ClinicalTrials.gov Registration
User’s Guide
What is ClinicalTrials.gov?

ClinicalTrials.gov is a service of the U.S. National Institutes of Health that acts as a registry and results database of publicly and privately supported clinical studies of human participants. The Department of Health and Human Services (HHS), the Food and Drug Administration, the National Institutes of Health (NIH), and the International Committee of Medical Journal Editors (ICMJE) all require the public registration of clinical trials and, in some cases, the posting of trial results.
When is Registration and Reporting Required?

ClinicalTrials.gov registration is required for all federally sponsored clinical trials or studies that meet FDA’s definition of an "applicable clinical trial" (ACT) regardless of funding. ACTs, as defined in section 402(j) of the PHS Act, include the following:

- Controlled clinical investigations (other than phase 1 investigations) of any U.S. Food and Drug Administration (FDA)-regulated drug or biological product for any disease or condition

- Certain studies of FDA-regulated medical devices, excluding small clinical trials to determine feasibility and certain clinical trials to test prototype devices, but including FDA-required pediatric postmarket surveillances of a device product

Checklist for Evaluating Whether a Clinical Trial is an Applicable Clinical Trial
What does registering with ClinicalTrials.gov achieve?

Researchers, authors, and sponsors have an ethical obligation to publish and disseminate research results, whether positive, negative, or inconclusive. As outlined by the ICMJE and ClinicalTrials.gov, registering your trial and posting results serves to:

• Help patients and the public know what trials are planned or ongoing into which they might want to enroll.
• Prevent selective publication and selective reporting of research outcomes.
• Prevent unnecessary duplication of research effort.
• Help give ethics review boards considering approval of new studies a view of similar work and data relevant to the research they are considering.
• Help editors and others understand the context of study results.
• Promote more efficient allocation of research funds.
How do I obtain an account in order to register?

Principal Investigators must register their own studies in the PRS (Protocol Registration & Results System) at [http://register.clinicaltrials.gov](http://register.clinicaltrials.gov). To obtain a user account or to appoint a designee to maintain the ClinicalTrials.gov record on their behalf, Principal Investigators must contact Chapman PRS Administrator: mibriggs@chapman.edu

Please note that only Principal Investigators can appoint their own designee(s) and a designee must have a Chapman.edu email address to qualify for a user account.
Tips and Recommendations

✓ Chrome and Firefox are more likely to let you “expand” text boxes to see more
✓ Use MS Word to create and edit these fields carefully
✓ Do not use first or second person. Replace “I” and “we” with “the investigator”; replace “you” with “participants”
✓ Typos and spelling errors are not acceptable
✓ Define all acronyms
✓ Use notes provided by PRS system to guide you (suggestions/reminders; not mandatory)
✓ The Draft Receipt function provides a copy of your record as it appears in PRS
Validation Messages

• As you enter information, system validation (error, warning and note) messages may appear and disappear.
• Start by entering information for all required data elements.
• Note that some data elements are required, while others are conditionally required (based on information entered for other data elements).
• Finish by addressing all remaining validation messages.
• Complete all required fields before checking/stressing on validation.
Public Site

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 264,317 research studies in all 50 states and in 203 countries.

Before participating in a study, talk to your health care provider and learn about the risks and potential benefits.

Find a study

- Recruitment status
  - Recruiting and not yet recruiting studies
  - All studies
- Condition or disease
- Other terms
- Country

Search

Patients and Families

Search for actively recruiting studies that you may be able to participate in or learn about new interventions/treatments that are being considered.

Researchers

Search the database to stay up to date on developments in your field, find collaborators, and identify unmet needs.

Study Record Managers

Learn about registering studies and about submitting their results after study completion.
Protocol Registration and Results System

Organization Name: ChapmanU. To obtain a new ClinicalTrials.gov user account, please contact mibriggs@chapman.edu
To create a new record, click the New Record link or use the Records drop down menu.

The system flags records with problems to be addressed.
This title will be displayed in search results.

IRB Protocol #

[*] Brief Title: A 24-Week Double Blind Trial of Remuverol in Adults with Condition A

[*] Acronym: (if any)

If specified, will be included at end of Brief Title in parentheses.

* Study Type:
  - Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol
  - Observational participants not assigned to intervention(s) based on a protocol; typically in context of routine care
  - Expanded Access availability of an experimental drug or device outside of a clinical trial protocol

Expanded Access records should only be created by the product manufacturer.

More explanations for this stage on next screen.
### The Help link contains examples and data entry tips

* Organization's Unique Protocol ID: Pro00000123

* Brief Title: A 24-Week Double Blind Trial of Remuverol in Adults with Condition A

[*] Acronym: (if any) If specified, will be included at end of Brief Title in parentheses.

* Study Type:
  - **Interventional** (or clinical trial) — participants assigned to intervention(s) based on a protocol
  - **Observational** participants not assigned to intervention(s) based on a protocol; typically in context of routine care
  - **Expanded Access** availability of an experimental drug or device outside of a clinical trial protocol

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* Required
* $^s$ Required if Study Start Date is on or after January 18, 2017
* [*] Conditionally required (see Definitions)

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The Definitions link contains the meaning of terms and useful information about field lengths
After you click “Continue”, you will see this dialog box.
If the clinical study is funded in whole or in part by a U.S. Federal Government agency, the complete grant or contract number must be submitted as a Secondary ID. NIH grants should have an activity code (3 or 4 numbers and letters, such as R01), institute code (2 letters), and a 6 digit serial number. They may have a dash (-) and suffix.

<table>
<thead>
<tr>
<th>* Organization’s Unique Protocol ID:</th>
<th>Pro00000123</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Brief Title:</td>
<td>A 24-Week Double Blind Trial of Remuverol in Adults with Condition A</td>
</tr>
<tr>
<td>[*] Acronym: (if any)</td>
<td></td>
</tr>
<tr>
<td>* § Official Title:</td>
<td>A 24-Week Double Blind Trial of Remuverol in Adults with Condition A</td>
</tr>
<tr>
<td>[*] Secondary IDs: (if any)</td>
<td></td>
</tr>
</tbody>
</table>

**Required by ICMJE; should be consistent with formal IRB title**
After you click “Quit”, you will see this dialog box
The Record Owner is the primary contact for the record. Only an administrator can change the Record Owner.

PI can now share access with study team members and support staff. PI is legally responsible for accuracy and veracity of the record, and for ensuring proper maintenance.
Click Open to edit information section by section.
As you fill in more information, the Record Summary will show your progress.

<table>
<thead>
<tr>
<th>Module Status</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Identification</td>
<td>✓</td>
</tr>
<tr>
<td>Study Status</td>
<td>✓</td>
</tr>
<tr>
<td>Sponsor/Collaborators</td>
<td>2 Warnings</td>
</tr>
<tr>
<td>Oversight</td>
<td>✓ 1 Note</td>
</tr>
<tr>
<td>Study Description</td>
<td>✓</td>
</tr>
<tr>
<td>Conditions</td>
<td>✓</td>
</tr>
<tr>
<td>Study Design</td>
<td>✓</td>
</tr>
<tr>
<td>Arms and Interventions</td>
<td>1 Warning 7 Notes</td>
</tr>
<tr>
<td>Outcome Measures</td>
<td>✓</td>
</tr>
<tr>
<td>Eligibility</td>
<td>✓</td>
</tr>
<tr>
<td>Contacts/Locations</td>
<td>1 Error</td>
</tr>
<tr>
<td>References</td>
<td></td>
</tr>
</tbody>
</table>
Update this date every time the record is updated and review for accuracy. This is how compliance is tracked.

Only use “Active, not recruiting” if data are still being collected. If data collection is complete, the status should be Completed or Terminated.

Select Actual once date has occurred

Select Anticipated for projections

Save button is always at bottom of each page
Completion Dates are based on **data collection**

They are **NOT** based on:

- data analysis
- database lock
- publication
- IRB closure

If you use these as Completion Dates, you may have **LATE RESULTS**
Primary and Study Completion Dates

**Remember:** Results for the primary outcome measure(s) are due within one year of the Primary Completion Date. Results for the secondary outcome measures are due one year after the completion date for that outcome.

* Primary Completion Date:  
  - Month: September  
  - Day: 15  
  - Year: 2019  
  - Type: Anticipated

* § Study Completion Date:  
  - Month: March  
  - Day: 15  
  - Year: 2020  
  - Type: Anticipated

In this example, Primary Outcome results are due by September 15, 2020. All study results must be entered by March 15, 2021. Some secondary results may be due earlier depending on data collection time frames.
Choosing sponsor

If the study is NIH funded, include the NIH Institute or Center as a Collaborator. Collaborators include other funders, etc. Add as many as necessary.

- Responsible Party must be listed as “Sponsor”
- Sponsor should be “Chapman University”
Refer to definitions and linked Checklist for these sections

If this is “Yes”, the IND/IDE information is required

For “Human Subjects Protections Review,” provide the IRB information outlined in the ClinicalTrials.gov Requirements for Posting.

You may leave this blank unless the protocol specifies if a data monitoring committee was established.

Neither of these questions is required.

Section 801 Clinical Trial = ACT; FDA-regulated intervention/Section 801 clinical trial are optional; will likely eventually be phased out. We recommend NOT answering it unless your institution has a specific policy.
Provide the IRB information outlined in the ClinicalTrials.gov Requirements for Posting.

Register **before** any enrollment begins.

Board Status: **Submitted, pending**

The following information is required if the study meets each of these criteria: not required to be registered under 42 CFR Part 11, not funded in whole or in part by the U.S. government, and is not conducted under an IND or IDE. [This information is not made public.]

- **Board Name:**
- **Board Affiliation:**
- **Board Contact:**
  - **Phone:**
  - **Extension:**
  - **Email:**
  - **Address:**
### Edit Study Description

**Brief Summary:**

The purpose of this study is to assess the safety and efficacy of Remuverol of treatment of Condition A.

Describe the study hypothesis in terms understandable to the lay public. It can be adapted from the informed consent, but omit any and all personal pronouns, (e.g. we, you).

**Detailed Description:**

Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria or Outcome Measures.

This field is optional and can be left blank. It does not have to be in lay language. It can be adapted from the background or aims section of the protocol, but do not copy and paste the entire protocol. This field cannot contain promotional language. Where applicable, explain uncertainties or exploratory nature of study. If there are any parts of the trial, which the public cannot know about while the study is ongoing without affecting scientific integrity, such as deception research or inclusion/exclusion criteria which could be easily faked in order to join a study (e.g. pain levels in order to have access to a controlled substance), it would be good to explain here, e.g. “Some inclusion/exclusion criteria are purposely omitted at this time to preserve scientific integrity. They will be included after the trial is complete.”
Enter each study condition, one per line. Use Search MeSH link to verify the correct condition term.

Keywords help users find studies in the database.
### Edit Interventional Study Design

**Help**  **Definitions**

<table>
<thead>
<tr>
<th>* Study Type:</th>
<th>Interventional</th>
</tr>
</thead>
<tbody>
<tr>
<td>* § Primary Purpose:</td>
<td>Treatment</td>
</tr>
<tr>
<td>* Study Phase:</td>
<td>Phase 2</td>
</tr>
</tbody>
</table>

Use "N/A" for trials that do not involve drug or biologic products.

<table>
<thead>
<tr>
<th>* § Intervventional Study Model:</th>
<th>Parallel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model Description:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>* § Number of Arms:</th>
<th>2</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>* § Masking:</th>
<th>Participant, Outcomes Assessor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care Provider</td>
<td>Investigator, No Masking</td>
</tr>
</tbody>
</table>

Masking Description: Check all roles that are masked or check No Masking.

<table>
<thead>
<tr>
<th>* § Allocation:</th>
<th>Randomized</th>
</tr>
</thead>
</table>

Select N/A for single-arm studies.

<table>
<thead>
<tr>
<th>* § Enrollment:</th>
<th>Number of Subjects: 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type:</td>
<td>Anticipated</td>
</tr>
</tbody>
</table>

---

**Check the “definitions” link**

**Give an honest estimate for anticipated enrollment (based on consent, not completion)**
Arms may not pre-exist based on how many arms you defined in the previous section. You must add each arm. Do not title your arm as Intervention or Arm 1. Arm title should be more descriptive.
List Placebo as a Drug intervention

Frequent PRSComment: The preferred format is to include *all* interventions that were pre-specified to be administered as part of the protocol, even if a particular intervention is not "of interest"
Errors must be fixed to move on. Click **edit** to resolve these Errors.

Cross-Reference tables will not exist for single arm studies. For multiple arm studies, you must link arms and interventions even when it seems that it’s obvious that Arm A does intervention A and Arm B does intervention B.
Outcome Measures

• Protocol/statistical analysis plan must be submitted with results and will be public for studies with a primary completion date of 1/18/2017 or later
  – Ensure coherence among protocol and registration for primary, secondary and “other” outcomes
  – PRS reviewers may assume all outcomes are primary or secondary unless they are specified in the protocol as other or exploratory

• Include all PRIMARY and SECONDARY outcomes (tertiary/exploratory are optional)

• Label outcomes as “primary” or “secondary” per the protocol
  – Can list more than one primary if applicable
Outcome Measures

• More registrations get rejected for inadequate Outcome Measure precision or inaccurate or multiple time frames than anything else.

• Outcome Measures should be specific and indicate what is being measured and is (or planned to be) reported.

• Remember the mantra: *Outcome Measures must be measurable outcomes.*
Outcome Measure Tips: Title

• Include the metric (i.e. scale, score, number, percentage)
  
  ❌ Ex: Safety
  ✔ Ex: Safety, as measured by number of subjects with at least one AE

• Be clear and concise; omit verbs
  
  ❌ Ex: To determine the maximum tolerated dose of Drug A in patients with breast cancer.
  ✔ Ex: Maximum Tolerated Dose of Drug A in patients with breast cancer

• List outcomes separately
  
  ❌ Ex: All-cause mortality, hospitalizations, ER visits
  ✔ Ex: Number of hospitalizations, Number of ER visits, Number of ER visits. Should be listed as 3 separate outcomes

• Exception: if a composite score of multiple measures will be used
  
  – Example: Count of individuals who experience any of the following: all-cause mortality, hospitalizations, and emergency room visits
Outcome Measure Tips: Time Frame

• Be specific (e.g. # of minutes, weeks, months)
  – Ex: Baseline, week 2
  – Ex: During hospitalization, approximately 5 days
  – Ex: Post-intervention, week 12

• If multiple time points are included:
  – If measuring change between the time points, add the word “change” to the title
  – If not measuring change, each time point needs to be listed as a separate outcome measure

• Remember that completion dates should reflect completion of data collection for your outcome measures. Refer back to study status section.

Average time, expected average time, or max assessment time would all be acceptable when the protocol cannot specify precise time frame.
Outcome Measure Tips: Description

• If a scale will be used, include the range and meaning of the scores
  – Example: The Hamilton Depression Rating Scale is used for rating the severity of depressive symptoms. Scores range from 0 to 50, with higher scores indicating greater severity of depression.

• If a scale is not linear (e.g. logarithmic), that would be good to note as well.
Outcome Measures: Example 1

Title: To determine the effect of Remuverol on pain in adults with Condition A

Description:

Time Frame: Baseline, 12 weeks

Outcome Measure Title: Change from baseline in pain, as measured by the Visual Analog Scale (VAS)

Outcome Measure Description: Scores are measured on a 100 mm VAS. The VAS ranges from 0 to 100 with 0 indicating no pain and higher scores indicating greater pain.

Outcome Measure Time Frame: Baseline, 12 weeks

There are 2 time points, so the word “change” is added to the title.
The Title includes the scale that will be used to assess change in pain.
The Description includes the range of the scale and what the scale means.
### Outcome Measures: Example 2

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
<th>Time Frame</th>
</tr>
</thead>
<tbody>
<tr>
<td>To assess the safety of Remuverol</td>
<td></td>
<td>End of study</td>
</tr>
<tr>
<td>Number of participants with at least one adverse event</td>
<td>Adverse events will only include those that are determined to be related to the study drug.</td>
<td>End of study (24 weeks)</td>
</tr>
</tbody>
</table>

- The title includes the metric
- The Time Frame includes the specific length of time
- The Description defines “adverse events”
**Inclusion / Exclusion Criteria**

- **Inclusion Criteria:**
  - Outpatients
  - At least 18 years old
  - Diagnosed with Condition A for at least 6 months

- **Exclusion Criteria:**
  - Any cardiovascular, hepatic, or renal disease
  - Pregnancy
  - Current use of narcotics

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**Gender Based:** No

[If applicable, indicate if participant eligibility is based on self-representation of gender identity.]

**Age Limits:**

- Minimum: 18 Years
- Maximum: N/A (No limit)

**Accepts Healthy Volunteers:** No

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**Use Inclusion / Exclusion Criteria** with **colon** followed by dashed list format

No paragraphs

**Make sure that all criteria you post are appropriate for the public to see.**

**Match informed consent more than protocol, if something might need to be masked from participants.**

**If necessary, use Detailed Description field to flag that the eligibility criteria are deliberately incomplete to preserve the scientific integrity of the study.**
### Edit Overall Contacts

**Central Contact Person:**
- **First Name:** Kathy
- **MI:** 
- **Last Name:** Coordinator
- **Phone:** 919-123-4567
- **Ext.:** 
- **Degree:** BA
- **Email:**

**Central Contact Backup:**
- **First Name:**
- **MI:**
- **Last Name:**
- **Degree:**
- **Phone:**
- **Ext.:**
- **Email:**

**Overall Study Officials:**
- **First Name:** Joe
- **MI:**
- **Last Name:** Investigator
- **Degree:** MD
- **Organizational Affiliation:** Duke University Medical Center
- **Official's Role:** Study Principal Investigator

**NOTE:** Study Official is required by the WHO and ICMJE.

Add the PI as a Study Official
Overall contact may be used to differentiate a study coordinator or administrator from the study official.

Contacts/Locations

Protocol Section  Help  Definitions

Edit

Overall Contacts

Central Contact Person: Kathy A. Coordinator, BA  919-123-4567
Central Contact Backup:
Overall Study Officials: Principal Investigator  Joe Investigator, MD
Duke University Medical Center

Copy locations... from a master list, extracted from this organization's records.

+ Add Location

All sites should be added for multi-site studies, only after the IRB has approved that location.
Site recruitment status must be consistent with overall recruitment status; if overall recruitment is not recruiting, no site can be recruiting.
Studies available in PubMed are linked automatically if the NCT# was included in the publication. Others need to be added manually.

Indicate if the reference provided reports results from this study.
**The Record Summary**

<table>
<thead>
<tr>
<th>Open</th>
<th>Preview</th>
<th>Draft Receipt (PDF, RTF)</th>
<th>Download XML</th>
<th>Delete</th>
</tr>
</thead>
</table>

**Spelling**

- **Identifiers:** [NCT ID not yet assigned]  Unique Protocol ID: Pro00000123
- **Brief Title:** A 24-Week Double Blind Trial of Remuverol in Adults With Condition A

**Protocol Section**

- **Module Status:**
  - Study Identification: ✔ 1 Note
  - Study Status: ✔
  - Sponsor/Collaborators: ✔
  - Oversight: ✔ 1 Note
  - Study Description: Information is required
  - Conditions: 2 Errors
  - Study Design: ✔
  - Arms and Interventions: ✔ 2 Notes
  - Outcome Measures: ✔
  - Eligibility: ✔
  - Contacts/Locations: 1 Error

**Errors** must be addressed before releasing the record.

**Warnings** indicate potentially serious issues that should be reviewed and addressed as needed.

**Notes** indicate other potential issues; address as needed.

**NOTE:** Study Official is required by the WHO and ICMJE.

When the Record Summary shows all green checks, the PI should carefully review the record. False statements are criminal under the regulations! For new registrations, the PI should read each section carefully.
The Record Summary – to complete

Record Summary

<table>
<thead>
<tr>
<th>Record Status</th>
<th>Entry Completed</th>
<th>Approved</th>
<th>Released</th>
<th>PRS Review</th>
<th>Public</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In Progress</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Next Step: Confirm data entry complete

- **Entry Complete**

Record Owner: Test User

Last Update: 01/23/2017 11:53 by Test User

Initial Release: [Not yet released]

Access List: 

- Upload: Allowed

PRS Review: [Not yet released]

Public Site: [Not yet registered]

FDAAA: ACT

Click **Entry Complete** to send the record to the Responsible Party for Approval and Release.

This study appears to be an ACT and is subject to federal regulations. The reasons why your trial is considered ACT will be displayed.
The Record Summary – User Information

The Record Owner is the primary contact for the record. Only an administrator can change the Record Owner.

Add the PI and anyone else who should have edit rights. The Record Owner can do this.

**Initial Release** date displays on the public site. This is important for FDAAA and ICMJE.
Can a Study Record be Deleted?

- Only if the study record has never been published on ClinicalTrials.gov
- Otherwise, No.
- ClinicalTrials.gov serves as a long-term public registry. Once a study record is published, it remains in the system even after a trial has closed.
- If you find a duplicate, contact ClinicalTrials.gov at register@clinicaltrials.gov.
PRS Review

Once the record is released, ClinicalTrials.gov conducts a manual review

• If major issues are identified, the record owner and RP will receive notification from ClinicalTrials.gov with comments
• The study will be reset to In Progress
• Study Owner/RP must correct the issues and re-release it **within 15 calendar days (new in 42 CFR 11)**
• If no major issues are identified, the study is assigned an NCT number and published on the public side of the database (clinicaltrials.gov)
• This process takes about 2-5 business days
• Even if it's published, advisory comments may be posted. Corrections are not mandatory
Ongoing Responsibilities of Record Owners

• Records can be transferred to other user accounts as staff change

• Records must be updated every 12 months and within 30 days of Recruitment Status changes or amendments that affect information in clinicaltrials.gov record, especially recruitment status, location and contact information

• Always update the Record Verification Date to indicate that you have updated or reviewed the record

• Records must be updated within 30 days after the completion date (last data collection)

• Failure to update information on ClinicalTrials.gov can result in penalties. There are more specific update requirements in 42 CFR 11.64
Checking your Problem Records

PRS System identifies current ‘Problem Records’

- Records that have not been marked as completed
- Active studies that have not been updated (or the Record Verification Date has not been updated)
- Records missing one or more FDAAA-required data elements:
  - Responsible Party
  - Study Start Date
  - Primary Completion Date
  - Primary Outcome Measure
- Records that appear to be overdue for FDAAA results reporting
Do You Need to Submit Results?

- All Applicable Clinical Trials (ACTs) are required to submit results.
- All NIH-funded trials begun on after 1/18/2017 and applied for on or after 1/18/2017 must report results, whether ACTs or not.
- Other grantors may require results submission.

Based on registration information entered, the system will assess whether the trial appears to be:
1) An ACT with results required by law.
2) A Non-ACT: results are not required by law, though NIH policy (if so funded) or other funders’ policies may still require results reporting.
3) Older trials may be designated Probable ACT or Probable Non-ACT.

Note: There is no reminder flag for NIH-funded trials.
Acknowledgements

This user guide was adapted from Weil Cornell which was developed as a collaborative effort on the part of ClinicalTrials.gov administrators at 11 academic medical centers around the nation to share efficient, best practices for most registrations based on their experience.

This slide set was developed collaboratively by contributors from

- Beth Israel Deaconess Medical Center,
- Boston University
- Cambridge Health Alliance
- Duke University
- Fred Hutchinson Cancer Research Center
- Harvard University
- Mayo Clinic
- Partners
- Rutgers State University
- University of Michigan
- University of Pittsburgh
- University of South Florida