**Protocol Feasibility Checklist:**

**Factors to consider:**

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| **1. Population** |
| Do you have access to the right patient population? |  |
| Will you need to recruit patients from external sources? If so, willsponsor provide funding? |  |
| Is the proposed enrollment goal realistic? |  |
| Is the proposed enrollment period realistic? |  |
| Will enrollment compete with other studies seeking the samepatients? |  |
| Are inclusion/exclusion criteria overly restrictive? (Consider the likelyscreen failure ratio and the number of screen failures) |  |
| Do you expect a significant number of adverse events? (How ill is thispopulation?) |  |
| **2. Protocol** |
| Is the protocol well designed? |  |
| Is the protocol ethical? Will the IRB have problems with it? |  |
| Is the study question important? |  |
| Will the subjects benefit from participating in the study? |  |
| Is the sponsor willing to consider suggestions or modifications if you do not think the protocol is feasible as written? (In case of sponsoredstudy) |  |
| Can other services (e.g., lab, radiology) meet the protocolrequirements? |  |
| Is necessary equipment available? |  |
| Are patient compliance problems likely? If so, will it be necessary to monitor subjects' compliance with time-consuming phone calls orpostcards? |  |
| Are case report forms complex? |  |
| Are drug or device storage/accountability requirements complicated? |  |
| Will the drug be available for patients at the end of the study? (Thiscan impact patient satisfaction.) |  |
| **3. Procedures** |
| Are procedures frequent? |  |
| Are procedures difficult, e.g., elderly patients asked to swallow pills? |  |
| Are procedures painful? |  |
| Is the dosing schedule complex? |  |
| **4. Staff** |
| Are qualified staff available? |  |
| If needed, is training available? |  |
| Does the PI have adequate time to devote to the protocol? |  |
| Are additional specialists needed? |  |
| Are study visits complex, presenting possible scheduling difficulties, e.g., how many different study staff will subjects encounter in a givenvisit? |  |
| **5. Budgets** |
| Does preliminary budget appear adequate?( Sponsors or investigatorgenerated) |  |
| If the study is canceled prior to enrollment, will the sponsor pay forpre-study activities, e.g., IRB submission, meetings, chart reviews? |  |
| Will sponsor pay for an adequate number of screen failures(especially important for difficult protocols)? |  |
| Will the proposed payment schedule allow you to keep afloat, e.g., adequate up-front payment; payments paced according to workrequired by protocol? |  |
| Any other protocol required equipments or procedure etc |  |
| **6. Other** |
| Is adequate space available? |  |
| Will electronic or remote data retrieval systems be used? If so, willsponsor provide training? |  |
| Does the sponsor/PI expect this study to be audited by the regulatorybodies? |  |