Clinical Trials Research Alliance (CTRA) and Investigator-Initiated Clinical Trials/Clinical Research

I. **Statement**: One of the primary goals of the CTRA is to expand and enhance investigator-initiated clinical trials/clinical research within Wright State University Boonshoft School of Medicine and Premier Health. As such, the CTRA is positioned to provide significant assistance and administrative support to clinician-scientists seeking to launch investigator-initiated clinical trials and clinical research projects. The CTRA provides clinical investigators with assistance in identifying funding opportunities, with protocol preparation and review, IRB submission, compliance oversight, developing budgets and tracking finances of a research study, and provides study coordinators (CRCs). *In general, any funded clinical trial or research project that involves a physician (or other WSU/Premier Health employed health care provider) as principal investigator (PI), that involves interactions and/or interventions with patients in the hospital or clinic setting, and where expenses are incurred by the hospital, clinic, or CTRA CRCs in the course of conducting the clinical trial or research project, needs to be run through and managed by the CTRA. Clinical trials/clinical research funded by an external entity, such as industry, or state/federal funded research, will be managed by the CTRA. Unfunded or under-funded investigator-initiated clinical trials/clinical research will be evaluated on a case-by-case basis (see Section IV Unfunded/Underfunded Research). It is imperative that clinician-investigators contact the CTRA early in the course of developing an investigator-initiated clinical trial or research project, so maximal assistance can be offered and the research project initiated as expeditiously as possible.*

II. CTRA Process - Investigator-Initiated Clinical Trial/Clinical Research Projects where an investigator is responding to a particular external funding opportunity, either from industry, a foundation, or a federal agency such as NIH.

1. *Investigators should contact the CTRA as soon as they decide to pursue a particular clinical trial/clinical research opportunity.* CTRA will make an initial determination whether the project is, in fact, one that should be handled through the CTRA. If yes,
2. PI and CTRA staff will determine the feasibility of the proposed clinical trial/clinical research project. Is the trial a 'cultural fit' for the institution? Is the environment proper to successfully conduct the trial? Are essential facilities available? Are there enough potential subjects to ensure successful recruitment into the clinical trial? If yes,
3. PI, with assistance from CTRA (L. Friedman, Medical Advisory Team [A. Pickoff, M. Bowman, T. Broderick]) will develop a draft study protocol.
4. Based on the draft study protocol, PI with assistance from CTRA (M. Wysong, B. Burnside) will develop a draft budget, and if necessary the Medicare Coverage Analysis (MCA).
5. Does draft budget cover the anticipated costs of the trial/project? If yes,
6. PI with assistance from CTRA Medical Advisory Team, any departmental grant writing/grant review team (and on occasion a professional external grant writer) will develop a full study protocol and final budget (M. Wysong, D. Mehling). (*Note: It is expected that all investigator-initiated protocols undergo an internal Scientific Review, in accordance with university and/or departmental policy, prior to final submission).*
7. J. Carstens, in coordination with the PI, will provide contracting support for CTRA clinical trials. RSP will provide contracting/grant support for all others.
8. PI with assistance from CTRA (R. Smith) prepares and submits IRB petition.

9. If FDA approval is required, PI will work with WSRI (Chad Reiter) to secure necessary FDA approvals.
10. If there are issues or potential issues regarding Intellectual Property, PI will contact WSU Office of Technology Transfer (WSU VP for Research Office).
11. PI submits protocol/grant to funding agency. *(Note: In the case of grant funded protocols, RSP must be involved in the submission of the grant to the funding agency on behalf of the PI, and, therefore, RSP needs to be aware of the planned proposal early in the process).*

Once the trial/study is funded and all regulatory issues addressed the project commences:

12. CTRA manages contracting with external agency (if applicable) and all financial aspects of the trial/project including tracking of expenditures, invoicing, payment disbursements (M. Wysong)
13. CTRA provides study coordinators (B. Burnside)
14. CTRA provides ongoing regulatory support (R. Smith)
15. CTRA provides compliance oversight of the trial/project (J. Carstens)
16. PI is responsible for the overall conduct of the trial/study in keeping with Good Clinical Practice (GCP), reporting any adverse events, determining whether an adverse event is study related, and timely submission of any required progress reports.
17. CTRA handles disbursements of any residual funds and indirects to PI or to PI's department, or practice administrator, per the policies of the CTRA (50% of residual funds, 12% of indirects are returned to the PI).

III. CTRA Process – Investigator-Initiated Clinical Trial/Clinical Research Projects where an investigator is <u>not</u> responding to a particular external funding opportunity

1. *Investigators should contact the CTRA for assistance early in the process of developing their project.* CTRA will determine the feasibility and importance of the proposed study and if the study should be handled through the CTRA. If yes,
2. PI, with assistance of CTRA, departmental resources, will develop a white paper describing the rationale for the proposed research study, a draft of a study protocol, and budget.
3. CTRA, WSRI, RSP will assist the PI in identifying potential funding sources (foundations, industry, venture capitalists etc.) for the proposed research project.
4. Once funding situation becomes known, refer back to II (6).

IV. CTRA Process – Unfunded/Underfunded Clinical Trials/Clinical Research Projects

1. If study budget does not cover all of the anticipated costs of the clinical trial/clinical research project *the PI should provide, in writing, some idea of how the budget deficit might be funded*. The budget shortfall may be addressed by funding from a number of sources that include: the department, the medical school, the hospital, CTRA, other external funding agencies. *If there is still a shortfall, an executive decision is made by CTRA leadership whether to proceed with the proposed trial/project.* (Please refer to Appendices A and B for the CTRA guidelines, and request form pertaining to unfunded/underfunded projects).

APPENDIX A – Unfunded/Underfunded Clinical Trials/Clinical Research

Unfunded/Underfunded Clinical Trials/Research Policy

The Clinical Trials Research Alliance (CTRA) is a partnership between Wright State University and Premier Health formed to increase the number and scope of clinical research studies conducted by the faculty of Wright State University Boonshoft School of Medicine (WSUBSOM) and the professional staff members of Premier Health hospitals. The primary mission of the CTRA is to provide full administrative support services to investigators conducting funded pharmaceutical industry sponsored trials, multi-center trials funded by an external agency, such as NIH, and funded investigator-initiated trials. The CTRA recognizes that from time to time there may be unfunded or underfunded clinical research projects and trials that may merit support by the CTRA because of potential benefits to the BSOM and/or the hospital(s).

In order to serve the BSOM, the hospital(s) and our investigators the following policy will be followed when considering CTRA support for unfunded clinical research.

1. The primary mission of the CTRA is the support of funded clinical trials/clinical research and funded research and will have priority over any and all unfunded clinical research projects. If resources/capacity permits, support for unfunded clinical research may be provided by the CTRA.
2. CTRA support of unfunded clinical research/clinical trials will be prioritized according to the following hierarchy (highest to lowest):
a) Clinical research that is required for maintenance of certification of key clinical programs (e.g., Trauma Service)
b) Clinical research that is required for maintenance of certification of key residency/fellowship programs.
c) Clinical research required for maintenance of Magnet Designation.
d) Clinical research that has a high likelihood of producing pilot data that will then be leveraged in grant applications to secure external funding to continue the research project.
e) All other unfunded research requests.
3. For all requests for CTRA support of unfunded research, investigators must first seek financial support from their BSOM department chair, hospital VP, hospital manager and/or director to cover expenses associated with the clinical trial/clinical

research project . In general, some degree of department/hospital support will be required for requests for research projects in the lower tiers of the hierarchy outlined in 2.

4. Requests for CTRA support of unfunded clinical research must be made in advance, and in writing to the CTRA, detailing the following:

a) Investigator name(s)

b) WSU BSOM Department (when applicable)

c) Affiliated Hospital

d) Title of Project

e) Duration of Project

f) Type of CTRA support requested (Is Clinical Research Coordinator/Research Assistant support being requested? IRB assistance? Budgeting?)

g) Classification of the project within the hierarchy outlined in 2 (i.e., key clinical program, required for certification of a residency program, etc.)

h) Description of department/hospital financial support of the project as described in paragraph 3.

i) Attestation that all investigators and research personnel have completed CITI training.

j) Signature of investigator(s) and, if applicable, Department Chair.

5. Requests will be reviewed by the CTRA Executive Committee and notification of approval of CTRA support and scope of the support, or notification of disapproval, will be provided in writing to the Investigator(s).

Policy Date: April 14, 2014

Revised: May 20, 2015

Responsible Party: Arthur S. Pickoff, MD

APPENDIX B - Unfunded/Underfunded Clinical Trials Request Form

1. Investigator name:
   _____

2. Co-Investigators (if applicable):
   - _____
   - _____
   - _____

3. WSU BSOM Department (if applicable)
   _____

4. Employed by:
   _____

5. Title of Project:
   _____

6. Duration of Project:
   _____

7. Type of CTRA support requested (CRC/Research Assistant, IRB assistance, budgeting, etc.):
   - _____
   - _____
   - _____

8. Classification of the project within the hierarchy outlined in paragraph 2 of policy. Please attach additional page if needed.

_____
_____
_____
_____
_____
_____

9. Description of department/hospital financial support of project as described in paragraph 3 of policy.

_____
_____
_____
_____
_____
_____

10. Attestation: The following investigators and research personnel have completed CITI training.

*_____
*_____

11. Signature of investigator(s) and department chair, if applicable.

_____Title:
_____
_____Title:
_____
_____Title:
_____

Please include a one page protocol summary with this form. Requests will be reviewed by the CTRA Executive Committee and notification of approval for CTRA support and scope of the support, or notification of disapproval, will be provided in writing to the investigator(s).

Policy Date: May 20, 2014
Revised June 5, 2015