# Boston Children's Hospital (BCH) Division of Newborn Medicine Discovery Pilot Grant For Clinical Research Intake Form

Title:

# **Principal Investigator:**

### Newborn Medicine mentor in BCH network (required for fellows):

Study type (check all that apply)

- Clinical / translational
- □ Epidemiology
- Health services research
- Quality improvement
- Observational
- □ Interventional (e.g. randomized trial)

#### Resources required (check all that apply)

- D Biostatistics including study design and analysis, manuscript preparation
- Database development, management
- □ Clinical research form development
- Survey development, administration
- Data abstraction
- □ Specimen collection
- □ Project management
- CTSU\* services e.g. specimen processing, neurodevelopmental assessment, nursing, nutrition
- □ Laboratory supplies and/or services

Site(s) (check all that apply)

- □ BCH
- BCH affiliated NICU(s) (Specify\_\_\_\_\_)
- $\square$  BIDMC
- D BWH
- □ MGH

\*CTSU = Clinical Translational Study Unit

### BCH Division of Newborn Medicine Discovery Pilot Grant For Clinical Research Concept Paper

Please complete the following sections (limit 1 page).

# Significance (3-4 sentences)

- Describe the clinical problem and how it relates to the health of newborn infants
- Specify the research gap the study will address

### **Specific Aims & Hypotheses**

Study Design (1-2 sentences each about the following)

- Study population
- Design (e.g. cohort study, case-control study, randomized trial)
- Data / specimen sources
- Main outcome & exposure variables
- Preliminary data analysis plan including power/sample size considerations

**Timeline** (1-2 sentences and/or table, for example "We plan to start the study on [date], enroll [number] patients over [months], and complete the study by [date]."

#### Potential Impact (1-2 sentences)

• If the project is successful, what is the next step towards further research and/or implementation into clinical care?