This document is for informational purposes only. All protocols must be officially submitted via the e-Protocol system. This document compiles the questions posed in e-Protocol for BIOMEDICAL EXPEDITED REVIEW.

PROTOCOL APPLICATION FORM
BIOMEDICAL EXPEDITED REVIEW
HUMAN SUBJECTS IN BIOMEDICAL RESEARCH
University of Massachusetts Amherst

1. Purpose of the study
a) Provide a brief lay summary of the purpose of the study.

b) What does the Investigator(s) hope to learn from the study?

2. Study Procedures
a) Describe all the procedures (in sequence) that human subjects will undergo in the research project. This section can be written in bullet form.

b) If applicable, list any investigator(s) who will be performing procedures such as blood draws. Describe the credentials and/or training of any individuals performing such procedures.

c) Alternative Procedures. Describe alternative procedures, in any, that might be advantageous to the subject. Describe all risks and benefits associated with the alternative procedure(s) or course(s) of treatment. Any standard treatment that is being withheld must be disclosed. This information must be included in the consent form.

d) Will it be possible to continue the more (most) appropriate therapy for the subject(s) after the conclusion of the study?

e) Study Endpoint. What are the guidelines or end points by which you can evaluate the alternative treatments during the study? If one treatment proves to be clearly more effective than another (or others) will the study be terminated before the projected total subject population has been enrolled? When will the study end if no important differences are detected?

f) State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in Section #16. (attachments)

3. Background
a) Describe past experimental and/or clinical findings leading to the formulation of the study.
b) Describe any animal experimentation and findings leading to the formulation of the study.

4. Radioisotopes or Radiation Machines

a) State whether the radiation procedures are performed as a normal part of clinical management for the medical condition that is under study or whether they are being performed because the research subject is participating in this project (extra CT scans, more fluoroscopy time, additional Nuclear Medicine studies, etc.). If some are Standard of Care and some are Not Standard of Care, check both boxes.

- [ ] NOT STANDARD OF CARE
  - If it is not standard of care, complete the rest of this section.

- [ ] STANDARD OF CARE
  - If it is only standard of care, skip the rest of this section.

For more information, see: http://www.umass.edu/research/comply/radioisotope.html

b) For radioisotope projects, provide the following radiation-related information:

   Identify the radionuclide and chemical form.

   For each dosage, provide the route of administration and the amount administered (mCi).

   Provide dosimetry information and reference the source documents (package insert, MIRD calculation, peer reviewed literature, attach the source documents electronically available).

c) For radiation machine projects, provide the following diagnostic procedures:

   For well-established radiographic procedures, identify the procedures and the number of times each will be performed on a single research subject.

   For each radiographic procedure, provide the setup and technique sufficient to permit dose modeling. The chief technologist can usually provide this information.

   For radiographic procedures that are not well-established, provide the FDA status of the machine, and information sufficient to permit dose modeling.

d) For radiation machine projects, provide the following therapeutic procedures:

   For a well-established therapeutic procedure, identify the area treated, dose per fraction and number of fractions. State whether the therapeutic procedure is being performed as a normal part of clinical management for the research subject's medical condition or whether it is being performed because the research subject is participating in this project.

   For a therapeutic procedure that is not well-established, provide FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions.
5. **Medical Equipment for Human Subjects**
   If medical equipment is being used for human subjects/patients, describe such equipment and if the use is normal practice for the population under study.

6. **Investigational Devices**
   Please list in the table below all Investigational Devices to be used on Subjects.

7. **Drugs, Reagents, or Chemicals**
   a) Please list in the table below all investigational drugs, reagents or chemicals to be administered to subjects during this study.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Source (e.g., Pharmacy, sponsor, etc.)</th>
<th>IND Regulations</th>
<th>Manufacturer</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
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</tbody>
</table>

   b) Please list in the table below all commercial drugs, reagents or chemicals to be administered to subjects during this study.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Source (e.g., Pharmacy, sponsor, etc.)</th>
<th>IND Regulations</th>
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</tbody>
</table>

8. **Subject Population**
   a) State how many subjects you propose to use and state the rationale for the proposed number.

   b) Describe the subject population, including the age range, gender, ethnic background, and type of subjects (e.g. students, subjects with cardiac problems, particular kind of cancer, etc.)

   c) State the number and rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, prisoners, economically and educationally disadvantaged, decisionally challenged, and homeless people.

   d) If women, minorities, or minors are not included, a clear compelling rationale must be provided. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc.

   e) State the number, if any, of subjects who are laboratory personnel, employees, and/or students. They should be presented with the same written informed consent. If compensation is allowed, they should also receive it.

   f) State the number, if any, of subjects involved in research conducted abroad and describe any unique cultural, economic or political conditions.
g) Describe your procedures for recruiting subjects, including how potential subjects will be identified for recruitment. Attach all recruitment materials (flyers, recruitment letters and/or emails, etc.) at the end of this application. Note: Potential subjects may not be contacted before IRB approval.

h) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

Identify exclusion criteria.

i) Describe your screening procedures.

j) Describe how you will be cognizant of other protocols in which subjects might be participating. Please explain if subjects will be participating in more than one study.

k) Compensation. Explain the amount and type of compensation (payment, experimental credit, gift card, etc.), if any, that will be given for participation in the study. Include a schedule for compensation and provisions for prorating.

l) Costs. Please explain any costs that will be charged to the subject.

m) Please state: A: The total expected duration of the study, including the time expected for data analysis (e.g., This study is expected to last 1 year) AND B: How much time each subject is expected to be involved in the study (e.g., The involvement of each subject will be 1-session for a total of 90 minutes).

9. Risks
HHS Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research..." Also included are risks to participant confidentiality and any discomforts, hazards, or inconveniences.

a) For the following categories include a description of risks:

Physical Well Being

Psychological well-being
Economic well-being
Social well-being

Breach of confidentiality (including audio/video taping)

For the following categories include a scientific estimate of the frequency, severity, and reversibility of risks. Wherever possible, include statistical incidence of complications of proposed procedures (from investigator’s brochure or package, insert where applicable).

Address any risks associated with:

Use of investigational drugs or devices.
Use of commercially available drugs, supplements, reagents or chemicals.

Performing procedures including all investigational, non-investigational and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).

Radioisotopes/radiation (e.g., X-rays, CT scans, DEXA).

b) For research conducted abroad, describe any risks associated with the unique cultural or political environment.

c) For grant funded studies, where the funder plans to pay for any necessary medical expenses, describe plans for ensuring medical or professional interventions.

d) Data Safety Monitoring

Is there a Data and Safety Monitoring Board (DSMB)? □ YES □ NO

If yes, describe its role and indicate who set up the Data and Safety Monitoring Board (e.g. Protocol Director).

If you have a Data and Safety Monitoring Plan (DSMP), briefly describe how you plan to ensure the safety of participants and the validity and integrity of research data. Attach the plan in Section 16.

e) Evaluation of level of risk. Please select one.

□ Minimal □ Moderate □ High

10. Benefits

a) Describe the potential benefit(s) to be gained by the subjects or by the acquisition of important knowledge which may benefit future subjects, etc. (This DOES NOT include compensation or extra credit).

11. Procedures to Maintain Confidentiality

a) Describe the procedures in place which protect the privacy of the subjects and maintain the confidentiality of the data, as required by the federal regulations, if applicable.

b) If information derived from the study will be provided to the subject’s physician, a government agency, or any other person or group, describe to whom the information will be given and the nature of the information.

c) Specify where and under what conditions study data will be kept, how specimens will be labeled and stored (if applicable), who has access to the data and specimens, and what will be available to whom.

12. Potential Conflict of Interest

a) Do any of the involved investigators or their immediate family (as described below) have consulting arrangements, management responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)? □ YES □ NO
b) Do any investigators or their immediate family have any financial relationship with the Sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment?  

YES ☐  NO ☐

c) Is any Investigator(s) a member of an advisory board with the Sponsoring company?  

YES ☐  NO ☐

d) Do any investigators receive gift funds from the Sponsoring company?  

YES ☐  NO ☐

e) Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol?  

YES ☐  NO ☐

"Immediate family" means a spouse, dependent children as defined by the IRS, or a domestic partner.

If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship, i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor. The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment.

If you answer yes to any of the questions above, you must file a Conflict of Interest disclosure statement located at http://www.umass.edu/research/ora/faccon.html.

13. Informed Consent Background

Provide consent process background information below.

Please complete the table below for each consent form and attach the consent form(s) at the end of this application.

<table>
<thead>
<tr>
<th>Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.</th>
</tr>
</thead>
<tbody>
<tr>
<td>How is consent being obtained?</td>
</tr>
<tr>
<td>What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?</td>
</tr>
</tbody>
</table>

If you are requesting a consent form waiver or alteration, address the following four points. A Yes/No response alone is not adequate.

1. The research involves no more than minimal risk to the subjects.  

YES ☐  NO ☐

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.  

YES ☐  NO ☐
3. The research could not practicably be carried out without the waiver or alteration.

YES □    NO □

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

YES □    NO □

14. Assent Background
All minors must provide an affirmative consent to participate by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minor subjects are not capable of assenting because of age, maturity, psychological state, or other factors.

Please complete the table below for each assent form and attach the assent form(s) at the end of this application.

<table>
<thead>
<tr>
<th>Who is obtaining child assent and parent consent? The person obtaining consent must be knowledgeable about the study and appointed by the PI to perform this function of the research.</th>
</tr>
</thead>
<tbody>
<tr>
<td>How is assent being obtained?</td>
</tr>
<tr>
<td>What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?</td>
</tr>
</tbody>
</table>

If you are requesting an assent form waiver, please explain the rationale for altering written assent for minors.

15. HIPPA
Are you using Protected Health Information (PHI)?

YES □    NO □

Protected Health Information (PHI) is health information that has been collected by a covered entity (e.g. a hospital or other organization providing health care) and has one or more of the following identifiers:
1. Names
2. Social Security Numbers
3. Telephone Numbers
4. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combing all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000
5. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
6. Fax numbers
7. Electronic mail addresses
8. Medical health records
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locations (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

Provide HIPAA background information, in the table below, for each waiver of authorization or alteration of authorization requested, e.g., waiver of authorization for access to medical records. Include HIPAA authorization language in the consent form(s) as appropriate, e.g., when enrolling subjects.

Use table below only when requesting waiver/alteration of HIPAA authorization.


a. Please provide a brief description of the protected health information for which use or access has been determined to be necessary.

b. Please mark the applicable boxes:

YES□  NO□ Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?

YES□  NO□ Do you certify that the research could not practicably be conducted without the waiver or alteration?

YES□  NO□ Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use of disclosure of protected health information would be permitted?

YES□  NO□ Do you certify that the research could not practicably be conducted without access to and use of the protected health information?

c) Please describe an adequate plan to protect any identifiers from improper use and disclosure.

d) Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

16. Attachments
At the end of this application, please attach all relevant documents listed below as well as any additional materials that will be provided to subjects.

- Copies of grants (including those submitted through OGCA)
- Recruitment materials (flyer, letter, newspaper ad etc)

- Questionnaires/Surveys

**Obligations**
Obligations of the Principal Investigator are:

**Modifications** - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes;

**Consent Forms** - All subjects will be given a copy of the signed consent form. Investigators will be required to retain signed consent documents for six (6) years after close of the grant or three (3) years if unfunded;

**Training** - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel;

**Adverse Events** - All adverse events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than ten (10) working days;

**Continuing Review** - IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review;

**Completion Report** - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select "Final Report."

☐ The Principal Investigator has read and agrees to abide by the above obligations.

Protocol Director: ___________________________ Date: __________

Faculty Sponsor: ___________________________ Date: __________