

## 1. Contacts and Title

### 1. Principal Investigator:

IRB Administrator

Email	Training	CoI Date
irb@hsc.utah.edu		

#### a. Position of Principal Investigator:

Faculty

Student

Staff

Resident/Fellow

Other

If Other, describe:

b. Will the Principal Investigator consent participants?  Yes  No

### 2. Contact Person(s) (if different from the PI):

Name	Email	Training
There are no items to display		

### 3. Internal Staff and Sub-Investigator(s) (Within the University of Utah):

Name	Email	Training	Obtaining Consent	CoI Date
There are no items to display				

### 4. External Sub-Investigator(s) (Investigators outside the University of Utah):

Last Name	First Name	Affiliation
There are no items to display		

### 5. Faculty Sponsor (if needed):

### 6. Guests:

Last Name	First Name	E-Mail
There are no items to display		

### 7. What type of application is being submitted?

New Study Application (or Amendment/Continuing Review)

### 8. Title Of Study:

EXEMPTION UMBRELLA: Molecular Analysis of Brain Tumors

### 9. Study Purposes and Objectives:

The purpose of this study is to allow for secondary analyses of previously collected clinical data and for molecular studies of pathology specimens in order to discover and validate molecular and clinical markers of prognosis, treatment effect, and risk of brain and spine tumors.

*This is a submission for an umbrella protocol that will cover all secondary data and tissue analyses conducted by the investigators on this application according to the aims above. This umbrella protocol meets the criteria for University of Utah IRB Exemption Category #7: "Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, where this information is personally identifiable or coded, AND:*

1. Research is not subject to FDA regulations.

2. Research is not federally funded.
3. Research is not contractually or otherwise subject to federal research requirements, including but not limited to research conducted under the Department of Veterans Affairs or under an NIH Certificate of Confidentiality.
4. Research does not involve prisoners as participants.
5. Research meets the University's ethical standards governing the conduct of the research, including appropriate provisions for the protection of privacy and confidentiality when identifiable and coded information are used.

## 10. Background and Introduction:

Gliomas are the most common primary malignant tumor of the central nervous system. Recent advances in metabolism, genetics, epigenetics, and genomics of gliomas have revolutionized our understanding of the categorization and evolution of gliomas. Much work remains to be done to apply this new understanding to the clinical care of brain tumor patients.

Secondary analyses of clinical and pathologic data serve many purposes. They facilitate the identification of clinically relevant subsets of patients and the identification and testing of molecular biomarkers. These kind of clinical-molecular correlative studies are necessary in the new era of precision medicine.

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PI: IRB Administrator

Submitted: 6/25/2013

Title: EXEMPTION UMBRELLA: Molecular Analysis of Brain Tumors

## 2. Study Location and Sponsors

### 1. Department:

ONCOLOGY

### 2. Location of Study:

University of Utah's Covered Entity (Health sciences, hospitals, and clinics)

### 3. Is this a Multicenter Study (i.e., the study involves other sites with other PIs):

Yes  No

#### a. If yes, are you the lead investigator of this study, or is this the central location for the study?

Yes  No

### 4. Indicate other locations that are participating in the study for which you, as the PI, are responsible:

Site Name	Other Site	Site Investigator	Investigator/Main Contact
There are no items to display			

#### a. How will adverse events, unanticipated problems, interim results, and changes to the research be communicated between the participating sites and the Principal Investigator?

### 5. Indicate the source(s) of funding obtained or applied for to support this study.

Sponsor	Sponsor Type	Sponsor Contact Information
View HCI NEURO/SPINE MULTIDISC PROG	UofU	74024

### 6. Does this study have functions assigned to a Contract Research Organization (CRO)?

Yes  No

If yes, CRO Contact Information:

### 7. Does this study involve use of the Utah Population Database (UPDB)?

Yes  No

## Sponsor Information

#### a. Sponsor:

HCI NEURO/SPINE MULTIDISC PROG

Previously, the following data was entered on your IRB application:

#### b. Sponsor Contact Information:

74024

#### c. If the funding type is "Federal Agency, or federal flow through", provide the following information:

**Grant Number:**

**Grant Awardee (Institution and Investigator):**

**Effective Start Date:**

**Effective End Date:**

**d. Are you working on this study with the University of Utah Office of Sponsored Projects to obtain this funding?**

Yes  No

**If no, please explain:**

N/A

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### 3. Participants

**1. Ages of Participants:**

18 and older (Consent form needed)

**2. Specific age range of participants (e.g., 7-12 years old, 60+, etc.):**

18+

**3. Indicate any vulnerable participant groups (other than children) included:**

None

**If "Other", please specify:**

**If "None" and no children are involved, answer the following question.**

**Has the participant selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?**

Yes  No

**4. Number of participants to be enrolled during the entire study:**

**At Utah:** approximately 2,000

**All Centers:** approximately 2,000

**5. Characteristics of Participants/Inclusion Criteria:**

Subjects for retrospective or tissue studies will be drawn from the neuro-oncology CCR database, which includes all patients with brain tumors in the UUHSC system.

The database will be queried usually based on diagnosis, identified either by WHO classification description or by ICD code. Other criteria that may be used to query the database may include, for example, age, gender, type of treatment, length of survival, tumor genetic alterations (e.g., IDH mutation status, EGFR amplification status, 1p/19q FISH results), tumor location, etc, that are all collected clinically.

**6. Participant Exclusion Criteria:**

None

**7. Is a substantial percentage of the participant population anticipated to be non-English speaking?**

Yes  No

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### 4. Study Information

**1. Design of Study (select all that apply):**

Secondary/Archival Data Analysis

**If Other, describe:**

**2. Does your study involve the use of any placebo?**

Yes  No

**3. Length of entire study, from initiation through closeout:** 15 years

**4. How will participants be recruited or identified for inclusion in the study?**

**a. Select all methods that will be used:**

Written or electronic record review

**b. Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):**

Eligible patients will be identified using the neuro-oncology CCR, the cancer registry, the electronic data warehouse, the electronic medical record, TRAC/itBioPath (IRB\_00010924), and similar collections of clinical patient data. Data and samples will be collected from these sources.

**5. How will consent be obtained?**

Waiver or Alteration of Informed Consent

**6. Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.**

We will use the neuro-oncology clinical cancer research database to track data. We will access data from the electronic medical record, electronic data warehouse, the cancer registry, and TRAC/itBioPath (IRB 10924). The database will be queried to identify groups of patients who meet particular criteria. Patient data may be verified in the electronic medical record. Groups of patients will be identified for retrospective clinical and molecular studies of brain and spine tumors.

For tissue studies, types of analyses may include PCR, immunohistochemistry, oncogene mutation identification by the Translational Oncology Core, Western Blotting, RNA microarray analysis, tumor copy number alteration by MIP analysis, etc.

**7. Are all procedures for research purposes only (non-standard or non-standard of care procedures)?**

Yes  No

**If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):**

**8. Is there a safety monitoring plan for this study?**

Yes  No

**9. Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.**

Statistical methods will depend on the particular question for studies. In general, studies will use cox survival analyses, t-tests/ANOVA of continuous variables such as age, and chi-square/Fisher exact tests for categorical variables such as gender. Statistical software available on the investigator's computers at HCI include SAS v9.3 and R v3.0.0.

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## Request for Waiver or Alteration of Consent

**Requested Waivers**

Date Created	Type of Request	Purpose of Waiver Request
View 6/25/2013	Waiver of Informed Consent	Review and analysis of all secondary data and tissue conducted by the investigators on this application according to the aims in this application.

## Request for Waiver or Alteration of Consent

**1. Purpose of the Waiver Request:**

Review and analysis of all secondary data and tissue conducted by the investigators on this application according to the aims in this application.

**2. Type of Request:**

Waiver of Informed Consent

**a. Will deception be used?**  Yes  No

**If yes, provide the rationale and describe the debriefing procedures:**

**3. List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc.).**

Names  
MRN  
Dates of procedures  
DOB

**4. Explain why the research could not practicably be conducted without the waiver or alteration. For example, complete the following sentence "If I had to obtain consent, the research could not be conducted because...":**

If consent were a requirement, the investigators would have to re-contact up to 2,000 individuals. Many of the patients are either deceased already or have moved away and therefore could not be reached in any practical way. The degree of effort would not be feasible for conducting this project.

**5. Explain why the research and privacy risk of the research are no more than *minimal*:**

The main risk is a breach of confidentiality, which is very unlikely. All PHI is kept in password protected databases on secure HCI computers. For analyses, PHI will be removed and replaced by study numbers.

**6. Describe the measures you will take to ensure the waiver or alteration will not adversely affect the rights and welfare of the *subjects*:**

Rights and welfare of subjects will not be adversely affected because all information was collected for clinical care, and the research will not change the treatment an individual receives.

**7. Explain how you will, if applicable and appropriate, provide the subjects with additional pertinent information *after* they have participated in the study, or indicate "*Not applicable*":**

Not applicable.

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## 5. Data Monitoring Plan

- 1. Privacy Protections:** Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **What precautions will be used to ensure subject privacy is protected?**

**Select all that apply:**

The collection of information about participants is limited to the amount necessary to achieve the aims of the research, so that no unneeded information is being collected

**Other or additional details (specify):**

- 2. Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. **What precautions will be used to maintain the confidentiality of identifiable information?**

**Select all that apply:**

Storing research data on password protected computers or in locked cabinets or offices

All data that will be transferred or transported outside of the institution will be encrypted

**Other or additional details (specify):**

- 3. Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?**

Yes  No

**If yes, describe the recording/images and what will become of them after creation (e.g., shown at scientific meetings, stored in the medical/research record, transcribed, erased, etc.):**

- 4. How will study data and documentation be monitored throughout the study?**

**Select all that apply:**

Periodic review and confirmation of participant eligibility

Periodic review of the transfer/transcription of data from the original source to the research record

Confirmation that all appropriate information has been reported to the sponsor, oversight agencies (such as the FDA), and/or IRB

Other or additional details (specify):

**Other additional details (specify):**

The study team will maintain a record of all specific projects and analyses that are conducted under this protocol, including documentation that each is conducted in accordance with the procedures and provisions described in this umbrella application. A report of the specific, individual projects/analyses will be submitted annually to the IRB via the ERICA Report Form for acknowledgement. This report will include the name of the investigators who conducted the specific project, the date the project began and ended (if ended), the actual or estimated number of patients whose data/tissue were/will be analyzed, and a short description of the specific aims and procedures for the projects.

The PI will ensure that any substantial amendments to the umbrella protocol, including changes in co-investigators, will be submitted to the IRB via an amendment application. The PI will also ensure that all possible unanticipated problems or instances of non-compliance related to any individual projects under this umbrella will be reported to the IRB according to standard IRB reporting policies.

- 5. Who will be the primary monitor of the study data and documentation?**

**Select all that apply:**

Principal Investigator

**Other or additional details (specify):**

- 6. How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?**

Annually

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## 6. Risks and Benefits

- 1. Describe the reasonable foreseeable risks or discomforts to the participants:**

Possible loss of confidentiality.

- 2. Describe the potential benefits to society AND to participants (do not include compensation):**

No direct benefit to participants.

Societal benefits include increased knowledge about brain tumors leading to better care and treatment of people with brain tumors.

- 3. Are there any costs to the participants from participation in research?**

Yes  No

**If yes, specify:**

- 4. Is there any compensation to the participants?**

Yes  No

- a. If yes, answer the following:**

**Specify overall amount:**

- b. Specify when participants will be paid (e.g. at each visit, at end of study, etc.):
- c. If applicable, please specify payment by visit or other time interval (e.g. \$10 per visit, etc.):
- d. If applicable, explain plan for prorating payments if participant does not complete the study:

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## 7. HIPAA and the Covered Entity

### 1. Does this study involve Protected Health Information (PHI) or de-identified health information?

Yes  No

#### a. If yes, select the method(s) of authorization that will be used:

Waiver or Alteration of Authorization

De-identified

If needed, select De-Identification Form: [Safe Harbor De-Identification](#)

#### b. If yes, will PHI be disclosed outside the Covered Entity?

Yes  No

If so, to whom?

And for what purposes?

### 2. Does this study involve any of the following:

#### a. The investigational use of a drug?

Yes  No

#### b. The investigational use of a medical device?

Yes  No

#### c. Is this an investigator-initiated drug or device trial lead by the Principal Investigator?

Yes  No

#### d. Exposure to radioisotopes or ionizing radiation?

Yes  No

#### e. Does the study involve cancer patients and address a cancer question?

Yes  No

#### f. Obtaining data or information from the UHSC Enterprise Data Warehouse (EDW) in a query outside of the Utah Population Database (UPDB)?

Yes  No

#### g. Any component of the Center for Clinical and Translational Science (CCTS)?

Yes  No

The Clinical Services Core (CSC)?

Yes  No

#### h. A Humanitarian Device Exemption (HDE)?

Yes  No

#### i. Creating or sending samples to a tissue bank/repository?

Yes  No

#### j. The use of human subjects and biological agents (e.g., staphylococcus aureus, adenovirus), or the deliberate transfer of recombinant DNA vectors/plasmids (recombinant DNA, or DNA or RNA derived from recombinant DNA) into human research participants?

Yes  No

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## Request for Waiver or Alteration of Authorization

### Request for Waiver of Authorization for **Recruitment Only**

*This option must only be used if you are reviewing PHI in order to identify eligible participants BEFORE approaching them to obtain consent and authorization. All other waiver requests must be entered below.*

#### Other Requests for Waivers of Authorization:

- Click "Add" below to add a new waiver request to this application.
- Click the waiver name link to edit a waiver that has already been created.
- To delete a waiver request, contact the IRB.

Date Created	Type of Request	Purpose of Waiver Request
<a href="#">View</a> 8/8/2013	Waiver of Authorization	Review and analysis of all secondary data and tissue conducted by the investigators on this application according to the aims in this application.

## Request for Waiver or Alteration of Authorization

### 1. Purpose of the Waiver Request:

Review and analysis of all secondary data and tissue conducted by the investigators on this application according to the aims in this application.

### 2. Type of Request:

Waiver of Authorization

### 3. List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc).

Names  
MRN  
Dates of procedures  
DOB

### 4. Explain why the PHI to be used or disclosed is the minimum necessary to accomplish the research objectives:

The identifiers are necessary for linkage across databases that are queried.

### 5. Explain why the research could not practicably be conducted without the waiver of authorization. For example, complete the following sentence: "If I had to obtain authorization, the research could not be conducted because..."

If authorization were a requirement, the investigators would have to re-contact up to 2,000 individuals. Many of the patients are either deceased already or have moved away and therefore could not be reached in any practical way. The degree of effort would not be feasible for conducting this project.

### 6. Describe your plan to protect the identifiers from improper use and disclosure, and indicate where the PHI will be stored and who will have access:

The main risk is a breach of confidentiality, which is very unlikely. All PHI is kept in password protected databases on secure HCI computers. For analyses, PHI will be removed and replaced by study numbers.

### 7. The identifiers must be destroyed 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. Describe how and when you will destroy the identifiers, or justify their retention:

Each individual project under this umbrella protocol will use identifiable information for the



time linkage and analysis is being conducted. Identifiers may be retained while publication is being sought, such that results can be verified. PHI will not be used beyond this point.

- 8. Describe the measures you will take to ensure the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research approved by the IRB:**  
Only investigators and study staff working on individual projects under this umbrella protocol will use and access PHI. Any research information disclosed outside of the covered entity will be de-identified.

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## Safe Harbor De-Identification

**1. This declaration applies to the following part(s) of this study:**

- A.  All of the information used or disclosed in this study.
- B.  The information received or collected from these sources:
- C.  The information shared with or disclosed to these groups: Any information disclosed outside of the U of Utah covered entity

**2. As the principal investigator for this study, I declare the following:**

- A. To the best of my knowledge, the information could not be used (alone or with other information) to identify an individual who is a subject of the information, and
- B. None of the following types of information, regarding subjects or relatives, employers, or household members of subjects, are used or disclosed in the part of this study indicated above:
- Names;
  - All geographic identifiers except state or the first three digits of a zip code (however, all data from the following 17 3-digit zips are combined together under "000": 036, 059, 063, 102, 203, 556, 692, 790, 821, 823, 830, 831, 878, 879, 884, 890, and 893)
  - The month and day (the year can be kept) from all dates directly related to an individual, including birth date, admission date, discharge date, date of death. Ages over 89 are combined in a single category of "Age 90 and older."
  - Telephone numbers;
  - Fax numbers;
  - Electronic mail addresses;
  - Social security numbers;
  - Medical record numbers;
  - Health plan beneficiary numbers;
  - Account numbers;
  - Certificate/license numbers;
  - Vehicle identifiers and serial numbers, including license plate numbers;
  - Device identifiers and serial numbers;
  - Web Universal Resource Locators (URLs);
  - Internet Protocol (IP) address numbers;
  - Biometric identifiers, including finger and voice prints;
  - Full face photographic images and any comparable images; and,
  - Any other unique identifying number, characteristic, or code, except as permitted for re-identification.

**3. If I assign a code or other means of record identification to allow de-identified information to be re-identified,**

- A. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual, and
- B. I will not use or disclose the code or other means of record identification for any purpose other than re-identification, and I will not disclose the mechanism for re-identification.

**4. Before I allow a code to be used to re-identify this information,**

- A. If the purpose of the re-identification is within the scope of the original protocol, I will obtain approval of an amendment from the IRB and comply with the requirements of HIPAA; or
- B. If the purpose of the re-identification is outside the scope of the original protocol, I will submit a full New Study Application, obtain IRB approval, and comply with the requirements of HIPAA.

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## 8. Resources and Responsibilities

**1. State and justify the qualifications of the study staff:**

All investigators are experienced researchers who have conducted multiple retrospective and tissue correlative studies.

**2. Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:**

All staff and investigators will perform CITI training or equivalent, as well as HIPAA training through the institution.

**3. Describe the facilities to be used for the research activities (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.):**

HCI computer network.

**4. Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.**

N/A

## Documents and Attachments

If any of your documents (such as investigational brochures, sponsor protocols, advertisements, etc.) are not available in an electronic format, please scan and save them as PDF files or contact our office for assistance.

**Naming Documents:** Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.

Examples:

- Consent Document Control Group 04/14/05
- Consent Document Treatment Group 4/14/05
- Sponsor Protocol 04/14/05 Version 2
- Assent Document (Highlighted Changes)

[Apple/Macintosh Users: MS Word documents must have a .doc file extension. See ERICA home page for instructions.](#)

**Print View: IRB Draft Protocol Summary**

**eProtocol Summary:**

Name	Version	Date Created	Date Modified
There are no items to display			

**Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:**

Name	Version	Date Created	Date Modified
There are no items to display			

**Parental Permission Documents:**

Name	Version	Date Created	Date Modified
There are no items to display			

**Assent Documents:**

Name	Version	Date Created	Date Modified
There are no items to display			

**VA Consent Documents:**

Name	Version	Date Created	Date Modified
There are no items to display			

**Surveys, Questionnaires, Interview Scripts, etc.:**

Name	Version	Date Created	Date Modified
There are no items to display			

**Full Protocol (company protocol, sponsor protocol, investigator-initiated protocol, etc.):**

Name	Version	Date Created	Date Modified
There are no items to display			

**Investigational Brochure (IB) for Investigational Drug or Drug/Device Package Insert:**

Name	Version	Date Created	Date Modified
There are no items to display			

**Grant Application:**

Name	Version	Date Created	Date Modified
There are no items to display			

**Literature Cited/References:**

Name	Version	Date Created	Date Modified
There are no items to display			

**Principal Investigator's Scholarly Record (CV/Resume):**

Name	Version	Date Created	Date Modified
There are no items to display			

**Faculty Sponsor's Scholarly Record (CV/Resume):**

Name	Version	Date Created	Date Modified
There are no items to display			

**Other Stamped Documents:**

*Only attach documents here as directed by the IRB, such as the Data/Information Request Form for UUHSC EDW.*

Name	Version	Date Created	Date Modified
There are no items to display			

**Recruitment Materials, Advertisements, etc.:**

Name	Version	Date Created	Date Modified
There are no items to display			

**Other Documents:**

Name	Version	Date Created	Date Modified
There are no items to display			

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