PDA Feeding Study

1. **Inclusion Criteria**
   - Birth weight: 401-1250 grams
   - Gestational age: $23^{1}/_{7} - 30^{6}/_{7}$ weeks
   - Already feeding but at a rate <60ml/kg/day or ready to begin feeding
   - Need pharmacological treatment for PDA
2. **Exclusion Criteria**
   - Contraindication for ibuprofen or indomethacin
   - Chromosomal abnormality
   - Congenital or acquired intestinal anomaly
   - Prior episode of necrotizing enterocolitis
   - Current feedings >60ml/kg/day
   - Presently on Inotropic support for hypotension

Study Drug Period
Interval of time between administration of the first dose of study drug (ibuprofen or indomethacin) and 24 hours after the last dose of study drug.

Study Drug Treatment
Study infants will be randomized into 4 groups:
1. indomethacin plus feeding
2. indomethacin without feeding
3. ibuprofen plus feeding
4. ibuprofen without feeding

Study Drug Dosing: Drug will be masked and given during a 48 hour interval

	Dose 1 (0 hr)	Dose 2 (12 hr)	Dose 3 (24 hr)	Dose 4 (48 hr)
Indomethacin	mg/kg	mg/kg	mg/kg	mg/kg
< 1000 gm BWt and < 7 days old	0.2	0.1	0.1	0.1
< 1000 gm BWt and ≥ 7 days old	0.2	0.2	0.2	0.2
≥ 1000 gm BWt	0.2	0.2	0.2	0.2
	Dose 1 (0 hr)	**Dose 2 (12 hr)**	**Dose 3 (24 hr)**	**Dose 4 (48 hr)**
Ibuprofen	mg/kg	mg/kg	mg/kg	mg/kg
All infants	10	Placebo (saline)	5	5

Administer drug over 30 min. following St. Paul Children's NICU protocol.

Feeding During Study Drug Period
1. Infants randomized to one of two "feeding" study groups, will receive 20Cal/oz. trophic enteral nutrition (MBM or Premature Formula) at 15ml/kg/day during the study drug period.
2. Infants randomized to one of two "withhold feedings" study groups, will be fasted during the study drug period.
3. After the study drug period, feedings will be returned to the pre-study volumes and advanced according to standardized feeding regime.

Schedule second echocardiogram 24 hours after last dose of study drug.