Sharing Access to A Study Team Member in ClinicalTrials.gov
Before you start

- Both the record creator (owner) and the study team member need ClinicalTrials.gov accounts. IF the study team member does not have an account, s/he should create one following the tip sheet linked here (Level 2 password required, or email UMMS-RegAffairs@med.umich.edu)
Enter ClinicalTrials.gov through Submit Studies (clinicaltrials.gov)
Choose PRS System

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Submit Studies

Submit Studies

ClinicalTrials.gov allows the registration of clinical studies with human subjects that assess biomedical and/or health outcomes and that conform to:

- Any applicable human subject or ethics review regulations (or equivalent)
- Any applicable regulations of the national or regional health authority (or equivalent)

New to registering studies? See For Study Record Managers.

Why Should I Register and Submit Results?

Learn about the purpose of study registration and results submission. Includes an overview of applicable laws and policies.

FDAAA 801 Requirements

Learn about Section 801 of the Food and Drug Administration Amendments Act and the basic requirements for registering clinical trials and submitting summary results, including information about the Responsible Party, Applicable Clinical Trials, deadlines, and penalties.

Protocol Registration and Results System (PRS)
Show them you’re human by typing in the day name; hit continue.
Login; Organization is UMichigan (or UMichiganCC)

IF you forgot your password, click Forgot password, and the email will come to you with a temporary one almost instantaneously. Don’t forget then to change your password later to something you’ll remember. One easy option is 5-6 characters from a password you use a lot followed by “4CT.gov”
Choose your study and open it

IF you need to change your password, do it with Accounts here.
• Pick the study to which you want to give your team member access. Select Edit.
• Once you see the study, you’ll see the owner and the words Access List. Click on Access List and a pull down menu of everyone in UMichigan’s system will open.
Step Seven

- Select the person/s to whom you want to give access by checking the box next to their name. Note they are largely alphabetical by first name. Make sure you click Save at the bottom of the page.
Verify Success

You should now see that person’s name in your Access List for that record.

Don’t forget to Log out!
Remember Your Responsibilities

- If you are the Responsible Party, you will still have to Approve and Release changes that the study team member makes to the record. Please proofread seriously, as all records in ClinicalTrials.gov are permanently archived and publicly accessible in each version. This is definitely a case of an ounce of prevention being worth a pound of cure.
Questions?

• Contact the Office of Regulatory Affairs.

• [email: UMMS-RegAffairs@med.umich.edu]

• [link: http://msa.med.umich.edu/regulatory_affairs/research/human/clinical-trials]

• 734 764-0634