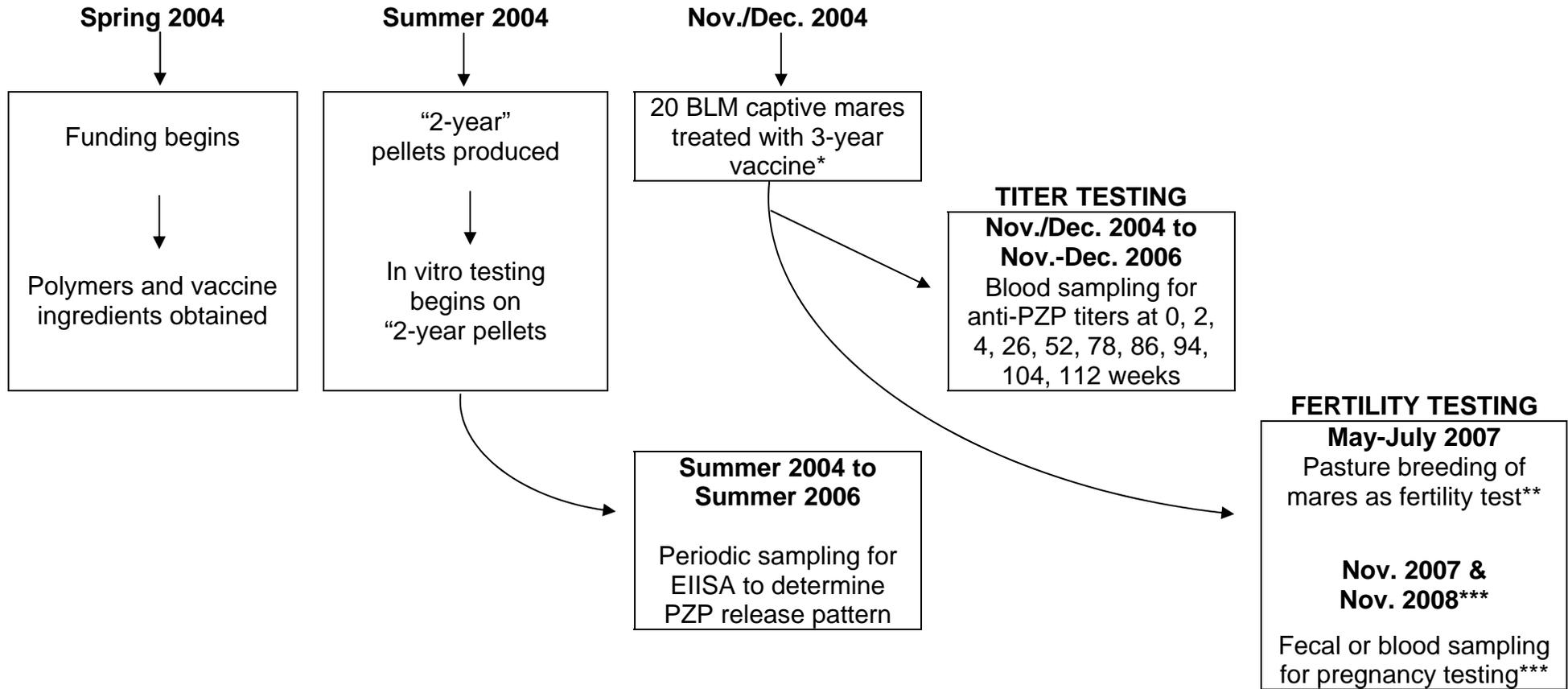


Revised Schedule for Testing of 3-4 Year PZP Vaccine



* **POSITIVE CONTROL**
8 mares will be treated with standard PZP/FCA injection + PZP/FIA boosters (1 mo, 1 yr, 2 yrs)

** **NEGATIVE CONTROL**
For the pasture-breeding portion of the study, 2 stallions known to have sired foals will be used. During this period 8-10 untreated mares will be included in the breeding pool to demonstrate fertility.

*** Effectiveness of 3rd and 4th years of vaccine action will be determined by pregnancy testing in November 2007 and November 2008, respectively. If infertility is sustained only through 2008, then reversibility will be assessed in 2007. If mares are infertile through 2008, then an additional year (through November 2009) will be needed to determine reversibility. This final year, if needed, will require extension of the project for one additional year, beyond the 4-year term of this proposal.

Revised Budget for Testing of 3-4 Year PZP Vaccine

YEAR 1

Personnel			
Principal Investigator	20% of FTE (includes 22% fringes)	\$18,300	MCO
Part-time lab technician	15-20 hours/week (includes 22.5% fringes)	\$15,000	MCO
		\$33,300	
Lab Supplies			
In vitro testing		\$ 3,000	MCO
Antibody titer testing		\$ 2,000	SCC
General		\$ 3,000	MCO
		\$8,000	
Vaccine Materials			
PZP		\$17,740	SCC/UCD
QA-21		\$ 4,960	HSUS
		\$22,700	
Pellet Preparation			
		\$ 3,000	MCO/Iowa
		\$3,000	
Communications			
	Phone, fax, mail	\$ 600	MCO
Shipping			
	Frozen vaccine/samples	\$ 600	MCO
Travel			
Field Work	(Vaccination & 1 follow-up site visit)	\$ 3,200	MCO
U. Iowa Consult Visit		\$ 1,200	MCO
		\$4,400	
		\$72,600	
		\$10,890	
		\$83,490	

* All aspects of captivity, care and blood sampling will be responsibility of BLM.

Revised Budget for Testing of 3-4 Year PZP Vaccine

YEARS 2-4

Category	Year 2	Year 3	Year 4
Personnel			
PI	\$18,832	\$14,124	\$14,689
Part-time lab technician	\$15,600	0	0
Lab Supplies			
in vitro testing	\$2,000	0	0
General	\$2,000	0	0
Communication	\$ 500	\$ 500	\$ 500
Travel			
Field Work (2 visits)	\$1,200	\$1,200	\$1,250
Direct Total	\$40,332	\$15,824	\$16,439
Indirect	\$ 6,020	\$ 2,373	\$ 2,466
Total	\$46,352	\$18,197	\$18,905

Revised Summary Budget

Budget Category	1 st Year	2 nd Year	3 rd Year	4 th Year	Totals
Personnel (Salary & Fringe Benefits)	\$33,300	\$34,432	\$14,124	\$14,689	\$96,545
Consultant Costs	0	0	0	0	0
Supplies	\$8,000	\$4,000	0	0	\$12,000
Vaccine Materials/Preparation	\$25,700	0	0	0	\$25,700
Communication/Shipping	\$1,200	\$500	\$500	\$500	\$2,700
*Domestic Travel	\$4,400	\$1,200	\$1,200	\$1,250	\$8,050
Total for Entire Proposed Period Direct + Indirect (15%)	\$83,490	\$46,352	\$18,197	\$18,905	\$166,944

Budget Justification

The budget addresses costs using captive mares for both titer testing and fertility testing (breeding). The indirect cost agreed upon by MCO and BLM for this project is 15%.

Personnel:

- 1) The PI is listed for 20% of FTE, based on knowledge of the commitment required for prior wild horse contraception studies. The effort refers to primary role in coordination and execution of the project, including PI lab work. The effort also includes intellectual contributions such as data interpretation and publications and administrative activities related to the project. Note that the amount is reduced in years 3 and 4 due to reduced FTE required.
- 2) No salary is requested for consultants due to limited funding availability for the proposed studies.
- 3) Part-time technician (only in year 1 and 2) will assist in lab work including in vitro studies, PZP/QA-21 assays, ordering supplies, mailings and lab maintenance.

Supplies: These costs will only occur in Years 1 and 2.

- 1) For in vitro testing includes: chemicals, vials, PZP and QA-21 assay supplies.
- 2) Antibody titer testing of blood samples to be done at SCC. Cost is based on costs for this in prior studies.
- 3) General supplies include FCA (primer-dose adjuvant), glass/plasticware, pipetting supplies and consumable lab items such as soap, buffers, weighboats, gloves, disposable syringes, needles, etc.

Vaccine Materials: This cost will occur only in year 1.

The cost of PZP is \$300/mg, and the cost of QA-21 is \$8.30/mg. Cost of FCA (for priming injection) is \$3.00 per dose (0.5 cc). FCA cost is incidental and is included in General Supplies section. The budgeted amount for vaccine materials/prep is based on treating 20 mares with 3-year vaccine and 8 mares with standard vaccine and boosters.

Pellet Preparation: This cost will occur only in year 1.

These funds will be used for either: 1) pellet preparation at Iowa or 2) consultation services by Dr. Douglas Flanagan (Iowa) and pellet preparation at MCO. This amount includes the cost of pellet materials, but not PZP/QA-21.

Communications and Shipping:

Costs of operating information and materials exchange in multi-institutional project with a non-laboratory component.

Travel:

This allows PI or specified consultant (Dr. Liu) to travel to field site or captive facility to immunize mares and one follow-up site visit per year. This allows PI and Iowa consultant (Dr. Flanagan) to meet for strategy discussion of the additional pellet required in "3+ PZP vaccine".

Sole-Source Justification

The application of a contraceptive to the regulation of feral horse populations has a number of prerequisites. These include effectiveness of treatment in lab and field, absence of side effects (physiological and behavioral), reversibility, reliability and safety (proven by extensive testing) and cost effectiveness. At the present time only one research group has the experience and only one contraceptive agent has the testing database to fulfill the prerequisites. The research group (consisting of J. Turner, J. Kirkpatrick, I. Liu, D. Flanagan and A. Rutberg) and the contraceptive agent upon which the 3⁺ PZP vaccine study will be based (PZP vaccine employing controlled-release pellets) are both justifiable for sole-source commitment for the following reasons:

- 1) Kirkpatrick, Turner and Liu have worked with the basic PZP vaccine in wildlife contraception for 16 years. Flanagan and Rutberg have contributed to this work for 11 years.
- 2) The controlled-release concept, initiated by the above group, has been studied by the group for all 11 years.
- 3) The group has tested controlled-release pellets for seven years and is the only group to do so.
- 4) The only contraceptive agent which has been thoroughly tested over the long-term for safety, effectiveness and reversibility is this group's controlled-release PZP vaccine.
- 5) Only this research group and this contraceptive agent have a record of successful field work with free-roaming feral horses.