

## UMDNJ Institutional Review Board Instructions for Completing Request for Continuing Review or Final Report Review of a Research Project

All on-going human studies at UMDNJ, including all schools and divisions, must be reviewed by the IRB at intervals appropriate to the degree of risk but not less than annually, for continuation of approval. Research not receiving continuing review and approval by the anniversary date will be discontinued per Federal Regulations and the Federal Wide Assurances (FWA), filed with the Office for Human Research Protection (OHRP), for each campus of UMDNJ.

Please refer to the campus specific instruction sheet for applicable information i.e., required number of copies and required documents.

Please answer all questions without leaving blanks. Put N/A if not applicable to your research project.  
Questions?

Call the UMDNJ-RWJMS New Brunswick/Piscataway IRB Office at (732) 235-9806

Call the UMDNJ-NJMS Newark Campus IRB Office at (973) 972-3608

Call the UMDNJ-SOM Stratford/Camden IRB Office at (856)-566-2712

Mail or Hand Deliver the appropriate documents to your campus IRB Office at one of the following addresses:

Institutional Review Board  
65 Bergen Street  
Fifth Floor  
Suite 511  
Newark, New Jersey 07101-1709  
<http://www.umdj.edu/irbnweb/>

Institutional Review Board  
390 George Street  
Fifth Floor  
Suite 506  
New Brunswick, NJ 08901  
<http://www2.umdj.edu/irbweb/>

Institutional Review Board  
40 East Laurel Road  
University Education Center, First Floor  
Suite 1106  
Stratford, NJ 08084  
<http://www3.umdj.edu/irbsweb/>

### PAGE ONE

- Verify the accuracy of the following information on the form: If any of the information has changed and you have not notified the IRB, please submit an amendment with this Request for Continuing Review.
  - Study Title
  - Principal investigator's name, department, address, fax number and e-mail address. Please make sure that the IRB has the most current and preferred contact information.
  - Co-Investigators/Study Personnel
  - Sponsor /Funding Status
- Verify protocol number and IRB Approval Expiration Date. This information is found on the IRB approval letter.

### PAGE TWO

#### RESEARCH SITES SUMMARY:

**Multicenter Study-** A study that is being carried out at multiple institutions that are not affiliated with UMDNJ

**Inter-institutional Study-** A study that is being carried out at multiple UMDNJ campuses (e.g. a study is being carried out at UMDNJ –NJMS and UMDNJ-RWJMS)

**Cooperative Agreement-**An inter-campus/institutional IRB agreement which allows investigators at one UMDNJ campus to undergo IRB review without requiring IRB review at another UMDNJ campus site for the same study (e.g. A study is being carried out at UMDNJ –NJMS and UMDNJ-RWJMS. The UMDNJ-NJMS Principal Investigator submits their study for IRB review at the UMDNJ-Newark Campus IRB. The Principal Investigator at UMDNJ-RWJMS would not be required to submit the same study for review by the UMDNJ-RWJMS IRB.)

**Project Sites and Cooperative Institutions of the Principal Investigator:** Please indicate each performance site where this study is being carried out. Satellite Sites- UMDNJ Affiliated locations such clinics or medical offices operated by UMDNJ.

## UMDNJ-IRB Instructions

**Item # 1:** IRB approval of your study expires 364 days from the date of review, this date may correspond with either the date of the IRB Full Board Meeting or the date when the IRB reviewer's comments/determination were received. The expiration date for your IRB approval can be found on the IRB Notice of Approval. **If you are submitting your IRB approval after the expiration date please note the following:**

- **No new subjects may be enrolled**
- **For safety reasons, subjects already on study drug should continue to be followed.**
- **FDA may not allow data collected after expiration to be used.**

If you are submitting your Request for Continuing Review after the expiration of your IRB approval and a month or less has elapsed since the expiration date, you must complete and submit the Protocol Reactivation form.

## PAGE THREE

### Status of Study Table

Please select the option(s), which most appropriately describe the current status of your study activities.

**Please Note: If you select Option B:**

**Consent forms submitted will not be stamped and returned. If you need to receive the consent form back on a study that is closed to enrollment, you must request it in writing with a justification as to why you need the consent form.**

**Section # 1.** The expiration date for the IRB approval of your study is noted on the IRB Notice of Approval (towards the middle of the document). If the study has expired and the approval has not lapsed for more than 30 days, you must also complete the Protocol Reactivation Form.

### Section # 2. Consent Form Summary:

Item E.: Total Number of Consent Forms for Stamping: Please note- If the study is no longer open to enrollment/recruitment, you are only required to submit copies of the most recently approved consent forms with the IRB's approval stamp). You are not required to submit clean copies of the consent form for stamping because a new IRB approved consent form will not be issued, as it will no longer be used (because all subjects have been consented).

2c. This number corresponds with the total number of consent/assent forms that you plan to use and need the IRB to approve.

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### Section # 5. Demographic Information

If the study is a chart review, laboratory or data analysis study: If section # 5 does not apply to your study, please indicate this and Skip to Section # 6.

**The following are definitions of ethnicity categories as described at:**

<http://www.fda.gov/cber/gdlns/racethclin.pdf>

#### **Ethnicity Definitions: (NIH)**

**White, not of Hispanic origin:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

**White/ Hispanic:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa in addition to having origins in Cuba, Mexico, Puerto Rico, South or Central America, or other Spanish culture, regardless of race. The term "Spanish origin" can also be used in addition to "Hispanic or Latino".

**Black or African American, not of Hispanic origin:** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American".

**Black/ Hispanic:** A person having origins in any of the black racial groups of Africa in addition to having origins in Cuba, Mexico, Puerto Rico, South or Central America, or other Spanish culture or origin, regardless of race.

**Asian or Pacific Islander:** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the

## UMDNJ-IRB Instructions

Philippine Islands, Thailand, and Vietnam; also including a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

**American Indian or Alaskan Native:** A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

### Section # 6

**Answer questions in Section # 6** by providing the number of medical records that have been accessed or the number of samples or specimens that have been collected and will be used for this study. If certain questions in section # 6 do not apply to your study, please indicate this by entering N/A for those questions that are not applicable.

### Section # 7 Cumulative Summary of Subjects Enrolled to Date

If your study is being carried out at multiple UMDNJ affiliated sites (e.g. RWJMS, SOM in Stratford) **and** you have requested to utilize an Inter-Institutional Agreement, you must provide a summary of subjects enrolled for each of these sites.

If you are only carrying out the study at one site, you may delete the additional tables and enter site specific information for the performance site.

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### Section # 8 DSMB Data Safety Monitoring Board

A Data Safety Monitoring Board is an independent committee that reviews clinical trial progress and safety, and advises the sponsor whether to continue, modify, or terminate a trial. The purpose of the DSMB is to assure that the safety of study subjects is protected while the scientific goals of the study are being met. Specifically, the DSMB is charged with monitoring the safety of participants and the quality of the data, as well as the appropriate termination of studies either when significant benefits or risks have been uncovered or when it appears that the clinical trial cannot be concluded successfully.

### Section # 9 Certificate of Confidentiality

According to the NIH "Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that if disclosed could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants."

For more information, see <http://grants1.nih.gov/grants/policy/coc/index.htm>

### Section # 10 Adverse Events/Protocol Deviation

An **adverse event (AE)** is an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention

A **serious adverse event (SAE)** is one that results in death, a life-threatening experience, inpatient hospitalization or prolongation of hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect during the course of the research study.

All incidents of adverse effects, injuries, or unanticipated problems experienced by subjects or others in research must be reported to the IRB. This report should be submitted as soon as possible, and in the case of events or problems occurring at this institution, **NO LATER THAN 10 WORKING DAYS** after investigators first learn of the

## UMDNJ-IRB Instructions

event or problem. Investigators should provide their assessment of the event or problem and support for any proposed changes to the protocol or project description and/or the informed consent document.

A **protocol deviation** is a divergence from a specific element of a protocol. Examples of deviations include non-adherence to eligibility/ineligibility criteria, any departure from the protocol treatment plan, or a missed test or measurement specified in the protocol.

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### Section # 15: Protected/Personal Health Information (PHI)

**Personal Health Information-** HIPAA has delineated Identifiers that are classified as personal health information. The identifiers are:

- 1) Name
- 2) Address (including street address, city, county, and zip code)
- 3) Names of Relatives
- 4) Names of Employers
- 5) Relevant Dates (including birth date)
- 6) Telephone/Fax Numbers
- 7) Age > 89
- 8) E-Mail Addresses/URL's/IP Addresses
- 9) Social Security Numbers
- 10) Medical Record/Prescription/Health Plan Numbers
- 11) Individual Account Numbers
- 12) Certificate or License Numbers
- 13) Vehicle Identification Numbers (VIN)
- 14) Device Identifiers and Serial Numbers
- 15) Biometric Identifiers, including finger and voice prints
- 16) Photographs and Other Images ( i.e. identifiable – full face )
- 17) Other Unique Identifying Numbers, Characteristics or Codes

15 F. Authentication is the identification of an individual communicating the information. For more information, please refer to the following policy: [http://www.umdnj.edu/opmweb/Policies/HTML/TechnologyServ/00-01-95-15\\_00.html](http://www.umdnj.edu/opmweb/Policies/HTML/TechnologyServ/00-01-95-15_00.html)

15 F. (a) Data stewardship \* is the operational responsibility for and management of particular datasets and other information. Data stewardship shall be vested in or shared by designated University personnel, offices, schools or units responsible for the creation or collection of the data, as delegated by the pertinent dean(s) or vice president(s). (\* "Data steward" may be used synonymously with "data custodian.")

15 G. In order to equip your computer with encryption capabilities for transmission of PHI, you must obtain a PKI (Public Key Infrastructure\*) certificate from the University and employ such certificates in conjunction with supported communication software whenever communicating information that is classified as confidential or sensitive. Application for PKI certificates may only be made in person at locations designated by IST (this information will be publicly available in the near future).

\*Public Key Infrastructure is a technology for enabling the secure transport of information accessible only to specific individual(s) and establishing non-repudiated identity of the sender.

For more information about this policy, please refer to the policy entitled "PROTECTION AND AUTHENTICATION OF ELECTRONICALLY COMMUNICATED CONFIDENTIAL OR SENSITIVE INFORMATION" at the following webpage: [http://www.umdnj.edu/opmweb/Policies/HTML/TechnologyServ/00-01-95-15\\_00.html](http://www.umdnj.edu/opmweb/Policies/HTML/TechnologyServ/00-01-95-15_00.html)

You may also want to contact Information Services and Technology. More information can be found at their website: <http://www.umdnj.edu/istweb/>

**Section L Repository**

**Human Tissue and Data Repositories** collect, store, and distribute human material or data for research purposes.

For more information, please refer to Guidelines for Human Tissue Repository:

<http://www.nhlbi.nih.gov/funding/policies/repos-gl.htm> or Office for Human Research Protections-Issues to Consider in the Research Use of Stored Data or Tissue: <http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm>.

**Section # 20 Conflict of Interest**

According to the UMDNJ Policy on Investigator Financial Disclosure and Conflict of Interest:

1. Each investigator planning to apply for or receiving funds for research, educational or service activities shall disclose to the Research Dean of the school or to the pertinent Vice President all those significant financial interests of the investigator and of the investigator's spouse and dependent children as described below:

- that would reasonably appear to be affected by the research, educational or service activities funded or proposed for funding, or
- in entities whose financial interests would reasonably appear to be affected by the research, educational or service activities funded or proposed for funding.

The UMDNJ Financial Disclosure Statement must be completed by all investigators, even if there is no conflict of interest. The UMDNJ Policy on Investigator Financial Disclosure and Conflict of Interest can be accessed at: [http://www.umdj.edu/opmweb/Policies/HTML/AcademicAff/00-01-20-89\\_00.html](http://www.umdj.edu/opmweb/Policies/HTML/AcademicAff/00-01-20-89_00.html))

**Investigator Assurance**

- The principal investigator must sign and date the form. **Others may not sign for the principal investigator.**

Please submit your request no later than the submission deadline for the meeting prior to your protocol expiration. (Refer to the attached meeting schedule) or access this information at:

Newark Campus: <http://www.umdj.edu/irbnweb/schedule.htm>

New Brunswick/Piscataway Campus: <http://www2.umdj.edu/irbweb/application/schedule.htm>

Stratford Campus: [http://www3.umdj.edu/irbsweb/deadlines\\_meeting.htm](http://www3.umdj.edu/irbsweb/deadlines_meeting.htm)

**Instructions for Number of Copies:**

**Newark Campus**

**New Brunswick Campus**

**Stratford Campus**

## UMDNJ-IRB Instructions

**The following information outlines the required documents for IRB Full Board Review by the UMDNJ Newark Campus-Office of the Institutional Review Board.**

Return the following to the IRB Office collated and stapled into 25 sets:

1 original set consisting of:

- a) A cover memo
- b) The Request for Continuing Review/Final Report form.
- c) 1 original of each consent form submitted to be stamped with re-approval date by IRB. One of each will be stamped and returned to the investigator
- d) The most recently approved protocol
- e) All questionnaires, advertisements and publications.
- f) Any attachments.
- g) Any outstanding Adverse Events, protocol deviations/ violations, proposed amendments, etc. at this time. **(Please include a justification for any changes to the previously approved protocol).**

2 sets consisting of:

- a) A cover memo
- b) The Request for Continuing Review/Final Report form.
- c) A copy of each consent form to be stamped with IRB continuing review approval date.
- d) The most recently approved protocol
- e) All questionnaires, advertisements and publications.
- f) Any attachments.
- g) Any outstanding Adverse Events, proposed amendments, protocol deviations/violations, etc. at this time.

21 remaining sets consisting of:

- a) A cover memo
- b) The Request for Continuing Review/Final Report form.
- c) The consent form(s) to be stamped with re-approval date by IRB.
- d) All questionnaires, advertisements and publications.
- e) Any attachments.
- f) Any outstanding Adverse Events, proposed amendments, protocol

The following information outlines the required documents for **Continuing Review** by the UMDNJ-New Brunswick / Piscataway Campus – Office of the Institutional Review Board.

For a **Full Board Review** follow Sections *I*, *II*, and *III*. Return the following to the IRB Office collated and stapled into 16 sets.

For an **Expedited Review** follow Sections *I* and *II* only. Return the following to the IRB Office collated and stapled into 4 sets.

***I One (1) Original set consisting of the following:***

1. A cover memo
2. The Continuing Review Form (Summary should be updated at each review)
3. Investigator Financial & Other Personal Interests Disclosure Form
4. 1 copy of a **new** grant or contract (if applicable) with required Request for Modification Form
5. 1 original of each consent form submitted to be stamped with re-approval date by IRB. One of each will be stamped and returned to the investigator
6. The most recently approved protocol
7. All questionnaires, advertisements and publications
8. Any attachments
9. Any outstanding Adverse Events, Protocol deviations/violations, Modification Forms, etc. at this time

***II Three (3) additional sets consisting of the following:***

1. A cover memo
2. The Continuing Review Form (Summary should be updated at each review)
3. Investigator Financial & Other Personal Interests Disclosure Form
4. 1 copy of a **new** grant or contract (if applicable) with required Request for Modification Form
5. 1 original of each consent form submitted to be stamped with re-approval date by IRB. One of each will be stamped and returned to the investigator
6. The most recently approved protocol
7. All questionnaires, advertisements and publications
8. Any attachments
9. Any outstanding Adverse Events, Protocol deviations/violations, Modification Forms, etc. at this time

***III Twelve (12) remaining sets consisting of the following:***

1. A cover memo
2. The Continuing Review Form (Summary should be updated at each review)
3. 1 original of each consent form
4. All questionnaires, advertisements and publications
5. Any attachments
6. Any outstanding Protocol Deviations/Violations, Modification Forms, etc. at this time

***\*\*All revisions require a Request for Modification form, and an updated version date on the document being revised.***

## UMDNJ-IRB Instructions

### The following information outlines the required documents for IRB Full Board Review by the UMDNJ-Stratford/Camden Campus-Office of the Institutional Review Board

Return the following to the IRB Office collated and stapled into 18 sets:

1 original set consisting of:

- a) A cover memo
- b) The Request for Continuing Review/Final Report form.
- c) 1 original of each consent form submitted to be stamped with re-approval date by IRB (One of each will be stamped and returned to the investigator). Also include a highlighted copy of the consent form **only if** changes were made to the document.
- d) The most recently approved protocol
- e) All questionnaires, advertisements and publications.
- f) Any attachments.
- g) Any outstanding Adverse Events, protocol deviations/ violations, proposed amendments, etc. at this time. **(Please include a justification for any changes to the previously approved protocol).**

4 sets consisting of:

- a) A cover memo
- b) The Request for Continuing Review/Final Report form.
- c) A copy of each consent form to be stamped with IRB continuing review approval date (and a highlighted copy of the consent form only if changes were made to the document).
- d) The most recently approved protocol
- e) All questionnaires, advertisements and publications.
- f) Any attachments.
- g) Any outstanding Adverse Events, proposed amendments, protocol deviations/violations, etc. at this time.

13 remaining sets consisting of:

- a) A cover memo
- b) The Request for Continuing Review/Final Report form.
- c) The consent form(s) to be stamped with re-approval date by IRB (and a highlighted copy of the consent form only if changes were made to the document.)
- d) All questionnaires, advertisements and publications.
- e) Any attachments.
- f) Any outstanding Adverse Events, proposed amendments, protocol