Breakthrough T1D
Participating Clinical Site Form

INSTRUCTIONS FOR APPLICANTS:

- This statement is intended to help Breakthrough T1D identify sites with interest and capacity to participate in trials funded through the current or future RFAs.
- Please email completed form and a biosketch/CV for the site lead/PI to: Courtney Ackeifi [cackeifi@BT1D.org] and Gianna Strand [gstrand@BT1D.org]
- If you are submitting on behalf of a larger hospital network or multi-site facility, please contact Gianna Strand [gstrand@Bt1D.org] for further instructions.

SECTION 1. Institutional Information and Contact Information

- Full name of institution (City, State, Country)
- Principal Investigator (Name, Title, Email, Phone)
- Clinical site coordinator (Name, Title, Email, Phone)
- Grant administrator (Name, Title, Email, Phone)

SECTION 2. Institutional Research Operations

How many clinical research studies that can enroll adults **with type 1 diabetes (T1D)** are currently active at your site?	interventional trials (drug, device)
	non-interventional studies (screening, longitudinal, nutrition, observational)
How many clinical research studies that can enroll adults **with cardiovascular disease (CVD)** are currently active at your site?	interventional trials (drug, device)
	non-interventional studies (screening, longitudinal, nutrition, observational)
How many competing trials that will enroll adults with T1D are in the pipeline to open in the next 6-9 months?	

IRB:

Does your site permit the use of: • Central IRB?	☐ Yes	☐ No	☐ Sometimes	☐ Unsure

• Multi-site single reliance IRB?	☐ Yes	☐ No	☐ Sometimes	☐ Unsure
• SMART IRB?	☐ Yes	☐ No	☐ Sometimes	☐ Unsure
Does your site allow IRB submission and contracting in parallel?	☐ Yes	☐ No	☐ Sometimes	☐ Unsure
Does your institution regularly provide translated consent materials if requested?	☐ Yes	☐ No		

Adult Participant Populations

Provide the number of **adult** T1D patients that fit the following criteria	
	active T1D patients treated at your site (visits within past 12 months)
	patients with T1D duration >10 years
	patients with T1D duration >20 years
	patients with T1D with comorbid CVD (LDL-C<1.4mmol/L, SBP<120mmHg, history of ischemic heart disease or HF)
	patients with T1D with comorbid kidney disease (eGFR<60 mL/min/1.73 m², ACR >30mg/g)
	patients with T1D are seen in your cardiology outpatient clinic per month
What percentage of patients with T1D are using a CGM?	
What percentage of patients with T1D are using a Hybrid Closed Loop (HCL) system?	
What CGM data collection capabilities does your site have?	
What is the average distance that a T1D patient travels to attend regular clinic visits? (miles/km)	
What tools are typically utilized for recruitment such as EMR screening, social media outreach, clinic flyers?	

SECTION 3. Infrastructure to Support Trial Execution

Do you have on-site Investigational Pharmacy, Investigational Drug Services (IDS), or equivalent?	☐ Yes	☐ No
Do you have dedicated research staff/nurses?	☐ Yes	☐ No

Please check the box if your site has the following capabilities:

☐ -80C freezer	☐ Sample processing, storage, and shipping
☐ Euglycemic insulin clamp	☐ Echocardiography
☐ Dual-energy X-ray absorptiometry (DXA) scan	☐ Endothelial Dysfunction Monitor (ENDO-Pat)
☐ Carotid-femoral pulse wave velocity (CF-PWV)	☐ Reactive Hyperemia Peripheral Arterial Tonometry (RH-PAT)
☐ Carotid intima-media thickness (CIMT) ultrasound	☐ Flow mediated dilation (FMD)
☐ Ambulatory blood pressure monitoring	☐ CT coronary angiography/calcium scoring
☐ Cardiac catheterization labs	

SECTION 4. Statement of Interest

[Describe the site's interest in participating in externally led trials funded through this RFA. Include areas of specific interest or capacity if applicable.]

I would like to be considered for only trials funded in this RFA	☐ Yes	☐ No
I would like Breakthrough T1D to retain my information confidentially for consideration for future clinical research collaborations	☐ Yes	☐ No

Other areas of T1D clinical research I would like to be considered for:

☐ T1D Screening	☐ Devices
☐ Non-insulin Therapies	☐ Complications
☐ Cell Therapies	☐ Disease Modifying Therapies