



Policy	P16
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Use of Commercial IRBs

POLICY

Wright State University (WSU) may rely on a commercial Institutional Review Board (IRB) to oversee the management and review of certain protocols when specified criteria are met. When entering into such a relationship, WSU will evaluate whether the commercial IRB has appropriate human subject protections in place. Such evaluation will include consideration of whether the commercial IRB is accredited. To assure accreditation standards are fulfilled, WSU will typically only rely on commercial IRBs that have accreditation from the Association for the Accreditation of Human Research Protection Programs. A fully executed IRB Authorization Agreement (IAA) is required before WSU may rely on a commercial IRB for review.

The PI is required to submit a request to the WSU IRB office prior to the first use of a commercial IRB. The WSU IRB staff will evaluate the commercial IRB to determine if the appropriate standards are met and if an IAA should be established.

A research study may be considered for review by a commercial IRB if the following conditions are met:

1. The project is a study that involves human subjects and is designed to evaluate prospectively the safety and/or effectiveness of new drugs or devices or behavioral intervention.
2. The protocol for the research study was designed and written by the sponsor.
3. The sponsor holds all INDs/IDEs for the protocol.
4. The only sponsor of the research is a for-profit entity/company.
5. The protocol is a national multi-site protocol where the protocol has already been reviewed or approved at other sites.
6. The WSU investigator has not previously submitted the study to the WSU IRB [only new research studies will be eligible for commercial IRB review. No transfer of research studies already submitted to the WSU IRB will be allowed].

A research study will not be considered for review by a commercial IRB if the study involves, including but not limited to, the following types of research:

1. The study is being performed at the VA Hospital
2. Xenotransplantation
3. Embryonic stem cells
4. Phase I clinical trials
5. Review and approval by other committees – e.g., studies that involve recombinant DNA, radioisotopes, biorepositories
6. Any research funds from a federal or other not-for-profit funding source

WSU retains final authority to determine whether a commercial IRB may be used by WSU researchers for studies fulfilling the above criteria.

The PI is responsible for completing and submitting the commercial IRB application to the commercial

IRB and providing a copy of all submissions and approval paperwork to the WSU IRB. The protocol submission will be assigned an IRB number and tracked within the WSU IRB system.

PROCEDURE FOR USE OF A COMMERCIAL IRB

- A. The Principal Investigator desiring to use a commercial IRB must contact the WSU IRB Coordinator to ensure that the commercial IRB has been approved for WSU investigators to use.
 1. If the commercial IRB has been previously disapproved for use, the investigator may not use the commercial IRB. The investigator may petition for new review of the commercial IRB if it is believed that there have been changes (such as AHRPP accreditation) that warrant reconsideration.
 2. If the commercial IRB has not been previously evaluated for use, the investigator must supply the full name and web address of the commercial IRB to the IRB coordinator.
 - i. The coordinator will research the commercial IRB to insure that it has been accredited by the Association for the Accreditation of Human Research Protection Programs (AHRPP). If it is AHRPP accredited, and the study fulfills the criteria listed above, the commercial IRB may be used by the investigator. If the commercial IRB has not been accredited by AHRPP, then the request must be referred to the IRB chair and Institutional Officer for further discussion and evaluation.
 - ii. If the commercial IRB meets appropriate standards, an IAA agreement may be prepared by the IRB coordinator or principal investigator for the study (see separate procedure)
 3. If the commercial IRB has been previously approved for use by WSU investigators, the PI may prepare the IAA agreement for the study, obtain the required WSU signatures, and proceed as described below.
- B. The PI is responsible for completing and submitting the commercial IRB application to the commercial IRB.
- C. The PI must submit the following to the WSU IRB. The WSU IRB will not perform a formal review of the protocol, but retains the right to disapprove the protocol should there be cause to do so, in which case the research will be immediately suspended.
 1. A completed WSU Petition for Research Using a Commercial IRB (necessary to provide assurance that research will be carried out in accordance with WSU procedures for human subject research)
 2. A copy of the protocol, informed consent document, and all approval letters from the commercial IRB
 3. A copy of the IAA agreement for the study
- D. If the study continues for more than a year, the documentation of continuing review by the commercial IRB must also be submitted to WSU for inclusion in the study file.
- E. The petition and documents submitted to the WSU IRB will be reviewed by the WSU IRB coordinator for completeness and will be assigned a WSU number for tracking purposes. All

documents will be held until 3 years after the completion of the study.

- F. The expiration date of commercial IRB studies will be the central IRB expiration date.
- G. For commercial IRB studies, the commercial IRB will become the IRB of record for the protocol, and the commercial IRB will be responsible for continuing review as well as review of subsequent amendments, unanticipated problems and adverse events as notified by the cooperative group.

PROCEDURE FOR CONTINUING REVIEW OF A COMMERCIAL IRB-APPROVED STUDY

The commercial IRB conducts continuing review for all studies. The WSU-IRB does not have to conduct a continuing review for studies for which the commercial IRB is the IRB of record.

PROCEDURE FOR AMENDMENT REVIEW OF A COMMERCIAL IRB-APPROVED STUDY

The commercial IRB reviews amendments for all studies. Amendments to a commercial IRB-approved study will not be reviewed by the WSU-IRB. When changes in an amendment include changes in the protocol or informed consent document, the investigator/research staff will submit one copy of the updated document(s) to the WSU-IRB for inclusion in the file.

PROCEDURE FOR SERIOUS ADVERSE EVENTS AND UNANTICIPATED PROBLEMS REVIEW

The commercial IRB reviews all adverse events and unanticipated problems related to the study. AEs and unanticipated problems submitted from a commercial IRB-approved study will not be reviewed by the WSU-IRB.

**Petition for Submission of a Protocol to a Commercial Institutional Review Board
Wright State University Office of Research and Sponsored Programs**

Date:

For RSP use only

IRB Assignment Number:

Title of Research Project:

Name of Commercial IRB:

☐ Check here to indicate all investigators have completed the required human subjects protection training offered by Collaborative Institutional Training Initiative (CITI)—see <http://www.citiprogram.org/> and IRB Policy P.5. (found in the IRB Standard Operating Procedures at http://www.wright.edu/rsp/IRB/irb_charter.html).

INVESTIGATOR POTENTIAL FINANCIAL CONFLICT(s) OF INTEREST:

1. Does the investigator or co-investigator(s) have a vested interest in any actual or *potential* commercial enterprise/business associated with any aspect of this protocol (other than patents)?

☐ Yes ☐ No

If yes, fully explain and identify the safeguards taken to prevent investigator bias in subject recruitment and/or the consent process:

2. Are there financial issues that may be of concern to potential subjects? If no, please certify this for all investigators by checking the following boxes to indicate that the investigator(s):

☐ Does not have ownership interest, stock options or other financial interest related to the research whose value, when aggregated for immediate family, represents $\geq 5\%$ interest in any one single entity

☐ Will not receive compensation related to the research whose amount is affected by the outcome of the research

☐ Has no equity interests in the sponsor of this study greater than \$10,000 (when aggregated for the immediate family), **or** does not have ownership interest, stock options, or other financial interest related to the research of any value whose value could not be determined through reference to publicly available prices

☐ Does not have Board or executive relationship related to the research, regardless of compensation

☐ Is/are receiving no payments by the sponsor greater than \$10,000 to the investigator's performing organization(s) exclusive of the costs of conducting the study

☐ Will receive no payments by the sponsor directly to the investigator(s), their spouses or dependent children

☐ Has no financial interests (other than patents) in any non-sponsored research

If all boxes above cannot be checked, please describe below (or in a separate attachment) how such financial arrangements will not adversely affect the interests of the research subjects, and how subjects will be given any information which may be material to potential subjects' decision-making process.

3. Does the sponsor hold all INDs/IDEs for the protocol? ☐ Yes ☐ No

RISK ASSESSMENT:

4. Does the study involve any risk to the subjects? Examples of risks/discomforts include: dizziness, nausea, embarrassment, social stigma (shame or disgrace), psychological distress, loss of employment, invasion of privacy and breach of confidentiality. ☐ Yes ☐ No

If yes:

- a. Indicate where these risks are described in the protocol and consent form/cover letter. ☐
- b. Are the risks/discomforts reasonable in relation to anticipated benefits (if any)? ☐ Yes ☐ No
- c. Indicate how risks to subjects have been minimized where possible. For example:
 - ☐ Subjects have received 24-hour emergency phone numbers
 - ☐ More frequent health exams or diagnostic tests are being performed to monitor for known or anticipated risks
 - ☐ Emergency equipment is available for use if needed
 - ☐ Specimens/samples already collected for standard treatment are used for research purposes whenever possible
 - ☐ Other (please specify)

SAFETY MONITORING:

A plan for data safety monitoring should be provided in any situation in which participants might be at greater than minimal risk of harm, including when a drug or device is being tested for safety or effectiveness for marketing approval, or in placebo-controlled trials, or when marketing drugs are being tested for another indication or compared for safety or effectiveness. A plan is required for all clinical trials, including the development or evaluation of clinical laboratory tests (e.g. imaging or diagnostic tests) if the test will be used for medical decision-making for the subject, or if the test itself imposes more than minimal risk for subjects.

5. Does the protocol require a safety data monitoring plan? ☐ Yes ☐ No. If yes:

- a. Will the research be monitored by a Data Safety Monitoring Board? ☐ Yes ☐ No
- b. If no, please explain how safety will be monitored

6. When applicable, will medical or psychological resources be made available to participants after their completion of the study, if the research produces consequences in which these services are required? ☐ Yes ☐ No ☐ N/A.

CONFIDENTIALITY AND PRIVACY:

- 6. Indicate the procedure for assuring confidentiality of the data (e.g. responses kept in locked safe, restricted access to information, etc.) or for assuring the anonymity of the subjects (e.g. no names on instrument(s), no personal identifiers linked to instrument(s), no in-person interviews/videos, etc.) Please note that student investigators must store study records or data in a Wright State location (i.e. not at home).
- 7. Indicate the procedure for assuring that method(s) used during data collection protect the privacy of the participants (for example, recruitment, obtaining of consent, or obtaining of data will be done in a private location or manner). Note: this does not refer to the confidentiality of the data.
- 8. Does the protocol involve immediate or future testing of genetic material and/or pedigree studies?
☐ Yes ☐ No

If yes, standard wording must be added to the consent document that cautions prospective subjects about the hazards of identifiable genetic findings toward future insurability and/or employability. See suggested wording in "Cover Letter/Consent Form Guidelines" (http://www.wright.edu/rsp/IRB/Consent_Guide.doc). In addition, wording should be added indicating compliance with the Genetic Information Nondiscrimination Act (GINA). See <http://www.wright.edu/rsp/IRB/GINA.pdf> for further information. Does the consent include the appropriate wording? ☐ Yes ☐ No If No, provide further information.

9. Have adequate safeguards been taken to protect against identifying, directly or indirectly, any individual subject in any report of the research project? ☐ Yes ☐ No If No, provide further information.
10. If identifiable medical information is being collected, indicate agreement to follow the HIPAA requirements published in the "Cover Letter/Consent Form Guidelines" (see http://www.wright.edu/rsp/IRB/Consent_Guide.doc). ☐ Yes ☐ No ☐ N/A

If no, is a waiver of the HIPAA privacy rule being requested? (Note: this is most commonly requested with studies limited to chart review) ☐ Yes ☐ No

If a waiver is being requested, all of the following questions must be completely answered:

- a. Explain why the research cannot reasonably be conducted without the waiver of authorization.
- b. Explain why the research cannot reasonably be conducted without access to and use of identifiable health information.
- c. Briefly describe the PHI (Protected Health Information) for which use and/or disclosure has been determined necessary.
- d. Describe the reasonable safeguards to protect identifiable information from unauthorized use or re-disclosure.
- e. Describe the reasonable safeguards to protect against identification, directly or indirectly, any patient in any report of the research.
- f. Describe the plan to destroy the identifiers at the earliest opportunity, consistent with the research. If there is a health or research justification for retaining identifiers, or if the law requires you to keep such identifying information, please provide this information as well.
- g. Provide written assurance that identifiable information will not be reused/disclosed to any other person or entity, unless such use is required by law, for oversight of the research study, or for other research permitted by law.

11. Will a Certificate of Confidentiality be requested from NIH? ☐ Yes ☐ No

- a. If yes, does the Consent Form advise the subjects of situations where the PI may voluntarily comply with state laws? ☐ Yes ☐ No
- b. If yes, has the standard confidentiality statement been modified to be consistent with Confidentiality Certificate protections? See <http://grants.nih.gov/grants/policy/coc/index.htm>. ☐ Yes ☐ No

STUDY SITE RESOURCES:

12. Please describe how the study will be locally administered by answering the following questions.

- a. State where you will be conducting the research study (e.g. Wright State University (WSU), Good Samaritan Hospital (GSH), etc.)
Include the address for any site not affiliated with WSU
- Name of site(s):
 - If other than WSU, Dayton Clinical Oncology Program (DCOP) or hospital facility, describe the facility where the study will be conducted
- b. How will the PI ensure that all research staff for the study are adequately informed of the research-related duties and functions?
- c. Are there adequate resources to complete the research study? ☐ Yes ☐ No
- d. Is there access to a population that will allow recruitment of the required number of participants?
☐ Yes ☐ No If no, explain how subjects will be recruited in item 17., below.

RECRUITMENT:

13. Will this research study recruit any subjects from the following “Vulnerable” categories? Check all that apply.

- ☐ Cognitively Impaired
- ☐ Fetuses
- ☐ Pregnant Women
- ☐ Prisoners
- ☐ Healthy Volunteers (applies only to more than minimal risk protocols)
- ☐ Others vulnerable to coercion (e.g. employee of research site or sponsor, students of investigator).

Describe:

- ☐ Minors (<18 years of age)

For research involving minors, please indicate which of the categories listed below accurately describes this protocol (refer to the appropriate section of 45CFR46, Subpart D)

- ☐ Not involving greater than minimal risk (46.404)
- ☐ Involving greater than minimal risk but of direct benefit to individual subjects (46.405)
- ☐ Involving greater than minimal risk, no direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject disorder or condition (46.406)
- ☐ Involving research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of minors (46.407)

14. Describe the population from which the researcher will recruit (or data source from which data will be obtained): . Note: if subjects are being recruited at a non-WSU site (e.g. local schools, prisons etc.) provide a copy of the permission to use that site signed by an institutional official, or, equivalently, approval from their IRB.

15. How will participants be recruited for this study? Attach copies of any materials given to prospective subjects and/or scripts of any oral communication used to recruit subjects.

16. What type of advertising will be used for this study? Check all that apply.

Note: If an advertisement is to be used, WSU policy requires prior written approval from the PI's department chair and dean. A copy of the advertisement with approval of the chair or dean must be submitted with this application for IRB review.

☐ No advertising will be used

☐ Newspaper

☐ Patient Recruitment Letter

☐ Other (describe)

☐ Poster

☐ Internet

☐ Brochure

☐ E-mail

☐ Web Site

☐ Radio or TV script)

17. State the approximate expected number and age range of participants to be enrolled. List each group, arm, cohort, etc. if applicable, including control groups, on separate lines. If only one group, description would be "All."

Group	NUMBER OF SUBJECTS						AGE RANGE OF SUBJECTS					
	All sites for which you are the PI			All other sites			All sites for which you are the PI			All other sites		

- a. Are subjects who might otherwise benefit from the research excluded from participation? ☐
Yes ☐ No.

If yes, provide scientific and ethical reasons for excluding these subjects .

- b. Is the subject population representative of the population base from which subjects could be selected with respect to gender representation (see NIH guidelines at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

☐ Yes ☐ No. If no, please explain. .

- c. Is the subject population representative of the population base from which subjects could be selected with respect to minority representation (see NIH guidelines at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

☐ Yes ☐ No. If no, please explain. .

18. Will subjects be paid or otherwise compensated? ☐ Yes ☐ No ☐ N/A. If yes:

a. What is the amount of the compensation?

b. If not monetary, what will be used for compensation?

c. What is the reason for compensation?

d. If subjects are to be remunerated, indicate how this remuneration will be prorated over the course of their participation.

19. Will the research involve the intentional use, of or introduction into, subjects of:

a. Biohazards (e.g. rDNA, microorganisms, biological toxins) requiring approval by the Institutional Biosafety Committee?

☐ Yes ☐ No

b. Radioisotopes, radiation, or x-rays requiring approval by the Radiation Safety Committee:

☐ Yes ☐ No

c. Hazardous chemicals (not covered elsewhere in this petition) requiring approval of Environmental Health and Safety?

☐ Yes ☐ No

20. Does the protocol involve exposure to human blood or body fluids by study personnel? ☐ Yes ☐ No

If yes, have study personnel received appropriate training? ☐ Yes ☐ No (If no, describe the steps that will be taken to ensure that training occurs).

INFORMED CONSENT:

21. Indicate who will be signing the informed consent (indicate all that may apply):

- ☐ Participant (adult)
☐ Legally authorized representative for participant

22. Please indicate if all elements of informed consent and HIPAA authorization are included in the consent document(s) ☐ Yes ☐ No. If no, explain why not.

23. Describe the process by which informed consent will be obtained and documented.

- a. The consent interview will be conducted by:
☐ Study staff ☐ Investigator or co-investigator ☐ Other (describe)
☐ N/A (e.g. if the consent process does not involve an interview)
- b. Is there a waiting period between the consent discussion and the signing of the consent document?
☐ Yes ☐ No ☐ N/A
- c. Will participants be allowed to review the document at home prior to signing? ☐ Yes ☐ No
☐ N/A
- d. Are there procedures in place to minimize the possibility of coercion or undue influence?
☐ Yes ☐ No. If no, please explain: ☐ N/A
- e. Will the language to be used in the informed consent document and/or consent interview be understood by the potential participants? ☐ Yes ☐ No ☐ N/A
- f. If consent will be obtained from adults who are cognitively impaired on a temporary basis at the beginning of the research, is there an opportunity (if appropriate) for these participants to provide consent after recovery of cognitive function? ☐ Yes ☐ No ☐ N/A
- g. Will a copy of the informed consent document be given to the participant?
☐ Yes ☐ No ☐ N/A

24. Are there anticipated costs to study participants? ☐ Yes ☐ No ☐ N/A. If yes, describe and justify the costs:

SIGNATURES AND CERTIFICATIONS

By signing and submitting this application, the Principal Investigator agrees that he/she:

1. Accepts responsibility for the scientific conduct of the project, and that the research will be conducted in full compliance with WSU policies and federal regulations.
2. Has provided the IRB with all the information on the research project necessary for use of a commercial IRB
3. Will submit all commercial IRB-initiated modifications of the protocol or consent to the IRB for inclusion in the study folder

4. Will submit documentation of ongoing commercial IRB continuing review to the WSU IRB for inclusion in the study folder
5. Will not put this research project into effect until IRB approval from the commercial IRB is received.
6. Has completed the required modules in the CITI training program, which can be found at <http://www.citiprogram.org/> (see also IRB Policy P.5.)

Signature of Principal Investigator	Date
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All other Investigators listed on the cover of this petition (if any) must sign to acknowledge their participation in this project:

Signature of Co-Investigator	Date	Signature of Co-Investigator	Date
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Signature of Co-Investigator	Date	Signature of Co-Investigator	Date
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