Research Proposal Outline and Précis

Format: 1 or 2 pages, same document format as 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)

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

Primary Research Question: (Holmes Chap. 2, Hulley 3rd Chap. 2, R&C Chap. 2)
Overall research hypothesis stated as a concise, specific question that can be objectively tested

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 describing the importance of this research to improving clinical medicine or advancing basic knowledge and answering the question why scarce dollars should be invested in this.

Study Design Type & Structure: (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 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

Variables: (Holmes Chap. 4, Hulley 3rd Chap. 4, R&C Chap. 5)
Predictor (independent):
Variable name, type (binary, discrete, categorical, continuous), measurement method if measured, expected mean, range, standard deviation if continuous, and methods for controlling subject, observer and laboratory variation if potentially significant (e.g., blocking, blinding, batching, replication)

Potential Confounders: (R&C Chap. 2,6, Hulley 3rd Chap. 9)
Variable name and method of minimizing influence

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: (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., SAS)

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 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

Initial References:
Several papers reporting key findings justifying this study, reporting similarly designed and executed studies, reporting a data analysis applicable to this proposal or reporting key but uncommon procedures proposed in this study