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| Supplemental Form: Investigational Devices |

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| Submit this form in addition to the IRB Research Proposal in IRBaccess when a study involves the use of investigational devices.  |

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| Study Number |
| Click or tap here to enter text. |

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| Device Information |
| *Additional sections may be generated by clicking the + button to the right of the table while its contents are selected. Click in the table below to access the Repeating Section Content Control.* |
| Name | Click or tap here to enter text. |
| Manufacturer | Click or tap here to enter text. |
| Select all that apply |
|[ ]  Marketed medical device being used according to FDA approved indication |[ ]  Investigational medical device |
|[ ]  New use for marketed medical device |[ ]  Other Device |
| Device Regulatory Category |
|[ ]  IDE Exempt (sponsor determined the device qualifies as exempt). |[ ]  Non-Significant Risk Device |
|[ ]  Significant risk device |  |
| Select who holds the Investigational Device Exemption for the device |
|[ ]  Not Required |[ ]  External to UT Sponsor or Investigator  |
|[ ]  UT Sponsor-Investigator |[ ]  UT Sponsor (Non-Investigator) |

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| Additional Documents: |
| For each device identified upload the following documentation as applicable: |
|[ ]  Description of the device |
|[ ]  Reports of prior investigations conducted with the device |
| **For IDE Exempt device, one or more of the following:** |
|  |[ ]  Documentation explaining how the device meets the criteria for an IDE exemption |
|  |[ ]  Communication from the sponsor verifying the IDE exemption |
|  |[ ]  Communication from the FDA verifying the IDE exemption |
|  |[ ]  External sponsor’s protocol explaining IDE exemption |
| **For nonsignificant risk device, one of more of the following:** |
|  |[ ]  Sponsor’s protocol including a justification for the nonsignificant risk determination |
|  |[ ]  Communication from the sponsor providing justification for the nonsignificant risk determination |
|  |[ ]  Communication from the FDA verifying the nonsignificant risk determination |
| **For significant risk devices, one or more of the following:** |
|  |[ ]  Sponsor’s protocol including IDE number |
|  |[ ]  Communication from the FDA verifying the IDE number |
|  |[ ]  Communication from the sponsor verifying the IDE number |