Research Proposal Outline and Précis (the major jigsaw puzzle pieces)

Format: 1 or 2 pages maximum, identical to proposal (1 inch margins, 1.5 line spacing and 10 point font) with line numbers for reviewer reference with the following headings (modified from Hulley 3rd, pg 15) 1/14

Proposal Title:
Concise, descriptive title providing information that engages and informs reviewer on topic and approach

Primary Research Question: (P&W Chap. 7, Holmes Chap. 2, Hulley 3rd Chap. 2, R&C Chap. 2)
Overall research hypothesis stated as a concise, specific question that clearly is objectively testable

Specific Aims:
Up to 4 bulleted, concise specific aims, specific aims being the logically sequenced (but not dependent) major steps, each with a clearly defined deliverable or accomplishment (key words - establish, identify, characterize, compare, correlate, demonstrate, validate), that are required to answer the question

Research Significance:
Up to 4 concise bulleted statements indicating to both area expert and non-expert scientists the gap between current knowledge and what we need to know, why we need to know it, and this study’s potential contribution to improving clinical medicine or advancing basic knowledge, indicating why scarce dollars and resources should be invested.

Study Design Type & Structure: (P&W Part III, R&C Chap. 3-4, Holmes Chap. 7-12, Hulley 3rd Chap. 9-12)
Study design name (e.g. RBCT, case-control, cohort), direction (retrospective, cross-sectional, prospective) if not clear in design type, experimental or observational, and if experimental the basis that makes the comparison experimental (e.g., randomized selection or allocation), nature of control, and basic structure

Study Subject Eligibility & Acquisition: (Holmes Chap. 3, Hulley 3rd Chap.3)
Statement of specific eligibility, inclusion and exclusion criteria (e.g., age range, breeds, prior history, condition severity range, previous treatment)
If subjects are recruited from a patient population, the anticipated sources and method of identifying (e.g, referring DVM’s, hospital or laboratory records, diagnostic lab submissions, necropsy materials) and the expected eligible recruitment rate and time frame

Variables: (P&W Part II, Holmes Chap. 4, Hulley 3rd Chap. 4, R&C Chap. 5)
Grouping (classification) Factor or Predictor (independent):
Methods for controlling potential subject, observer and laboratory variation (e.g., blocking, blinding, batching, replication), variable name, type (binary, discrete, categorical, continuous), measurement method if measured, expected mean, range, standard deviation if continuous

Potential Confounders: (R&C Chap. 2,6, Hulley 3rd Chap. 9)
Cofounder identification (e.g, age, breed) and method of minimizing influence (e.g., matching, randomization)

Outcome (dependent):
Variable name, type (binary, discrete, categorical, continuous), measurement method if measured, expected mean, range, standard deviation if continuous, and method of controlling systematic and random observer and laboratory variation if potentially significant (e.g., blinding, batching, replication)

Statistical Analysis: (P&W Part IV, Holmes Chap. 5, Hulley 3rd Chap. 5)
Method of data recording, validation, manipulation and storage (e.g., Excel spreadsheet)
Statistical analysis method (e.g, paired t-test, logistic regression, repeated measures ANOVA) for outcome variable(s) and software package (e.g., R)

Sample Size: (Van Belle Chap. 2, Holmes Chap. 6, Hulley 3rd Chap. 5, 6, R&C Chap. 3,)
Minimum clinically, biologically or economically important difference in outcome variable, alpha and power
Estimated standard deviation and source of this estimate (pilot study, reference, estimate based on range)
Sample size and formula, graph or table citation or sample size software from which estimate was derived

Initial Budget (per subject or experimental unit):
Per subject cost of acquiring and holding, supplies, laboratory costs per sample and totals
Per subject time cost of animal procedures, imaging, acquiring and processing specimens and totals

Key References:
Key primary refereed scientific papers reporting 1) findings justifying this proposal, 2) key but non-standard procedures proposed for this study, 3) validation of a scoring system proposed for this study, 4) a well done data analysis applicable to this proposal, or reporting a similar well designed, or 5) well executed studies this study mimics

Key Collaborators: (experts needed for project and who have agreed to participate other than VCS mentor)
Key collaborators contributing critical expertise investigators don’t have (e.g., histologists, radiologists, surgeons)