**Institution Information**

**OMB #: 0925-0753**

Expiration Date: 07/31/2021

**STATEMENT OF CONFIDENTIALITY**

The purpose of the information collection is to conduct reviews of clinical trial studies. NCI guidelines mandate the participation of institutions in the CIRB for Network group studies. You are being requested to complete this instrument so that we can conduct activities involved with the operations of the NCI CIRB Initiative. Although your participation in Network group research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law.

**NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN**

Public reporting burden for this collection of information is estimated to average 40 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0753). Do not return the completed form to this address.

Please refer to the Quickguide on [Completing The Annual Signatory Institution Worksheet](#) for further guidance.
Reason for submission:
Revised submission of the Annual Signatory Institution Worksheet About Local Context

Approval Letter for your reference
UT MDAnderson_SIW_appr_072618.pdf Support Document

Signatory Institution Information
Submitting User Information
Nassaj, Nadia MS
Email: mnassaj@mdanderson.org

Name of Signatory Institution
University of Texas MD Anderson Cancer Center
1515 Holcombe Blvd.
Unit 1437
Houston, TX, 77030

If there are any changes to the Submitting User Information, please update within the user’s Identity and Access Management (IAM) account.

1. What type of studies does this Signatory Institution intend to open with the CIRB?
Phase 2/3 and Large Phase 2 Adult Studies
ETCTN and Group Phase 1 and 2 Adult Studies
Cancer Prevention and Control Studies
Pediatric Studies
2. Verify the list of Component Institutions

- M D Anderson Cancer Center
- MD Anderson Regional Care Center-Bay Area
- MD Anderson Regional Care Center-Katy
- MD Anderson Regional Care Center-Sugar Land
- MD Anderson Regional Care Center-The Woodlands
- Proton Therapy Center

If there are any changes to the list of Component Institutions, update your roster in Roster Update Management System (RUMS).

3. Verify the list of Affiliate Institutions

Entered: 04/06/18  By: Nassaj, Nadia MS
removed Banner and Kelsey in RUMS

- Lyndon Baines Johnson General Hospital

If there are any changes to the list of Affiliate Institutions, update your roster in the Roster Update Management System (RUMS).

State and Local Law

4. What is your state law and corresponding institutional policy regarding legally authorized representatives?

Please see attachment

If applicable, an attachment can be added here.

LARs in Texas.pdf  Support Document

5. What are the other state or local laws that govern the conduct of research at your institution?

Please see attachment

If applicable, an attachment can be added here.

CIRB7  Support Document
6. What is the age of majority in your state?

18

**Research Oversight**

7. Do you have an IRB that operates at your Signatory Institution?

Yes

If Yes, identify the office, the person, and the person’s title at your institution to whom the IRB reports.

**Office Name**

Office of Clinical Research Administration

**Responsible Person**

Aman Buzdar, M.D.

**Phone**

713-745-7139

**Email Address**

abuzdar@mdanderson.org

8. Identify the office, the person, and the person’s title at your institution responsible for the oversight of the conduct of research for studies open under the CIRB. (This person cannot be a Principal Investigator who will open studies with the CIRB or someone who enrolls or interacts with study participants at study visits.)

Please refer to the **Oversight Q&A** Quickguide for further guidance.
### Office Name
Vice President of Clinical Research Administration

### Responsible Person
Aman Buzdar, M.D.

### Phone Number
713-745-7139

### Email address
abuzdar@mdanderson.org

### Describe, in detail, how this person(s) ensures the safe and appropriate performance of the research at the Signatory Institution and at all Component and Affiliate Institutions, including:

**NOTE:** SOPs, organizational charts, and other documents to support the oversight structure should be attached after item 8(e).

**a) Ensuring the initial and ongoing qualifications of investigators and research staff.**

In his role as the VP, Clinical Research Administration, Dr. Aman Buzdar oversees the Clinical Research Support Center (CRSC). The CRSC is responsible for the initial and ongoing human subjects research education and training of all research investigators and research staff. The Research Education team is a resource for information, education and guidance to support and facilitate the conduct of clinical research. The group develops comprehensive education programs to support learning needs from initial training to advanced skill development. Education is provided in the form of classroom instruction, online training, specialized workshops, and individualized instruction.

The Office of Protocol Research, also under Dr. Buzdar’s oversight, confirms that an investigator has met all of the educational requirements to conduct human subjects research prior to accepting protocols for review.
b) Overseeing the conduct of the research, including how the person identified fulfills this responsibility.

As the VP for Clinical Research Administration, Dr. Buzdar’s primary objective is to coordinate the research of MD Anderson investigators in order to conduct the highest quality clinical research at MD Anderson. His office is devoted to the needs and protection of all those participating in or conducting clinical research while maintaining high ethical standards and strict compliance with all regulatory policies. He serves as the primary advocate for the needs of clinical research.

As the institutional official (IO), Dr. Buzdar is responsible for overseeing the conduct of the Clinical Research and Psychosocial, Behavioral and Health Services Committees, through which protocol and scientific review and prioritization is affected. He recommends to the President all appointments to these committees as well.
- Dr. Buzdar staffs the Clinical Research Impact Committee, which monitors the quality and appropriateness of protocols at MD Anderson.

c) Monitoring protocol compliance, including how the person identified fulfills this responsibility.

The CRSC, under the leadership of Dr. Buzdar, is responsible for the oversight of ongoing research. The Clinical Research Audit Group evaluates the conduct of clinical trials to assist in identifying compliance and process concerns and collaborates with research teams to offer guidance, education, and resources to promote quality research. The group strives to ensure that the audit process is constructive, effective, and efficient and the knowledge derived will be used to improve research practice.

- Dr. Buzdar represents the interests of both individual investigators as well as the institution as a whole in developing ways to promote compliance with federal and local clinical research regulations.
d) Maintaining compliance with state, local, or institutional requirements related to the protection of human subjects.

Through his direct oversight, the Office of Protocol Research (OPR) provides regulatory services to departments across MD Anderson that are involved with human subjects research. OPR is responsible for the handling of administrative and regulatory aspects of protocol submission, review, revision, and ultimately approval, activation, and continuing review. Some of the administrative functions of OPR include the coordination of several committees that are designed to provide scientific review and approval for new research protocols. These committees include:
- Clinical Research Committee (CRC)
- Psychosocial, Behavioral, and Health Services Research Committee (PBHSRC)
- Institutional Review Board (IRB)
- Data Safety Monitoring Board (DSMB)
- electronic Protocol Accrual Auditing Committee (ePAAC)
- All MD Anderson IRBs (n=5) are registered with the Office for Human Research Protections (OHRP) and are associated with the Federalwide Assurance Document FWA-363. MD Anderson acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects in research. The involvement of human subjects in research will not be permitted until the IRB has reviewed and approved the research protocol and informed consent has been obtained in accordance with and to the extent required by 45 CFR 46.116. Each study is assigned to a home IRB based on the scope of the research project. The study will remain assigned to this specific IRB until termination.

OPR collaborates closely with the Institutional Compliance Office to assure that policies and procedures are consistent with state, local, and institutional requirements. Consistent with its commitment to excellence, MD Anderson has developed a comprehensive Institutional Compliance Program designed to continuously monitor its high-risk areas and ever-changing federal and state statutes, regulations, and health care program requirements.

e) Providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research.

Dr. Buzdar oversees the Office of Protocol Research. This office is responsible for ensuring all 21CFR50.25 requirements regarding the necessary and additional elements of informed consent are included in all MD Anderson informed consent documents. This includes 21CFR50.25 subpart (7), which states that the informed consent must include an explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject. A number is included with this explanation in all MD Anderson consent forms.
- Additionally, MD Anderson maintains a Compliance Hotline, which forwards any human subjects research related issues or concerns directly to Dr. Buzdar so that he may adequately address the patients’ needs.

If applicable, an attachment(s) can be added here for questions a through e.

No answer provided.
9. Identify the office, the person, and the person’s title at your institution responsible for identifying, managing, and reporting to the CIRB potential unanticipated problems and/or serious or continuing noncompliance

<table>
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<tr>
<th>Office Name</th>
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<td>Office of Protocol Research</td>
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<table>
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<tr>
<th>Responsible Person</th>
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<tr>
<td>Wanda Quezada</td>
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<tr>
<th>Phone Number</th>
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<tr>
<td>713-563-5445</td>
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<tr>
<td><a href="mailto:wquezada@mdanderson.org">wquezada@mdanderson.org</a></td>
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Describe, in detail, how this person(s) identifies and manages and reports to the CIRB potential unanticipated problems and/or serious or continuing noncompliance.

The Associate Director (AD) for the Office of Protocol Research is responsible for reviewing and assessing reports of non-compliance and unanticipated problems as related to the conduct of human subjects protocols in collaboration with a committee designated by the VPCRA, which includes the Institutional Compliance, the VP for Clinical Research Administration. The designated committee will receive reports of non-compliance or unanticipated problems from any source. Once the reports are administratively reviewed by the appropriate regulatory office, they are immediately reported to both the designated committee and the VPCRA. In parallel with the committee notification, the AD will assess the report, meet with the investigators to clarify information, confer with Institutional Compliance and the VP for Clinical Research Administration, as needed. The AD will submit a preliminary assessment to the committee for review during their convened meeting. Once the committee has made a final determination, this determination is sent to the investigator, and the AD is copied. If the report requires reporting to regulatory agencies or Sponsors, the AD will work collaboratively with Institutional Compliance, the committee and the VP Clinical Research to draft the letter, compile relevant documentation, and report the event to regulatory agencies and/or Sponsors. The VPCRA is the final reviewer for any communication going to regulatory agencies or Sponsors regarding an unanticipated problem or other non-compliance event. OPR maintains an electronic file that includes historical information for all unanticipated problems and other compliance concerns. This report is presented to the IRB Executive Session quarterly (or as frequently as needed), and is also shared with the VPCRA and Institutional Compliance as part of the institution’s quarterly risk monitoring efforts.

If applicable, an attachment can be added here.

No answer provided.

Financial Conflicts of Interest

10. Describe how the Signatory Institution gathers and evaluates Principal Investigator and research staff financial conflicts of interest for studies on the CIRB menu. Any policies related to the management of conflict of interest should be attached.

Please see attachment

If applicable, an attachment can be added here.

CIRB11 Support Document
Institutional Policies Pertaining to the Consent Form for CIRB-Approved Studies

11. Describe your institutional policies and guidelines that govern the informed consent document.

Please see attachment

If applicable, an attachment can be added here.

CIRB12 Support Document

12. Provide the boilerplate language that is added to the CIRB-approved consent form. This is standard language required by the institution that is inserted into the existing CIRB-approved consent form, such as, birth control language, coverage of research injury, required phone numbers for the study doctor, and a person unaffiliated with the study who can answer general clinical trial questions, etc.

Note: Boilerplate language cannot replace language in the CIRB-approved consent form without CIRB approval. Any language that will be replaced must be clearly identified in the submission. Required NCI Consent Form template language and the risks for agents cannot be changed.

Please refer to the Boilerplate Q & A Quickguide for further guidance.

Attached are the research consent templates that include the MD Anderson boilerplate language.
If applicable, an attachment (in Word format) can be added here.

**Note:** If you are submitting an updated Worksheet and have revised boilerplate language, submit a "track changes" and a clean Word version of the boilerplate language to clearly indicate what has changed from the current CIRB-approved boilerplate language.

**Entered:** 07/03/18  **By:** Nassaj, Nadia MS

Please note, we have removed the statement "Please Note: This section will be used in lieu of the signature section of all NCI ICDs. All appropriate information is captured in the MD Anderson text.["] from our templates. No other changes have been made.

**Entered:** 07/16/18  **By:** Nassaj, Nadia MS

Errors have been corrected. The consent templates have been organized by template type, and include the Spanish and English versions, and COT. A tracked changes document has also been included, it is titled MD Anderson tracked changes to informed consent - please note starting on page 93 of 100 includes the iConsent signature box templates.

- MD Anderson Clinical Harris Health ICD Packet - English-Spanish-and CoT v4 - 7_12_18.pdf
- MD Anderson Clinical ICD Packet - English-Spanish-and CoT v4 - 7_12_18.pdf
- MD Anderson PA Harris Health ICD Packet - English-Spanish-and CoT v4 - 7_12_18.pdf
- MD Anderson PA ICD Packet - English-Spanish-and CoT v4 - 7_12_18.pdf
- MD Anderson Psychosocial Harris Health ICD Packet - English-Spanish-and CoT v4 - 7_12_18.pdf
- MD Anderson Psychosocial ICD Packet - English-Spanish-and CoT v4 - 7_12_18.pdf
- MD Anderson Tracked Changes to Informed Consent Documents v4 - 7_12_18.docx
13. Provide the institutional letterhead used for the informed consent document, if applicable (attach a blank copy of letterhead to be used).

Entered: 07/10/18  By: Tuggle, Catherine

12/13: There are a number of errors in the attached ICDs, Spanish translations and CoTs: the dates of the CoT for the CIRB ICD and the Spanish translation do not match; there are 2 Spanish CIRB Psychosocial ICDs but both say CIRB PA in the body of the text; there does not appear to be a Spanish or English or COT for CIRB Psychosocial so perhaps they need to be deleted; Harris Health Psychosocial ICD translation CoT is dated 9-9-2016 but the translation and English version are dated 7-3-18. Please organize these attachments so the English, Spanish and CoT for each are together. Remove any documents which are no longer in use.

No answer provided.

14. Provide any other institutional requirements for the informed consent documents or additional documents used in research at your institution.

Per an IRB Authorization Agreement between MD Anderson and Harris Health, the MD Anderson IRB provides oversight whenever an MD Anderson faculty participates as the investigator in a study conducted at a Harris Health facility. As such, investigators are allowed to utilize one consent document which combines the MD Anderson and Harris Health injury language.

Electronic Consent Module: MD Anderson has recently adopted the use of electronic consenting to facilitate the research consent process for all clinical studies. Investigators are encouraged to utilize this process when consenting a patient in the outpatient clinic areas. The module allows the consent to be attached to the patient’s electronic medical record. "The module has been risk assessed and does comply with the 21 CFR 11 requirements".

If applicable, an attachment (in Word Format) can be added here.

No answer provided.
15. Provide the institution’s plan for implementation of changes to the boilerplate language, letterhead, or other institutional requirement identified in this submission for any study currently open with the CIRB. This language should be used for any initial study opening with the CIRB.

The institution has a dedicated staff of Scientific Editors that reports to the Office of Protocol Research (OPR). The OPR Scientific Editors review the informed consent document to assure that IRB and Sponsor requirements are included in the informed consent document prior to the study being implemented. The OPR Scientific Editors are primarily responsible for assuring that boilerplate language or other institutionally-mandated language is included in the consent document. The OPR procedures include a requirement for the OPR Scientific Editors to review and approve the consent document prior to releasing the consent in our electronic system for patient enrollment.

Community Descriptors

16. Does the community have a positive attitude toward the conduct of research?

Yes

If No, please explain.

No answer provided.

17. Is there anything else the CIRB should know about the anticipated study participant population at the Signatory Institution?

No

If Yes, please explain.

No answer provided.
Additional Information

18. Is there anything else the CIRB should know about the Signatory Institution’s local context?

Yes

If Yes, please explain.

The IRB has a policy for reporting unanticipated problems and protocol deviations/violations for review. In order to appropriately monitor our local patient population, investigators will be required to comply with this local IRB policy. In addition to complying with the NCI CIRB reporting guidelines for serious adverse events, investigators will also comply with the local IRB policy for reporting serious internal adverse events and unanticipated problems.

Privacy issues related to CIRB studies will be handled by the Institutional Compliance Privacy Officer, Krista Barnes, JD in consultation with Dr. Aman Buzdar. Required reporting for privacy breaches will be reported by the Institution.

Investigators will be required to complete a protocol abstract and a checklist prior to implementing a study at MD Anderson. These documents will allow MD Anderson the ability to collect information necessary for publishing the studies on our clinicaltrials.org website. Completion of the checklist will allow us to capture data elements as required by our NCI Core Grant. Copies of both forms are attached.

If applicable, an attachment can be added here.
Additional Materials for Review (If Applicable)

Complete this section if you have any of the following additional materials to be reviewed by the CIRB.

19. Translated documents. Translated documents include, the institution’s boilerplate language, short forms, template assent form, or template document for consent at age of majority. If short forms are being submitted for review, attach your institutional policy for short form use.

Note: The following documents are required when submitting translated material:
1. CIRB-approved English language document(s) corresponding to the translated document with a version or version date
2. Translated version(s) of the CIRB-approved English language document with a version or version date that matches the English version
3. Translator’s Certificate(s) of Accuracy or equivalent document(s) with reference to the version or version date

No answer provided.

If applicable, an attachment can be added here.

No answer provided.

20. Assent form or consent at the age of majority form documents used by the Signatory Institution.

Procedures for consenting children to research are included in the informed consent policies, and are attached below. Enter "N/A" for adult studies or how assent is documented for Pediatric and age of majority.

If applicable, an attachment can be added here

10.0 IRB Policy on Obtaining Informed Consent for Participation and Authorization for Uses and Disclosures of PHI.pdf
10.9 Consenting Children to Research Protocols.pdf