

IUPUI/CLARIAN  
INSTITUTIONAL REVIEW BOARDS

**INSTRUCTION PACKET**

v05/01/09

**For Submitting Applications to the IRB**

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## SECTION I: INTRODUCTION

The purpose of this packet is to give access to and guidance on how to complete the forms for submission to the IUPUI/Clarian IRBs. All policies and procedures are contained within the IUPUI/Clarian Standard Operating Procedures (SOPs) located at: <http://www.iupui.edu/~respoly/human-sop/human-sop-index.htm>.

### **Specific IUPUI/Clarian Standard Operating Procedures (SOPs) include:**

1. Auditing of Research Involving Human Subjects
2. Biological Specimens in Research
3. Confidentiality and Privacy
4. Conflict of Interest Reporting to the IRB
5. Data Management
6. Emergency Use of Investigational Agents
7. Exempt and Expedited New Study Process
8. Facilitated Review
9. Humanitarian Use Devices
10. Informed Consent
11. Investigational Device Accountability
12. Investigational Drug Accountability
13. IRB Operations
14. Recruitment of Human Participants
15. Reporting
16. Research Personnel Requirements
17. Responsibilities of Principal Investigators
18. Safety Monitoring Plans
19. Security of Research Data
20. SOP Process
21. Student Projects
22. Unanticipated Problems and Noncompliance
23. Vulnerable Populations
24. Using the Western Institutional Review Board (WIRB)

The administrative support services for the IUPUI/Clarian IRBs are provided by Research Compliance Administration (RCA) and the Methodist IRB Office. If an investigator is uncertain about whether research requires IRB review, the appropriate office should be contacted for guidance.

## SECTION II: PROTOCOL REVIEW PROCESS

### **Instructions and Forms for Completing IRB Submissions**

The person responsible for overseeing a research project (principal investigator or PI) involving human subjects must ensure appropriate IRB review and approval is obtained before undertaking any project activities. In the case of student projects, this individual is the faculty sponsor. Please refer to the Checklist for Determining Whether an Activity Requires Review (available at <http://www.iupui.edu/~resgrad/spon/download2.htm>) to determine if your project requires IRB review and whether applicable laws that govern research will apply to your project. Instructions for completing the required forms are available in this instruction packet or from RCA or the Methodist IRB office. Submission forms can be obtained at: <http://www.iupui.edu/%7Eresgrad/spon/download2.htm>.

Applications and any related documents are to be forwarded to the appropriate office where they will be processed and directed to the appropriate committee for review.

### **Deadlines**

There are no deadline requirements for submission to the IRB, **except for full review research protocols**. The deadlines for submitting full review research protocols are indicated under [Section IV](#) of this instruction packet. These deadlines are strictly adhered to. Early submissions will increase opportunity for discussion and resolution of issues in advance of the deadline. Incomplete or hand-written submissions will not be accepted for review, and proposals submitted after the deadline will not be reviewed until the following month. Therefore, investigators may minimize the time it takes to receive final approval by carefully preparing the submission so that it meets the guidelines of the IRB on its first submission.

### **IRB Reviews**

All activities requiring review by the IRB (refer to the Checklist for Determining Whether an Activity Requires Review available at <http://www.iupui.edu/~resgrad/spon/download2.htm> for information on activities that require IRB review) must receive final approval (or acceptance) from the IUPUI/Clarian Institutional Review Board (IRB) or appropriate delegate as well as any other reviews required by IUPUI/Clarian (see [Section VI](#)) prior to initiation of the activity. For human subjects research greater than minimal risk, applications should be submitted to the IRB that is best able to assess the role of the subject in the proposed research and to determine whether provisions have been made for protection of the subject's rights and welfare. A listing of the specific expertise on each IRB committee can be found under [Section IV](#) of this instruction packet.

Generally, research that involves risks principally of a medical or physical nature are to be submitted to the biomedical IRBs (IRB-02, IRB-03 (Methodist), IRB-04, or IRB-05). Research involving risks that are principally behavioral, psychological, or social in nature are to be submitted to the behavioral/social sciences IRB (IRB-01). Any subsequent materials submitted for review (e.g. amendments, continuing reviews, etc.) will be reviewed by the IRB that initially reviewed the research unless there is justification to do otherwise.

### **Just-In Time Review for NIH Proposals Involving Human Subjects Research**

The NIH Just-in-Time procedures make it no longer necessary to obtain IRB approval within 60 days of proposal submission. Investigators are now required to obtain IRB approval when there is evidence that funding will be received. Investigators should not submit research applications to the IRB until there is evidence that the proposal is in a fundable range. This procedure should not be problematic since the priority score is assigned early and allows adequate time to run the study through the IRB process. Additionally, this procedure allows the investigator to make changes, as requested by the study section, before the study is submitted to the IRB.

### **Human Subjects Protection Test Requirement**

All principal investigators and co-investigators who are directly interacting or intervening with subjects must pass the human subjects protection test before they can participate in research activities. The course and test can be found at: <http://www.iupui.edu/%7Eresgrad/Human%20Subjects/human-menu.htm>.

### **Investigator 101 Requirement**

New principal investigators involved in research with human subjects are required to complete the Investigator 101 Course and pass the test, which was developed by the Office of Human Research Protections on the appropriate conduct of clinical and non-clinical research. This requirement, as established by the IUPUI Institutional Review Board (IRB) Executive Committee in 2004, applies to all new principal investigators that submit protocols to the IUPUI/Clarian IRBs, including both behavioral

and biomedical protocols at all levels of submission (exempt, expedited, and full board review). The three-hour course may be completed in multiple sessions. To obtain a copy of the Investigator 101 Course on a compact disc (CD) free of charge, contact Research Compliance Administration at 317.274.8289 or [resrisk@iupui.edu](mailto:resrisk@iupui.edu).

### **Withdrawal of a Human Subjects Research Application from the Review Process**

The IRB recognizes that research applications in the process of review may be withdrawn by the sponsor and/or the investigator. Any changes in the status of the research must be submitted to RCA or the Methodist IRB Office.

## **SECTION III: COLLABORATIONS, MULTICENTER STUDIES, OFFSITE RESEARCH AND NON-AFFILIATED INVESTIGATORS**

While most human subjects research studies at IUPUI/Clarian will take place in IUPUI/Clarian facilities by IUPUI/Clarian investigators only, there are many variables which may allow for collaborations with multiple sites or multiple investigators. With the approval of the Department or Agency Head, when IUPUI is participating in a cooperative project, it may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. In those instances, other requirements may apply. Note that in the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human participants and for complying with all applicable policies. See below for frequent scenarios affecting human subjects researchers on this campus and whether a submission to an IUPUI/Clarian IRB may be required. When conducting research on any IU or Purdue campus, refer to [Appendix B](#) for determinations as to where to send IRB submissions.

### **Definitions:**

**Engaged in Human Subjects Research<sup>1</sup>:** An institution becomes "engaged" in non-exempt human subjects research when its employees or agents<sup>2</sup> for the purpose of the research obtain:<sup>3</sup> (i) data about the subjects of the research through intervention or interaction with them; (ii) identifiable private information about the subjects of the research; or (iii) the informed consent of human subjects for the research. If your research is funded by the Department of Education, please refer to the following website for additional information: <http://www.ed.gov/policy/fund/guid/humansub/guidan1.html>

#### **A. Examples of Institutions Engaged in Human Subjects Research**

In general, institutions are considered *engaged* in an HHS-conducted or -supported non-exempt human subjects research project (and, therefore, would need to hold or obtain OHRP-approved FWAs and certify IRB review and approval to HHS) when the involvement of their employees or agents in that project includes any of the following:

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<sup>1</sup> Adapted from Guidance on Engagement of Institutions in Human Subjects Research, OHRP, October 10, 2008, available at <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>.

<sup>2</sup> Employees and agents, including students, are individuals performing institutionally designated activities and acting on behalf of the institution or exercising institutional authority or responsibility.

<sup>3</sup> **Obtain:** Obtaining identifiable private information means receiving or accessing identifiable private information or identifiable specimens for research purposes. OHRP interprets obtain to include an investigator's use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator.

- (1) Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research (i.e. awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.
- (2) Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures. Examples of invasive or noninvasive procedures include drawing blood; collecting buccal mucosa cells using a cotton swab; administering individual or group counseling or psychotherapy; administering drugs or other treatments; surgically implanting medical devices; utilizing physical sensors; and utilizing other measurement procedures.

*See scenarios B.(1), B.(2), and B.(3) below for limited exceptions.*

- (3) Institutions whose employees or agents intervene for research purposes with any human subject of the research by manipulating the environment. Examples of manipulating the environment include controlling environmental light, sound, or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions.

*See scenarios B.(1) and B.(3) below for limited exceptions.*

- (4) Institutions whose employees or agents interact for research purposes with any human subject of the research. Examples of interacting include engaging in protocol dictated communication or interpersonal contact; asking someone to provide a specimen by voiding or spitting into a specimen container; and conducting research interviews or administering questionnaires.

*See scenarios B.(1), B.(2), B.(3), and B.(4) below for limited exceptions.*

- (5) Institutions whose employees or agents obtain the informed consent of human subjects for the research.
- (6) Institutions whose employees or agents **obtain** for research purposes identifiable private information or identifiable biological specimens **from any source** for the research. It is important to note that, in general, institutions whose employees or agents obtain identifiable private information or identifiable specimens for non-exempt human subjects research are considered engaged in the research, even if the institution's employees or agents do not directly interact or intervene with human subjects. In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to:
  - (a) observing or recording private behavior;
  - (b) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and
  - (c) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

In general, OHRP considers private information or specimens to be individually identifiable as defined in 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

*See scenarios B.(1), B.(2), B.(3), B.(7), B.(8), B.(9), and B.(10) below for limited exceptions.*

**B. Examples of Institutions Not Engaged in Human Subjects Research:**

Institutions would be considered **not** engaged in an HHS-conducted or -supported non-exempt human subjects research project (and, therefore, would not need to hold an OHRP-approved FWA or certify IRB review and approval to HHS) if the involvement of their employees or agents in that project is **limited to one or more** of the following. The following are scenarios describing the types of institutional involvement that would make an institution **not** engaged in human subjects research; there may be additional such scenarios:

- (1) Institutions whose employees or agents perform commercial or other services for investigators provided that **all** of the following conditions also are met:
  - (a) the services performed do not merit professional recognition or publication privileges;
  - (b) the services performed are typically performed by those institutions for non-research purposes; and
  - (c) the institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

The following are some examples, assuming the services described would not merit professional recognition or publication privileges:

- an appropriately qualified laboratory whose employees perform routine serum chemistry analyses of blood samples for investigators as a commercial service.
- a transcription company whose employees transcribes research study interviews as a commercial service.
- a hospital whose employees obtain blood through a blood draw or collect urine and provide such specimens to investigators as a service.
- a radiology clinic whose employees perform chest x-rays and send the results to investigators as a service.

- (2) Institutions (including private practices) not selected as a research site whose employees or agents provide clinical trial-related medical services that are dictated by the protocol and would typically be performed as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site by clinical trial investigators (e.g., medical history, physical examination, assessment of adverse events, blood test, chest X-ray, or CT scan) provided that **all** of the following conditions also are met:
  - (a) the institution's employees or agents **do not** administer the study interventions being tested or evaluated under the protocol;
  - (b) the clinical trial-related medical services are typically provided by the institution for clinical purposes;
  - (c) the institution's employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research; and
  - (d) when appropriate, investigators from an institution engaged in the research retain responsibility for:
    - (i) overseeing protocol-related activities; and
    - (ii) ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.

Note that institutions (including private practices) not initially selected as research sites whose employees or agents administer the interventions being tested or evaluated in the

study—such as administering either of two chemotherapy regimens as part of an oncology clinical trial evaluating the safety and effectiveness of the two regimens—generally would be engaged in human subjects research (see scenario B.(3) below for a limited exception). If such an institution does not have an FWA, its employees or agents may be covered by the FWA of another institution that is engaged in the research through an Individual Investigator Agreement. See

<http://www.hhs.gov/ohrp/humansubjects/assurance/guidanceonalternativetofwa.pdf>.

- (3) Institutions (including private practices) not initially selected as a research site whose employees or agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis (e.g., an oncologist at the institution administers chemotherapy to a research subject as part of a clinical trial because the subject unexpectedly goes out of town, or is unexpectedly hospitalized), provided that **all** of the following conditions also are met:
  - (a) an investigator from an institution engaged in the research determines that it would be in the subject's best interest to receive the study interventions being tested or evaluated under the protocol;
  - (b) the institution's employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research;
  - (c) investigators from the institution engaged in the research retain responsibility for:
    - (i) overseeing protocol-related activities;
    - (ii) ensuring the study interventions are administered in accordance with the IRB-approved protocol; and
    - (iii) ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol; **and**
  - (d) an IRB designated on the engaged institution's FWA is informed that study interventions being tested or evaluated under the protocol have been administered at an institution **not** selected as a research site.
- (4) Institutions whose employees or agents:
  - (a) inform prospective subjects about the availability of the research;
  - (b) provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators;
  - (c) provide prospective subjects with information about contacting investigators for information or enrollment; and/or
  - (d) seek or obtain the prospective subjects' permission for investigators to contact them.

An example of this would be a clinician who provides patients with literature about a research study at another institution, including a copy of the informed consent document, and obtains permission from the patient to provide the patient's name and telephone number to investigators.

- (5) Institutions (e.g., schools, nursing homes, businesses) that permit use of their facilities for intervention or interaction with subjects by investigators from another institution.

Examples would be a school that permits investigators from another institution to conduct or distribute a research survey in the classroom; or a business that permits investigators from

another institution to recruit research subjects or to draw a blood sample at the work site for research purposes.

- (6) Institutions whose employees or agents **release** to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research.

Note that in some cases the institution releasing identifiable private information or identifiable biological specimens may have institutional requirements that would need to be satisfied before the information or specimens may be released, and/or may need to comply with other applicable regulations or laws. In addition, if the identifiable private information or identifiable biological specimens to be released were collected for another research study covered by 45 CFR part 46, then the institution releasing such information or specimens should:

- (a) ensure that the release would not violate the informed consent provided by the subjects to whom the information or biological specimens pertain (under 45 CFR 46.116), or
- (b) if informed consent was waived by the IRB, ensure that the release would be consistent with the IRB's determinations that permitted a waiver of informed consent under 45 CFR 46.116 (c) or (d).

Examples of institutions that might release identifiable private information or identifiable biological specimens to investigators at another institution include:

- (a) schools that release identifiable student test scores;
- (b) an HHS agency that releases identifiable records about its beneficiaries; and
- (c) medical centers that release identifiable human biological specimens.

Note that, in general, the institutions whose employees or agents **obtain** the identifiable private information or identifiable biological specimens from the releasing institution would be engaged in human subjects research. [See scenario A.(6) above.]

- (7) Institutions whose employees or agents:
- (a) obtain coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information (such as name or social security number); and
  - (b) are **unable** to readily ascertain the identity of the subjects to whom the coded information or specimens pertain because, for example:
    - the institution's employees or agents and the holder of the key enter into an agreement prohibiting the release of the key to the those employees or agents under any circumstances;
    - the releasing institution has IRB-approved written policies and operating procedures applicable to the research project that prohibit the release of the key to the institution's employees or agents under any circumstances; or
    - there are other legal requirements prohibiting the release of the key to the institution's employees or agents.
- (8) Institutions whose employees or agents access or utilize individually identifiable private information **only** while visiting an institution that is engaged in the research, provided their research activities are overseen by the IRB of the institution that is engaged in the research.

- (9) Institutions whose employees or agents access or review identifiable private information for purposes of study auditing (e.g. a government agency or private company will have access to individually identifiable study data for auditing purposes).
- (10) Institutions whose employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.
- (11) Institutions whose employees or agents author a paper, journal article, or presentation describing a human subjects research study.

**Coded:** Coded means that (a) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, and/or combination thereof (i.e., the code); and (b) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

**Federalwide Assurance:** An assurance of compliance with the HHS regulations (45 CFR 46) for the protection of human subjects. This is required of any institution engaged in human subjects research (not otherwise exempt) that is conducted or supported by any agency of the U.S. Department of Health and Human Services (HHS). A federalwide assurance (FWA) is obtained from the Office for Human Research Protections (OHRP).

**Letter of Cooperation:** A letter or agreement acknowledging and allowing research with human subjects to be conducted at an institution or organization.

**Guidelines for Interpretation:**

**Performance sites that are engaged:**

1. **When federal funding is involved:** When IUPUI/Clarian investigators are conducting non-exempt research, the institution where the research will be done is “engaged” meeting the definition above, and federal funding is involved, the institution that is engaged must have a Federalwide Assurance (FWA) approved by the Office of Human Research Protections (OHRP) which designates the appropriate IUPUI/Clarian IRB as an IRB of record. A list of approved assurances is available at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>. If the institution in which you are conducting research is not on this list, or has not designated an IUPUI/Clarian IRB, please contact the RCA Office for details on how to proceed and how to obtain an FWA.
2. **When no federal funding is involved or if the research meets the criteria for exemption:** When IUPUI/Clarian investigators are conducting exempt research at an unaffiliated institution or conducting non-exempt research at an institution which meets the definition of “engaged” above and federal funding is *not* involved, the institution must submit a **Letter of Cooperation**. This letter shall be submitted to the IUPUI/Clarian IRB of record with the research submission. The investigator must be aware of any requirements for IRB approval at the unaffiliated institution; i.e., if IRB approval is required at the unaffiliated institution, a copy of that approval shall be submitted to the IUPUI/Clarian IRB of record.
3. **When IU is one site in a multicenter study:** Regardless of the funding source, a multicenter human subjects protocol in the format agreed upon by the multicenter group may be accepted by the IRB. However, the informed consent statement must conform to the format required by the IUPUI/Clarian IRB.

An institution is considered engaged when its employees or agents maintain "operations centers" or "coordinating centers" for multi-site collaborative research. Where institutional activities involve no interaction or intervention with subjects, the IRB need not review each collaborative protocol. However, the IRB should determine and document that the operations or coordinating center has sufficient mechanisms in place to ensure that (i) management, data analysis, and Data Safety and Monitoring (DSM) systems are adequate, given the nature of the research involved; (ii) sample protocols and informed consent documents are developed and distributed to each collaborating institution; (iii) each collaborating institution holds an applicable OHRP-approved Assurance, if applicable; (iv) each protocol is reviewed and approved by the IRB at the collaborating institution prior to the enrollment of subjects; (v) any substantive modification by the collaborating institution of sample consent information related to risks or alternative procedures is appropriately justified; and (vi) informed consent is obtained from each subject in compliance with HHS regulations. The local PI is responsible for forwarding the above information to the IRB for review and approval. When the local PI serves as the lead-site investigator, he/she takes on the above-listed responsibilities.

4. **When utilizing a cooperating department within the IUPUI system:** If it is anticipated that another department within the IUPUI/Clarian system or its affiliated institutions may be engaged in human subjects research, a co-investigator from each cooperating department must be listed under Section XXI of the summary safeguard statement.

#### **Performance sites that are not engaged:**

Institutions (e.g., schools, nursing homes, businesses) that do not meet the definition of "engaged" above (e.g., a school permits investigators to test students whose parents have provided written permission for their participation; a business permits investigators to solicit research volunteers at the worksite) do not need to obtain an FWA regardless of funding source. However, the IRB will still require a **Letter of Cooperation** from the site allowing it to be used in research by the IUPUI/Clarian investigator.

#### **Relying on Another Institution's IRB Approval:**

1. **When IUPUI faculty are collaborating with Purdue University:** IUPUI and Purdue University have entered into a cooperative agreement which allows for only one IRB review to take place, i.e., both sites do not have to review and approve the study when human subjects research is being conducted at both sites or involves investigators from both sites. Please contact the RCA Office for more details.
2. **When Purdue pharmacy faculty wish to conduct research at an IUPUI facility:** IUPUI and Purdue have entered into an agreement which allows for review by one of the IUPUI IRBs when Purdue Pharmacy faculty will conduct human subjects research at an IUPUI facility. Please contact the RCA Office if you are a Purdue Pharmacy faculty member wishing to conduct research at IUPUI for more details.
3. **When both IU Bloomington (IUB) and IUPUI campuses and/or faculty are involved in research:** IUB and IUPUI have entered into an agreement which allows for review by only one campus when the investigator resides on campus (IUPUI or IUB) and the research will be conducted on the other campus. If you are an investigator on one of these IU campuses and wish to conduct human subjects research on the other campus, please contact the RCA Office for details on where and how to apply.
4. **When both Bloomington Hospital and IUPUI are involved in research:** Bloomington Hospital and IUPUI have entered into an agreement which allows for review by only one campus when the investigator resides on campus (IUPUI or Bloomington Hospital) and the research will be conducted on the other campus. If you are an investigator on one of these campuses and wish

to conduct human subjects research on the other campus, please contact the RCA Office for details on where and how to apply.

5. **When conducting a phase III or IV adult or phase II, III or IV pediatric oncology Cooperative Group trial:** IUPUI/Clarian has obtained an assurance listing the National Cancer Institute Central IRB (NCI CIRB) as the IRB of record for eligible oncology research. Please contact the RCA Office for more details.
6. **When conducting certain minimal risk research:**
  - a. The IUPUI/Clarian IRB may agree to accept an unaffiliated institution's IRB approval in lieu of local review when an unaffiliated investigator at an institution with IRB approval for minimal risk research requests access to IUPUI/Clarian facilities, faculty, staff, students, or subjects. Please contact the RCA Office for details.
  - b. The IUPUI/Clarian IRB may defer their review to an unaffiliated institution's IRB when an unaffiliated investigator with IRB approval at their site who is conducting and coordinating multi-center, minimal-risk research requests to be the IRB of record for all sites. An IRB Authorization Agreement may be required. See a sample IRB authorization agreement: <http://www.hhs.gov/ohrp/humansubjects/assurance/iprotsup.rtf> and contact the RCA Office before proceeding.

### **Non-Affiliated Investigators**

1. When a researcher is aware of or reasonably anticipates that an individual not employed or otherwise affiliated with IUPUI/Clarian (e.g. the subject's local physician who is not affiliated with IUPUI/Clarian and does not have local IRB approval for the protocol at his/her facility) will be playing a role in the design, conduct or reporting of the research, including persons obtaining consent and handling identifiable information, or will be making independent decisions about the inclusion or exclusion of participants in the study, steps should be included to address that scenario within the body of the protocol and in Section D of the summary safeguard statement before submission of the protocol to the IRB.
2. When the participation of a non-affiliated investigator is not anticipated prior to submission of the protocol to the IRB, the participation will require IRB approval by means of an amendment to the study which will, most often, be reviewed using the expedited review procedure before the non-affiliated practitioner may participate in protocol-specific procedures. The amendment must specifically describe what procedures will be performed by the non-affiliated investigator.
3. A specific, written agreement must be established with any non-affiliated investigator prior to interacting or intervening with human subjects. See [Guidelines Concerning Participation by Non-Affiliated Investigators in Research Protocols](#) for additional information and for the agreement.
4. The non-affiliated investigator must be listed in Section XX of the summary safeguard statement. The summary safeguard statement must specifically describe what procedures will be performed by the non-affiliated investigator, including whether or not the non-affiliated investigator will be interacting or intervening with subjects.
5. If the non-affiliated investigator will be interacting or intervening with subjects, evidence of having passed an approved human subjects protection test must be submitted to the IUPUI/Clarian IRB. Approved human subjects tests include: IU Human Subjects Protection Test, NCI exam, NIH exam, CITI exam, and any human subjects protection test from a Council on Governmental Relations (COGR) institution<sup>4</sup>.

### **Submission of the Same Research Project from Different Investigators**

In general, when two investigators wish to submit the same protocol separately, the investigators are encouraged to collaborate when possible. If the investigators have indicated that it is not possible to collaborate on the conduct of the specific protocol, each investigator must submit a memo to the IRB with

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<sup>4</sup> Please visit [http://www.cogr.edu/files/COGR\\_Membership.cfm](http://www.cogr.edu/files/COGR_Membership.cfm) for a list of COGR institutions.

their study application materials which explains the circumstances and which requests to conduct the same study. This memo will be forwarded to the IRB with the application materials such that the IRB can make the appropriate determination regarding the conduct of the study.

**SECTION IV: IRB DEADLINES, MEETINGS, AND EXPERTISE**

The Institutional Review Boards (IRBs) at IUPUI and Clarian Health Partners are responsible for the review and approval of all research involving human subjects conducted under the auspices of these (and affiliated) institutions. There are five IRBs, each of which are qualified and constituted to review the type of research submitted to it. The expertise of each board is listed below.

<b>IRB</b>	<b>Specialty</b>
IRB-01	Research in the behavioral and social sciences
IRB-02	Biomedical research in hematology/oncology, nephrology, infectious diseases, pediatrics, neurology, endocrinology, genetics, and general medicine
IRB-03 (Methodist)	Biomedical research conducted solely or primarily at the Methodist Hospital campus or at a Methodist affiliate site (i.e. the majority of subjects will be enrolled at Methodist Hospital or a Methodist affiliate site)
IRB-04	Biomedical research in pediatrics, hematology/oncology, dentistry, cardiology, psychiatry, surgery, OB/GYN, and general medicine
IRB-05	Biomedical research in infectious diseases, pediatrics, ophthalmology, radiology, hematology/oncology, gastroenterology, psychiatry, surgery, endocrinology, and general medicine

Please note the expertise of each IRB and submit your research application accordingly. Biomedical research to be conducted solely at Methodist Hospital and/or a Methodist affiliate site, and studies for which the majority of the patients will be enrolled at Methodist Hospital or a Methodist affiliate site, should be submitted to IRB-03. All other biomedical research should be submitted to IRB-02, IRB-04, or IRB-05. The principal investigator is responsible for making an initial determination regarding which IRB to submit to; however, RCA staff may transfer the IRB to another IRB if appropriate. If you have questions about which IRB to submit your study, please contact the RCA office.

A list of IRB deadlines and meeting dates, can be found at: <http://www.iupui.edu/~resed/irbeddescript.htm>. IRB-01 meetings are usually held on the 1<sup>st</sup> Friday of each month; IRB-02 meetings are usually held on the 2<sup>nd</sup> Tuesday of each month; IRB-03 meetings are usually held on the 2<sup>nd</sup> Thursday of the month; IRB-04 meetings are usually held on the 3<sup>rd</sup> Tuesday of each month; and IRB-05 meetings are usually held on the 4<sup>th</sup> Wednesday of each month, approximately two weeks after the deadline. Please pay particular attention to the deadlines to ensure that the submission meets the deadline requirements for the specific IRB that will be reviewing the study. Also, please note that subsequent documentation (e.g. amendments, continuing reviews, etc.) must be submitted to the IRB that originally reviewed the study.

Please visit [http://www.iupui.edu/%7Eeresgrad/spon/irb\\_submit.htm](http://www.iupui.edu/%7Eeresgrad/spon/irb_submit.htm) to submit your research application.

## SECTION V: SUBMISSION REQUIREMENTS & REVIEW PROCESS

The review processes are explained in more detail as follows:

### **Non-Research Student Projects:**

Although the IRB was established to review and approve research involving human subjects, the institution (IUPUI/Clarian) has given the IRB the responsibility and authority to review non-research student projects to ensure appropriate ethical principles have been considered. To determine whether a student activity is eligible for non-research student project review, please see the Checklist for Determining Whether an Activity Requires IRB Review (available at <http://www.iupui.edu/~eresgrad/spon/download2.htm>). The preliminary determination that a student project is eligible for non-research student project review is made by the faculty sponsor; however, the IRB makes the final determination. Please allow 5-10 working days for processing this type of review. There are no deadlines for non-research student projects.

Submit the following documents electronically via the IRB submission website at: [http://www.iupui.edu/%7Eeresgrad/spon/irb\\_submit.htm](http://www.iupui.edu/%7Eeresgrad/spon/irb_submit.htm).

- Application Form for Non-Research Student Projects: must be submitted by the faculty sponsor
- Instruments (e.g. surveys, questionnaires, etc.), if applicable

### **Non-Human Subjects Research:**

Although the IRB was established to review and approve research involving human subjects; the institution (IUPUI/Clarian) has given the IRB the responsibility and authority to review some non-human subjects research (e.g. research not subject to FDA or Common Rule definitions of human subjects research) to ensure HIPAA requirements have been considered. To determine whether an activity is eligible for this type of review, please see the Checklist for Determining Whether an Activity Requires Review by the IUPUI/Clarian IRB. The preliminary determination that a research activity is not subject to FDA or Common Rule definitions of human subjects research is made by the investigator; however, the IRB makes the final determination. Please allow 5-10 working days for processing this type of review. There are no deadlines for non-human subjects research.

Submit the following documents electronically via the IRB submission website at: [http://www.iupui.edu/%7Eeresgrad/spon/irb\\_submit.htm](http://www.iupui.edu/%7Eeresgrad/spon/irb_submit.htm).

- Application for Non-Human Subjects Research
- Instruments (e.g. data collection sheets), if applicable

### **Exempt from Full Review:**

The preliminary determination that a research project is eligible for exempt review is made by the investigator; however, the IRB makes the final determination. Please allow 5-10 working days for Exempt Review processing. There are no deadlines for exempt research; however, if the IRB determines that the research does not qualify for exempt or expedited review, it must be resubmitted for full review in accordance with the deadline dates. Therefore, it is recommended that exempt research be submitted a few weeks prior to the deadlines listed above in the event that full review is required. Early submissions will increase opportunity for discussion and resolution of issues in advance of the investigator's deadline.

Submit the following documents electronically via the IRB submission website at: [http://www.iupui.edu/%7Eeresgrad/spon/irb\\_submit.htm](http://www.iupui.edu/%7Eeresgrad/spon/irb_submit.htm).

- Exempt Research Checklist
- (1) copy of the complete grant proposal **for NIH-funded research only**<sup>5</sup>. For grant proposals that will apply to multiple research studies, a one time submission of the proposal is deemed sufficient.
- Research instruments (surveys, questionnaires, interview guide, etc.), as applicable

### **Expedited and Full Board Review**

Some research projects may not require review by the fully-convened IRB (see the Expedited Research Checklist available at <http://www.iupui.edu/~resgrad/spon/download2.htm>). The preliminary determination that a research project is eligible for expedited review is made by the investigator; however, the IRB makes the final determination. If an IRB determines that a study does not meet the requirements for expedited review, the study must then be submitted for full review by the specified deadline date. Please allow 10-15 working days for Expedited Review processing. It is recommended that expedited research be submitted a few weeks prior to the deadlines listed above in the event that full review is required. Early submissions will increase opportunity for discussion and resolution of issues in advance of the investigator's deadline. There are no deadlines for expedited research.

If the study does not qualify as a non-research student project, a non-human subjects research project, or exempt or expedited review, full review by the IRB is required.

For projects requiring expedited or full board review, submit the following documents (where applicable) electronically via the IRB submission website at: [http://www.iupui.edu/%7Eresgrad/spon/irb\\_submit.htm](http://www.iupui.edu/%7Eresgrad/spon/irb_submit.htm).

- **Expedited Research Checklist**
- **Documentation of Review and Approval (DRA)**
- **Summary Safeguard Statement (SSS):** A response must be provided for each item. "See Attached" and/or "n/a" are NOT acceptable responses.
- **Informed Consent Statement (ICS) (where applicable):** Careful review of the Informed Consent Statement Checklist (available at <http://www.iupui.edu/~resgrad/spon/download2.htm>) is important in the preparation of this document.

*NOTE: If the research study is a National Institute of Health (NIH) multicenter clinical trial, a copy of the NIH-approved sample informed consent document must be submitted as a condition for review and approval of the local informed consent statement. Any deletion or substantive modification of the information about risks or alternative procedures contained in the sample informed consent document must be justified in writing by the investigator and approved by the IRB.*

- **Authorization for the Release of Health Information for Research**
- **Recruitment Checklist and Telephone Scripts:** The Recruitment Checklist describes the process and methods used to identify, recruit, or screen subjects into a research study involving health information. In addition, telephone scripts used to recruit or screen subjects for eligibility into a research study must be submitted to the IRB for approval. This script must be included with an explanation of what will be done with the personal information if the caller ends the

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<sup>5</sup> If the principal investigator is the recipient of federal monies to fund his/her research, he/she must submit a copy of the entire grant application for the IRB to review. If the principal investigator is a sub-contractor or recipient of federal pass-thru monies, the IRB does not need to see the entire grant application.

interview or simply hangs up.<sup>6</sup> See Recruitment Checklist for more details regarding the guidelines for using an individual's health information to identify, contact and/or recruit subjects into a research study.

- **Recruitment materials:** Any written material or advertisement to be seen or heard by prospective research subjects and methods and modes of communication used to recruit research subjects must be submitted for IRB review and approval. No advertisement, method, or mode of advertising the research study to subjects may be employed until IRB approval is granted.
- **Instruments:** Include the instrument(s) used for questionnaires or surveys, etc.
- **Protocol:** All expedited and full review research applications must include a protocol separate from the Summary Safeguard Statement in order to receive IRB review. For NIH studies, the entire grant proposal must also be submitted. A protocol template is available at <http://www.iupui.edu/~resgrad/spon/download2.htm>; however, the protocol MUST include at a minimum, the following:
  1. Statement of the purpose and objectives of the research project;
  2. Outline of the research plan, including details of subject recruitment (see Recruitment Checklist if health information will be used for this purpose);
  3. Subject inclusion and exclusion criteria, an estimate of the number of subjects to be studied, and procedures to be performed;
  4. Description of procedures for data analysis including observations and measurements to be made to fulfill the objectives of the study, justification of the number of subjects to be enrolled, the kind of control group to be used, if any, and a description of methods to be used to minimize biases on the part of subjects, investigators and analysts;
  5. Review of pertinent literature;
  6. Toxicology data, in the case of drug studies;
  7. Information regarding data and safety monitoring;
  8. Description of the safeguards used to protect the confidentiality and security of health information, if applicable
- **Clinical Investigator's Brochures (CIBs) or package inserts for all drugs being used in the research (biomedical research):** Investigational brochures must be forwarded at the time of submission to the IRB when investigational drugs or devices are used. Studies involving FDA-approved pharmaceuticals should either include the package insert or contain within the protocol a complete description of information included in the package insert (i.e., toxicities, recommended dosing, etc.).
- **Mentor letter:** required for all new investigators in the Department of Medicine
- **Complete grant proposal (for NIH-funded research only<sup>7</sup>):** For grant proposals that will apply to multiple research studies, a one time submission of the proposal is deemed sufficient.

#### **Additional notes for all submissions:**

- All documents must be neatly typed and legible with any acronyms spelled out the first time they are used.
- INCOMPLETE applications will NOT be reviewed by the IRB.
- The investigator is responsible for keeping a copy of all documents submitted to the IRB.
- The SAME title must appear on all forms.

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<sup>6</sup> See FDA Information Sheets, [Recruiting Study Subjects, Section B: Receptionist Scripts](#) for additional information.

<sup>7</sup> If the principal investigator is the recipient of federal monies to fund his/her research, he/she must include a copy of the entire grant application for the IRB to review. If the principal investigator is a sub-contractor or recipient of federal pass-thru monies, the IRB does not need to see the grant.

For assistance in preparing materials, call Research Compliance Administration at 317/274-8289 or the Methodist IRB Office at 317/962-8240.

## **IRB Actions**

**Non-Research Student Projects.** The IRB may accept or deny non-research student projects. If the application is denied, a reason for its denial will be provided.

**Application for Non-Human Subjects Research.** The IRB may accept or deny this type of research. If the application is denied, a reason for its denial will be provided.

**Minimal Risk (Exempt or Expedited) Research Applications.** The IRB may accept or deny this type of research. Note that expedited research may be disapproved only after review in accordance with the full Board review procedure.

**Research Involving Human Subjects and More Than Minimal Risk.** The IRB may take any of the following four actions:

- **Final Approval:** The IRB has requested no changes in the study and the PI may commence the research only after receiving written IRB approval indicated by a signed copy of the Documentation of Review and Approval with a cover letter from RCA or the Methodist IRB office outlining the additional responsibilities for conducting research at IUPUI or Clarian.
- **Provisional Approval:** The IRB has granted contingent approval pending specific revisions requested by the IRB. The PI must respond in writing to the provisions and an expedited reviewer must review the PI's response before final approval can be granted. The PI's response does not require review by the full board. RCA or the Methodist IRB office will communicate the provisions to the investigator by sending a cover letter with an excerpt of the meeting minutes detailing the IRB's discussion and requested provisions. Once the responses are reviewed and approved by the IRB or its designee, the PI may commence the research only after receiving written IRB approval indicated by a signed copy of the Documentation of Review and Approval with a cover letter from RCA or the Methodist IRB office outlining the additional responsibilities for conducting research at IUPUI or Clarian.
- **Tabled:** The IRB requests substantive clarifications or modifications regarding the submission documents that are directly relevant to the determination required by the IRB. The research study was deferred for reconsideration at a subsequent IRB meeting after the PI has responded in writing to modifications requested by the IRB.
- **Disapproval:** Significant study concerns exist such that the IRB does not feel that the project can be conducted as currently proposed. This means the study cannot be resubmitted in the same form. The PI will be notified in writing of reasons for disapproval. Note that a research activity may be disapproved only after review in accordance with full Board review procedure.

Upon completion of the review, the investigator will receive a written response from the IRB shortly after the meeting. Any questions raised by the IRB must be responded to in writing within sixty (60) days (provisionally approved or tabled studies). No research activities may be initiated until the PI receives written final approval from the IRB. The investigator is responsible for notifying the sponsor if the IRB finds that a device presents a significant risk to the subjects.

## SECTION VI: ADDITIONAL REVIEWS <sup>8</sup>

**Infectious Agents, Hazardous Materials or Other Chemicals:** For additional information regarding the safe use and disposal of infectious agents, hazardous materials or other chemicals, contact the Department of Environmental Health and Safety at (317) 274-2005 or visit <http://www.ehs.iupui.edu/ehs/>.

**Radiation and/or Radioactivity:** If the study involves the use of radiation and/or radioactivity in addition to what is already used for standard clinical treatment or the subject would receive radiation exposure only due to participation in the research, approval must also be obtained from the appropriate radiation committee. Final approval for a research study cannot be granted until appropriate documentation is received from the radiation safety committee, if applicable. Further information and sample risk statements for radiation exposure can be obtained from the Radiation Safety Office, Clinical Building, Room 159, (317) 274-4797 or online at <http://radsafe.iusm.iu.edu/>. If radioactive materials are used at Methodist Hospital, no specific radiation approval is required prior to submission. However, the Research Review Committee will review the radiation component after submission.

**Indiana Clinical Research Center (ICRC):** If you will be using the facilities of the ICRC, University Hospital, Room 5595, further additional information or submission may be required. Please contact the CCRC at (317) 274-4356 to obtain additional requirements prior to completing IRB submission. You must provide the Center with all documentation submitted to the IRB, i.e., protocols, amendments, ongoing reviews, etc.

**Veterans Affairs (VA):** All recruitment or research to be conducted at the VA must be approved by an IUPUI/Clarian IRB prior to submission to the VA for approval by the VA Research and Development Committee. If your project is funded by the VA and/or if you will be recruiting from or conducting any part of your research at the VA facilities, the following is to be included in the IRB submission:

- a. Indicate recruitment or research will be conducted involving VA subjects and/or at the VA (see Section III of the summary safeguard statement);
- b. Include the VA Form 10-1086 Informed Consent Statement.

Further information and requirements regarding VA approval and necessary forms may be obtained by calling the VA Research Office at (317) 988-2527.

**Wishard Hospital and Clinics:** All studies to be conducted within Wishard Health Services (including the hospital, OB/GYN clinic and Regenstrief clinics) that involve Wishard patients, services, or facilities, must be approved by Wishard administration prior to the research commencing.

Approval is NOT required for studies being conducted ONLY in the primary care clinics using ResNet or for data extraction studies (i.e. those that do not require any direct patient contact or the use of Wishard services or facilities) that are conducted by the Regenstrief Institute. In these cases, separate approval processes and/or oversight already exist.

Wishard Health Services approval may be obtained by emailing the summary safeguard statement to Dr. Lisa Harris at [leharris@iupui.edu](mailto:leharris@iupui.edu). Flag this e-mail as URGENT with the subject line of the email stating “research approval needed.” You do not need to wait until you receive IRB approval of the summary safeguard statement before forwarding. In fact, simultaneous submission to Dr. Harris and the IRB is

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<sup>8</sup> Applicable reviews and approvals required by IUPUI/Clarian must be granted before research may commence.

preferred. It is Dr. Harris's intention to respond within 3 days. If you do not hear back within 3 days, resend your information to her. If you receive an "out of office" notice, please forward your request to Jessica Barth, Dr. Harris's designee, at [Jessica.barth@wishard.edu](mailto:Jessica.barth@wishard.edu).

**Scientific Review Committee:** If you will be involving **cancer patients** in your study, approval from the Scientific Review Committee (SRC) may be required. The only exception is if you are doing a retrospective chart review involving cancer patients, which does NOT require SRC approval. Please contact the SRC at (317) 274-0930 or [crosrc@iupui.edu](mailto:crosrc@iupui.edu) for additional information. You must receive SRC approval prior to submitting your research application to the IRB. This approval must be included with your IRB submission paperwork. At Methodist, this is not a requirement, as the Research Review Committee will be reviewing the study after study submission.

**Department of Education:** If your research is funded by the Department of Education, additional requirements may apply. Please contact Research Compliance Administration for additional information.

**Department of Defense:** If your research is funded by the Department of Defense, additional requirements may apply. Please contact Research Compliance Administration for additional information.

**Bureau of Prisons:** If you intend to involve prisoners (view definitions located within the **Vulnerable Populations SOP**) within a federal prison facility in your research, additional requirements apply. Refer to the **Vulnerable Populations SOP** for information with regard to involving prisoners and complete the **Request for Prisoners in Research Form**. For research conducted or supported by DHHS, obtain additional approval of the involvement of prisoners in the research from DHHS prior to initiating the study.

**Department of Corrections:** If you intend to involve prisoners (view definitions located within the **Vulnerable Populations SOP**) within a Department of Corrections prison facility in your research, additional requirements apply. Refer to the **Vulnerable Populations SOP** for information with regard to involving prisoners and complete the **Request for Prisoners in Research Form**. For research conducted or supported by DHHS, obtain additional approval of the involvement of prisoners in the research from DHHS prior to initiating the study.

## **PRINCIPAL INVESTIGATOR AND FACULTY SPONSOR ELIGIBILITY AT IUPUI/CLARIAN**

These guidelines are applicable for determining whether an individual is eligible to serve as a principal investigator for a human subjects research study or a faculty sponsor for student projects. Because human subjects research and student projects are being conducted and overseen by both faculty at IU and medical staff at Clarian, please refer to the appropriate guidelines below for determining eligibility.

**Principal Investigator:** The responsible leader of a team of investigators (and research team), who has the ultimate responsibility for the conduct of the research.

**Faculty Sponsor:** Full or part-time faculty employed by IUPUI/Clarian who engage in classroom instruction, supervise on or off campus internships, clinical experiences or practica, or mentor students who are conducting independent projects.

### **Principal Investigator and Faculty Sponsor Eligibility at IU:**

The following academic appointee classifications **ARE** eligible to serve as principal investigators and/or faculty sponsors:

1. **FACULTY** with the following titles: (1) Special Professorship; (2) Professor; (3) Associate Professor; (4) Assistant Professor; and (5) Instructor.
2. **LIBRARIANS** with the following titles: (1) Librarian; (2) Associate Librarian; (3) Assistant Librarian; and (4) Affiliate Librarian.
3. **ADMINISTRATIVE OR SPECIAL STATUSES** with the following titles: (1) President; (2) Vice President; (3) Chancellor; (4) Vice Chancellor; (5) Dean; (6) Associate Dean; (7) Assistant Dean; (8) Chairman; (9) Director; (10) Acting 1 to 5; (11) Visiting; (12) Adjunct-Compensated; (13) Emeritus (Case-by-Case); (14) Part-Time; and (15) Clinical.
4. **RESEARCH STAFF** with the following titles: (1) Senior Scientist; (2) Associate Scientist; and (3) Assistant Scientist.

The following academic appointee classifications are **NOT** eligible to serve as principal investigators and/or faculty sponsors (\*see special exceptions below):

1. **OTHER INSTRUCTIONAL STAFF** with the following titles: (1) Lecturer; (2) Associate; (3) Assistant; and (4) Teacher.
2. **PROFESSIONAL STAFF** with the following title: Health Center Physician.
3. **RESEARCH STAFF** with the following titles: (1) Research Associate; (2) Senior Scholar; (3) Associate Scholar; (4) Assistant Scholar; and (5) Post Doctoral Fellow.
4. **STUDENT ACADEMIC APPOINTMENTS** with the following titles: (1) Associate Instructor; (2) Faculty Assistant; (3) Graduate Assistant; (4) Student Counselor; (5) Academic Intern; and (6) Research Assistant.

\* Individuals in schools other than the Schools of Medicine, Nursing, and Dentistry, desiring to serve as principal investigators or faculty sponsors, must either meet the eligibility requirements as outlined above or must receive special dispensation from their School's Chair.

**Principal Investigator Eligibility at Clarian/Methodist.** Physicians must be a member of the Clarian medical staff ("Active" status, "Associate" status, or "Provisional" status), as verified by the Medical Staff Office. Non-physician eligibility requests, (examples: physical therapists, pharmacists, nurses, other Clarian staff), are approved on a case-by-case basis. In these cases, a letter of approval is required from the department head or upline official.

**Other eligibility considerations (not included above) are as follows:**

- a. Student projects must be submitted to the IRB by an eligible principal investigator or faculty sponsor.
- b. Any principal investigator in the department of medicine who is submitting to the IRB for the first time must identify a mentor within their department and submit a letter from that individual demonstrating their support.
- c. The eligibility of emeritus faculty and faculty on sabbatical will be considered on a case-by-case basis. Among the factors to be considered are location and nature of the research, relation of research to the faculty member's regular University assignment, etc.
- d. Adjunct faculty (not compensated) are eligible when the research is a function of the adjunct relationship and for which the school assumes responsibility.
- e. Other special status appointments, e.g., non-paid visiting and non-paid clinical appointees, alone are not necessarily considered eligible.
- f. When an IU employee is doing research on behalf of another organization, e.g., in a consultant relationship with compensation provided by the other institution or in a student status at another institution (i.e., not IU), the responsibility for the review is with the other organization/institution.

INDIANA UNIVERSITY  
 PROTOCOL REVIEW PROCEDURES  
 for  
 HUMAN SUBJECTS

<u>Campus or Unit</u>	<u>Proposal Transmittal</u>	<u>Initial Protocol Review</u>	<u>Certification of Status</u>		<u>Continuing Reviews, Amendments, and All Similar Documentation</u>
			<u>At Proposal Submission (Pending/Approved)</u>	<u>Follow-up, Approvals and Renewals</u>	
All IUB* <sup>9</sup>	IUB	IUB	IUB	IUB	IUB
Medical Sciences/IUB	IUPUI	IUPUI	IUPUI	IUPUI	IUPUI
All IUPUI	IUPUI	IUPUI	IUPUI	IUPUI	IUPUI
Regional Centers for Medical Education** <sup>10</sup>	IUPUI	IUPUI	IUPUI	IUPUI	IUPUI
Columbus Center	IUPUI	IUPUI	IUPUI	IUPUI	IUPUI
Purdue University Pharmacy at IUPUI	Purdue	IUPUI	Purdue	Purdue	IUPUI
Regional Campuses	IUB	Regional Campuses	IUB	Regional Campuses	Regional Campuses
Central System	IUB	IUB	IUB	IUB	IUB

NOTE: This chart applies to all research or training protocols involving human subjects, for funded or non-funded projects. Active committees are found only on campuses where needs exist.

Regardless of the campus or unit, any research to be conducted in a Clarian facility must be reviewed by an IUPUI IRB.

PROTOCOLS INVOLVING HUMAN SUBJECTS WILL BE REVIEWED ON A CAMPUS SPECIFIC BASIS WITH THE EXCEPTION OF THE SCHOOL OF MEDICINE. All School of Medicine protocols, including the Regional Centers for Medical Education, will be reviewed by the IUPUI/Clarian IRBs. Campus specific is defined as the campus where the faculty applicant is located. Other variables may require that a decision to modify a normal procedure be made by the campus research administration offices representing the campuses involved.

<sup>9</sup> Except for Medical Sciences.

<sup>10</sup> Lafayette and Muncie Centers are not processed through IU.