- **Form 5A: NCI Adult CIRB Application for Treatment Studies**
  Section L. was added to include Amendment-Specific Information. This change is necessary to clarify necessary information to the public for the CIRB. The additional time to complete this section is minimal. No additional burden to the public is foreseen.

Text deleted	Text added
	"SECTION L: AMENDMENT-SPECIFIC INFORMATION This section should be completed only when this application is being updated as the result of an amendment to the study 1.0 Briefly describe what prompted this amendment: ___ 2.0 Are any of the changes in this amendment significant enough to impact a study participant's willingness to continue participation in the research? [box] Yes [box] No 2.1 If yes, describe how these findings will be presented to study participants. ___ 2.2 If yes, should the study participants be reconsented? [box] Yes [box] No If yes, indicate how study participants will be reconsented (letter, addendum, reconsent). ____ Provide drafts of reconsent documents.
	Important Note: Please send the completed CIRb application and the informed consent document(s) to adultcirb@emmes.com

NCI ADULT CENTRAL IRB (CIRB) APPLICATION FOR TREATMENT STUDIES

OMB#: 0925 – 0625 Expiry Date: 1/31/2014

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 is confidential and protected 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 2 hours 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 (0925-0625*). Do not return the completed form to this address.

SECTION A: GENERAL INFORMATION

COOPERATIVE GROUP:

GROUP STUDY NUMBER:

STUDY VERSION DATE:

STUDY TITLE:

STUDY CHAIR	
Name	
Title	
Specialty	
Site	
Address	
Phone #	
E-mail	
FAX #	

STUDY CO-CHAIR (If applicable)	
Name	
Title	
Specialty	
Site	
Address	
Phone #	
E-mail	
FAX #	

CONTACT PERSON	
Name	
Title	
Specialty	
Site	
Address	
Phone #	
E-mail	
FAX #	

WILL THIS BE ON THE CTSU MENU?

PLEASE NOTE: CIRB membership includes individuals who are not part of the oncology and/or the scientific community. Therefore, you must use lay language (non medical, non legal terms) and define all terms unique to science when completing this application.

SECTION B: SUMMARY OF STUDY

Please answer each of the following questions in 250 words or less per question.

1. **State the question that this study will answer (i.e. hypothesis or study objectives):**

2. **Describe the background research that has led to your hypothesis/study objectives:**

3. **Describe the study.** (Include schema.)

4. **How will the research design answer the hypothesis?**

5. **How will the new information gained from this study impact the treatment for this disease or condition?**

6. **Will participants be required to discontinue or modify any current medication, or be denied any standard of care for any condition, in order to be eligible for participation?**

7. **Is there an interim safety monitoring plan for this study?**

☐ Yes ☐ No If yes, please explain.

SECTION C: PARTICIPANTS

1. **Number of participants to be enrolled in the study:**

2. Participant profile (Check all that apply.)

Gender:

☐ Male

☐ Female

Ethnicity

☐ American Indian or Alaska Native

☐ Asian

☐ Native Hawaiian or Other Pacific Islander

☐ Black or African American (not of Hispanic origin)

☐ White (not of Hispanic origin)

☐ Hispanic or Latino

3. Specify the age range of eligible participants:

If participants under the age of 18 years old are eligible, an assent form must be submitted.

4. Which of the following vulnerable populations are eligible to be participants (Check each item yes or no. A "no" indicates that all persons in that category are excluded.):

Incompetent persons (excluding minors): ☐ Yes ☐ No

(Incompetent persons include those who have a legal guardian or those whose mental status prevents them from giving truly informed consent and making decisions [such as those with advanced Alzheimer's disease]).

Physically or Mentally Disabled/Challenged ☐ Yes ☐ No

(Handicapped persons include those with a physical or mental impairment which substantially limits one or more major life activities [e.g. speaking, breathing, learning, working, caring for oneself, performing manual tasks, walking, seeing, hearing, etc.], has a record of such an impairment, or is regarded as having such an impairment)

Women with reproductive potential:	☐ Yes	☐ No
Pregnant women:	☐ Yes	☐ No
Men with reproductive potential:	☐ Yes	☐ No
Minorities:	☐ Yes	☐ No
Prisoners:	☐ Yes	☐ No

4A. Explanation of Exclusion: Federal IRB regulations require equitable selection of participants. In addition, NIH policy requires that minorities and women be adequately represented as research participants. If you checked "no" to any of the categories above, you must provide a scientific reason for such exclusion.

5. Recruitment

a) Provide the participant recruitment plan.

b) Provide any recruitment materials (if applicable) that participants will see.

c) Will the participants be paid or receive any other inducements (e.g., free medication, free medical care) for participating? ☐ Yes ☐ No If yes, please explain.

6. Will the participants bear any costs which are not a part of standard of care?

☐ Yes ☐ No

If yes,

a) List the relevant tests, procedures, hospitalizations, etc., for which the participants would be financially responsible.

b) Are there available means of subsidizing these extra costs for participants who cannot afford them?

☐ Yes ☐ No If yes, please explain.

SECTION D: DRUGS

1. Please provide the following information for all drugs to be used in this study. (This includes the study drugs PLUS any other medications specified in the study that the participant will receive while on this study):

Drug/study drug:

Manufacturer:

Supplier:

Is the drug/study drug being used under an IND?

☐ Yes (submit copy of Investigator's Brochure) ☐ No

IND# : _____ Holder of IND: _____

Drug/study drug:

Manufacturer:

Supplier:

Is the drug/study drug being used under an IND?

☐ Yes (submit copy of Investigator's Brochure) ☐ No

IND# : _____ Holder of IND: _____

Drug/study drug:
Manufacturer:
Supplier:
Is the drug/study drug being used under an IND?

☐ Yes (submit copy of Investigator's Brochure) ☐ No

IND# : _____ Holder of IND: _____

a.) Does this study include an off-label use of an FDA-approved drug?

☐ Yes ☐ No

If yes, please explain. (e.g. Has an IND been applied for? Is this study exempt from an IND? If exempt, please provide official FDA documentation.)

2. For all study drugs, include the following information:

(Study drugs are all drugs that are investigational or are being studied or compared, alone or as part of a regimen.)

a) The name of the study drug/regimen:

b) Likely/bothersome effects that are study drug/drug class/regimen specific:

c) Less likely effects that are study drug/drug class/regimen specific:

d) Rare but serious effects that are study drug/drug class/regimen specific:

Risks and side effects related to temozolomide include those that are:

Likely

-

Less Likely

-

Rare but Serious

-

SECTION E: RADIATION

1. Does this study involve radiation? ☐ Yes ☐ No (If no, skip to Section F.)

2. Specify the type of radiation that the participant will receive:

☐ Diagnostic ☐ Therapeutic ☐ Both

3. Will the participant receive radiation greater than normally received in the course of standard of care for this disease or condition?

☐ Yes ☐ No If yes, please explain.

4. Is any radiation modality experimental?

☐ Yes ☐ No If yes, list the risks associated with the experimental modality.

SECTION F: RISKS, BENEFITS AND ALTERNATIVES

1. List any known or foreseeable risks or discomforts to the participant from procedures or treatment associated with the study intervention(s). List the frequency and complications associated with each.

2. List measures planned to minimize risks identified in Question # 1.

3. How do the potential benefits outweigh the risks inherent in participating in the study?

4. **How would you treat this participant in a non-investigational setting? Please describe the treatment that is considered standard of care, as well as any alternative procedures or drugs or other courses of therapy that might be used, if such alternatives exist.**

SECTION G: GENETIC RESEARCH

Will the research identify genetic characteristics?* ☐ Yes ☐ No

If no, go to Section H.

*It may be useful to think of genetic research as being carried out on a continuum comprising of four stages: (1) to discover the pattern of inheritance of a disease and to catalog the range of symptoms involved (pedigree studies); (2) to localize and identify specific genes (positional cloning studies); (3) to develop techniques for determining the presence of specific DNA mutations (DNA diagnostic studies); and (4) to develop treatments for genetic disease at the DNA level (gene therapy research).

If yes:

a) **Will results be disclosed to the participants?**

☐ Yes ☐ No

If yes, describe in what way:

If yes, how will they be given the option to not receive the results?

b) **Will research findings be disclosed to participants' physicians for clinical use?**

☐ Yes ☐ No

If yes, Will this plan be discussed with the participants and their consent obtained?

c) **Will the possible psychological and social risks of genetic research be adequately considered in the consent process? Will appropriate counseling be provided, both as part of the consent process and also when communicating test or other research results to participants? Please explain.**

d) Will the data be protected from disclosure to third parties, such as employers and insurance companies? Describe confidentiality measures.

e) How are tissue samples secured?

f) What will happen to the tissue samples in the event that a participant withdraws from the study?

SECTION H: STORAGE OF SPECIMENS FOR FUTURE RESEARCH STUDIES

Does this study involve collection of specimens for future research studies?

☐ Yes ☐ No (If no, skip to Section I.)

If yes:

a) What are the types and amounts of specimens to be collected? Justify the types and amounts.

b) How will the specimens be linked to the participants?

c) For what types of research do you anticipate using the samples in the future?

d) How will access to the specimens be governed?

e) What procedure will be used if the participant withdraws consent after the specimen has been collected and stored?

SECTION I: ANCILLARY STUDIES

Will participants enrolled in this study be asked to register in any ancillary/companion studies?

☐ Yes ☐ No

If yes, are these studies:

- ☐ Mandatory
- ☐ Optional
- ☐ Both

PLEASE NOTE:

The CIRB will review any new ancillary/companion study regardless of whether participation is mandatory or optional.

*If an ancillary/companion study is already open, the policy is as follows. If a study **requires** that its participants also enroll in an ancillary/companion study, the CIRB must review the ancillary/companion study. A separate, Ancillary Study Application, the ancillary/companion study, and associated informed consent document(s) must be submitted to the CIRB for review and approval. Once an ancillary/companion study has been approved, it will not need to be resubmitted with each treatment study that it accompanies.*

The CIRB will review all ancillary/companion studies whose participation is mandatory for participants enrolled in an associated main treatment study, regardless of when the ancillary/companion study was activated and open to enrollment.

The CIRB will not review an ancillary/companion study if participation is optional and the study was activated and open to enrollment prior to the associated main treatment study's submission for CIRB review.

SECTION J: CONFLICTS OF INTEREST

1. **Does the Study Chair or any principal involved in the development or coordination of this study have any significant financial conflicts of interest as defined in the Conflict of Interest Policy for Cooperative Group Phase 3 Clinical Trials?**

   ☐ Yes ☐ No If yes, please answer question #2.

2. **Does the Cooperative Group have a management plan in place to address the conflicts disclosed in question #1?**

   ☐ Yes ☐ No If yes, please provide a copy of the management plan

SECTION K: INFORMED CONSENT

Please submit a copy of the informed consent document(s) for this study along with this application.

SECTION L: AMENDMENT-SPECIFIC INFORMATION

This section should be completed only when this application is being updated as the result of an amendment to the study.

1.0 Briefly describe what prompted this amendment: _____

2.0 Are any of the changes in this amendment significant enough to impact a study participant's willingness to continue participation in the research?
☐ Yes ☐ No

2.1 If yes, describe how these findings will be presented to study participants. _____

2.2 If yes, should the study participants be reconsented?
☐ Yes ☐ No

If yes, indicate how study participants will be reconsented (letter, addendum, reconsent). _____

Provide drafts of reconsent documents.

Important Note: Please send the completed CIRB application and the informed consent document(s) to adultcirb@emmes.com.

NCI ADULT CENTRAL IRB (CIRB) APPLICATION FOR TREATMENT STUDIES

OMB#: 0925 – 0625 Expiry Date: 1/31/2014

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 is confidential and protected 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 2 hours 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 (0925-0625*). Do not return the completed form to this address.

SECTION A: GENERAL INFORMATION

COOPERATIVE GROUP:

GROUP STUDY NUMBER:

STUDY VERSION DATE:

STUDY TITLE:

STUDY CHAIR	
Name	
Title	
Specialty	
Site	
Address	
Phone #	
E-mail	
FAX #	

STUDY CO-CHAIR (If applicable)	
Name	
Title	
Specialty	
Site	
Address	
Phone #	

E-mail	
FAX #	

CONTACT PERSON	
Name	
Title	
Specialty	
Site	
Address	
Phone #	
E-mail	
FAX #	

WILL THIS BE ON THE CTSU MENU?

PLEASE NOTE: CIRB membership includes individuals who are not part of the oncology and/or the scientific community. Therefore, you must use lay language (non medical, non legal terms) and define all terms unique to science when completing this application.

SECTION B: SUMMARY OF STUDY

Please answer each of the following questions in 250 words or less per question.

1. **State the question that this study will answer (i.e. hypothesis or study objectives):**

2. **Describe the background research that has led to your hypothesis/study objectives:**

3. **Describe the study.** (Include schema.)

4. **How will the research design answer the hypothesis?**

5. **How will the new information gained from this study impact the treatment for this disease or condition?**

6. **Will participants be required to discontinue or modify any current medication, or be denied any standard of care for any condition, in order to be eligible for participation?**

7. **Is there an interim safety monitoring plan for this study?**

☐ Yes ☐ No If yes, please explain.

SECTION C: PARTICIPANTS

1. **Number of participants to be enrolled in the study:**

2. **Participant profile** (Check all that apply.)

Gender:

☐ Male

☐ Female

Ethnicity

☐ American Indian or Alaska Native

☐ Asian

☐ Native Hawaiian or Other Pacific Islander

☐ Black or African American (not of Hispanic origin)

☐ White (not of Hispanic origin)

☐ Hispanic or Latino

3. **Specify the age range of eligible participants:**

If participants under the age of 18 years old are eligible, an assent form must be submitted.

4. **Which of the following vulnerable populations are eligible to be participants** (Check each item yes or no. A "no" indicates that all persons in that category are excluded.):

Incompetent persons (excluding minors): ☐ Yes ☐ No

(Incompetent persons include those who have a legal guardian or those whose mental status prevents them from giving truly informed consent and making decisions [such as those with advanced Alzheimer's disease]).

Physically or Mentally Disabled/Challenged ☐ Yes ☐ No

(Handicapped persons include those with a physical or mental impairment which substantially limits one or more major life activities [e.g. speaking, breathing, learning, working, caring for oneself, performing manual tasks, walking, seeing, hearing, etc.], has a record of such an impairment, or is regarded as having such an impairment)

Women with reproductive potential: ☐ Yes ☐ No

Pregnant women: ☐ Yes ☐ No

Men with reproductive potential: ☐ Yes ☐ No

Minorities: ☐ Yes ☐ No

Prisoners: ☐ Yes ☐ No

4A. Explanation of Exclusion: Federal IRB regulations require equitable selection of participants. In addition, NIH policy requires that minorities and women be adequately represented as research participants. If you checked "no" to any of the categories above, you must provide a scientific reason for such exclusion.

5. Recruitment

a) Provide the participant recruitment plan.

b) Provide any recruitment materials (if applicable) that participants will see.

c) Will the participants be paid or receive any other inducements (e.g., free medication, free medical care) for participating? ☐ Yes ☐ No If yes, please explain.

6. Will the participants bear any costs which are not a part of standard of care?

☐ Yes ☐ No

If yes,

a) List the relevant tests, procedures, hospitalizations, etc., for which the participants would be financially responsible.

b) Are there available means of subsidizing these extra costs for participants who cannot afford them?

☐ Yes ☐ No If yes, please explain.

SECTION D: DRUGS

1. Please provide the following information for all drugs to be used in this study. (This includes the study drugs PLUS any other medications specified in the study that the participant will receive while on this study):

Drug/study drug:

Manufacturer:

Supplier:

Is the drug/study drug being used under an IND?

☐ Yes (submit copy of Investigator's Brochure) ☐ No

IND# : _____ Holder of IND: _____

Drug/study drug:

Manufacturer:

Supplier:

Is the drug/study drug being used under an IND?

☐ Yes (submit copy of Investigator's Brochure) ☐ No

IND# : _____ Holder of IND: _____

Drug/study drug:
Manufacturer:
Supplier:
Is the drug/study drug being used under an IND?

☐ Yes (submit copy of Investigator's Brochure) ☐ No

IND# : _____ Holder of IND: _____

a.) Does this study include an off-label use of an FDA-approved drug?

☐ Yes ☐ No

If yes, please explain. (e.g. Has an IND been applied for? Is this study exempt from an IND? If exempt, please provide official FDA documentation.)

2. For all study drugs, include the following information:

(Study drugs are all drugs that are investigational or are being studied or compared, alone or as part of a regimen.)

a) The name of the study drug/regimen:

b) Likely/bothersome effects that are study drug/drug class/regimen specific:

c) Less likely effects that are study drug/drug class/regimen specific:

d) Rare but serious effects that are study drug/drug class/regimen specific:

Risks and side effects related to temozolomide include those that are:

Likely

-

Less Likely

-

Rare but Serious

-

SECTION E: RADIATION

1. Does this study involve radiation? ☐ Yes ☐ No (If no, skip to Section F.)

2. Specify the type of radiation that the participant will receive:

☐ Diagnostic ☐ Therapeutic ☐ Both

3. Will the participant receive radiation greater than normally received in the course of standard of care for this disease or condition?

☐ Yes ☐ No If yes, please explain.

4. Is any radiation modality experimental?

☐ Yes ☐ No If yes, list the risks associated with the experimental modality.

SECTION F: RISKS, BENEFITS AND ALTERNATIVES

1. List any known or foreseeable risks or discomforts to the participant from procedures or treatment associated with the study intervention(s). List the frequency and complications associated with each.

2. List measures planned to minimize risks identified in Question # 1.

3. How do the potential benefits outweigh the risks inherent in participating in the study?

4. How would you treat this participant in a non-investigational setting? Please describe the treatment that is considered standard of care, as well as any alternative procedures or drugs or other courses of therapy that might be used, if such alternatives exist.

SECTION G: GENETIC RESEARCH

Will the research identify genetic characteristics?* ☐ Yes ☐ No

If no, go to Section H.

*It may be useful to think of genetic research as being carried out on a continuum comprising of four stages: (1) to discover the pattern of inheritance of a disease and to catalog the range of symptoms involved (pedigree studies); (2) to localize and identify specific genes (positional cloning studies); (3) to develop techniques for determining the presence of specific DNA mutations (DNA diagnostic studies); and (4) to develop treatments for genetic disease at the DNA level (gene therapy research).

If yes:

a) Will results be disclosed to the participants?

☐ Yes ☐ No

If yes, describe in what way:

If yes, how will they be given the option to not receive the results?

b) Will research findings be disclosed to participants' physicians for clinical use?

☐ Yes ☐ No

If yes, Will this plan be discussed with the participants and their consent obtained?

c) Will the possible psychological and social risks of genetic research be adequately considered in the consent process? Will appropriate counseling be provided, both as part of the consent process and also when communicating test or other research results to participants? Please explain.

d) Will the data be protected from disclosure to third parties, such as employers and insurance companies? Describe confidentiality measures.

e) How are tissue samples secured?

f) What will happen to the tissue samples in the event that a participant withdraws from the study?

SECTION H: STORAGE OF SPECIMENS FOR FUTURE RESEARCH STUDIES

Does this study involve collection of specimens for future research studies?

☐ Yes ☐ No (If no, skip to Section I.)

If yes:

a) What are the types and amounts of specimens to be collected? Justify the types and amounts.

b) How will the specimens be linked to the participants?

c) For what types of research do you anticipate using the samples in the future?

d) How will access to the specimens be governed?

e) What procedure will be used if the participant withdraws consent after the specimen has been collected and stored?

SECTION I: ANCILLARY STUDIES

Will participants enrolled in this study be asked to register in any ancillary/companion studies?

☐ Yes ☐ No

If yes, are these studies:

☐ Mandatory

☐ Optional

☐ Both

PLEASE NOTE:

The CIRB will review any new ancillary/companion study regardless of whether participation is mandatory or optional.

*If an ancillary/companion study is already open, the policy is as follows. If a study **requires** that its participants also enroll in an ancillary/companion study, the CIRB must review the ancillary/companion study. A separate, Ancillary Study Application, the ancillary/companion study, and associated informed consent document(s) must be submitted to the CIRB for review and approval. Once an ancillary/companion study has been approved, it will not need to be resubmitted with each treatment study that it accompanies.*

The CIRB will review all ancillary/companion studies whose participation is mandatory for participants enrolled in an associated main treatment study, regardless of when the ancillary/companion study was activated and open to enrollment.

The CIRB will not review an ancillary/companion study if participation is optional and the study was activated and open to enrollment prior to the associated main treatment study's submission for CIRB review.

SECTION J: CONFLICTS OF INTEREST

1. **Does the Study Chair or any principal involved in the development or coordination of this study have any significant financial conflicts of interest as defined in the Conflict of Interest Policy for Cooperative Group Phase 3 Clinical Trials?**

   ☐ Yes ☐ No If yes, please answer question #2.

2. **Does the Cooperative Group have a management plan in place to address the conflicts disclosed in question #1?**

☐ Yes ☐ No If yes, please provide a copy of the management plan

SECTION K: INFORMED CONSENT

Please submit a copy of the informed consent document(s) for this study along with this application.

Important Note: Please send the completed CIRB application and the informed consent document(s) to pediatriccirb@emmes.com.