Protocol Review Flow Chart – Renewals - R1, R2, R3 (Level A-D)

Performed at the Subcommittee Level

**Renewals are generally best reviewed in comparison mode (split screen)

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1 **Changes** –are there any changes being requested at the time of renewal. (i.e.: numbers/experimental design/personnel/administrative)

If changes are being requested are they well detailed and justified? Have the changes been adequately incorporated into the body of the protocol?

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2 **Outcomes**- Has an adequate update been provided for the previous approval period?

Have there been any complications, incidents or issues during the past approval period (lab tours, post approval monitoring, incident reports) that were or should be brought forward.

Have or could endpoints be refined?

Has the PI addressed the numbers that were used as compared to those approved during the last approval period? If numbers have changed has the justification been adjusted accordingly? If the numbers have not changed does the original justification still apply? If usage was low and numbers requested remain unchanged, has an explanation or justification been provided?

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3 **Consideration of Alternatives**- have the 3R's (Replacement, Reduction, Refinement) been addressed since the last full submission?

Has the appropriate renewal version been checked off (R1-R3) and have the 3Rs for this protocol evolved? Has an updated literature search for alternatives been included?

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4 **Procedures with Animals**
New guidelines, policy (CCAC or University) or standard operating procedures – have there been any changes to guidelines, policy or procedure that would warrant a change to this protocol?

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5 Discussion and final decision.