATION**

*(Ethical principles are based on Declaration of Helsinki. Please refer to explanations of the ethical consideration in the Declaration of Helsinki)*

|  |  |  |
| --- | --- | --- |
| **10.1. Ethical issues** | **Yes/ No** | **Justification if yes** |
| 1. Are human participants included in the study? | Yes | All the healthy live newborns will be included |
| 1. Are **vulnerable members** of the population required for this research? *(includes age under 18, pregnant women etc)* | Yes | All the healthy live newborns will be included |
| 1. Are there any risks involved for the participants? If yes, identify clearly what are the expected risks for the human participants in the research and provide a justification for these risks. | No |  |
| 1. Are there any benefits involved for the participants? If yes, identify clearly what are the expected benefits for the participants. | Yes | Normal physiological skin changes will be noted. Unwanted medical intervention for the normal skin condition will be avoided. |

**10.2. Clearly indicate the participant’s responsibilities in the research. What is expected of the research participants during the research?**

The newborn, by the motherside, will be examined for skin changes.

***10.3. Obtaining the Consent :***

***10.3.a. How will the informed consent be obtained from the research participants?***

The written informed consent will be obtained from the research participant’s parent.

***10.3.b. Who will obtain the consent from the study participants?***

The researcher himself will obtain the consent from the study participants.

***10.3.c. Is there anything being withheld from the research participants at the time the informed consent is being sought? Mention “YES” or “NO”***

No

*If yes, explain*

**INFORMED CONSENT FORM / ETHICAL ISSUES:**

**Statements required in the Informed Consent Form include:**

1. Clear **purpose of the research**
2. **Voluntary participation**
3. **Rights to withdraw** from the study: A statement that the human participants can withdraw from the study at any time without giving reason and without fear.
4. Statement to **assure confidentiality** of the participant’s details.
5. Statement **of compensation** that might be given to the research participant and or their community (if any).
6. **Risk of participation**
7. **Benefits of the participation**
8. A statement indicating that the participants has **understood** all the information in the consent form and is willing to volunteer / participate in the research.
9. Signature space for the research participants, a witness with the date.

*Note- Informed Consent form should be submitted in English language and in the language appropriate to the research participants, example- Nepali.*

**11. BUDGET PLAN** *(Include the details of anticipated budget for your research. Only few examples of the items are listed, you may add up items based on the nature of your research. Please note that the figures in the table are just examples)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SN** | **Items** | **Unit** | **Unit cost (NRs)** | **Total**  **(NRs)** |
| 1 | Ethical clearance | - | - | 500 |
| 2 | Cost for printing/ photocopy | 500 | 2 | 1000 |
| 3 | Allowance for participants | 100 | 100 | 10000 |
| 4 | Laboratory cost |  |  |  |
| 5 | Payment to research assistant |  |  |  |
|  |  |  |  |  |
|  | Total |  |  |  |

**Annexes**

1. Annexes should include
2. References
3. Data Collection Instruments including data collection forms, self reported outcome measures, questionnaires etc
4. Information Sheet and Informed consent form (Should be in English and also in the language of participants)
5. List of abbreviations
6. Recently updated Curriculum Vitae of Principal Investigator
7. For Students- Approval letter from Academic Supervisor

# **REFERENCES**

1. Haveri F IA. A Cross-Sectional Prospective Study of Cutaneous Lesions in Newborn. ISRN Dermatology. 2014:1-9
2. Moosavi Z HT. One year survey of cutaneous lesions in 1000 consecutivenewborns. Pediatric Dermatol. 2006;26:61-3
3. Rivers JK FP, Dibdin C. A prevalence survey of dermatosis in the Australian neonate. J Am Acad dermatol. 1990;23:77-81
4. Rivers JK FP, Dibdin C. A prevalence survey of dermatosis in the Australian neonate. J Am Acad dermatol. 1990;23:77-81
5. Shajari H SA, Sajadian e al. The incidence of birthmarks in iranian neonates. Acta Medica Iranica. 2007;45(5):424-6
6. Lorenz S MC, Segerer H et al. Skin changes in newborn infants in the first 5 days of life. Hautarzt. 2000;51(6):396-400
7. Zagne V FN. Dermatoses in the first 72 h of life: A clinical and statistical survey. Indian Journal of Dermatology, Venereology, and Leprology. 2011;77(4):470-6
8. Ferahbas A US, Akcakus M et al. Prevalence of Cutaneous Findings in Hospitalized Neonates: A Prospective Observational Study. Pediatric Dermatology. 2009;26(2):139-42.
9. Oyedegi O MV, Ogunlesi T et al. Dermatoses in the Nigerian Newborn. Research Journal of Medical Sciences. 2008;2(1):19-22.
10. Sachdeva M KS, Nagpal M et al. Cutaneous changes in newborn. Indian J Dermatol Venereol Leprol. 2002;68(6):334-7

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date** | **Name** | **IP No** | **AGE(Mother)** | **BG(Mother)** | **Parity** | **Gest**  **age** | **MOD** | **Wt/**  **Sex** | **SKIN CHANGE**  **Day 1** | **SKIN**  **Day 2** | **SKIN**  **Day 3** |
|  |  |  |  |  |  |  | VD  CS |  | * Mongolian spot(MS) * Erythema toxicum(ET) * Milia * Stork bite(SB) * Others (plz specify..) | * MS * ET * Milia * SB * Others | * MS * ET * Milia * SB   Others |
|  |  |  |  |  |  |  | VD  CS |  | * Mongolian spot * Erythema toxicum * Milia * Stork bite * Others (plz specify..) | * MS * ET * Milia * SB * Others | * MS * ET * Milia * SB * Others |
|  |  |  |  |  |  |  | VD  CS |  | * Mongolian spot * Erythema toxicum * Milia * Stork bite * Others (plz specify..) | * MS * ET * Milia * SB * Others | * MS * ET * Milia * SB * Others |

PROFORMA

**CURRICULUM VITAE**

**Dr. ASIM SHRESTHA   
MBBS, MD Paediatrics**

Dhulikhel Hospital, Kathmandu University Hospital  
Nepal Medical Council Registered No. 8126

Age- 33 years

Date of Birth- 16th November, 1983

Marital Status: Married to Dr. Smriti Shrestha (Dermatologist)

Children : 1 daughter (5 years of age)

Permanent Address- Gongabu-4, Kathmandu.

Email: kums\_asim@yahoo.com

Phone No: 9860391547/ 9841327568

**Academic qualifications:**

|  |  |  |  |
| --- | --- | --- | --- |
| Degree | Institution | University | Year |
| MD Paediatrics | College of Medical Sciences, Bharatpur | Kathmandu University | 2014 |
| MBBS (Bachelor in Medicine and Bachelor in Surgery) | Kathmandu University School of Medical Sciences (KUSMS), Dhulikhel | Kathmandu University | 2008 |
| Intermediate in science (I Sc.) | Kathmandu University | Kathmandu University | 2002 |
| School Leaving Certificate (SLC) | Notre Dame School, Bandipur, Tanahun | Nepal Government | 2000 |

**Work Experiences:**

1. Worked as a Medical Officer at Dhulikhel hospital, Kathmandu university teaching hospital in Department of Paediatrics Feb 2009-December 2009
2. Worked as a Medical Officer at Man Mohan Memorial Community Hospital Jan 2010- Feb 2010.

3. Worked as a Lecturer in Pediatrics at Taishan Medical University, Taian, Shangdong, China March 2010-July2010

4. Worked as a Lecturer in Pediatrics at Qiqihar Medical University, Qiqihar, China Sept 2010-Jan 2011.

**Research work:**

1. Attended seminar on Paediatric Advanced Life Support(PALS) conducted by Indian Academy of Paediatrics(IAP) in BPKIHS, Dharan on April 2013.
2. Attended ‘Workshop on Neonatal Ventilation’ conducted by doctors from AIIMS, India under NEPAS on December 2014

**Thesis entitled:** Clinical Profile and Risk factors of Neonatal Hypoxic Ischemic Encephalopathy

**INFORMED CONSENT FORM / ETHICAL ISSUES:**

**CONSENT FORM**

**Skin Changes in Newborn in Dhulikhel Hospital**

I hereby agree with my own will and volunteer to participate in the study mentioned above. The main purpose of this study is to identify skin changes in newborn .The study has been explained to me by the researchers and I understand the purpose and implications of this research.

The information is provided and the questions are asked in a language I understand. I understand that this participation is entirely voluntary.

I can withdraw my consent to participate at any time without prejudice to the extent that my record can be removed from the research.

All personal reports will be treated confidentially by the researchers.

Principle researcher: Dr. Asim Shrestha

Signature: . . . . . . . . . . . . . . . . . . .

Participant’s name: . . . . . . . . . . . . . . . . . .

Signature: . . . . . . . . . . . . . . . . . . .............

Address:....................................................

Date: . . . . . . . . . . . . . . . . . . ....................

**ABBREVIATIONS**

NICU-Neonatal Intensive Care Unit