Expedite 6/17/07

| CLINICAL RESEARCH PROTOCOL **CONTINUING** REVIEW APPLICATION | PROTOCOL NO. 02-CC-0247 | PRINCIPAL INVESTIGATOR (NIH Employee Name, Inst/Br, Address, Telephone and email): Marion Danis, M.D., CC/BE, 10/1C118, 301 435-8727 |
|---|---|---|

PROTOCOL TITLE: Values at the Bedside: A Survey of European Physicians Regarding Ethical Dilemmas in Clinical Practice

PROTOCOL STATUS:
- ☐ Renew -Recruitment of participants has not yet begun.
- ☒ Renew -Participants are currently being recruited or enrolled.
- ☐ Renew -No longer recruiting or enrolling participants, subject follow-up only.
- ☐ Renew -Participants have completed study; study and data analyses ongoing.
- ☐ Renew -Clinical Hold/Recruitment or enrollment of participants suspended.
- ☐ Terminate -Study closed. Participants have completed study. Recruitment and data analysis complete.

SUMMARY OF PROTOCOL ENROLLMENT (Aggregate): Only when the NIH is the coordinating site, provide totals and enrollment table for other site.

| NIH Site | Other Sites | Total | |
|---|---|---|---|
| | 2100 | | Accrual ceiling by IRB |
| | 0 | | New subjects accrued since last CR |
| | 656 | | Aggregate total accrued |

Are you currently recruiting healthy volunteers? ☒ No ☐ Yes
Will the protocol involve adults unable to give informed consent? ☒ No ☐ Yes

Have analyses by sex, racial/ethnic subgroups been conducted for Phase 3 Clinical Trials as required? ☐ No ☐ Yes (answer a and b) ☒ N/A

a. Have analyses been reported? ☐ No (explain in narrative) ☐ Yes
b. Have significant differences been found? ☐ No ☐ Yes

Have any non-NIH Investigators or sites been added since the last review?
- ☒ No
- ☐ Yes (Identify the persons or sites and describe the collaboration in the summary report)

WITH THIS REVIEW, I AM REQUESTING A CHANGE TO THE FOLLOWING:
*Include Name, Inst/Branch, Telephone, Address, e-mail. Check box if an NIH Employee and initial line. Attach sheet if necessary.

PRINCIPAL INVESTIGATOR:
Delete: _____
Add*: ☐ _____

EXTRAMURAL ADJUNCT PRINCIPAL INVESTIGATOR:
Delete: _____
Add: _____

MEDICAL ADVISORY INVESTIGATOR:
Delete: _____
Add*: _____

LEAD ASSOCIATE INVESTIGATOR:
Delete: _____
Add*: ☐ _____

RESEARCH CONTACT:
Delete: _____
Add*: ☐ _____

ASSOCIATE INVESTIGATOR(S):
Delete: _____
Add*: ☐ _____

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET, etc.) check all that apply:
- ☒ None
- ☐ Medically indicated
- ☐ Research indicated. Since the last review,
  - ☐ Research usage HAS NOT changed.
  - ☐ Research usage HAS changed. (Explain in summary report)

INVESTIGATIONAL NEW DRUG/DEVICE: ☒ None ☐ IND ☐ IDE
*If reporting more than one IND/IDE, list on attached sheet.

FDA No. _____
Name: _____
Sponsor: _____
Who is the manufacturer of the above entity? _____

Does the protocol involve a Tech Transfer Agreement? ☒ No ☐ Yes

Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?
- ☒ No
- ☐ Yes (Append a statement of disclosure)

Have there been any amendments since the last review?
- ☒ No
- ☐ Yes (Describe briefly in the attached narrative.)

Have there been any changes in the informed consent process or documentation since the last review?
- ☒ No
- ☐ Yes (Describe in Summary report)

Have there been any changes in the subject population, recruitment or selection criteria since the last review?
- ☒ No
- ☐ Yes (Explain changes in the attached narrative.)

Have any unexpected complications or side effects been noted since the last review?
- ☒ No
- ☐ Yes (Identify and explain in the attached narrative.)

Have any subjects withdrawn from this study since the last IRB approval?
- ☒ No
- ☐ Yes (Discuss in the attached narrative.)

Has any information appeared in the literature, or evolved from this or similar research, that might affect the IRB's evaluation of the risk/benefit analysis of human subjects involved in this protocol?
- ☒ No
- ☐ Yes (Discuss in the attached narrative.)

Has the NIH IRP COI Guide been distributed to new NIH investigators?
☐ No ☐ Yes ☒ N/A

Has the NIH IRP COI Guide been distributed to new Non-NIH investigators?
☐ No ☐ Yes ☒ N/A

CONFLICTS OF INTEREST REVIEW?
Date submitted to IC DEC: _____ Date cleared by IC DEC: _____

| | | | | | |
|---|---|---|---|---|---|
| SIGNATURE | Marion Danis<br>Principal Investigator | Marion Danis, M.D.<br>Print/Type Name | Date | 5/3/07 | Send to Accountable Investigator |
| RECOMMENDATION | Maggy Dams<br>Accountable Investigator | Marion Danis, M.D.<br>Print/Type Name | Date | 5/3/07 | Send to Branch Chief, or CC Dept. Head of Accountable Investigator |
| | [signature]<br>Br Chief/CC Dept. Head of Acct. Invest | Ezekiel Emanuel<br>~~David Henderson~~, M.D.<br>Print/Type Name | Date | 5/8/07 | Send to Clinical Director |
| APPROVALS | [signature]<br>Clinical Director | ~~David Henderson~~, M.D.<br>Print/Type Name | Date | 5/8/2007 | Send to Chair, Institutional Review Board |
| | [signature]<br>Chair, For Institutional Review Board | Glenn Grave<br>Print/Type Name | Date | 5/21/2007<br>Protocol & Consent Approved Effective | Send to Office of Protocol Services, through IRB Protocol Coordinator |
| COMPLETION | Bianca Driggins<br>Protocol Specialist | | Date | 6/13/07 | |