IRB#:
Researcher's Name:

Tarrant County College District
Offsite Locations
Research Performed at Non-TCCD Sites and Locations

The TCCD IRB may approve human subject research that is proposed to occur at, or in collaboration with, non-TCCD sites or locations when appropriate documentation demonstrating the support and collaboration of the offsite location(s) and compliance with federal requirements is provided.

The documentation necessary for TCCD approval of offsite human subject research is dependent upon several factors, including but not limited to: (a) the degree of risk to participants, (b) TCCD's relationship with the site, (c) the source of research funding and (d) the degree of responsibility TCCD personnel will assume.

Please Note:

- Details of the research performed at non-TCCD sites by TCCD researchers must be provided in the District's IRB protocol narrative.
- Offsite collaborators who will interact with TCCD subjects and/or will have access to subject identifiable records or data for the purposes of study performance must be a part of the TCCD research team.
- When TCCD employees or students wish to recruit participants or perform TCCD IRB-approved research at non-TCCD sites, a copy of the site permission or approval letter, signed by an authorized individual, must accompany the TCCD IRB application submission.
- Use of federal funds to compensate offsite locations or individuals performing human subject research **will require** an agreement negotiated by the Office of Grant Development and Compliance.

Section 1: Offsite Location Information

Add **one** off-site location at a time. For each site you must complete Questions 2-6. Repeat this process to add another off-site location. **DO NOT** add multiple sites at one time.

1. **Please check the appropriate box that describes the location where TCCD IRB approved research will occur.**

☐ Hospital/Clinics
List here:

☐ Other Universities, Institutions or Organizations
List here:

☐ Elementary, Middle or High Schools
List here:

☐ Community Centers
List here:

☐ Prisons/Detention Centers/Halfway Houses
Note: The *Vulnerable Prison Population* form must also be filled out.
List here:

☐ Nursing Homes
List here:

☐ Other Site(s)
List here:

2. Provide the contact information for the individual responsible for the research at the offsite location listed above or for the individual authorizing access to the site:

***Required**

Contact Person*:

Mailing Address 1:

Mailing Address 2:

City:

State:

Zip:

Telephone Number*****:

E-mail Address:

3. Does the location checked above have an Institutional Review Board (IRB)?

☐ Yes ☐ No

a. If **yes**, provide a copy of their IRB approval letter and approved consent form, if applicable; or a letter from the IRB waiving the requirement for IRB review.

b. If yes, provide the contact information for the IRB:

***Required**

Name of IRB*:

IRB Contact Person*:

Mailing Address 1:

Mailing Address 2:

City:

State:

Zip:

Telephone Number*:

E-mail Address:

4. **Will the employees of the offsite location participate in the recruitment and/or selection of subjects?**

☐ Yes ☐ No

5. **Will the employees of the offsite location intervene with subjects by performing procedures or by manipulating the environment (e.g., controlling the research environment, leading social interactions, recording data) for research purposes?**

☐ Yes ☐ No

6. **Will the employees of the offsite location provide, collect or have access to identifiable study data?**

☐ Yes ☐ No

7. **Will TCCD-managed federal funds be used to compensate the offsite location or its employees to perform human subjectsresearch?**

☐ Yes ☐ No

a. If yes, does the location have a Federal Wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP) to accept federal funds for human subject research?

☐ Yes -- please provide their FWA # here:
☐ No

Section 2: TCCD Serving as a Coordinating Center

8. **Will TCCD serve as the Coordinating Center of a multi-site study (i.e., the TCCD researcher is the lead investigator of a multi-center clinical investigation or TCCD is the lead institution of a multi-site study)?**

☐ Yes ☐ No

If ***yes***, complete the following questions (Questions 8-10). Be sure to include IRB approval documentation (approval letter and informed consent document, if applicable) from each participating site as attachments to your application or modification request.

9. **Describe the plan to manage the research project to ensure that the research is carried out in an ethical manner and to ensure adequate human research protections at all participating sites.**

10. **Discuss how the following information relevant to the protection of human subjects is <u>recorded and shared between the participating sites</u>:**

    a. Data and Safety Monitoring, Interim Findings, Adverse Events, Unanticipated Problems to Participants or Others and other information that may impact risks to subjects or others:

    b. Modifications/amendments to the protocol or consent document(s):

11. **Does each participating site have written procedures for assuring prompt reporting to the <u>TCCD IRB</u> of any unanticipated problems involving risk to participants or others, any serious or continuing non-compliance and any suspension or termination of IRB approval for cause.**

☐ Yes ☐ No

Email forms and supporting documentation to: irb.irpe2@tccd.edu.