Date: 8/2/2013 3:25:11 PM

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IRB_00065804 **Created:** 5/31/2013 1:27 PM

PI: **Submitted:** 5/31/2013

Title: Congress Studies Umbrella Protocol

1. Contacts and Title

1. Principal Investigator:

Email	Training	CoI Date

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:
Congress Studies Umbrella Protocol

9. Study Purposes and Objectives:

The overall goal of the research is to understand the motivations and behavior of members of Congress and staff, including in activities that take place behind the scenes, through various forms of analysis including interviews.

This is a submission for an umbrella protocol that will cover all the research conducted by the principal investigator that meet the criteria identified in Exempt Categories of Research numbers 2 and number 3:

Exemption Category 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

a. Information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects and

b. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.
c. Research involves children, with the exception of research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. (45 CFR 46.101(b))
d. Research is subject to FDA regulations.
e. Research involves prisoners as participants.
f. Research fails to meet the University's ethical standards governing the conduct of the research.

Exemption Category 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures interview procedures or observation of public behavior that is not exempt under paragraph #2 if:

a. The human subjects are elected or appointed public officials or candidates for public office, or
b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
c. Research is not subject to FDA regulations.
d. Research does not involve prisoners as participants.
e. Research meets the University's ethical standards governing the conduct of the research.

10. Background and Introduction:

This research aims to understand the behavior of members of Congress individually and Congress as a collective institution. Most important congressional action takes place behind the scenes and is not readily understood through the analysis of publicly available data alone. Interviews with members of Congress and their appointed staff allow the researcher to investigate these behind the scenes activities and the motivations of lawmakers engaging in them. In addition, through interviews public data can be connected to these non-public acts for additional analyses.

A list of citations related to this study can be found attached to this form.

2. Study Location and Sponsors

1. Department:
POLITICAL SCIENCE DEPARTMENT

2. Location of Study:

University of Utah - Main Campus (Outside the Covered Entity)

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

There are no items to display

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**

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.):**
   Members of Congress are 25 years or age and older. Staff can be any adult age, but are likely to be at least 22.
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: indeterminant

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

   Participants may include any elected member of the United States Congress and the staff hired and appointed by the elected members.
6. **Participant Exclusion Criteria:**

   None.
7. **Is a substantial percentage of the participant population anticipated to be non-English speaking?**

   ○ Yes ◉ **No**

4. Study Information

1. **Design of Study (select all that apply):**
   Interviews and Focus Groups
   If Other, describe:
2. **Does your study involve the use of any placebo?**
   ○ Yes ◉ **No**
3. **Length of entire study, from initiation through closeout:** The blanket protocol should be reviewed and updated (if needed) annually.
4. **How will participants be recruited or identified for inclusion in the study?**
   a. **Select all methods that will be used:**
      Other

      Potential participants include all elected members of Congress, who are readily identifiable, and their paid staff, who are identifiable through public record.
   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.):**

      Members of Congress and staff are generally hesitant to grant interviews and for this reason a true random sample of participants is not realistic. Instead, interviews are obtained using a cluster, or snow-ball, sampling procedure. Initial participants are cold-contacted by the

      researcher. Each participants is then asked to refer additional potential participants who are then contacted using this reference. This process allows the researcher access to individuals who otherwise may be biased against granting an interview.
5. **How will consent be obtained?**
   Informed Consent Process (with or without a document)

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

Methods of study include data analyses, interviews, and case studies. Since this blanket protocol intends to cover many studies, the following example is provided to communicate work typical of what will be conducted:

An intensive study of the role informational asymmetries play in the influence of congressional party leaders and committee chairs in the legislative process will be conducted. This study will involve the collection and analysis of public data on congressional activities, interviews, case studies.

Collection and Analysis of Public Data. Data on legislative histories and roll-call votes in Congress are publicly recorded and updated by the Library of Congress. These data are accessible online using THOMAS (http://thomas.loc.gov). Data are collected on a sample of important legislation considered in the House of Representatives between the 1999 and 2010. These data include the subject matter of the legislation, bill referral, the schedule of the legislative process, procedural mechanisms employed, and data on roll-call votes taken. These data are collected primarily by the principal investigator but may also be collected by research assistants.

Interviews. Interviews with members of Congress and staff are conducted, transcribed and analyzed by the principal investigator alone. Information obtained from the interviews is used anonymously with participants identified only as either a member or staffer, and by the institutional position they hold (party leader, committee leader, rank-and-file). The interviews themselves are semi-structured and are composed primarily of open-ended questions. Participants are identified for interview using a cluster (or snow-ball) sampling method and are contacted via email. Consent for the interview is obtained first via email, and then again orally immediately prior to the interview taking place. The interviews are audio-recorded with consent from the participant and can be ended by the participant at any time. All interviews occur either in person or by phone. Forty interviews are conducted in total.

The purpose of the interviews is to investigate aspects of the legislative process not observable through the analysis of public data including activities that take place behind the scenes, such as information sharing and communication among lawmakers, and vote-whipping. The interviews also allow the researcher to understand the motivations of lawmakers in taking the activities that are observable in public. For this study, specifically, the interviews investigate the means by which leaders and chairs exploit their informational advantages in Congress to pressure rank-and-file partisans to follow their lead.

Attached to this application is an example contact email, example oral consent and recording consent, and an example interview script.

Case Studies. Case studies are of specific bills to illuminate how the the actions of party leaders and committee chairs in the legislative process influences what is included in the legislative text considered in Congress and ultimately what is passed into law. In applying what is learned through interviews and data analyses to tangible cases, the lessons are made more concrete.

Statistical Methods & Data Analysis: Evaluation includes assessment of the evidence gained through interviews, statistical analyses of the public data, and presentation of the case studies.

First, the interview evidence presents the importance of information to lawmakers' jobs, and the motivations of party leaders and committee chairs to exploit their informational advantages. In addition, the interviews identify the specific tactics used by leaders and chairs to exploit their advantages.

Second, the public data on legislation and legislative action are analyzed to demonstrate how procedural techniques identified in the interviews are used by leaders and chairs and to what affect. Specifically, various multivariate regression analyses are employed to isolate the impact of the specified factor controlling over other known predictors of aggressive procedural maneuvers and of roll-call voting behavior. These analyses specifically examine important legislation considered in the House of Representatives between 1999 and 2010. In total more than 500 bills are analyzed.

Third, case studies apply the lessons from the interviews and statistical analyses to tangible cases. The case studies primarily draw on legislative histories, bill texts and summaries, and on newspaper coverage of specific bills.

Data Management: The public data on legislation is stored simultaneously on the principal investigator's password-protected office and home computers and is accessible by the principal investigator and any research assistants hired. Since these data are all public data they do not require any additional protection.

Data and recordings from the interviews are securely and safely stored to ensure the privacy and confidentiality of the participants. Recordings from the interviews are on mini-cassettes and are stored in a locked cabinet in the principal investigator's office. Each cassette is labeled only with an identification number corresponding to each participant. Data on each participant including their name, institution positional, and identification number are stored separately on the principal investigator's password-protected computer in a password-protected folder. Additionally, transcripts of each interview are stored in a separate password-protected folder and are identified only by each participants' identification number. Only the principal investigator has access to the cassettes, files, and transcripts. The emails used to contact each participant are not connected in any way to the identification numbers and are deleted shortly after the interview takes place.

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.**

Specific methods and analyses will vary based on each project's unique needs. However, consistent with the example provided in #6 above, the following is an example of analyses typically conducted:

Statistical Methods & Data Analysis: Evaluation includes assessment of the evidence gained through interviews, statistical analyses of the public data, and presentation of the case studies.

First, the interview evidence presents the importance of information to lawmakers' jobs, and the motivations of party leaders and committee chairs to exploit their informational advantages. In addition, the interviews identify the specific tactics used by leaders and chairs to exploit their advantages.

Second, public data on legislation and legislative action are analyzed to demonstrate how procedural techniques identified in the interviews are

used by leaders and chairs and to what affect. Specifically, various multivariate regression analyses are employed to isolate the impact of the specified factor controlling over other known predictors of aggressive procedural maneuvers and of roll-call voting behavior. These analyses specifically examine important legislation considered in the House of Representatives between 1999 and 2010. In total more than 500 bills are analyzed.

Third, case studies apply the lessons from the interviews and statistical analyses to tangible cases. The case studies primarily draw on legislative histories, bill texts and summaries, and on newspaper coverage of specific bills.

IRB_00065804 **Created:** 5/31/2013 1:27 PM

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Consent Process

1. **The following investigators and internal staff will obtain consent (as indicated on the Contacts and Title Page):**

   There are no items to display

   List by name, role, and affiliation any others who will obtain consent (e.g. Dr. John Smith, Co-Investigator, etc.).
   None.

2. **Describe the location(s) where consent will be obtained.**
   Consent will be obtained over email when participants are initially contacted and again in person or over the phone immediately before the interview.

3. **Describe the consent process(es), including the timing of consent. Describe whether there is a waiting period between the consent process and obtaining consent from the participant (i.e., any time between informing participants and actually obtaining consent).**

   Consent will be obtained twice. First, consent will be obtained for the interview when potential participants are contacted via email. At this time potential participants will be informed of the purpose of the study and the anonymous nature of the interview. Participants can ignore or refuse to be interviewed. Second, consent will again be obtained orally immediately before the interview. The study again will be described as will how their interview responses will be used anonymously. They will have the opportunity to ask questions or refuse to consent before the formal interview begins.

   The PI will ensure that any consent documents or verbal consent discussions used for the projects include at a minimum the following elements:
   (1) That participation is voluntary.
   (2) That their participation is for academic research.
   (3) A description of the procedures.
   (4) The name and contact information of the principal investigator.

4. **Describe what measures will be taken to minimize the possibility of coercion or undue influence.**
   Each consent process will include a oral or written discussion of the elements described above. Participants will be allowed to ask questions about their participation in the study.

5. **Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and participant.**
   Participants will have the opportunity to ask questions after the initial email and again immediately before the interview.

6. **Will a legally authorized representative (LAR) be used?**

   ○ Yes ◉ **No**

   If yes, describe when the use of an LAR might arise in this study population and what the frequency of an LAR will be during the enrollment period.

7. **Will a language other than English be used to obtain consent?**
   ○ Yes ◉ **No**

   If yes, complete the following:

   a. **Please indicate which form will be used:**

      If using the short form, please provide justification for why a full, translated consent document will not be used:

   b. **Describe whether translation services will be used for the consent process and how the consent process will be conducted?**

8. **Are you requesting that documentation of informed consent be waived by the IRB (a consent process in place, but no documentation of consent, e.g. questionnaire cover letter, web-based consent, consent without signature, etc.)?**
   ◉ **Yes** ○ No

   If yes, complete the following:

   a. **Explain why the waiver of consent documentation is being requested.**
      The waiver of consent documentation is being requested because there is minimal risk to participants. Consent from participants will be obtained twice before the interview begins (once over email and once orally). If participants wish not to participate they can refuse, and during the interview they can refuse to answer any question or end the interview at any time. Ultimately, the information provided is entirely at the discretion of the participant.

entirely at the discretion of the participant.

b. Justification for the waiver is one of the following:

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

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 research intervention is conducted in a private place

   Discussing the study with participants individually instead of in front of a group

   De-identification of photos, audio tapes, or video tapes of the participant that will be made during the study

   Other or additional details (specify):

   Other or additional details (specify):
   Participants have the option to refuse to answer any specific questions or end the interview at any time. In general they have absolute control over what is and is not shared.

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

   Participant identifiers will be stored separately from the coded, participant data

   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.):
   Recordings of each interview (when consented by the participant) will be made on mini-cassette tapes and will be stored on a locked cabinet labelled only with an identification number. Only the principal investigator will have access to the tapes. The tapes will be destroyed when the research project is complete.

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

   Select all that apply:

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

   Other or additional details (specify):

   Other additional details (specify):
   All interview materials, files, and data are managed and maintained by the principal investigator alone, and are securely stored. No research assistants or other persons will have access.

   The PI 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.)?**
   Data and documentation monitoring will be ongoing for as long as each individual project is alive. A report of individual studies taking place will be submitted to the IRB every year via the Report Form in ERICA. The reports will include the names of the studies and a short description of each. The report will also confirm that the studies were conducted according to the Umbrella Protocol.

6. Risks and Benefits

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

   The are no known risks to the participants. Participants can refuse to answer any questions or end the interview at any time. Participation is completely voluntary and the information provided is entirely at the discretion of the participants.

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

   This studies conducted under this umbrella protocol will improve scholarly and public understanding of the United States Congress, congressional representatives and senators, and the lawmaking process. Through interviews an understanding of behind the scenes activities and the motivations of lawmakers will be achieved that could not through the analysis of public data alone.

   There are no known benefits to the participants.

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:**

IRB_00065804 **Created:** 5/31/2013 1:27 PM
PI: **Submitted:** 5/31/2013
Title: Congress Studies Umbrella Protocol

8. Resources and Responsibilities

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

   See the attached c.v. of the principal investigator.

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:**

   These studies will be conducted primarily by the principal investigator. Any research assistants employed will receive prior and ongoing training for the specific work they are hired to accomplish. No staff will be employed to assist with the interviews.

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

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.**
   Not applicable.

IRB_00065804 **Created:** 5/31/2013 1:27 PM

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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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Finish Instructions

Finish Instructions

1. **To view errors, select the "Hide/Show Errors" option at the top or bottom of the page. If you have errors on your application, you won't be able to submit it to the IRB.**
2. **Selecting the Finish button will NOT submit the application to the IRB.**
   You MUST select the "Submit" option on the workspace once you've selected the "Finish" button.
3. **If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.**