UNIVERSITY of CALIFORNIA, SAN DIEGO
SCHOOL OF MEDICINE

Rady Children's Hospital San Diego

Division of Neonatology – Feasibility and Scientific Review Submission Form *Submit completed form to* ***NICUStudies@health.ucsd.edu***

I. Date Submitted:

Title:

II. Principal Investigator:

Contact Email: **Contact Phone:**

Co-Investigator/Dept. (if applicable):

III. Additional documents submitted for review:

- ☐ IRB Research Plan or Master Protocol (*required*)
- ☐ Approval emails/letters from relevant units/leadership (*required, if applicable*)
- ☐ Statement of Feasibility (i.e. PI effort, subject availability, resources needed) (*required*)
- ☐ Consent Form(s)
- ☐ Budget
- ☐ Other:

IV. Study Location *(check all that apply)*

- ☐ UCSD Jacobs Medical Center* *Level III – 52 beds*
- ☐ UCSD Hillcrest Medical Center *Level II – beds*
- ☐ RCHSD/Rancho Springs Medical Center *Level II – 13 beds*
- ☐ RCHSD/Palomar Medical Center *Level II – 4 beds*
- ☐
- ☐ Rady Children's Hospital – San Diego *Level IV – 54 beds*
- ☐ RCHSD/Scripps Memorial Hospital La Jolla *Level III – 14 beds*
- ☐ RCHSD/Scripps Memorial Hospital Encinitas *Level II - 8 beds*
- ☐ RCHSD/Scripps Mercy *Level II - 19 beds*
- ☐ RCHSD/Scripps Chula Vista *Level II – 10 beds*

*Must present project at JMC Research Meeting and obtain approval from Unit Director

V. Type of Submission

- ☐ Investigator Initiated Clinical Trial
- ☐ Chart Review
- ☐ Observational
- ☐ Industry Sponsored Clinical Trial *Sponsor:*
- ☐ Network/Multicenter Clinical Trial (participating site)
- ☐ Survey/Questionnaire

VI. Funding

- ☐ Funding not necessary
- ☐ Funding proposal in development
- ☐ Funding proposal under review

Specify:

- ☐ Division funding
- ☐ NIH funded
- ☐ Extramural, non-NIH funding

Specify:

VII. Does this study involve collaboration with another department, laboratory, or service provided by an entity outside the Department of Pediatrics? ☐ NO ☐ YES (*if yes, please explain below)*

VIII. Consent

☐ Written informed consent

☐ Waiver of written consent

IX. Population/Accrual

1. Gestational Age:
2. Weight Criteria:
3. Diagnosis:
4. Total Enrollment Numbers/Records to be Reviewed:
5. Are you aware of any studies that may compete in terms of enrollment? ☐ YES ☐ NO

X. Sample Collection? ☐ NO ☐ YES *(if yes, complete the following)*

☐ Whole Blood ☐ Serum ☐ Breast Milk ☐ Saliva ☐ Urine ☐ Stool

☐ Other

Source of sample(s):

Total vol. and # of sample(s):

XI. Will Investigational/Commercial drugs be administered? ☐ NO ☐ YES *(if yes, complete below)*

Drug Name:

Sponsor/Manufacturer:

XII. Will an investigational device be used? ☐ NO ☐ YES (*if yes, is device exempt?* ☐ NO ☐ YES)

XIII. Stakeholder Involvement

Will the study involve the following? If yes, to what extent? *(check all applicable)*

Resources Needed		***Specify involvement needed***
☐	Nursing	
☐	RT	
☐	Newborn	
☐	Investigational Pharmacy	
☐	Other (Dietary, IT, OT, HRIF, etc.)	
☐	Fellows (as a group)	☐ Screening/Consenting ☐ Data Collection ☐ Regulatory Documentation ☐ Data Entry ☐ Other:
☐	Division Research Team	☐ Screening/Consenting ☐ Data Collection ☐ Regulatory Documentation ☐ Data Entry ☐ Sponsor/Multicenter Correspondence ☐ Database Creation/Management ☐ Unit Education ☐ Sample Collection/Processing ☐ Other:

Reminder: Send relevant stakeholder approvals (emails/letters) to the Division Research Team