November 14, 2007

Dear Researchers,

We would like to personally welcome you to the Office of Human Research Protection. Our goals are to balance the protection of human subjects with the need to move research forward, and to promote and maintain an open and cooperative relationship with the research community. With that being said, we are here to assist you in your human research endeavors.

We are pleased to have incorporated the CITI Training course into our educational program. CITI provides a wealth of information regarding human subject protections. If you have not yet completed CITI, please note that all researchers are required to do so prior to IRB approval of your research studies. See the CITI linked below for further details.

In addition to the online course, we also publish a newsletter on a quarterly basis. Please feel free to submit any contributions to the newsletter. Please check the website regularly as we will be posting information regarding national conferences such as Public Responsibility in Medicine Research (PRIM&R).

Often, the IRB submission process can be confusing and tedious however, our goal is to provide researchers with a clear picture of the IRB submission process. We have created a number of tools including checklists and flowcharts to help you navigate through our processes. Additionally, we have revised our policies and procedures to provide a clearer framework for the office.

Any feedback would be greatly appreciated as we strive to make improvements to our office.

We look forward to working with you!

Sincerely,

The IRB Team
Welcome to Tulane University's Biomedical IRB Workshop
November 15, 2007

Goals of the Workshop

To introduce and explain new office procedures.

To assist you in gaining more knowledge concerning the IRB.

To discuss issues and challenges faced in the IRB submission process.

Mission of the IRB Office

To balance the protection of human subjects with the need to move research forward.

To promote and maintain an open and cooperative relationship with the research community.
Regulatory Framework

- The Department of Health and Human Services and the Food and Drug Administration govern human research in the United States.
- DHIRM regulations apply to all human research projects (45 CFR Part 46).
- FDA regulations apply only to drug and device trials (21 CFR Parts 50 and 50a).
- International research conducted by investigators who are based in the US must comply with both the US and the human subjects regulations of the research site.

Compliance Requirements

- The federal regulations apply to human research activities regardless of funding source.
- The IRB must review the planned research and issue a final approval prior to initiation of any human research project by Tulane personnel.
- Researchers are required to comply with all directives of the IRB regarding human subjects research.

Results of Non Compliance

Corrective actions may be imposed by either the IRB or the federal oversight agencies for non-compliance with IRB requirements:
- Data collected may be barred from use.
- Research protocols may be suspended or permanently closed.
- An investigator may be prohibited from conducting research.
- The federal government may revoke the IRB's approval to operate.
IRB Educational Requirement

- CITI Training (Course in the Protection of Human Research Subjects).
- The IRB requires that all research personnel complete the CITI training.
- A research protocol cannot be approved if the research personnel have not completed CITI.
- CITI training has to be refreshed every three years.
- The course and any additional educational information is available on the IRB website under the Education link.

What is Biomedical Research

- Research that is conducted to contribute to an increased understanding of disease processes, new treatments and interventions, and the prevention and control of infectious and chronic diseases in clinical medicine and public health.
- Research involving human biological specimens (i.e. collecting or accessing tissues or genetic material for research purposes).

Overview of Research

- Exempt: These protocols must satisfy the regulatory requirements set forth in 45 CFR 46.101(b) or 21 CFR 50.10(c).
- Expedited: Research which adheres to the criteria set forth in 45 CFR 46.110 and 21 CFR 50.110 may be reviewed outside of a full board meeting.
- Full Board: Refer to the IRB Submission Checklist for the number of copies to submit for the full board to review.
IRB Communication and New Office Processes

- Email is our primary form of communication.
- Do not submit studies to Dr. James or Roxanne Johnson.
- Submit studies directly to the IRB Office either in person, via campus mail or through irbmaint@tulane.edu.
- Items hand delivered to our office are date stamped by PI/coordinator themselves and put into the incoming box at the front desk.

Submission Tools and Checklists

- IRB office has created a number of flow charts and checklists to assist with the submission process. Please refer to the checklist page on the website.
- Always refer to the IRB submission checklist, which gives detailed instructions and requirements for each type of submission, this will ensure that your submission is complete.

Initial Submission Process

Submission Requirements:

- A Detailed Cover Letter (required for ALL IRB submissions)
- The Biomedical Initial Submission Project Summary
- Your Research Protocol or Plan
- Consent/Assent Forms
- Any Other Forms
- Any Written Surveys/Questionnaires/Advertisements (If applicable)
- Grant Form (If applicable)
Your Cover Letter Should Include:

- The title of your study
- Your study number (if applicable)
- The type of submission (initial submission, continuing review, etc.)
- The nature of the submission and any special requests
- A list of all enclosures (Usually a bulleted list)
- All contact information for the PI AND Study Coordinator, if applicable

There is a sample cover letter for your reference on our website.

The Biomedical Initial Submission Project Summary Packet

- This 7 page packet is located on our website under the Primary Forms link.
- You are allowed to click and add the information specific to your study.
- There are helpful tips and information to guide you in filling out the form.
- Fill out the form completely. Do not state "see attached".

Must Include any Special Forms
Also found on our website under Secondary Forms

Form A: Faculty Sponsor
Form B: Research Involving Pregnant Women or Fetuses
Form C: Research Involving Prisoners
Form D: Research Involving Minors
Form E: Biological Specimen Banking
Form F: Request for Waiver or Alteration to Consent and Authorization Requirements
Form G: Research Involving Subjects Who Do Not Speak English
Form H: Research Involving Deception
Form I: Research Involving Medical Devices
Form J: Research Involving the Use of a Drug
Form K: Research Involving Cognitively Impaired Subjects
Grant and Contract Routing Form

- This form is ONLY required if the research is funded by a federal agency or pharmaceutical company.
- Contact the Office of Research Administration for more information regarding funded research.
  www.som.tulane.edu/researchadmin

Interdepartmental Form

- Interdepartmental Forms must be submitted with Initial Submissions and Continuing Reviews for Industry/Pharmaceutical sponsored studies.
- Initial submission fee is $1500
  Continuing review fee is $750

Consent Forms and Assent Forms

- Use our Template online under Secondary Forms; the template is detailed and explains the process well.
- Must have the Tulane Header and be dated at the bottom of each page.
- If working with children, you must either complete the Assent Form (template available on website) or add an additional signature line to the consent form (for participants ages 12+).
Questionnaires/Surveys

You also must include in your submission any surveys, questionnaires, and/or advertisements that you plan to utilize in your research.

Incomplete Submissions

- The IRE Office will not enter any incomplete submissions into the database.
- If incomplete, coordinator/PI is notified via email of missing items.
- The notification email contains a deadline for receipt of items, which is generally within five business days of notification.
- Submit the missing items along with the email notification.
- Items not received by the deadline are sent back to the investigator via campus mail.

Incomplete Submissions

Main Reasons Why Submissions are Incomplete
- Unclear or missing cover letter
- Consent/assent forms are not updated
- Supplemental forms not included
- Missing surveys/interviews/sample questions
- Translation certification not included
- Protocol not included
- Grants & Contract Routing Form not included (if applicable)
- Interdepartmental Form not included (if applicable)
**Submission Deadlines**

- Submit studies in a timely manner.
- A preliminary review is completed within 72 hours of receipt of submission.
- Submitting your study at least a week before the deadline will allow us enough time to assist you with completing your application if it is determined to be incomplete.

**Submission Deadlines (continued)**

- Your study will not make the meeting if your submission is determined to be incomplete at the deadline.
- Submissions are due at 12 noon on the deadline dates. **NO EXCEPTIONS!!**
- Your submission date is given once the submission is determined to be complete.

**Biomedical Committee Meeting Dates**

<table>
<thead>
<tr>
<th>Submission Deadline Date</th>
<th>Biomedical Committee Meeting Date</th>
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<tbody>
<tr>
<td>January 7, 2008</td>
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Preliminary, Provisional and Tabled Responses

- Meeting Actions: Initial submissions will receive action letters within 10 days after a meeting.
- Responses must be received by IRB office within three months of date of letter. Otherwise, protocol is administratively closed.
- All responses MUST adequately address each issue raised by the Committee or Chair.

Approvals with Multiple IRBs

What you need to submit:

1. Detailed cover letter explaining what you are requesting and listing what you are submitting.
2. The other institution's approval letter for your research.
3. All documents that were submitted to and approved by the other institution.
4. Initial submission form
5. Protocol

Adverse Events

DEFINITION
- Any untoward or unfavorable occurrence (either physical or psychological) that happens to a research participant during or after s/he has received research interventions.
- Only some must be reported to the IRB
Unanticipated Problems

**DEFINITION**
- Any research-related occurrence that was not foreseen prior to the start of the research project
  - All must be reported to the IRB

AE and UP Reporting

Unanticipated Problems

A. Adverse Event
B. Unplanned Problem
C. Problems Partly Due to Research

Under 45 CFR part 46: Do not report A; Report B and C.

Adverse Event Reporting

- Only adverse events that meet the following criteria need to be reported to the IRB on an ongoing basis:
  - It is unexpected, AND
  - It is related or possibly related to participation in the research, AND
  - It suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

Adverse events that do not meet the above criteria should be summarized and reported at continuing review time.
Adverse Event Reporting (cont.)

Tulane University

An adverse event is "unexpected" if:
- It was not foreseeable prior to beginning the research
  - Not listed in the protocol-related documents as a
    risk; or
  - Occurs at a greater frequency or severity than
    previously anticipated
  AND
- It is not the result of any underlying disease, disorder or
  condition.

Adverse Event Reporting (cont.)

Tulane University

- An adverse event is "possibly related" to the research
  if there is a reasonable possibility that the adverse
  event may have been caused by the procedures
  involved in the research.
  - The research team is in the best position to make this
    determination.

AE and UP Reporting (cont.)

Tulane University

- All reportable adverse events must be submitted to
  the IRB using the appropriate reporting form.
- Report unanticipated problems in a detailed letter to
  the IRB. This letter should include:
  - A description of the problem;
  - How it occurred;
  - The number of participants actually and potentially
    affected; and,
  - An explanation of the steps you have taken to
    remediate or mitigate the problem.
AE and UP Reporting (cont.)

Events that do not meet the criteria for ongoing reporting will be sent back to the investigator with a letter explaining our review criteria.
- If your sponsor requires you to submit an event that does not meet our criteria, explain this in a detailed cover letter and use the IRB letter as evidence of compliance with their directive.
- If you, as the PI, feel the need to report an event that does not meet the criteria due to your own concerns, report promptly and explain this in a detailed cover letter.

AE and UP Reporting (cont.)

REPORTING TIMEFRAMES:
- Reportable adverse events and unanticipated problems that are serious should be reported to the IRB within 1 week of the first awareness of the PI.
- Deaths that are related to the study should be reported within 24 hours.
- All other reportable adverse events or unanticipated problems should be reported within 2 weeks of knowledge that the situation occurred.

International Research

- Special attention should be given to local customs and to local cultural and religious norms in drafting written consent documents AND when requesting a waiver of consent using FORM F.
- If the research involves Non-English speakers, you must submit FORM G.
International Research (continued)

- International protocols must be approved by the local equivalent of an IRB.
- When no equivalent board or group exists, investigators must rely on local experts or community leaders to provide approval of research.
- Evidence of the "local approval" must be submitted prior to final approval by the Tulane IRB.

Translation Certification

- We must receive a signed letter stating that all items translated (consents, questionnaires, surveys, etc.) are correct.
- Certifications cannot be signed by the PI or anyone that is involved with the study.

Retrospective Chart Reviews

What you need to submit:
1. Detailed cover letter explaining what you are submitting and what you are requesting.
2. Initial Submission Form
3. Form R, Waiver of HIPAA Authorization and Consent
4. Protocol
Previously Closed Studies

Submit all previously closed studies as initial submissions.

What you need to submit:

1. Detailed cover letter including study number, what you are requesting, what you are submitting, why your study was closed and why you wish to re-open your study.
2. Updated consents (if applicable)
3. Any updated materials such as surveys/questionnaires/advertisements
4. Initial Submission form
5. Updated protocol

Continuing Review

- Unless your research is EXEMPT, you MUST complete a continuing review application annually.

- We send out 60 and 30 day notices to remind you that your study is nearing an expiration.

Continuing Review (continued)

What to Submit:

- A detailed cover letter including study number, what you are requesting, and listing what you are submitting.
- Updated consents (if open to enrollment)
  *Note: Please do not send in a copy of your last approved consent form with our approval stamp. Submit a new consent form with a new version date in the footer.
- Any updated materials
- Continuing Review application
  *Note: Please completely fill out all 3 pages of the continuing review application.
- Updated protocol (if applicable)
Continuing Review (continued)

No Progress Reports
- Closure of Study – If a protocol has not been approved prior to the expiration date, it is administratively closed by the IRB.
- Expired Protocols – Once a protocol approval expires, no further research can be conducted or data collected. Any research occurring after protocol expiration represents a compliance concern.

What's new

- Website has recently been revamped for your convenience.
- Completed the preliminary application process for the AAHRPP accreditation.
- Preparing to move forward with an electronic protocol management system in coordination with ORA.

IRB Contact Information:

Tulane University
Office of Human Research Protection
Health Sciences Institutional Review Board
Tidewater Building, Suite 1705, TW-36
1440 Canal St.
New Orleans, LA 70112
Phone: 988-2665 Fax: 988-4766
Email: irbmain@tulane.edu
IRB STAFF

Roxanne Johnson, Director
Email: djohnson@tulane.edu

Amanda Mills, Senior Program Coordinator
Email: amills@tulane.edu

Tanisha Banks, Biomedical Program Coordinator
Email: tbanks@tulane.edu

Carla Siclione, Social/Behavioral Program Coordinator
Email: casciolone@tulane.edu

Terral Lewis, Records Coordinator
Email: tlewis@tulane.edu

We hope the presentation was informative!

Please feel free to ask questions at this time.
Roxanne
<table>
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<tr>
<th>IRB Review Timeline</th>
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<td>* Risk refers to risk to human subjects as defined by 45 CFR 46</td>
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<th>Full Board</th>
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<td>Greater than Minimal Risk</td>
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<tr>
<th>Expedited</th>
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<tr>
<td>Minimal Risk</td>
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<td>and fits into one of the OHRP categories</td>
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<tr>
<td>Submission Deadline Dates</td>
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IRB Submission Checklist

Principal Investigator

Study Title

Please use this checklist to verify that your submission is complete.

Answer the following questions before submitting ANY documentation to the IRB office:

1. Have you included a detailed cover letter, explaining the submission and stating each item being submitted? □ YES □ NO
2. If not exempt, have you used the Tulane template for your consent form with the appropriate header and version date? □ YES □ NO
3. Does your research require the use of supplemental forms (A - L)? If so, have you included them with your submission? □ YES □ NO
4. Does your research include Non-English speakers? If so, have you translated the consent form, surveys, and questionnaires, if applicable? Have you included a letter certifying the translations? □ YES □ NO
5. Have you checked the spelling, grammar and consistency of your submission? □ YES □ NO
6. Have all research personnel involved with the protocol completed the CITI training? □ YES □ NO

If you have answered YES to all of the above questions, if applicable, please proceed to the checklist below:

New Submissions

<table>
<thead>
<tr>
<th>Exempt Protocols:</th>
<th>YES</th>
<th>N/A</th>
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<tbody>
<tr>
<td>(1) Exemption Request Form</td>
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<tr>
<td>(1) Copy of the Protocol</td>
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<tr>
<td>(1) Copy of the Information Sheet (in lieu of the consent form)</td>
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<tr>
<td>(1) Copy of any Questionnaires and/or Surveys</td>
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<td>□</td>
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<tr>
<td>(1) Copy of any Proposed Advertisement/Recruitment Materials</td>
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<tr>
<th>Expedited Protocols and All Social/Behavioral Protocols:</th>
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<tbody>
<tr>
<td>(1) Initial Submission Form (Project Summary)</td>
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<tr>
<td>(1) Copy of the Protocol</td>
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<td>□</td>
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<tr>
<td>(1) Copy of the Consent, Assent and HIPAA Authorization Forms</td>
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<tr>
<td>(1) Copy of any Questionnaires and/or Surveys</td>
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<tr>
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<td>(1) Copy of the Proposal Routing Form</td>
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<tr>
<td>(1) Interdepartmental Transfer Form for fee payment (industry-sponsored studies only)</td>
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<tr>
<th>Biomedical Full Board Protocols:</th>
<th>YES</th>
<th>N/A</th>
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<tr>
<td>(10) Copies of the Initial Submission Form (Project Summary)</td>
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<tr>
<td>(2) Copies of the Protocol</td>
<td>□</td>
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</table>
**Full Board Protocols:**

| (10) Copies of the Consent, Assent and HIPAA Authorization Forms | YES | N/A |
| (2) Copies of any Questionnaires and/or Surveys | ❌ | ❌ |
| (2) Copies of any Proposed Advertisement/Recruitment Materials | ❌ | ❌ |
| (1) Copy of the Investigator's Brochure or Package Insert | ❌ | ❌ |
| (1) Copy of the Wallet ID Card (if required in the consent) | ❌ | ❌ |
| (1) Copy of the Evacuation Contact Card | ❌ | ❌ |
| (1) Copy of the Signed Clinical Trial Agreement* | ❌ | ❌ |

*Please contact the Office of Research Administration (504-988-5613) if you are conducting a clinical trial and the agreement has not been finalized.

Tulane Institutional policy requires IRB and ORA approval prior to commencing research.

(1) Copy of the Grant and Contract Routing Form | ❌ | ❌ |

(1) Interdepartmental Transfer Form for fee payment (industry-sponsored studies only) | ❌ | ❌ |

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**Continuing Reviews:**

| (1) Continuing Review Form | YES | N/A |
| (1) Copy of the updated Project Summary | YES | N/A |
| (1) Copy of the Current Consent and Assent Forms (if open to accrual) | YES | N/A |
| (1) Copy of the DSMB Report | YES | N/A |
| (1) Copy of any new or updated materials | YES | N/A |
| (1) Interdepartmental Transfer Form for fee payment (industry-sponsored studies only) | YES | N/A |

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**Amendments/Revisions:**

| (1) Amendment Request Form | YES | N/A |
| (1) Copy of the Amendment/Revision | YES | N/A |
| (1) Updated Protocol | YES | N/A |
| (1) Copy of the updated Consent and Assent Forms (if open to accrual) | YES | N/A |
| (1) Copy of any new or updated materials | YES | N/A |

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**Local Adverse Events:**

| (1) Adverse Event Reporting Form (one event per form) | YES | N/A |
| (1) Copy of any new or updated materials | YES | N/A |

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**Non-Local Adverse Events:**

| (1) Offsite Adverse Event Reporting Form (multiple events may be submitted on one form) | YES | N/A |
| (1) Copy of any new or updated materials | YES | N/A |
Checklist for exempt review procedure
(authorized by 45 CFR 46.101 (b) (1) - (6) )

Name of PI: ___________________________ Date ___________________________

Title of Study: ___________________________________________________________

Note to investigator
If you wish to have your protocol considered for exempt review, please complete the following form. This will help you decide if the research qualifies for this type of review. Categories for Exempt Review are determined by the OHRP and Institutions and IRBs may not create new categories of exempt research under 45 CFR 46. If during the self-review process, you find that the research does not fit into one of the six exemption categories, please submit your research for expedited or full board review.

If you feel your research still qualifies for exempt review, please send this form with the completed application form and protocol summary to the IRB for exempt review.

Please note, it is not guaranteed that your protocol will be processed via the exempt review process. The IRB makes the final determination regarding the appropriate review category.

Every protocol involving human subjects must be seen by the IRB. The researcher cannot determine that the research is exempt from IRB review. Doing so is a violation of Tulane University OHRP Policies and Procedures.

Categories of research that qualify for Exemption:
* Only procedures listed in one or more of the following activities may qualify. Inclusion on this list merely means that the activity is eligible for exemption. The final determination is made by the IRB.
** Research involving prisoners or identifiable health information does NOT qualify for exemption

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>YES</th>
<th>NO</th>
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<tbody>
<tr>
<td>(1) Research conducted in established or commonly accepted educational settings involving normal educational practices, such as, (i) research on regular and special education instructional strategies or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods</td>
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<tr>
<td>(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation</td>
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<tr>
<td>CATEGORY</td>
<td>YES</td>
<td>Irrelevant</td>
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<tr>
<td>(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2 if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter.</td>
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<td>(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects</td>
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<tr>
<td>(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs (ii) procedures for obtaining benefits or services under these programs (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs</td>
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<tr>
<td>(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Name of IRB Reviewer

__________________________

Signature of IRB Reviewer

__________________________

Date

__________________________
Checklist for expedited review procedure  
(authorized by 45 CFR 46.110 and 21 CFR 56.110)

Name of PI: ____________________________ Date: ____________________

Title of Study: ____________________________

Note to investigator

If you wish to have your protocol considered for expedited review please complete the following form. This will help you decide if the research qualifies for this type of review. Expedited review is the most common reason for FDA citations and any research that is questionable as to its eligibility for expedited review will be sent to full board. If, during the self-review process, you have any doubt about the research complying with the expedited regulations please do not use this process but submit your protocol to the full Board.

If you feel your research still qualifies for expedited review please send this form with the detailed cover letter, completed application form, protocol and informed consent (if required) to the IRB for expedited review.  

Please note, it is not guaranteed that your protocol will go via the expedited review process.

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson, or by one or more experienced reviewers designated by the chairperson from among members of the IRB, in accordance with the requirements set forth in 45 CFR 46.110.

<table>
<thead>
<tr>
<th>CRITERION</th>
<th>COMMENT</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do the research activities present no more than minimal risk to human subjects? (Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations and tests.)</td>
<td>This item must be answered YES to qualify for expedited review.</td>
<td>⬜️</td>
<td>⬜️</td>
</tr>
<tr>
<td>Will identification of the subjects and/or their responses reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation or be stigmatizing, (unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal)?</td>
<td>This item must be answered NO to qualify for expedited review.</td>
<td>⬜️</td>
<td>⬜️</td>
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<tr>
<td>Is this classified research involving human subjects? (Classified means withheld from general circulation for reasons of national security)</td>
<td>This item must be answered NO to qualify for expedited review.</td>
<td>⬜️</td>
<td>⬜️</td>
</tr>
</tbody>
</table>

Categories of research that may be reviewed by the IRB through an Expedited Review Procedure:

Only procedures listed in one or more of the following categories qualify.
The activities listed should not be deemed to be of minimal risk simply because they are included on this list.
Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)(a) Research on drugs for which an investigational new drug application 21CFR Part 312 is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is no eligible for expedited review)</td>
<td></td>
</tr>
<tr>
<td>(1)(b) Research on medical devices for which</td>
<td></td>
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<tr>
<td>(i) an investigational device exemption application (21CFR Part 812) is not required; or</td>
<td></td>
</tr>
<tr>
<td>(ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labelling</td>
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<tr>
<td>(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:</td>
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</tr>
<tr>
<td>(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week; or</td>
<td></td>
</tr>
<tr>
<td>(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50ml or 3ml/kg in an 8 weeks period and collection may not occur more frequently than 2 times per week</td>
<td></td>
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<tr>
<td>(3) Prospective collection of biological specimens for research purposes by non-invasive means. Examples:</td>
<td></td>
</tr>
<tr>
<td>(a) hair and nail clippings in a non disfiguring manner;</td>
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<tr>
<td>(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;</td>
<td></td>
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<tr>
<td>(c) permanent teeth if routine patient care indicates a need for extraction;</td>
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<tr>
<td>(d) excreta and external secretions (including sweat);</td>
<td></td>
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<tr>
<td>(e) unaccumulated saliva collected in an un-stimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;</td>
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<tr>
<td>(f) placenta removed at delivery;</td>
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<tr>
<td>(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;</td>
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<tr>
<td>(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;</td>
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<tr>
<td>(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;</td>
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<tr>
<td>(j) sputum collected after saline mist nebulization.</td>
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<tr>
<td>(4) Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:</td>
<td></td>
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<tr>
<td>(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy;</td>
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<tr>
<td>(b) weighing or testing sensory acuity;</td>
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<td>(c) magnetic resonance imaging;</td>
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<tr>
<td>(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography,</td>
<td></td>
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<tr>
<td>CATEGORY</td>
<td>YES</td>
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<tr>
<td>------------------------------------------------------------------------</td>
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<tr>
<td>ultrasound, diagnostic imaging, doppler blood flow and echocardiography;</td>
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<tr>
<td>(c) moderate exercise, muscular strength testing, body composition</td>
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<tr>
<td>assessment and flexibility testing where appropriate given the age,</td>
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<tr>
<td>weight and health of the individual.</td>
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<tr>
<td>(5) Research involving materials (data, documents, records or specimens)</td>
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<tr>
<td>that have been collected, or will be collected solely for non-research</td>
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<tr>
<td>purposes (such as medical treatment or diagnosis). (Note: some research</td>
<td></td>
</tr>
<tr>
<td>in this category may be exempt from the HHS regulations for the</td>
<td></td>
</tr>
<tr>
<td>protection of human subjects. 45 CFR 46.101(b)(4). This listing refers</td>
<td></td>
</tr>
<tr>
<td>to research that is not exempt.)</td>
<td></td>
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<tr>
<td>(6) Collection of data from voice, video, digital or image recordings</td>
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<tr>
<td>made for research purposes.</td>
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<tr>
<td>(7) Research on individual or group characteristics or behavior</td>
<td></td>
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<tr>
<td>(including, but not limited to, research on perception, cognition,</td>
<td></td>
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<tr>
<td>motivation, identity, language, communication, cultural beliefs or</td>
<td></td>
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<tr>
<td>practices and social behavior) or research employing survey,</td>
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<tr>
<td>interview, oral history, focus group, program evaluation, human factors</td>
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<tr>
<td>evaluation, or quality assurance methodologies. (Note: some research</td>
<td></td>
</tr>
<tr>
<td>in this category may be exempt from the HHS regulations for the</td>
<td></td>
</tr>
<tr>
<td>protection of human subjects. 45 CFR 46.101(b)(2) and</td>
<td></td>
</tr>
<tr>
<td>(b)(3). This listing refers to research that is not exempt.)</td>
<td></td>
</tr>
</tbody>
</table>

Name of IRB reviewer: __________________________________________

Signature of IRB reviewer: ___________________________ Date: __________
SAMPLE COVER LETTER

Date

Committee on Use of Human Subjects
1440 Canal Street, Ste. 1705
TW-36
New Orleans, LA 70112

Re: “Study to Determine How People Drive in Heavy Traffic” (IRB # 00-00000)

Enclosed please find a request to open a new study. We are requesting an expedited
review of the protocol. The study will be based on an interview to be administered over
the phone; we are therefore requesting a waiver of signed informed consent. Enclosed are
the following documents:

1. One copy of the Initial Submission packet, with Form F.
2. One copy of the protocol.
3. One copy of the script for verbal consent.
4. One copy of the questionnaire.

Please do not hesitate to contact me at 000-0000 or by e-mail at drive@car.edu if you
need any thing further. My mailing address is IC-00.

Sincerely,

I.C. Drive, PhD
Tulane University Health Sciences Center
Grant and Contract Routing Form

(1) Date Submitted to Grants & Contracts: ____________________________
(2) Proposal Number: (G&C Use) ____________________________
(3) Agency Deadline (Arrival): ____________________________
(4) Call for Pick-Up: ____________________________
(5) Principal Investigator: ____________________________
(6) Department: ____________________________
(7) School: ____________________________
(8) Office Telephone: ____________________________

(9) Second Contact Person: ____________________________
(10) Department: ____________________________
(11) School: ____________________________
(12) Office Telephone: ____________________________

(13) Project Title: ____________________________________________________________________________

(14) Sponsoring Agency: ____________________________

(15) Program Name: ____________________________

(16) Type of Agency (check one): [ ] Federal [ ] State [ ] Corporate [ ] Foundation [ ] Association [ ] Other

(17) Check One: [ ] Grant [ ] Contract

(what is the RFA#?) ____________________________________________________________________________

(what is the RFP#?) ____________________________________________________________________________

(18) Check All That Apply: [ ] Research [ ] Drug Study [ ] Multi-Purpose [ ] Training [ ] Clinical Trial

(19) Check One: [ ] New Application [ ] Continuation [ ] Competing Renewal [ ] Supplement [ ] Resubmission

BUDGET INFORMATION

(20) Direct Costs Requested: ____________________________
(All Years)

(21) Indirect Costs: ____________________________
(All Years)

(22) Total Costs: ____________________________

(23) Project Period: ____________________________

(24) Direct Costs Requested for Budget Period: ____________________________

(25) Indirect Costs for Budget Period: ____________________________

(26) Budget Period: ____________________________

(27) Percent Effort, F.L.: ____________________________

(28) Indirect Cost Rate: ____________________________

(29) Cost Share Commitment [ ] NO [ ] YES AMOUNT: ____________________________

PROJECT INFORMATION

Does this project involve: [ ] Human Subjects? ___ [ ] YES ___ [ ] NO

(31) Animals ___

(32) Recombinant DNA? ___

(33) Cancer Research? ___

(34) Increased need for space/utilities? ___

(35) Key Word/Subject Area: [ ] Cancer [ ] Infectious Disease [ ] AIDS [ ] International [ ] Environmental

[ ] Women's Health [ ] Gene Therapy [ ] Community [ ] Cardiovascular [ ] Prevention

[ ] Infants & Children [ ] Other, describe ____________________________

(36) PRINCIPAL INVESTIGATOR CERTIFICATION

My signature below certifies that 1) I am not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from current transactions by any federal department or agency; 2) I have received, read, understand and will abide by the University's policy on Conflict of Interest; and 3) I agree to be bound by the terms and conditions of the outside sponsored award agreement which supports this activity and by Tulane policies.

[ ] Yes [ ] No To the best of your knowledge, do any faculty or you as the person responsible for the design, conduct and reporting of this project (or your spouse or dependent children) have any financial interest such as royalty, equity, or any other payments (e.g. consulting, salary, etc.) in the sponsor or in other entities having a financial interest in intellectual property, products or services which are the subject of the proposed research that exceed $10,000 in current value or exceed a 5% ownership interest? If yes, please attach explanation.

(37) Principal Investigator: ____________________________ Date: ____________________________

APPROVALS

(38) Department Chairperson(s): ____________________________ Date: ____________________________

(39) Department Chairperson(s): ____________________________ Date: ____________________________

(40) Office of Grants & Contracts Admin: ____________________________ Date: ____________________________

(41) Office of the Dean: ____________________________ Date: ____________________________

Please return two (2) copies of this proposal with the original routing form to the Office of Grants and Contracts.

* [ ] Check here if you want Grants & Contracts to forward human subjects or animal care protocols to those committees. If checked, provide extra copies of the proposal and requisite forms as required.

Revised 10/30/95
FREQUENTLY ASKED QUESTIONS

1. What qualifies as human subjects' research (and thus requires IRB approval)?
Any systematic investigation, involving living human beings, that is designed to develop or contribute generalizable knowledge. Any data obtained by the investigator though intervention or interaction with subjects or which collects identifiable private information, qualifies as human subjects research.

2. When is my submission going to be processed?
The length of time that it takes to review an IRB submission depends significantly on the quality of the application, when it is received by the IRB, and the type of review that it requires. Submissions that are incomplete will not be processed until all documents have been submitted to the IRB. Exempt reviews normally take 1-2 weeks from the date the application is determined to be complete. Expedited reviews usually take 3-4 weeks and full board reviews normally take 4-8 weeks from the date the application is determined to be complete, depending upon the extent of the revisions required by the reviewer(s).

Keep in mind that incomplete submissions (as well as inadequate number of copies) will delay the amount of time it takes to process and review the application. Please deliver your submission in a timely manner. We cannot allow exceptions once the submission deadline has passed.

3. The submission instructions posted on the website suggest that I qualify for Expedited Review. Does this mean that my proposal will be reviewed and approved more quickly?
No. If in fact your proposal is determined to be expeditable, this does not mean that your submission will be processed more quickly. It merely means that you proposal is required to be reviewed by only one or two reviewers instead of the entire committee; research is generally of minimal risk for study participants.

4. How will I know that I have approval to conduct my research?
If the study being proposed complies with federal regulations and Tulane policies regarding the rights and welfare of human subjects, the IRB Chair sends an approval letter to the principal investigator and the study coordinator. E-mail notification is sent as well.

5. When can I begin my research?
No research activities may be initiated prior to notification from the IRB Chair to the
principal investigator that the study has been either exempted or approved. No Tulane entity is authorized to grant approval for human subjects research other than the IRB.

6. What would be the consequences if I were to forget to submit my application for continuing review?
As a courtesy to investigators, the IRB sends study renewal reminders two months and one month prior to the expiration of the study. It is the responsibility of the principal investigator to ensure that the continuing review submission is delivered to the IRB office in time to be reviewed at the meeting prior to the study's expiration. We ask that you not submit continuing review applications more than 60 days prior to the expiration date, but do please submit them at least 30 days before the expiration date. Studies which expire are allowed no further activity; such activity would be in violation of Tulane policy and federal regulations. The IRB will administratively close expired studies and send the principal investigator a closure letter. If a renewal request is received within 30 days of study closure, the request will be processed as continuing review. After 30 days following expiration, the investigator is required to submit a detailed cover letter with the rationale for re-opening the study, together with any necessary documentation.

7. Do HIPAA regulations apply to data sets containing protected health information (PHI)?
Yes. Protected health information is any information that relates to the past, present or future physical or mental health or condition of an individual. HIPAA regulations require researchers to have valid authorization for all uses and disclosures of research-related PHI. A valid authorization must include specific elements:

- A description of the PHI being used.

- A statement of the purpose of the use of PHI.

- A list of those who can use the PHI.

- A list of those who can receive the PHI, including the possibility of re-disclosure.

- A statement that once PHI is disclosed by the recipient it may no longer be protected by the privacy rule.

- Information about the expiration of the authorization.

- Information about the right to revoke the authorization.

- Individual identifiable health information consists of:

  • Names
- Social security numbers
- Geographic information including street address, city, county, precinct, zip code, and their equivalent geocodes.
- Voice and fax telephone numbers
- Web universal resources locators (URL) and Internet Protocol (IP) address numbers e-mail addresses
- Health plan beneficiary numbers, medical record numbers, or other health plan account numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Biometrics identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- All elements of dates (excluding year) including birth date; admission date, discharge date, date of death

Information is considered de-identified if all of the above identifiers have been removed, and there is no reasonable basis for belief that the remaining information could be used to identify a particular person.

8. Can the HIPAA form be changed so the study subjects can better understand it?  
No. The IRB will not review your authorization form unless it appears in the Tulane authorization template, with Tulane boiler-plate language (this is not applicable to studies conducted at the Veterans Affairs Hospital).

9. I will be conducting interviews which I will audio tape and later transcribe. Does my study qualify for Exemption from IRB Review?  
No. Audio and video recordings are not allowed in exempt studies. Your study may qualify for expedited review if it meets the criteria outlined in the expedited review guidelines.

10. I have transferred to Tulane from another institution at which I had an open study involving human subjects research. What would I need to do to transfer the study to Tulane?  
You must submit for review all of the paperwork from your original submission, along with documentation of the original approval from your former institution. We will review it as a new study. Normally, such studies would be in the follow-up or data analysis stage; studies
specific to a population at another institution would more likely be transferred to a principal investigator at that institution.

11. I am new to human subjects research; your website talks about CITI training. What does that involve, and what are your requirements for continuing education? CITI stands for the Collaborative IRB Training Initiative, a web-based training package maintained by the University of Miami. We require CITI to be used for our mandatory training. Tulane University pays an annual fee to give our research community access to the various modules. Anyone engaged in human subjects research must complete the module specific to their discipline. The CITI training module expires two years after the date of completion. At that time, researchers will be required to take the CITI refresher course.

12. Does a retrospective chart review qualify for exempt status? No, these types of studies will be reviewed according to the expedited submission process.