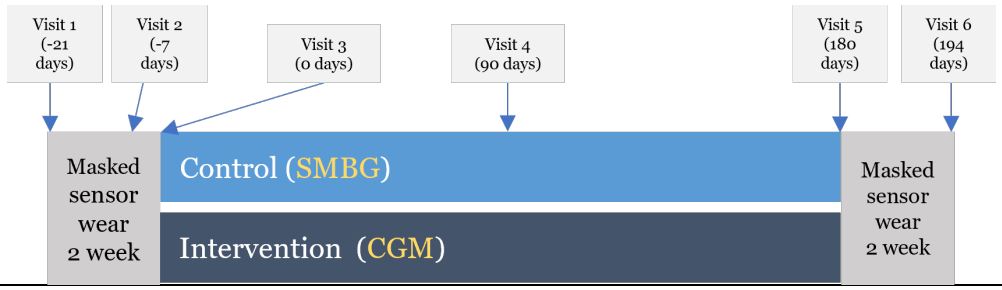
Abbott Diabetes Care
Investigator Initiated Study Proposal Form

<table>
<tr><td>Study Title</td><td>[study title]</td></tr>
<tr><td>Investigator(s)</td><td>[Investigator(s) responsible for the research]</td></tr>
<tr><td>Institution(s)</td><td>[Institution(s) involved with the research. Ensure to indicate planned number of sites and countries. and indicate how many site(s) and countries where data will be collected in this study.]</td></tr>
<tr><td>Contact information</td><td>[contact details: physical and e-mail address]</td></tr>
<tr><td>Plain language abstract</td><td>[Describe the overall research aims and project’s value in non-technical terms.]</td></tr>
<tr><td>Study Timeline</td><td>[Please provide approximate anticipated timeline for this study]
<table>
<tr><th><u>Milestones</u></th><th><u>Date</u></th></tr>
<tr><td>Ethical approval</td><td>MMM/YYYY</td></tr>
<tr><td>Recruitment start</td><td>MMM/YYYY</td></tr>
<tr><td>Data collection complete</td><td>MMM/YYYY</td></tr>
<tr><td>Publication submission</td><td>MMM/YYYY</td></tr>
</table></td></tr>
<tr><td>Objectives</td><td>[Specific objectives or hypotheses.]</td></tr>
<tr><td>Trial design</td><td>[Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory).]</td></tr>
<tr><td>Eligibility criteria</td><td>[Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions. For those with diabetes, please include details around diagnosis and medication.]</td></tr>
<tr><td>Interventions</td><td>[Interventions for each group with sufficient detail to allow replication, including how and when they will be administered. Please include clear description regarding how CGM will be used in this study]</td></tr>
<tr><td>Outcomes</td><td>[Primary outcome, secondary outcomes, and other exploratory outcomes, including the specific measurement variable, analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome.]
For example:
Primary outcome: Change of TIR (baseline vs. 6 months)
Secondary outcomes: Change of HbA1c, TAR, TBR, body weight
Exploratory outcomes: questionnaires (qualify of life, diabetes distress scale, etc.)</td></tr>
<tr><td>Participant timeline</td><td>[Time schedule of participant activities. A schematic diagram is recommended.]
For example:
Visit 1 (-21 days) -> enrolment, consent, baseline measurement (blood</td></tr>
</table>

<table>
<tr><td></td><td>
drawing, physical exam, blinded CGM installation for baseline assessment, and questionnaires)

Visit 2 (-7 days) -> Download blinded CGM
Visit 3 (0 day) -> randomization, start unblinded CGM, education per study group
Visit 4 (90 days) -> blood draw, physical exam, and questionnaires
Visit 5 (180 days) -> blood draw, physical exam, and questionnaires), blinded CGM installation
Visit 6 (194 days) -> Download blinded CGM



</td></tr>
<tr><td>Sample size</td><td>[Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations.]</td></tr>
<tr><td>Support requested</td><td>Describe support requested from Abbott in detail, including any materials (devices, sensors, strips), funding and/or technical support.
For example:
<table>
<tr><th colspan="2"><u>Type of support requested</u></th><th><u>Amount</u></th></tr>
<tr><td rowspan="4">Product Support</td><td>Sensors – Please itemize for blinded and unblinded use.</td><td># of sensors</td></tr>
<tr><td>Readers</td><td># of readers</td></tr>
<tr><td>Mailer kits (for returning used sensors to study site(s)</td><td># of mailer kit</td></tr>
<tr><td>BGM Materials: Glucose meters (including model), strips, lancets and lancing devices</td><td># of each item</td></tr>
<tr><td colspan="2">Financial Support – Please itemize into specific line items</td><td>$ amount</td></tr>
<tr><td colspan="2">Technical Support</td><td>Describe in detail what support is needed.</td></tr>
</table>
</td></tr>
<tr><td>Publication Plan</td><td>[plan for publication and/or presentation at a major conference]</td></tr>
<tr><td>Attachments (Required)</td><td>☐ Investigator CV
☐ Declaration of Eligibility for Research Support</td></tr>
<tr><td>Attachments (Optional for this proposal)</td><td>☐ Study Protocol
☐ Proof of IRB/IEC/IACUC approval of the study
NOTE: If approved for support, these will be required before support is provided</td></tr>
</table>