CCP Lab
Human Subject Experimental Guidelines & Procedures
Certifications

There are several certifications that lab members may need to complete:
• CITI (Collaborative Institutional Training Initiative) aka human subjects training
• HIPPA certification (needed if you have NIL access, med campus interactions, but not if East building or CCIR only, ex. observing scans)
• MR certification for scanning (Research Assistant will set up appt. after completion of test)
• Environmental Health and Safety (if working as research team member at medical campus)
• Undergraduate Research Agreement (if an undergrad)
Certifications

CITI module must be completed to be added to any existing IRB

Personal Profile on MyIRB to be completed after CITI Completion to be added to an IRB

CITI and HIPAA must both be completed to have access to NIL/CSG/Blue Arc

MR Safety Certification must be completed before participating in scans

MR screening form must be completed with lab before participating in scans
Running an Experiment

Reserving Rooms

Access the Lab Resource Scheduler  (you must be granted CCP Lab permission)
http://psychscheduler.wustl.edu/

CCP Available Testing Rooms
338A&B
336B
102/106
Also Departmental Rooms
342 A-H (grad testing room)
Running an Experiment

Testing Computers

• Users Must Log in and out of testing computers
• Prefer you create your own user – please use lab password for ease of access by lab staff
• Testing computers are not backed up by the department or the lab
• You are responsible for backing up your data and your scripts (Kevin will provide further information on this).
• Send/back up data at earliest possible time – do not use testing computers to store your data! Kevin will provide details on the procedure.
• All have newest version of Eprime 2.0 installed, if you need additional software, please request
Consent Forms and Demographics

File your consent forms

- Please file your consent forms in the filing cabinets located outside of testing rooms 338 A&B in the lab.
- Label each folder with Study Number and PI
- Please lock the cabinet (the keys are located in the storage closet in the 340 bay)
- Separate Folder for Consents (Please keep in date order)
- Separate Folder Folders for demographic forms (Please keep in date order)
- MR screen forms (if applicable) accompany consent forms
- Check requests separate file with the consent forms
- **NO SUBJECT NUMBERS** on Consents, Demographics or MR Screen Forms
- Consent forms must be retained for 6 years after the study is closed.
Study Data

• Data/subject numbers/spreadsheets are to be kept separate from consent forms at all times.
• Keep paper data in locked filing cabinet, locked suite (people normally prefer to keep these at their work stations, desks). This is fine as long as consents are not located there.
• Coding by subject number – it is fine to code by subject number and keep a copy of this at your work station – however, it must also be secured.
• Computerized data, follow the procedures in your protocol, normally password protected document on a password protected computer, behind WUSTL firewall and only engaged members of research team have access.
• Data retention – you are to retain your data in whatever form it was collected as specified in your IRB. Typically, we state that all data will be kept until the completion of data analysis. If you will convert files from paper to electronic, you should specify in your IRB and indicate if you will retain the paper or shred it and the time frame within this will occur (ex. 1 year after DA is complete).
Study Audit/IRB Renewal

- Upon IRB renewal, consents will be counted and examined for lab compliance (signatures, date order, correct versions)
- Electronic data and scripts will be archived
- Paper data will be examined and housed in lab accessible location
- Data retention – you are to retain your data in whatever form it was collected as specified in your IRB. Typically, we state that all data will be kept until the completion of data analysis.
- When data is completely de-identified, it may be kept indefinitely.
Project Binders

- Project binders provide a central location for all relevant documents needed for an experiment.
- There is an example binder on top of the consent form filing cabinets.
- The binder should include a copy of all forms used, instructions for running the task, counter balancing sheets, and most importantly an informational “read me” sheet.
- The Read me sheet should include:
  - Who is running the study.
  - Which computers the study was run on.
  - Names of eprime scripts (updated each time a change was made, indicating what that change was; e.g., Task_V1.es2, Task_V2.es2- font size altered 8/23/13)
  - Location of files on the server
  - Location of any paper consents/demographics and paper/Indiv data
Central Data Archiving

• To promote transparency in the lab, and eliminate stray data, all Scripts, data, and documentation should be uploaded into a project specific folder on the server within ..../CCP/CCP_Repository folder. This is intended for behavioral data. Imaging data is not to be redundant.
  – To create the project folder use the name of your study _ initials ( ie. Liquid_feedback_MK)
  – This folder should have a minimum of 3 sub folders
    • Raw data
    • Scripts
    • Documentation
      – Additional folders should be added to- included analysis ( spss sheets, diagrams etc) and drafts when a study is being published.
Quarterly Audits

• A quarterly audit is a short meeting with each researcher every 3 months, to ensure all projects are adhering to IRB Protocol and Lab Best Practices.

• Things reviewed in an audit include:
  – Location of consents/demographics
  – Location of paper data
  – Verification that project folder on the server is up to data with all data and scripts
  – Updated enrollment
    – If good practices have been followed the Audit takes no more than a few minutes per study.
Red Cap is an online database tool that is great at tracking projects, as well as collecting demographic information, and survey responses.

Using Red Cap individual difference and survey data can be exported in statistic ready formats (Excel, SPSS, STAI, R)

Reverse scoring can be accounted for, eliminating the room for errors in scoring by hand.

All data is backed up and logged. If any changes are made the log displays who changed what, when.

Surveys can be sent out to subjects before or after their experiment session, or completed at the time of their study on a computer or tablet.

There are a few IRB considerations when using Red Cap. Make sure your IRB is amended as needed to utilize online collection.

Before going live with cognitive tests, see lab administrator to ensure copyright licensing agreements are in effect

https://redcap.biostat.wustl.edu/redcap/srvrs/
Related Websites

CCP Lab http://ccpweb.wustl.edu/

CCP Group http://ccpmac1.wustl.edu/groups/ccpgroup/

CSG http://research.wustl.edu/Cores/AddUpdateCore/CoreRecords/Pages/158.aspx

Normally new members will have to attend a mandatory information session on Experimetrix. Details will be sent via departmental listserv

Lab Resource Scheduler http://psychscheduler.wustl.edu/
(you must be granted CCP Lab permission – let Carol know)

MyIRB (policies and contact information) http://hrpohome.wustl.edu/

Neuroimaging (NIL, RIIS system) http://www.nil.wustl.edu/

Redcap https://redcap.biostat.wustl.edu/redcap/srvrs/

Research Gateway https://research.wustl.edu/Pages/ResearchGateway.aspx
(all administrative systems at WU)