Attachments for 0925-0046-16

#16B CIRB Model Pilot Surveys

#16C Institution Worksheet for CIRB Pilot

#16D Principal Investigator Worksheet for CIRB Pilot

#16E Study-Specific Worksheet for CIRB Pilot

#16F Study Transfer Worksheet for CIRB Pilot

OMB #: 0925-0046-16
Exp. Date: 2/28/13

Attachment B: CIRB Model Pilot Surveys

A Pilot Study to Test a Proposed New Model for the NCI's CIRB

You have been selected for participation in this survey because of your affiliation with [ORG NAME], which is participating in the CIRB Pilot Study. This survey asks your opinions and experiences participating in the pilot study and about the proposed CIRB model. The information you provide will be used to guide NCI's decision whether or not to adopt the proposed new independent CIRB model.

Your participation in this survey is voluntary and there are no penalties for not responding to the survey. The CIRB initiative is interested in your point of view and appreciates your participation.

The information you provide will be kept private under the Privacy Act.. Your name will be stored separately from your answers in a secure environment. Your institution name will not be identified with your responses, only descriptors as to its type and size. During analysis, survey answers will be combined across all respondents and reported in the aggregate. NCI and your employer will not be informed of your personal responses to survey questions.

If you have any technical questions about the survey, please contact Dan Eckstein:

DEckstein@novaresearch.com
NOVA Research Company
4600 East-West Highway, Suite 700
Bethesda, MD
(301) 986-1891

BASELINE SURVEY

a) Background/characteristics

The following questions ask about your experience at your institution and with its IRB process.

1. Thinking of your role in cooperative group studies, what is your primary position at your institution? If you have dual roles, please pick the role whose viewpoint you will be representing.

    i. IRB Chair*
    ii. IRB staff person*
    iii. IRB Administrator/Director*
    iv. Institutional Official
    v. Principal Investigator*
    vi. Research Coordinator*
    vii. Other research staff
    viii. Institutional Legal Council
    ix. Other _____

2. How many years have you been involved in the CIRB process at your institution?
    _____# years

3. On average, how many hours do you spend each month fulfilling your CIRB-related responsibilities?
    _____# hours/month

4. Please indicate the number of IRB staff at your institution:
    i. ____# of full-time employees
    ii. _____# of part-time employees

5. Please indicate the number of IRB staff involved in processing cooperative group studies?
    i. ____# of full-time employees
    ii. _____# of part-time employees

b) Assess satisfaction of current model

The following questions ask your opinions of the current CIRB facilitated review model, as well as your existing IRB model. *Note: items in [ ] are for participating sites; items in ( ) are for non-participating sites.*

1. Overall, how would you rate your [satisfaction with] (perceptions of) the <u>current</u> CIRB facilitated review model?
    i. [not at all satisfied <→very satisfied] (negative←>positive)
    ii. (Open ended follow up) Please use the space below to briefly elaborate on your response

iii. [FOR PARTICIPATING SITES ONLY]
    a. Which statement best describes your institution's use of the CIRB facilitated review model?
        a. We use the CIRB for Adult studies only
        b. We use the CIRB for Pediatric studies only
        c. We use the CIRB for both Adult and Pediatric studies
    b. Thinking of the types of studies you checked in the above question, which statement best applies? We use the CIRB for…
        a. All cooperative group studies
        b. Most cooperative group studies
        c. Some cooperative group studies
        d. Few/none of the cooperative group studies

2. How efficient is your current IRB model for processing cooperative group studies?
    i. (Not at all efficient ← → very efficient)

3. Thinking of your current IRB processes for cooperative group studies, how would you rate your satisfaction with each of the following: (not at all satisfied <--> very satisfied)
    i. Time required to obtain local IRB approval
    ii. Paperwork required to submit for local IRB approval
    iii. Communication between the research staff and IRB staff
    iv. The process used to review local unanticipated problems
    v. The process used to report local unanticipated problems
    vi. Access to your IRB for guidance in the event of local unanticipated problems
    vii. (Open ended follow up) Please use the space below to describe your biggest concern with your current IRB model.

4. How important is it to you that NCI's CIRB attains accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)?
    i. (Not at all important <→ Very important)
    ii. (Open ended follow up) Why or why not?

5. How important is it to you that the Office for Human Research Protections (OHRP) is involved in the development of the CIRB model?
    i. (Not at all important <→ Very important)
    ii. (Open ended follow up) Why or why not?

c) Assess perceptions of new model/pilot

The following questions ask your opinions and expectations about the <u>new</u> CIRB independent model that you will use during the pilot. Please answer from your own perspective.

1. Overall, what is <u>your reaction</u> to the new CIRB model?
    i. (Very negative <→ Very positive)

2. Overall, what are <u>your</u> <u>colleagues'</u> reactions to the new CIRB model?
    i. (very negative <→very positive)

3. For each benefit listed below, please indicate how likely you believe your institution will experience it as a result of using the new CIRB model with cooperative group studies (Not at all likely <→ very likely)
    i. You will open studies faster
    ii. You will open more cooperative group studies
    iii. The paperwork burden to open a study will be reduced
    iv. It will reduce IRB oversight costs to your institution
    v. Less staff time will be needed to oversee the IRB processes
    vi. There will be a reduced liability risk to your institution as CIRB will be the sole IRB of Record
    vii. The PI can decide to open cooperative group studies without formally presenting to your local IRB Board first
    viii. (Open ended follow up) What other possible benefits to your institution do you see in using the new model?

4. When considering becoming part of the pilot, please rate how much concern your institution had for each: (not at all concerned <→ very concerned)
    i. Maintaining the quality of human subjects protection review
    ii. Ability of CIRB to adequately review and assess all local context considerations, including recruitment materials developed by the Cooperative Group or locally
    iii. Ability of CIRB to review unanticipated problems occurring locally and respond in a timely manner
    iv. Adapting your internal systems to the new CIRB model
    v. Workload increase on your PIs
    vi. Shifting the responsibility of review of locally-occurring adverse events from your local IRB to the CIRB
    vii. (Open ended follow up) What other concerns, if any, do you or your institution have about the new CIRB model?

5. What effect do you believe the new model will have on <u>your own</u> workload?
    i. (increase, decrease or stay the same)_

d) Tracking Measures:

Please provide the time it takes for each of the following activities for cooperative group studies. Please feel free to stop and save your responses if you need to find this information from additional resources at your institution.

1. How many hours, on average, does it take to complete your local forms to submit a study to your local IRB for review? _____ # hours using CIRB/_____ # hours not using CIRB

2. How many days, on average, does it take for your local IRB to approve a study once they receive the forms required? _____ # days using CIRB/_____ # days not using CIRB

3. How many days, on average, does it take for your local IRB to prepare and submit a report to OHRP/FDA about any local unanticipated problems with a study? _____ # days using CIRB/_____ # days not using CIRB

4. How many days, on average, does it take to get amendments reviewed and approved at your local IRB? _____ # days using CIRB/_____ # days not using CIRB

5. Are the numbers provided above generated from a database tracking system or are they estimates? _____database _____ estimates

e) Satisfaction with the pilot

The following questions ask about your satisfaction with the start up of the pilot program.

1. [Describe pilot briefly.] How much do you agree/disagree with the following statement: I am glad that my institution has decided to participate in this pilot.
    i. (Strongly Disagree ←> Strongly Agree)
    ii. (Open ended follow up) Please use the space below to elaborate on your answer.

2. How satisfied are you with how the CIRB pilot program is progressing?
    i. (Very satisfied ← → very unsatisfied)
    ii. What is working well?
    iii. (Open ended follow up) What steps could be taken to improve the experience of participating in the pilot thus far?

3. Please rate the amount of information provided to you about the pilot. Do you believe it is:
    i. (Too little, just right, too much)
    ii. (Open ended follow up) What, if any, additional information about the pilot would be of help to you?

4. Indicate how much you agree with the following statement: I believe the information communicated is sufficient to know what to expect for our participation in the pilot.
    i. (Strongly agree ← → strong disagree)
    ii. (Open ended follow up) How could information about the pilot be better communicated?

5. Compared to [the original CIRB model] (your current IRB process for cooperative group studies), how easy or difficult do you believe it will be to maintain the new independent CIRB model? *Note: items in [ ] are for participating sites; items in ( ) are for non-participating sites.*
    i. (Very easy ← → very difficult)
    ii. (Open ended follow up) Please elaborate on your response.

6. How much change was required by your institution to start participation in the pilot?
    i. (Not at all, very little, some, a lot)
    ii. (Open ended follow up) What changes were required to start up participation in the pilot?

7. Based on your current understanding of the new model, how likely is it that you would recommend it to your colleagues at other institutions?
    i. (Very likely ← → very unlikely)

FOLLOW UP SURVEY—Midpoint

a) Assess satisfaction of new model

The following questions ask your satisfaction thus far with the new CIRB independent model that you have been using during the pilot. Please answer from your own perspective.

1. Overall, how would you rate your satisfaction with the new CIRB independent review model?
    i. (Not at all satisfied <→ very satisfied)

2. Compared to the **original, facilitated review CIRB model**, please indicate which statement best describes your level of preference for the **new, independent CIRB model**:
    i. I **prefer the facilitated model a lot more** than the independent model
    ii. I **prefer the facilitated model somewhat more** than the independent model
    iii. I **prefer the independent model somewhat more** than the facilitated model
    iv. I **prefer the independent model a lot more** than the facilitated model
    v. I do not have a preference between the two models, both are **equally good**
    vi. I do not have a preference between the two models, both are **equally bad**
    vii. I have not had enough experience with the independent model to decide.
        a. (Open ended follow up) Please use the space below to briefly elaborate on your response.

3. Thinking of when you've used the new CIRB model for cooperative group studies, how would you rate your satisfaction with each of the following: (not at all satisfied <--> very satisfied)
    i. Time required to obtain CIRB approval
    ii. Paperwork required to submit for CIRB approval
    iii. Communication between the research staff and CIRB staff
    iv. The process used to review local unanticipated problems
    v. The process used to report local unanticipated problems
    vi. Access to the CIRB for guidance in the event of local unanticipated problems
    vii. (Open ended follow up) Please use the space below to describe your biggest concern with the new CIRB model.

b) Assess effectiveness of new model/pilot

The following questions ask your opinions about the new CIRB independent model that you have been using during the pilot thus far. Please answer from your own perspective.

1. Overall, what is your reaction thus far to the new CIRB model?

i. (Very negative <→ very positive)

2. Overall, what are <u>your</u> <u>colleagues' reaction</u> thus far to the new CIRB model
    i. (Very negative <→ very positive)

3. For each benefit listed below, please indicate the extent to which you believe your institution is experiencing each of the following when using the new CIRB model with cooperative group studies (Not at all likely <→very likely)
    i. You are opening studies faster
    ii. You are opening more cooperative group studies
    iii. The paperwork burden to open a study is reduced
    iv. It has reduced IRB oversight costs to your institution
    v. Less staff time is needed to oversee the IRB processes
    vi. There is a reduced liability risk to your institution as CIRB is the sole IRB of Record
    vii. The PI can decide to open cooperative group studies without formally presenting to your local IRB Board first
    viii. [include any new benefits listed from baseline survey]
    ix. (Open ended follow up) What other benefits is your institution experiencing as a result of the new model?

4. Considering your past few months of involvement in the pilot, please rate how much concern your institution has for each: (not at all concerned<→ very concerned)
    i. Maintaining the quality of human subjects protection review
    ii. Ability of CIRB to adequately review and assess all local context considerations, including recruitment materials developed by the Cooperative Group or locally
    iii. Ability of CIRB to review all unanticipated problems occurring locally and respond in a timely manner
    iv. Adapting your internal systems to the new CIRB model
    v. Workload increase on your PIs
    vi. Shifting the responsibility of review of locally-occurring adverse events from your local IRB to the CIRB
    vii. (Open ended follow up) Please use the space below to describe your greatest concern related to the new CIRB model.

5. What effect has the new model had on <u>your own</u> workload?
    i. (It has increased, It has decreased, or Stayed the same under the new model)

6. (Open ended follow up) How could the new model be improved so that it is more useful?

c) Tracking Measures:

Please provide the time it takes for each of the following activities for cooperative group studies. Please feel free to stop and save your responses if you need to find this information from additional resources at your institution.

1. How many hours, on average, does it take to complete and submit the Study-Specific Worksheet "About Local Context" for CIRB Review? _____ # hours

2. How many days, on average, does it take to receive confirmation from CIRB that your institution can accrue to the study? _____ # days

3. How many days, on average, does it take to prepare the management plan and CIRB submission for locally-occurring potential unanticipated problems? _____# days

4. How many days, on average, does it take to get amendments reviewed and approved by the CIRB? _____ # days

5. Are the numbers provided above generated from a database tracking system or are they estimates? _____database _____ estimates

d) Satisfaction with the pilot

The following questions ask your satisfaction with the pilot program itself. Please answer from your own perspective.

1. How much do you agree/disagree with the following statement: I am glad that my institution is participating in this pilot.
    i. (Strongly Disagree <-> Strongly Agree)
    ii. (Open ended follow up) Please use the space below to elaborate on your answer.

2. How satisfied are you with how the pilot of the new CIRB model is progressing?
    i. (Very satisfied ← → very unsatisfied)
    ii. (Open ended follow up) What is working well?
    iii. (Open ended follow up) What steps could be taken to improve the experience of participating in the pilot?

3. Please rate the amount of information provided to you about the pilot. Do you believe it has been:
    i. (Too little, just right, too much)
    ii. (Open ended follow up) What, if any, additional information about the pilot would be of help to you?

4. Indicate how much you agree with the following statement: I believe the information communicated was sufficient to know what to expect for our participation in the pilot.
    i. (Strongly agree ← → strong disagree)
    ii. (Open ended follow up) How could information about the pilot be better communicated?

e) Perceptions toward adopting the new model

The following questions ask your opinions toward adopting the new CIRB model long-term. Please answer from your own perspective.

1. Compared to [the original, facilitated CIRB model] (your previous IRB process for cooperative group studies), how easy or difficult has it been to maintain the new, independent CIRB model? *Note: items in [ ] are for sites that were already participating prior to the pilot; items in ( ) are for non-participating sites.*
    i. (Very easy ← → very difficult)
    ii. What steps would facilitate other institutions seeking to maintain use of the new model?

2. Overall, how much has the new CIRB model improved the operational efficiency of your institution's IRB process for cooperative group studies?
    i. (Not at all, very little, some, a lot)
    ii. (Open ended follow up) What internal changes has your institution needed to make to participate effectively in the new CIRB model?

3. How much confidence does your institution have in the long-term effectiveness of the new CIRB model?
    i. (Not at all, very little, some, a lot)

4. How likely is it that you would continue to use the new CIRB model if you were given the opportunity?
    i. (Very likely ← → very unlikely)
    ii. (Open ended follow up) What would improve your willingness to use the new CIRB model in the future?

5. How likely is it that you would recommend the new CIRB model to your colleagues at other institutions?
    i. (Very likely ← → very unlikely)
    ii. (Open ended follow up) What would improve your willingness to recommend the new CIRB model to others?

6. *[For institutions who had not previously participated in the CIRB]* How likely is it that your institution will now enroll as a CIRB participant if the new model is permanently available?
    i. (Very likely ← → very unlikely)
    ii. (Open ended follow up) What would improve its willingness to participate in the CIRB?

FOLLOW UP SURVEY—Endpoint

a) Assess satisfaction of new model

The following questions ask your satisfaction with the new CIRB independent model that you used during the pilot. Please answer from your own perspective.

1. Overall, how would you rate your satisfaction with the new CIRB independent review model?
    i. (Not at all satisfied <→ very satisfied)

2. Compared to the **original, facilitated review CIRB model**, please indicate which statement best describes your level of preference for the **new, independent model**:
    i. I **prefer the facilitated model a lot more** than the independent model
    ii. I **prefer the facilitated model somewhat more** than the independent model
    iii. I **prefer the independent model somewhat more** than the facilitated model
    iv. I **prefer the independent model a lot more** than the facilitated model
    v. I do not have a preference between the two models, both are **equally good**
    vi. I do not have a preference between the two models, both are **equally bad**
    vii. I have not had enough experience with the independent model to decide.
        a. (Open ended follow up) Please use the space below to briefly elaborate on your response.

3. Thinking of when you used the new CIRB model for cooperative group studies, how would you rate your satisfaction with each of the following: (not at all satisfied <--> very satisfied)
    i. Time required to obtain CIRB approval
    ii. Paperwork required to submit for CIRB approval
    iii. Communication between the research staff and CIRB staff
    iv. The process used to review local unanticipated problems
    v. The process used to report local unanticipated problems
    vi. Access to the CIRB for guidance in the event of local unanticipated problems and adverse events
    vii. (Open ended follow up) Please use the space below to describe your biggest concern with the new CIRB model.

b) Assess effectiveness of new model/pilot

The following questions ask your opinions about the new CIRB independent model that you used during the pilot. Please answer from your own perspective.

1. Overall, what is your reaction to the new CIRB model?
    i. (Very negative <→ very positive)

2. Overall, what is <u>your</u> <u>institution's reaction</u> to the new CIRB model?
    i. (Very negative <→ very positive)

3. For each benefit listed below, please indicate how likely your institution experienced it as a result of using the new CIRB model with cooperative group studies (Not at all likely <→very likely)
    i. You opened studies faster
    ii. You opened more cooperative group studies
    iii. The paperwork burden to open a study was reduced
    iv. It saved your institution money to oversee the IRB processes
    v. It reduced IRB oversight costs to your institution
    vi. There was a reduced liability risk to your institution as CIRB was the sole IRB of Record
    vii. The PI could decide to open cooperative group studies without formally presenting to your local IRB Board first
    viii. [include any new benefits listed from baseline survey]
    ix. (Open ended follow up) What other benefits did your institution experience as a result of the new model?

4. Considering your overall involvement in the pilot, please rate how much concern your institution has for each: (not at all concerned<→ very concerned)
    i. Maintaining the quality of CIRB human subjects protection review
    ii. Ability of CIRB to adequately review and assess all local context considerations, including recruitment materials developed by the Cooperative Group or locally
    iii. Ability of CIRB to review all unanticipated problems occurring locally and respond in a timely manner
    iv. Adapting your internal systems to the new CIRB model
    v. Workload increase on your PIs
    vi. Shifting the responsibility of review of locally-occurring adverse events from your local IRB to the CIRB
    vii. (Open ended follow up) Please use the space below to describe your greatest concern related to the new CIRB model.

5. What effect did the new model have on <u>your own</u> workload?
    i. (It increased, It decreased, or Stayed the same under the new model)

6. (Open ended follow up) How could the new model be improved so that it is more useful?

c) Tracking Measures:

Please provide the time it takes for each of the following activities for cooperative group studies. Please feel free to stop and save your responses if you need to find this information from additional resources at your institution.

1. How many hours, on average, did it take to complete and submit the Study-Specific Worksheet "About Local Context" for CIRB Review? _____ # hours

2. How many days, on average, did it take to receive confirmation from CIRB that your institution can accrue to the study? _____ # days

3. How many days, on average, did it take to prepare the management plan and CIRB submission for locally-occurring potential unanticipated problems? _____# days

4. How many days, on average, did it take to get amendments reviewed and approved by the CIRB? _____ # days

5. Are the numbers provided above generated from a database tracking system or are they estimates? _____database _____ estimates

d) Satisfaction with the pilot

The following questions ask your satisfaction with the pilot program itself. Please answer from your own perspective.

5. How much do you agree/disagree with the following statement: I am glad that my institution participated in this pilot.
    i. (Strongly Disagree <-> Strongly Agree)
    ii. (Open ended follow up) Please use the space below to elaborate on your answer.

6. How satisfied were you with how the pilot of the new CIRB model progressed?
    i. (Very satisfied ← → very unsatisfied)
    ii. (Open ended follow up) What worked well?
    iii. (Open ended follow up) What steps could be taken to improve the experience of participating in the pilot?

7. Please rate the amount of information provided to you about the pilot. Do you believe it was:
    i. (Too little, just right, too much)
    ii. (Open ended follow up) What, if any, additional information about the pilot would have been of help to you?

8. Indicate how much you agree with the following statement: I believe the information communicated was sufficient to know what to expect for our participation in the pilot.
    i. (Strongly agree ← → strong disagree)
    ii. (Open ended follow up) How could information about the pilot been better communicated?

e) Perceptions toward adopting the new model

The following questions ask your opinions toward adopting the new CIRB model long-term. Please answer from your own perspective.

1. Compared to [the original, facilitated CIRB model] (your previous IRB process for cooperative group studies), how easy or difficult has it been to maintain the new, independent CIRB model? *Note: items in [ ] are for sites that were already participating prior to the pilot; items in ( ) are for non-participating sites.*
    i. (Very easy ← → very difficult)
    ii. What steps would facilitate other institutions seeking to maintain use of the new model?

2. Overall, how much did the new model improve the operational efficiency of your institution's IRB process for cooperative group studies?
    i. (Not at all, very little, some, a lot)
    ii. (Open ended follow up) What internal changes did your institution have to make to participate effectively in the new CIRB model?

3. How much confidence does your institution have in the long-term effectiveness of the new CIRB model?
    i. (Not at all, very little, some, a lot)

4. How likely is it that you would continue to use the new CIRB model if you were given the opportunity?
    i. (Very likely ← → very unlikely)
    ii. (Open ended follow up) What would improve your willingness to use the new CIRB model in the future?

5. How likely is it that you would recommend the new CIRB model to your colleagues at other institutions?
    i. (Very likely ← → very unlikely)
    ii. (Open ended follow up) What would improve your willingness to recommend the new CIRB model to others?

6. *[For institutions who had not previously participated in the CIRB]* How likely is it that your institution will now enroll as a CIRB participant if the new model is permanently available?
    i. (Very likely ← → very unlikely)
    ii. (Open ended follow up) What would improve its willingness to participate in the CIRB?

Attachment 16C: Institution Worksheet for CIRB Pilot

OMB#: 0925 – 0046-16 Expiry Date: 2/28/2013

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. Your participation is completely voluntary. You are subject to no penalty if you choose not to provide all or any part of the requested information. Data collected as part of the NCI CIRB review will be kept secure to the extent provided by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be held in confidence and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0046-16). Do not return the completed form to this address.

Annual Institution Worksheet About Local Context for CIRB Review

These questions pertain to the Principal Investigator's primary practice location. Answer each question as completely as possible. This form will be returned to you annually for updating.

1) General Information
   A. Name of institution
   B. Mailing address
   C. Phone number
   D. Name of institution's contact person who can answer questions about responses provided on this form
   E. Phone number and email address for institution's contact person (Include mailing address if different from above.)

2) State and Local Law
   A. What is your state law and corresponding institutional policy regarding legally authorized representatives?
   B. What is age of majority in your state?
   C. Are there any other state or local laws that govern the conduct of research at your institution?

      Yes No

      If yes, list the state or local laws that govern the conduct of research at your institution and provide an explanation how your institution currently ensures compliance for each state or local law.

3) Research Compliance Office
   A. Identify the office at your institution responsible for research compliance, including potential unanticipated problems and/or serious or continuing noncompliance.

      Office:

   B. Provide the primary contact information for this office.

      Name:
      Phone number:
      Email:

4) Institutional Policies pertaining to the Informed Consent Document for Cooperative Group Studies
   A. Describe your institutional policies and guidelines that govern the informed consent document regarding these topics:
      a. Boilerplate language required by the institution in each informed consent document (such as birth control language, coverage of research injury, required phone numbers, etc.)
      b. Use of institutional letterhead (attach a blank copy of letterhead to be used)
      c. Other:

      Note: The language provided in Question #4 will be reviewed and approved by the CIRB. Changes to this language require CIRB review and approval before implementation.

5) Community Demographics
   List the zip codes that comprise your institution's catchment area. The CIRB Operations Office will obtain demographic data from the US census track using the zip code(s).

6) Community Attitudes:
   A. Does the community have a positive attitude toward the conduct of research?
      Yes No

      If no, please explain:

This form will be returned to the institution's contact person annually for updating.

Attachment 16D: Principal Investigator Worksheet for CIRB Pilot

OMB#: 0925 – 0046-16 Expiry Date: 2/28/2013

STATEMENT OF CONFIDENTIALITY

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NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0046-16). Do not return the completed form to this address.

Annual Institution Worksheet About Local Context for CIRB Review

These questions pertain to the Principal Investigator's primary practice location. Answer each question as completely as possible. This form will be returned to you annually for updating.

5) General Information
   F. Name of institution
   G. Mailing address
   H. Phone number
   I. Name of institution's contact person who can answer questions about responses provided on this form
   J. Phone number and email address for institution's contact person (Include mailing address if different from above.)

6) State and Local Law
   D. What is your state law and corresponding institutional policy regarding legally authorized representatives?
   E. What is age of majority in your state?
   F. Are there any other state or local laws that govern the conduct of research at your institution?

      Yes No

      If yes, list the state or local laws that govern the conduct of research at your institution and provide an explanation how your institution currently ensures compliance for each state or local law.

7) Research Compliance Office

C. Identify the office at your institution responsible for research compliance, including potential unanticipated problems and/or serious or continuing noncompliance.

Office:

D. Provide the primary contact information for this office.

Name:
Phone number:
Email:

8) Institutional Policies pertaining to the Informed Consent Document for Cooperative Group Studies

B. Describe your institutional policies and guidelines that govern the informed consent document regarding these topics:

a. Boilerplate language required by the institution in each informed consent document (such as birth control language, coverage of research injury, required phone numbers, etc.)
b. Use of institutional letterhead (attach a blank copy of letterhead to be used)
c. Other:

Note: The language provided in Question #4 will be reviewed and approved by the CIRB. Changes to this language require CIRB review and approval before implementation.

5) Community Demographics

List the zip codes that comprise your institution's catchment area. The CIRB Operations Office will obtain demographic data from the US census track using the zip code(s).

6) Community Attitudes:

B. Does the community have a positive attitude toward the conduct of research?

Yes No

If no, please explain:

This form will be returned to the institution's contact person annually for updating.

Attachment E: Study-Specific Worksheet for CIRB Pilot

OMB#: 0925 – 0046-16 Expiry Date: 2/28/2013

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. Your participation is completely voluntary. You are subject to no penalty if you choose not to provide all or any part of the requested information. Data collected as part of the NCI CIRB review will be kept secure to the extent provided by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be held in confidence and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0046-16). Do not return the completed form to this address.

Study-Specific Worksheet About Local Context for CIRB Review

1) Study ID Number and Title:

2) General Information:
   A. Name of Principal Investigator

   B. Will the research be conducted at any locations not listed on the **Annual Principal Investigator Worksheet About Local Context for CIRB Review** hereafter known as the Annual PI Worksheet?
   Yes No
   If so, please provide the mailing address.

   C. Current Phone number

   D. Are there any sub-investigators who will be enrolling subjects on this clinical trial who are not listed on the annual worksheet? Yes No

   If so, please provide their names.

The CIRB has your current Annual PI Worksheet on file. Please indicate in this section of this Study-Specific Worksheet only the information that is **different** from the Annual PI Worksheet.

1. General Information
   ☐ No change
   ☐ Changed, Describe changes

2. PI Resources
   - ☐ No change
   - ☐ Changed, Describe changes

3. Recruitment
   - ☐ No change
   - ☐ Changed, Describe changes

4. Compensation to Study Participants
   - ☐ No change
   - ☐ Changed, Describe changes

5. Informed Consent Process
   - ☐ No change
   - ☐ Changed, Describe changes

6. Pharmacy Information
   - ☐ No change
   - ☐ Changed, Describe changes

7. Measures to Protect Confidentiality
   - ☐ No change
   - ☐ Changed, Describe changes

8. Measures to Protect Privacy
   - ☐ No change
   - ☐ Changed, Describe changes

9. Emergency Resources
   - ☐ No change
   - ☐ Changed, Describe changes

10. Using a Legally Authorized Representative
    - ☐ No change
    - ☐ Changed, Describe changes

11. Vulnerable Populations
    - ☐ No change
    - ☐ Changed, Describe changes

12. Additional Confirmations –Pregnant Women
    - ☐ No change

☐ Changed, Describe changes

Confirmation of Intent to Comply:

I, as Principal Investigator, confirm I will comply with the Federal regulations pertaining to human research protections and Cooperative Group directives pertaining to this study. As Principal Investigator, I confirm that I oversee all sub-investigators and research staff assisting with this study and am responsible for their compliance with the same.

Attachment 16F: Study Transfer Worksheet for CIRB Pilot

OMB#: 0925 – 0046-16 Expiry Date: 2/28/2013

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. Your participation is completely voluntary. You are subject to no penalty if you choose not to provide all or any part of the requested information. Data collected as part of the NCI CIRB review will be kept secure to the extent provided by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be held in confidence and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0046-16). Do not return the completed form to this address.

One Time Study Transfer Worksheet for CIRB Review

This worksheet should only be completed by IRB staff with permission to submit a Facilitated Review Acceptance Form (FRAF). Only IRB staff with such permission can access the worksheet.

In order to participate in the pilot of the CIRB model redesign, it is necessary to transfer studies for which your IRB has conducted a facilitated review to the new review model.

The following is a list of studies for which your IRB has submitted a FRAF. The CIRB understands that local context concerns for these studies were considered by your IRB as a part of facilitated review. Please indicate to the CIRB any changes made to the protocol or informed consent document as a result of your IRB's review of local context for each study.

NOTE: Boilerplate language and letterhead changes as described in the Annual Institution Worksheet About Local Context for CIRB Review hereafter known as the Annual PI Worksheet, Question #3, do not have to be repeated on this Worksheet.

1. Study ID and Title (pre-filled)
   a. Did your IRB make any changes to the following based on review of local context considerations?
      1. Protocol ☐ No ☐ Yes, describe changes _____
      2. Informed Consent Document ☐ No ☐ Yes, describe changes _____
      3. Other Study Materials ☐ No ☐ Yes, describe changes _____

   b. Select the Principal Investigator for this study from the drop-down menu below.

c. The CIRB has your current Annual PI Worksheet on file. Indicate any sub-investigators who will be enrolling participants on this clinical trial who are not listed on the Annual PI Worksheet.

The above will be repeated for each study for which the IRB submitted a FRAF.

I understand the CIRB is now the sole IRB of Record per the new model for the transferred studies.

_____

Name of IRB Representative Completing this Worksheet

_____

IRB Representative Title