

Some Statistics*

- 82% of adults use internet or use email
 - 53% of American adults age 65 and older use the internet or email, only 34% for age 76 and older
- 67% of online adults use social networking sites -
As of December 2012:
 - 15% of online adults say they use Pinterest
 - 13% of online adults say they use Instagram
 - 6% of online adults say they use Tumblr
 - 67% of online adults say they use Facebook
 - 16% of online adults say they use Twitter
 - 20% of online adults say they use LinkedIn

Pew Research Center <http://pewinternet.org/>

Social Networking Sites		The Social Networking Sites
% of internet users who use social networking sites		
All internet users (n=1,282)		67%
Gender		
a	Men (n=544)	62
b	Women (n=738)	71 ^a
Race/ethnicity		
a	White, Non-Hispanic (n=1,022)	65
b	Black, Non-Hispanic (n=176)	68
c	Hispanic (n=154)	72
Age		
a	18-29 (n=312)	83 ^{bc}
b	30-49 (n=512)	77 ^a
c	50-64 (n=312)	57
d	65+ (n=366)	32
Education attainment		
a	Less than high school/high school grad (n=142)	66
b	Some college (n=512)	69
c	College + (n=728)	65
Household income		
a	Less than \$30,000/yr (n=602)	72
b	\$30,000-\$45,999 (n=312)	65
c	\$46,000-\$74,999 (n=266)	66
d	\$75,000+ (n=514)	66
Urbanity		
a	Urban (n=512)	70 ^a
b	Suburban (n=512)	67
c	Rural (n=258)	62

Source: Pew Research Center's Internet & American Life Project Post-Election Survey, November 14 – December 06, 2012. N=1,822 internet users. Interviews were conducted in English and Spanish and on landline and cell phones. Margin of error is +/- 2.6 percentage points for results based on internet users.

Note: Percentages marked with a superscript letter (e.g., ^a) indicate a statistically significant difference between that row and the row designated by that superscript letter, among categories of each demographic characteristic (e.g., age).

Mobile*

- Mobile tools such as smartphones, tablets, netbooks, and laptop computers are now a primary source of Internet connectivity (all developed countries)
- 87% of American adults have a cell phone
 - ~350 million adults, from <50 in 1995
 - 68% ages 65 and older, 56% ages 76 and older
- 45% of American adults have a smartphone
- 79% of cell phone owners say they use text messaging on their cells
- 26% of American adults own an e-reader
- 31% of American adults own a tablet computer

[*http://pewinternet.org/](http://pewinternet.org/)

Cell Phone and Smartphone Ownership
% of American adults within each group who own a cell phone and the % who own a smartphone

	Cell Phone	Smartphone
All adults (n=2,261)	87%	45%
Gender		
a. Men (n=1,054)	87	45
b. Women (n=1,207)	86	42
Race/ethnicity		
a. White, Non-Hispanic (n=1,532)	87	43
b. Black, Non-Hispanic (n=247)	89	48
c. Hispanic (n=231)	83	44
Age		
a. 18-29 (n=335)	93 ^{ab}	65 ^{cd}
b. 30-49 (n=685)	93 ^{ab}	59 ^{cd}
c. 50-64 (n=603)	89 ^a	32 ^d
d. 65+ (n=638)	68	12
Education attainment		
a. No high school diploma (n=205)	71	22
b. High school grad (n=662)	86 ^a	38 ^b
c. Some college (n=598)	89 ^a	49 ^{bc}
d. College + (n=776)	92 ^{ab}	61 ^{cd}
Household income		
a. Less than \$30,000/yr (n=665)	82	31
b. \$30,000-\$49,999 (n=336)	88 ^a	40 ^b
c. \$50,000-\$74,999 (n=336)	91 ^a	50 ^{bc}
d. \$75,000+ (n=514)	94 ^{ab}	68 ^{cd}
Urbanity		
a. Urban (n=1075)	87	49 ^a
b. Suburban (n=1,115)	85	46 ^a
c. Rural (n=631)	88	30

Source: Pew Internet Post-Election Survey, November 14 – December 09, 2012. N=2,261 adults ages 18+. Interviews were conducted in English and Spanish.

More*

- 55% of adult cell owners use the internet on their mobile phones
 - About 50% have an app (narrowly defined repetitive tasks)
- 40% of cell phone owners use a social networking site on their phone, and 28% do so on a typical day
- Young people, blacks, Hispanics, the highly educated and those with a higher annual household income are more likely to use SNS on their phones than other groups

Global Mobile *

- Uptake of technology tools in less-developed regions of the world has been dominated by small, wireless devices
- The number of mobile-connected devices will exceed the world's population in 2013
- By 2017 there will be nearly 1.4 mobile devices per capita (10 billion mobile Internet devices in use)
- Two-thirds of the world's mobile data traffic will be video by 2017
- The Middle East and Africa will have the strongest mobile data traffic growth of any region

*http://www.cisco.com/en/US/solutions/collateral/ns341/ns525/ns537/ns705/ns827/white_paper_c11-520862.html

Teens and Technology*

- 95% of all teens ages 12-17 are now online
- 78% of teens have a cell phone and 47% of those own smartphones
- 93% of teens have a computer or access to one (80% have desktop/laptop, 23% have tablets)
- 75% of all teens text, and 63% say that they use text to communicate with others every day
 - 40% prefer text rather than call

*<http://pewinternet.org/>

Teens & Social Networks

80% of online teens use social network sites:

- 93% have an account on Facebook
- 25% use Instagram
- 24% have an account on Twitter
- 7% have an account on a Yahoo site
- 6% have an account on YouTube
- 2% have an account on each of the following: Skype, myYearbook, and Tumblr
- 1 in 7 use Pinterest

Agenda

- Social media
 - Erin Winstanley, Ph.D. – University of Cincinnati College of Medicine
 - Gloria Miele, Ph.D. – Columbia University College of Physicians and Surgeons
- Mobile devices
 - Jennifer Sharpe Potter, University of Texas Health Science Center
- REDCap
 - Lynn Simpson, Harvard Catalyst | Harvard Clinical and Translational Science Center

Using New Media Tools in the Design and Conduct of Clinical Trials

2013 Society for Clinical Trials Workshop
May 19, 2013



Erin L. Winstanley, Ph.D.

University of Cincinnati College of Medicine, Department of Psychiatry & Behavioral Neuroscience
Ohio Valley Node of the NIDA Clinical Trials Network

#sct2013ps10

What is New Media?

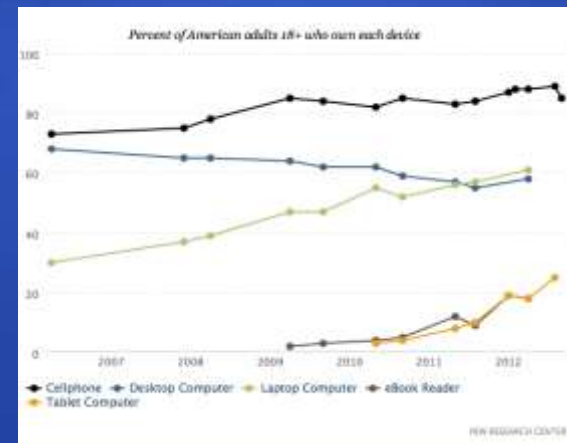
Definition of: **new media**

- (1) The forms of communicating in the digital world, which includes publishing on CDs, DVDs and, most significantly, over the Internet. It implies that the user obtains the material via desktop and laptop computers, smartphones and tablets. Every company in the developed world is involved with new media. Contrast with [old media](#). See [digital convergence](#).
- (2) The concept that new methods of communicating in the digital world allow smaller groups of people to congregate online and share, sell and swap goods and information. It also allows more people to have a voice in their community and in the world in general. See [social media](#).

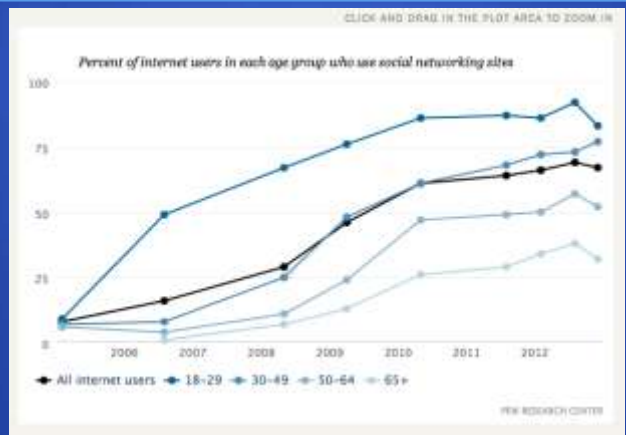
How Can We Use New Media in Research?

- Advertise studies
- Recruit & track study participants
- Maintain contact with research participants
- Communicate information to research participants
- Drive traffic to research website
- Integrate into EFIC plan
- To conduct research
- Disseminate research findings

Device Ownership



Social Networking Site Use



Facebook

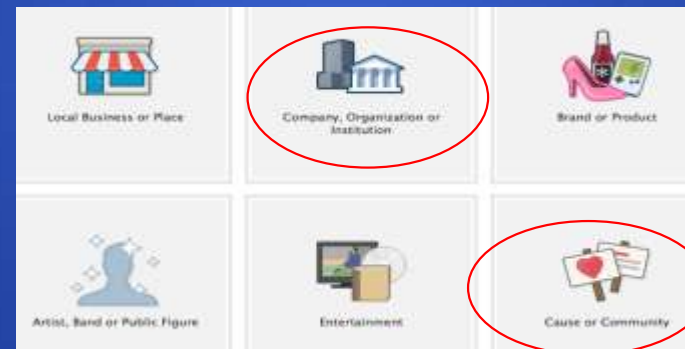
Facebook

- Founded in 2004 & >4k employees
- Most frequently used social media tool
- More than 1.06 billion monthly users worldwide



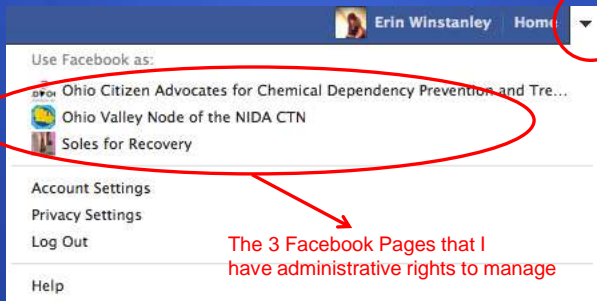
FACEBOOK FEATURES	WHAT YOU CAN DO
Posting information, pictures, videos, weblinks, or notes	Post the PAMI video, post links to CTN articles in the library, share links for important conferences
Communicating via mail or instant chat	Communicate with individuals within groups/organizations when you don't have their email address
Schedule events, track RSVPs, & link to directions	Advertise your dissemination/training events, quickly notify participants of any agenda or location changes
Choose your friends & manage dissemination	Disseminate information to only targeted groups

Choose your Page type



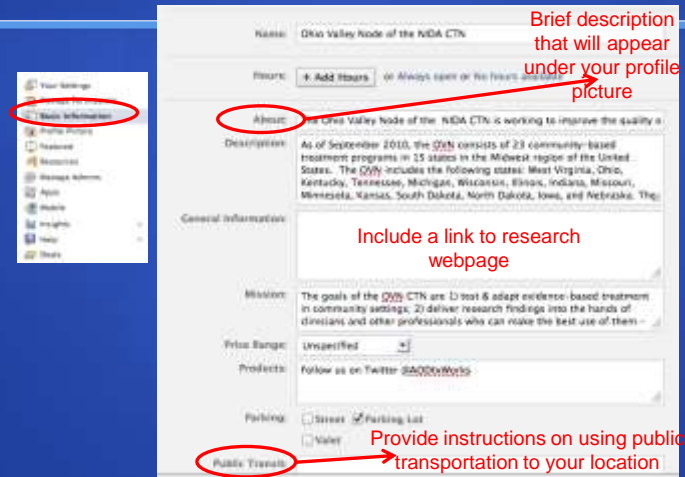
Manage FB Accounts

Select this arrow to switch between personal and page accounts



The 3 Facebook Pages that I have administrative rights to manage

Setting Up a FB Page

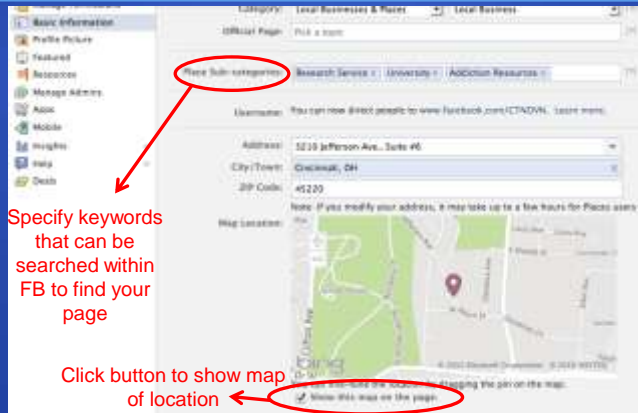


Brief description that will appear under your profile picture

Include a link to research webpage

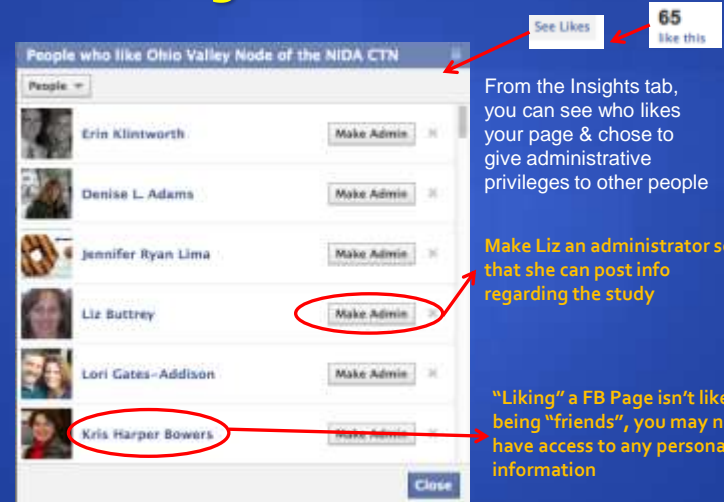
Provide instructions on using public transportation to your location

Setting Up a FB Page



Company Page

FB Page Administrators

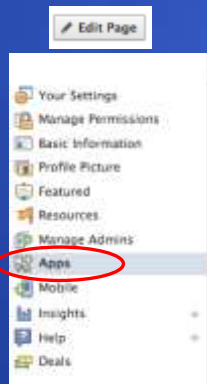


From the Insights tab, you can see who likes your page & chose to give administrative privileges to other people

Make Liz an administrator so that she can post info regarding the study

Liking a FB Page isn't like being friends, you may not have access to any personal information

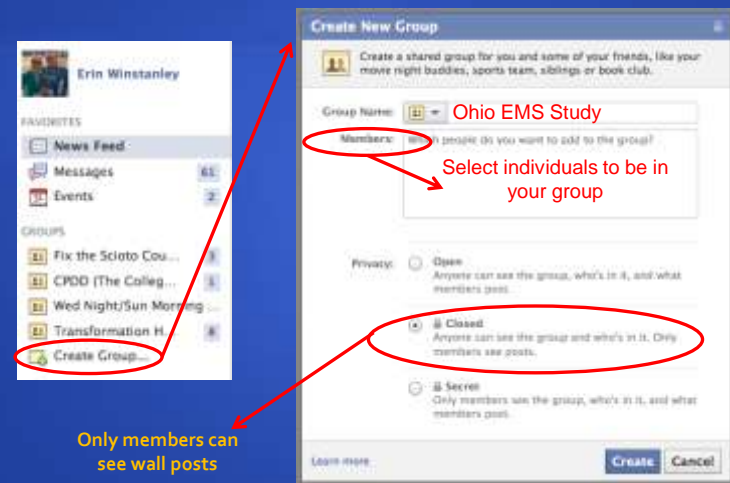
Adding Apps to a FB Page



FB applications can be used to enhance your page:

- Notes
- Videos
- Link with LinkedIn Profile (My LinkedIn Profile)
- Link with Twitter account (Tweets to Pages)
- Contact Form (ContactMe)
- PDF Tab
- Events calendar
- Polls
- Mailing list sign-up

Create a Group in FB



Facebook Set-Up Options

FB Usernames

www.facebook.com/OVNCTN

The screenshot shows the Facebook page management interface. On the left is a navigation menu with options: Your Settings, Manage Permissions, Basic Information, Profile Picture, Featured, Resources, Manage Admins, Apps, Mobile, Insights, Help, and Deals. The 'Resources' section is expanded, showing 'Select a username' circled in red. On the right, under 'Develop your page', there is a link for 'Best practices guides to make your Page engaging'. Under 'Connect with people', there are links for 'Advertise on Facebook', 'Select a username' (circled in red), 'Tell your Fans', 'Use social plugins', and 'Link your Page to Twitter'. Red arrows point from the 'Select a username' link in the right-hand column to the URL above and to the circled 'Select a username' link in the left-hand column.

Usernames are used to generate web address for your page

Once you have 25 likes, you can chose a username

Manage Privacy Settings

There are multiple ways to manage privacy



Privacy Settings

Personal Page

Control Privacy When You Post

You can manage the privacy of your status updates, photos and information using the inline audience selector -- when you share or afterwards. Remember: the people you share with can always share your information with others, including apps. Try editing your timeline info to see how it works or learn more.

What's on your mind?

friends Post

Manage Privacy Settings

You can manage the privacy settings for your posts, but not once it's been shared

Wall Ohio Valley Node of the N... · Everyone (Most Recent)

Share: Status Photo Link Video Question

What's on your mind?

Personal or Professional Page

Public Share

Public

Target by:

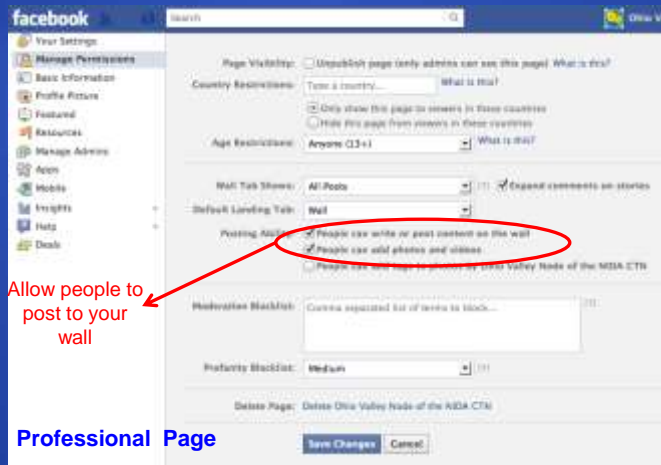
Location / Language

Ohio Valley Node of the NIDA CTN
The continuing debate of drug #dependen
/zoSY7x

Who should see this post?

Manage Privacy Settings

Edit Page



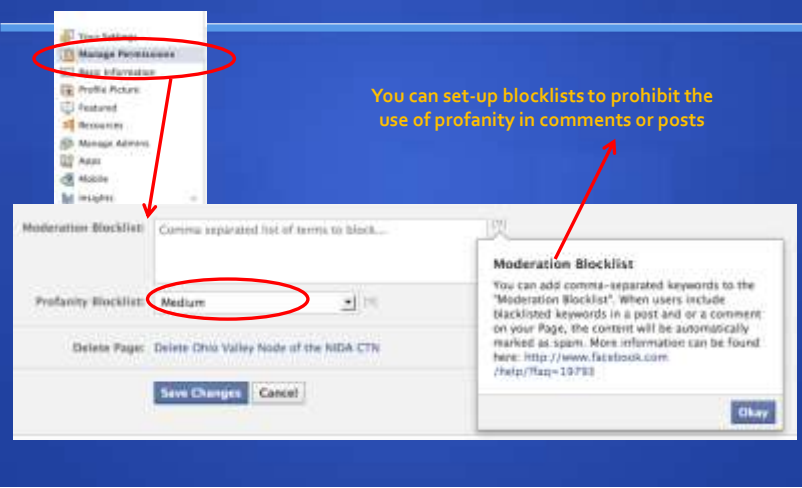
Allow people to post to your wall

Professional Page

Save Changes Cancel

Keep it Clean

Edit Page



You can set-up blocklists to prohibit the use of profanity in comments or posts

Moderation Blocklist: Comma separated list of terms to block...

Profanity Blocklist: Medium

Delete Page: Delete Ohio Valley Node of the NIDA-CTN

Save Changes Cancel

Moderation Blocklist

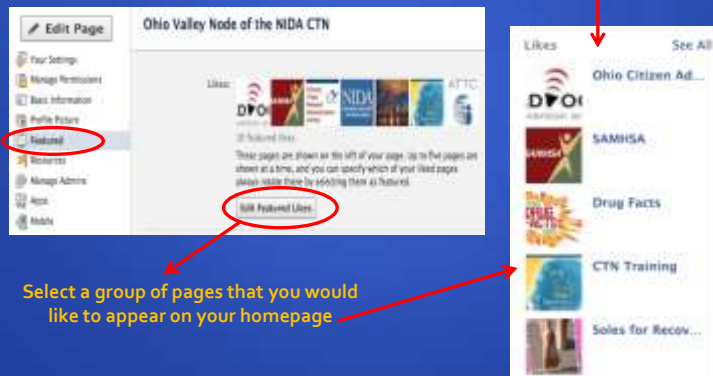
You can add comma-separated keywords to the "Moderation Blocklist". When users include blocked keywords in a post and/or a comment on your Page, the content will be automatically marked as spam. More information can be found here: <http://www.facebook.com/help/?faq=19783>

Okay

“Like” on Facebook

“Like” other Pages to see their updates in your newsfeed

Featured pages “liked” by the OVN



The screenshot shows the Facebook interface for the 'Ohio Valley Node of the NIDA CTN' page. On the left, the 'Liked' section is highlighted with a red circle. Below it, a list of liked pages is shown, including 'Ohio Citizen Ad...', 'SAMHSA', 'Drug Facts', 'CTN Training', and 'Soles for Recov...'. A red arrow points from the text 'Featured pages “liked” by the OVN' to the 'Liked' section. Another red arrow points from the text 'Select a group of pages that you would like to appear on your homepage' to the 'Add Featured Likes' button at the bottom of the liked pages list.

Select a group of pages that you would like to appear on your homepage

Facebook Example

Click “Like” to see posts in your newsfeed



The screenshot shows a Facebook post from the 'UNC Clinical Research Studies' page. The post title is 'Perimenopausal Women Needed for Research Study'. The post content includes a description of the study and a 'Continue Reading...' link. A red circle highlights the 'Like' button on the post, with a red arrow pointing from the text 'Click “Like” to see posts in your newsfeed' to it. The post also shows 439 likes and a 'Message' button.

Facebook Example

Heartview's Facebook Wall:

The screenshot shows the Facebook wall for Heartview. On the left, a post titled "Weather Announcement" is circled in red, with an arrow pointing to it from the text "Keep patients informed of programming changes". On the right, two comments are circled in red, with an arrow pointing to them from the text "Customers can comment on your wall". Below the comments, a "Like" button is circled in red, with an arrow pointing to it from the text "See which pages Heartview 'likes'".

Facebook Examples

The screenshot shows the Facebook page for the AIDS Clinical Trials Group (ACTG). The cover photo features a word cloud with terms like "TREATMENT", "CO-INFECTION", "RESISTANCE", "EFFECTS", "RESERVOIRS", "UNDERSTANDING", "NEUROLOGICAL", "AGING", "INCLUDING", "POPULATIONS", "NEUROPATHY", "START", "HEALTH", "TOXICITIES", "WOMEN'S", "HEART", "IMMUNE", "STRATEGIES", "HIV", "HEPATITIS", "REGIMENS", "FLUSHING", "DISORDERS", "RESTORATION", "TUBERCULOSIS", and "LETTER". The page name "AIDS Clinical Trials Group" is circled in red. Below the name, the text "New-Profit Organization" is circled in red, with an arrow pointing to it from the text "See which pages Heartview 'likes'". A red play button icon is also circled in red.

Facebook Examples

2012 Annual ACTG Network Meeting Public · By ACTG Clinical Trials Group Page Events Join Watch

Sunday, July 15, 2012

July 16-20, 2012
Washington, DC

The meeting will be held immediately prior to the XIX International AIDS Conference July 27-27, 2012 in Washington, DC, to minimize travel for our international colleagues.

The scientific and other major sessions are likely to be held July 18-20, to reduce the amount of time that the investigators and others who will be attending the international conference need to be away. We expect that July 16 and 17 will primarily include training, community, and resource committee sessions.

Grand Hyatt Washington
1000 4th St. NW, Washington, District of Columbia
[View Map](#) - [Get Directions](#)

Categories: [College \(3\)](#) [Mayle \(2\)](#) [Ethan Del Valle](#)

[Expert](#) [Report](#)

Hands-On Example Facebook

Twitter

Twitter

- Limits communications to 140 characters
- Over 200 million users
- 155 million Tweets per day worldwide



librarycongress

✓ Following

Library to acquire ENTIRE Twitter archive -- ALL public tweets, ever, since March 2006! Details to follow.

More Library of Congress
Location: Washington, DC
Web: <http://www.loc.gov>
We're not the largest library in the world, with millions of books, recordings, photographs, maps and manuscripts in our collections.

1 95,487 2,207
Following Followers Feed

Tweets 880
Favorites
Actions
View librarycongress report for spam

Twitter Example

The screenshot shows the Twitter profile for the NIH Clinical Center (@NIHClinicalCtr). The profile header includes the NIH logo, the name "NIH Clinical Center", and the handle "@NIHClinicalCtr". Below the header, it states: "The NIH Clinical Center is the nation's largest hospital devoted entirely to clinical research." and provides the address "Bethesda, MD" and website "http://clinicalcenter.nih.gov". The profile shows 1,432 tweets, 106 followers, and 26,848 people following. The main content area displays a list of tweets, with the most recent one from the NIH Clinical Center stating: "Prostate cancer is being studied at the NIH Clinical Center. Learn more... <http://bit.ly/25G06E1>".

What Should I Post?

The screenshot shows a Twitter feed with four tweets:

- MICHR** (@UM_MICHR) - 5 Oct 11: MICHR, PRMC team up on new **clinical research** communications toolkit to help researchers recruit volunteers for studies. <http://jmp/htKcK>. Followed by GIC_sarah, jstam and 8 others. Expand.
- NIH Clinical Center** (@NIHClinicalCtr) - 22 Feb 11: Ever wonder about the outcomes from NIH **clinical research** studies? Learn about research results for the public at... <http://fb.me/N8ldtsB>. Expand.
- NIH Human Resources** (@NIHforJobs) - 3 Jan 11: #NIH hiring a Diagnostic Radiologic **Technologist** working **clinical & research** studies in Dept. of **Radiology** <http://bit.ly/#2dsJ> #CT #MRI. Followed by NIDNews and 4 others. Expand.
- JAMA** (@JAMA_current) - 21 Dec 10: JAMA commentary looks at why women are underrepresented in **clinical research** studies and how to fix it <http://bit.ly/guIMAL>. Followed by Abby Reinack, MD and 4 others. Expand.

Twitter Emergency Response Plan

The screenshot shows a news article with the headline "Boston Marathon: With no phones, text and social media help get out updates". Below the article are two tweets from the account @BME (Boston Marathon Emergency). The first tweet says "Boston Police just announced shutting down all Cell Phone towers. broadstreat.com/lists/food/49... #BostonMarathon". The second tweet says "If you are trying to reach friends or family and can't get through via phone, try texting instead (use karabachidh)".

National Rx Drug Abuse Summit

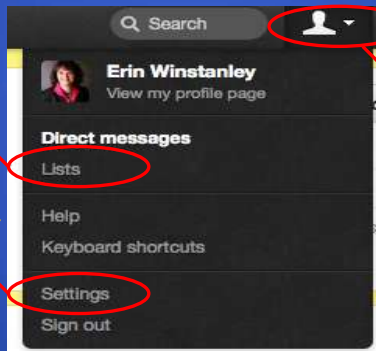
The screenshot shows a Twitter thread from the account @RxDursummit. The tweets are:

- Erin Winstanley @ACDOutlets: Dr. Volkow @RxDursummit is sharing the results of #FRESH COATS study. *Annotation: Hashtag your organization*
- Erin Winstanley @ACDOutlets: Dr. Volkow @RxDursummit: characteristics of better pain meds: 1) slow release formulations & 2) reduce formulations to reduce abuse liability.
- Erin Winstanley @ACDOutlets: Dr. Volkow @RxDursummit: Veterinarians receive 75 hrs of medical training on pain, whereas physicians only receive 7 hrs.
- NIDAnews @NIDAnews: NIDA Director Dr. Volkow discusses the impact of prescription drugs on the brain. *Annotation: Retweet what others are saying*
- Erin Winstanley @ACDOutlets: Dr. Volkow @RxDursummit: the primary prescriber of opioids to individuals 10-19 years old is dentists. *Annotation: # & abbreviation used to identify conference tweets*

Managing Your Twitter Account

Create "lists" to organize the twitter accounts that you follow

Select to change your account settings



Select this button to manage your account

Twitter Terminology

@ = use immediately before a username to generate a link to the user's profile

= use to create keywords or topics (e.g., #nidactn)

DM = "direct message" between Tweeters

FF = "Following Fridays," use #FF to recommend Tweeters

RT = "Retweet," post/share another user's tweet



Other Social Media Tools

Blogs

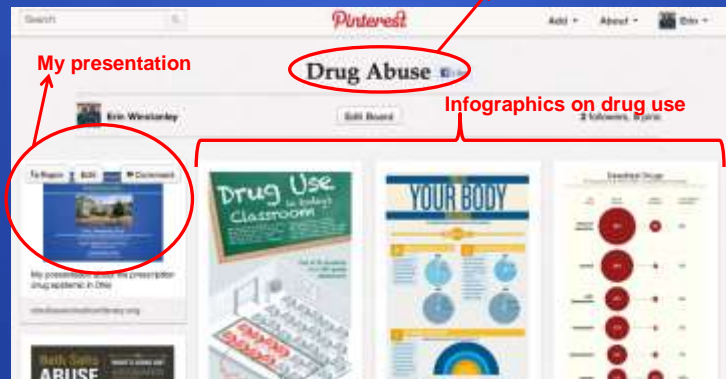
- Blogs are a social media platform
- Interactive & can combine text, video, photos, audio & links
- Readers can leave comments
- Free blog platforms Wordpress.com or Blogger.com



Pinterest

- Pinterest is an online pinboard

I have a bulletin board called "drug abuse"



LinkedIn

- Over 100 million professionals
- Connect with professionals & seek employment
- Forum for job-related questions
- Very easy to use, very professional



Cool Applications within LinkedIn:

- Use SlideShare to share presentations
- Use TripIt to connect with your network when you travel

LinkedIn Example

ATTC LinkedIn Group

Start: Discussion Post

Start a discussion or share something with the group.

Choose Your View - Type a question for the group or post information

hy5ell news.com · 1 day ago
#Wikimedia Commons Research has shown

IRETA's Weekly Social Media Mail
- Check out this training - Ment

Like Comment Flag More

Most Popular Discussions

The DSMV is changing the definition from abuse /dependence to substance use disorder mild to severe. I'm not sure if this is a move in...

Michael G. Bricker · 7 months ago · Many insightful comments - Lets not forget that we still have the ASAM criteria to help inform the "mild => severe" decision. Be ...

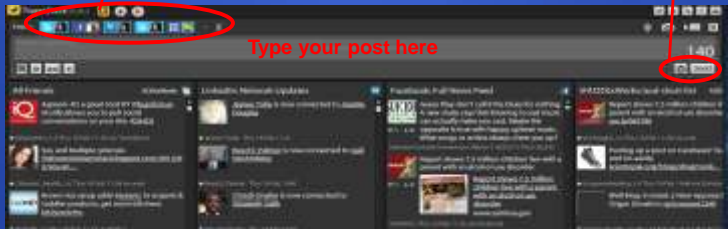
Tips, Tricks & Helpful Hints

TweetDeck

Select which account to post the information to

Click "Send" to post

Type your post here



Simultaneously view the newsfeeds across multiple accounts

Hootsuite

Select which account to post the information to

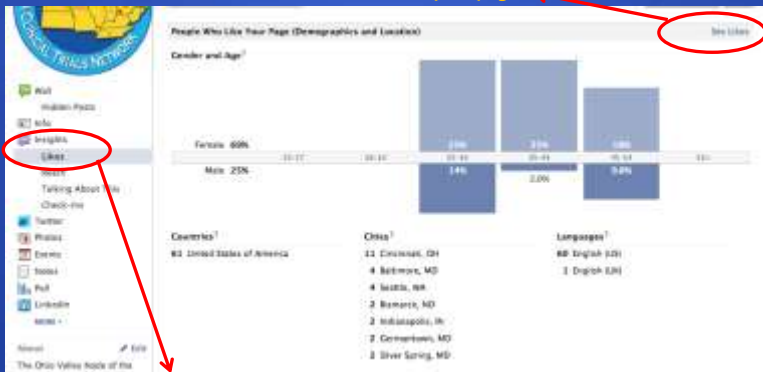
Type your post here



Simultaneously read your Twitter "Lists"

FB Insights

Click on this tab to see who "likes" your page



Click on this tab for aggregate data about people who "like" your page

FB Insights

See Likes

Click on this tab to see micro-level data on who "likes" your FB page





Managing Your Newsfeeds

Click on this arrow for a particular person

Like - Comment - Share · about an hour ago ·

Filter the quantity of posts that appear in your newsfeed

Personal Page

Managing Your Newsfeeds

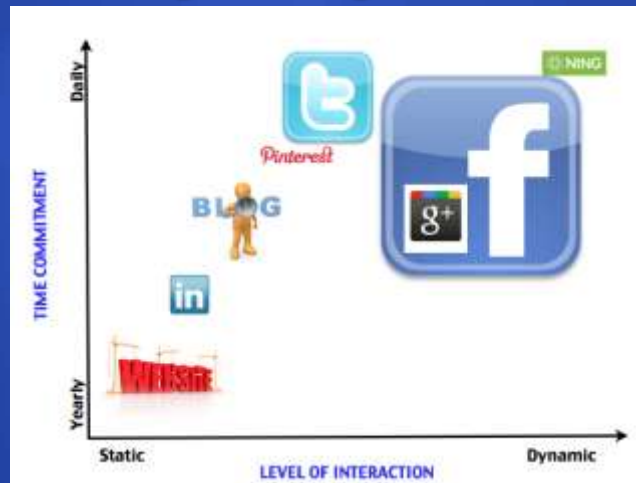


View your profile page

Click to organize the Twitter accounts you follow

Padlock sign means that the list is locked, it cannot be viewed by the public

Choosing the Right Platform



Comparison Chart

	Facebook	LinkedIn	Twitter	Google+
Maintain & Build relationships	Personal & professional	Professional	Personal & professional	Personal & professional
Disseminate information	Yes	Yes	Yes	Yes
Post pictures/videos	Yes	No	Yes, but limit use	Yes
Organize events	Yes	Yes	No	?
Educate colleagues/patients	Public	Professionals	Public	Public
Advertise products/services	Yes	Limited	Yes	Yes
Recruit research participants	Yes	Yes	Yes	Yes
Increase website traffic	Yes	Limited	Yes	Yes
Rapid disseminate during an emergency	Yes, strong reach	No	Yes, strong reach	Yes

The Landscape of Social Media Users

	% of Internet users who....	The service is especially appealing to ...
Use Any Social Networking Site	57%	Adults ages 18-29, women
Use Facebook	67	Women, adults ages 18-29
Use Twitter	16	Adults ages 18-29, African-Americans, urban residents
Use Pinterest	15	Women, adults under 50, whites, those with some college education
Use Instagram	13	Adults ages 18-29, African-Americans, Latinos, women, urban residents
Use Tumblr	6	Adults ages 18-29

Source: Pew Research Center's Internet & American Life Project Post-Election Survey, November 14 – December 09, 2012. N=1,802 internet users. Interviews were conducted in English and Spanish and on landline and cell phones. Margin of error is +/- 2.6 percentage points for results based on internet users. Facebook figures are based on Pew Research Center's Internet & American Life Project Omnibus Survey, December 13-16, 2012. Margin of error for Facebook data is +/- 2.9 percentage points for results based on internet users (n=860).

Using New Media Tools in the Design and Conduct of Clinical Trials:

2013 Society for Clinical Trials Workshop
May 19, 2013



Gloria M. Miele, Ph.D.

Columbia University College of Physicians and Surgeons, Department of Psychiatry

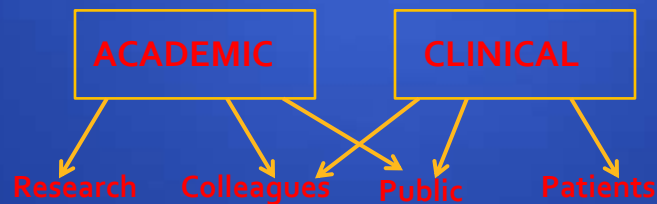
#sct2013p10

Social Media Communication Strategy



Social Media Policies

- Where do you work?
- What are your objectives?
 - Define your audience
 - Know your competition
 - What resources (time & \$) you will invest



Policy Content

- Determine who is responsible for social media activities
- Define scope of content
- Establish privacy expectations
- Define comment policy
- Federal laws & regulations
- Protection of patient confidentiality
- Monitor content & evaluate performance
- Address defamation, slander & libel



Social Media Policies

Educate employees:

- Limitations of privacy settings
- Third party access or storage
- Permanency of a digital footprint
- Consequences of policy violations
- Laws applicable to digital communications

OSMA Best Practices:

1. Accountability & accuracy
2. Honesty & transparency
3. Respect
4. Lawfulness
5. Management
6. Monitor internet
7. Be collaborative
8. Add value

Ask Yourself



Legal Considerations

- Consider having your workplace policy on social media reviewed by a lawyer
- Office of the National Labor Relations' report on social media cases in August 2011
 - Facebook posts may or may not be grounds for termination
 - Example case of employee discussing work at mental institution to FB "Friends" only and was rightfully terminated

"It was spooky being alone overnight in a mental institution ... one client was cracking her up, & that employee did not know whether the client was laughing at her, with her or at the client's own voices"

6 degrees of separation between you & Kevin Bacon



Using Social Media as a Recruitment Tool



Target Your Reach with Facebook Ads

- Demographics
 - Location, Language, Education, Work
 - Age, Gender, Marital Status
 - Zip code
 - Interests
- Pay per click or per impression (how many people see it)
 - Set a budget for a campaign
 - Per campaign/day caps are available



9

Examples of Facebook Advertisements

<p>It's all about you</p>  <p>Are you 16-25 years and live in Victoria? We want to know what you think about health. Fill in a survey and go in a draw to win prizes</p>	<p>Tell us what you think</p>  <p>Tell us what health issues are important to you, fill in a survey and help improve the health and wellbeing of young Victorian women</p>
--	--

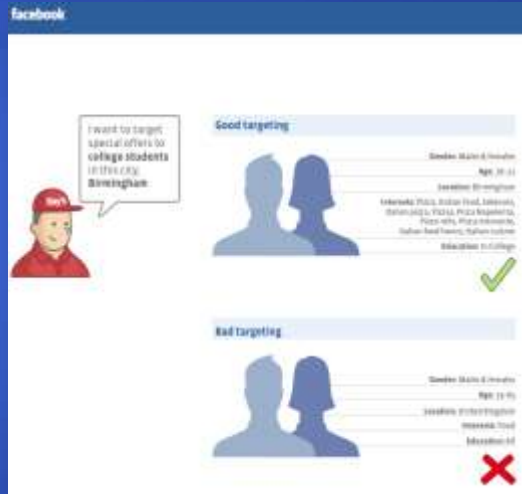
Web-Based Recruiting for Health Research Using a Social Networking Site:
An Exploratory Study

<http://www.jmir.org/2012/1/e20/>

Facebook Ads



- ✓ Go to resources, getting started guide ads



http://ads.ak.facebook.com/ads/FacebookAds/Getting_Started_Guide.pdf

11

Tweet Your Way to More Participants

- Use Twitter to connect with other providers/agencies in your area
- Tweet about your study
- Include contact info, link to web site with study information
- Use hashtags (e.g., #research #addiction #women) to improve search



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Other Approaches

- Post on discussion boards
- Link on web sites
- Connect with and share info on research with other professionals on LinkedIn
- Use a group page for “snowball sampling”



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Social Networking Guidance is Under Development

- Still no guidelines OHRP and minimal discussion from FDA
- IRBs are beginning to develop their own guidelines
- Need to look to standards written for print advertising and apply to other approaches
 - E.g., “Guidance for IRBs and Clinical Investigators” (e.g., DHHS 45 CFR 46)

Sample IRB Guidance



"The guidelines are comprised of requirements and recommendations that are consistent with the basic IRB principles applied to all research involving human participants."



"The IRB does not consider sites that require a login and password to be publicly available data, therefore participants must be consented. Members of sites that require a login have an expectation of privacy and do not expect that anything they post will be used for research purposes."



"All studies, including those using computer and Internet technologies, must ensure that the procedures fulfill the principles of voluntary participation and informed consent, maintain the confidentiality of information obtained from or about human participants, and adequately address possible risks to participants including psychosocial stress and related risks."

IRB Best Practices for Using New Media

- Communicate with IRB – present your situation and ask for guidance
- Include social media plan in protocol
- Include potential risks in consent form
 - "There may be costs associated with text messaging"
 - "There may be increased risk to privacy"
 - Include explicit description of how page is set up and how social media will be used to communicate

Exercise: Research Your IRB's Social Media Policy



CASE EXAMPLE: NIDA'S CLINICAL TRIALS NETWORK WEB-BASED INTERVENTION STUDY



CTN-0044 Study Design

- Effectiveness trial of web-based intervention plus contingency management (Therapeutic Education System [TES], Bickel, Marsch, Buchhalter & Badger [2008]) in outpatient treatment programs
- 10 sites in 9 nodes
- 510 participants
- Original contact and locator forms included email, cell phone and texting, but not social media

Campbell et al. (2012). *Contemporary Clinical Trials*.

Introducing Social Media as a Contact and Location tool

- Three of 10 sites participated
- Required IRB amendments and changes to consent
- Requested social media contact info from newly randomized participants and those who returned for follow-up
- Gave sites flexibility to implement as they chose

Preliminary Findings



- The majority of all participants agreed to be contacted by email and/or texting
- Participants were 50% more likely to respond to a text than an email
- At sites using social media, one third to two thirds of participants agreed to be contacted using Facebook
 - One third of participants did not have social media or computer access
- Of those who agreed to be contacted using Facebook, about half were successfully contacted

Those Most Likely to Agree to Be Contacted



Lessons Learned and Best Practices

- Set up profile for research team using strictest privacy settings
 - "friends only"
- Do not add "friends" to study page nor allow requests to be added
- Allow only basic study contact information to be visible to others.
- Allow Facebook users only to send direct messages to the study page
- Block posting on page



More Best Practices for Contact and Location Efforts

- Cross-reference profile search results with other locator information in order to confirm participant's identity.
 - Is that the real Joe Smith?
- Content of messaging may need IRB review and approval
- Consider, note and subscribe to participant's preferred method of communication
 - Facebook, texting, email or phone
- Systematize research staff's approach to using social media

Create a Social Media Strategy

- Include in protocol, IRB submission, consent and Operations Manual
- Determine who will manage the page
- How will social networking be used?
 - Along side phone and email?
 - Last resort when more conventional methods are not effective?

Exercise: Draft Your Own Social Media Strategy



Questions??



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THE HARVARD CLINICAL
AND TRANSLATIONAL
SCIENCE CENTER



Research Electronic Data Capture

Data Management and Survey Tool

Lynn Simpson, MPH

Research Data & Analytics Services Manager

The Harvard Clinical and Translational Science Center

Partners HealthCare, Research Computing

Enterprise Research Infrastructure & Systems (ERIS)

<http://catalyst.harvard.edu>



Background

2004: Initially developed and deployed at **Vanderbilt U. Medical Center**

Paul Harris: Researchers needed help managing data for small/medium sized non-trial research projects and will do the right thing (secure, audit trails, etc) if provided an easy way to get needed tools

Solution: Metadata-driven application

2006: REDCap License available at **no charge** to institutional partners other institutions and a consortium of domestic and international users was formed.

<http://www.project-redcap.org/>

2008: Harvard awarded CTSA – Harvard Catalyst
REDCap selected as EDC tool



Today: REDCap Consortium

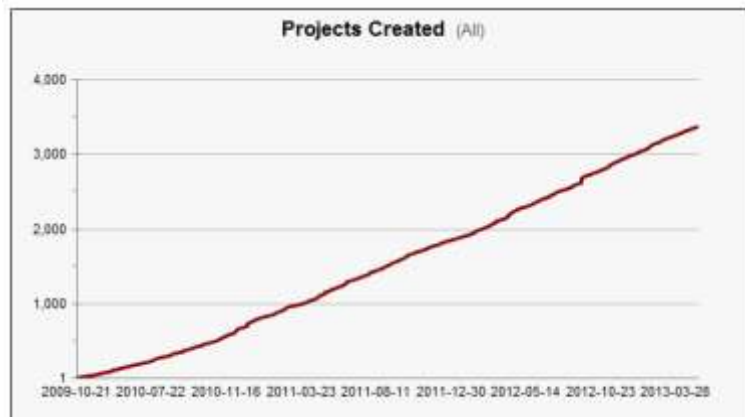
620+ active partners

56 Countries



Today: Harvard Catalyst / Partners HealthCare

3320+ Projects





REDCap is a **web-based** application designed to give **Researchers** and **Clinicians** the capacity to **create** and **manage databases** and **surveys** in order to support data capture for **research**

4



Project Settings

There are two data collection instrument types:

1. Data Entry Forms: Data entry by study team
2. Survey: Data entry performed by subjects, participants

There are two data collection formats:

1. Classic: One record per patient
2. Longitudinal: One record per patient per event, with the possibility of defining multiple arms

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REDCap Longitudinal Design

Research Electronic Data Capture

Study ID 121

Data Collection Instrument	Events for Arm 1: Drug A							
	Enrollment (1)	Visit 1 (2)	Visit 2 (3)	Visit 3 (4)	Follow-Up Month 1 (5)	Follow-up Month 2 (6)	Follow-up Month 3 (7)	Study Exit (8)
Demographics	●							
Contact Info	●							
Baseline Data	●							
Visit Lab Data	●	●	●	●	●	●	●	●
Patient Morale Questionnaire	●	●	●	●	●	●	●	●
Visit Blood Workup			●		●		●	●
Visit Observed Behavior			●		●		●	●
Completion Data								●
Completion Project Questionnaire								●

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6



Data Security

- **Data Hosted by Institution**
- **Institution can determine level of security:**
 - HIPAA
 - 21 CFR Part 11
 - FISMA

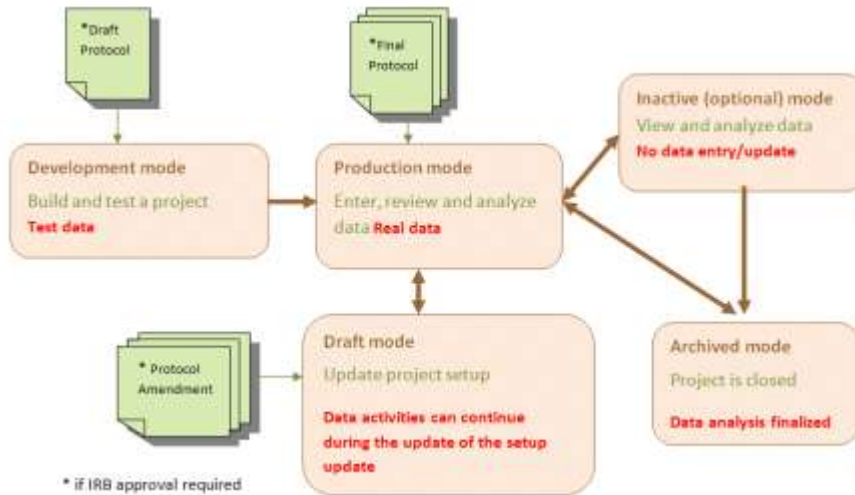


For Example:

“Survey Monkey and other externally hosted online survey tools do not have specific documentation in regards to being HIPAA compliant; and therefore are not held to the same compliance and ethical standards as Partners HealthCare.”

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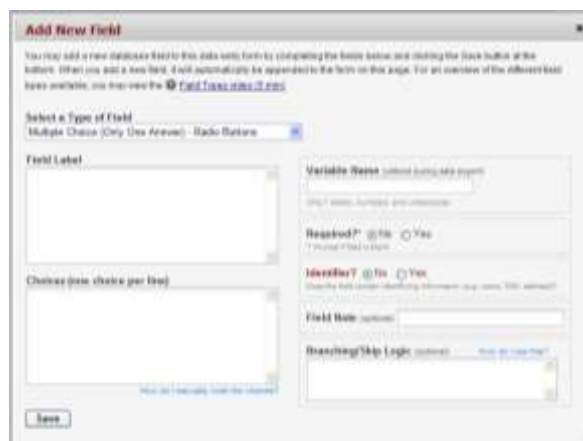


Development: Online Form Editor

Q: How much experience with programming, networking and/or database construction is required to use and design EDC tools in REDCap?

A: No programming, networking or database experience required.

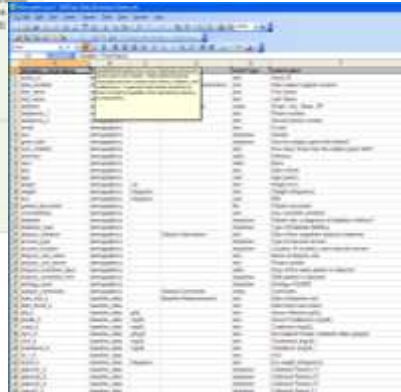
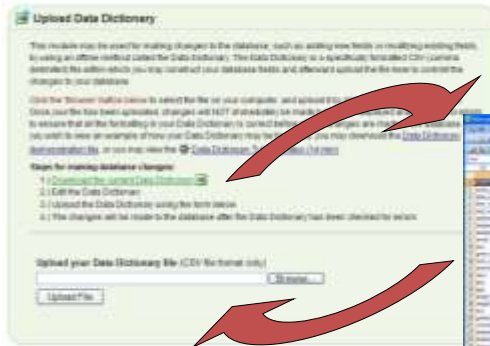
Use Point-and-Click interface to design your EDC tool(s).



The screenshot shows the 'Add New Field' interface in REDCap. It includes a 'Select a Type of Field' dropdown menu with 'Multiple Choice (Only One Answer) - Radio Buttons' selected. There are input fields for 'Field Label', 'Field Name', and 'Field Title'. A 'Required?' checkbox is checked. There are also 'Identifier?' and 'Branching/Skip Logic' options. A 'Save' button is at the bottom left.



Development : Data Dictionary



Or use “Off-line” Excel .csv File to build forms



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Development: Shared Library

REDCap Library:

Accepting requests for open domain assessments

REDLOC:

- Builds Forms
- Obtains Licensing Requirements



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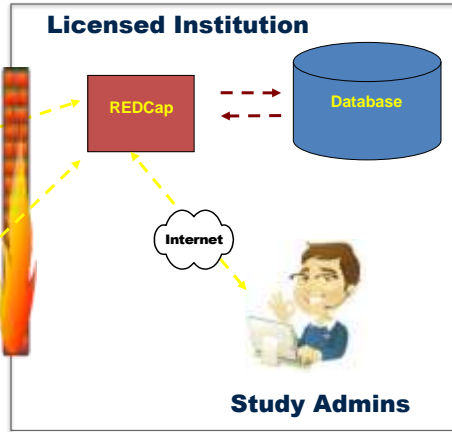


Production: Data Entry

**Site Monitors
Sponsor
Data Managers
Clinical Sites**



**Survey Respondents
Participants**



Data Management Applications

Applications	
	Calendar
	Data Export Tool
	Data Import Tool
	Data Comparison Tool
	Logging
	File Repository
	User Rights
	Data Access Groups
	Graphical View & Stats
	Report Builder

Calendar - View and edit project calendar for scheduling and event tracking

Data Export Tool - Extract data fields from database to Microsoft Excel, SPSS, SAS, R, STATA software (Ability to de-identified data sets)

Data Import Tool - Add and edit data by importing data into database from a Microsoft Excel file

Data Comparison Tool - Compare database records entered by designated data entry persons (double data entry)

Logging - View and export a list of all changes made to the database, including data exports, data changes, and the creation or deletion of users

File Repository - View, upload, and download project files; view and download previous data exports (data and syntax stored files)

User Rights - View and edit users database access, basic rights and data entry rights

Data Access Groups - Restrict access to database records by group, users in the same Data Access Group can access records created by that group.

Graphical View & Stats - View Plots (graphical representations) and Descriptive Statistics for data entry forms

Report Builder - View, edit, copy, delete and download custom reports; query database in real time and display data in a table format.



User Rights

Editing existing user "harrisea"

Basic User Rights

- Calendar
- Data Export Tool
 - No Access
 - De-identified
 - Full Data Set
- Data Import Tool
- Data Comparison Tool
- Logging
- File Repository
- User Rights
- Data Access Groups
- Graphical View & Stats
- Reports & Report Builder
- Lock / Unlock Records
- Database Setup / Design

Expiration Date (if applicable):

Data Entry Rights

	None	Read	Edit
Demographics	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Baseline Data	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Month 1 Data	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Month 2 Data	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Month 3 Data	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Month 4 Data	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Completion Data	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Customize Each User:
Application Rights
Data Entry Rights



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Audit Trail

Logging

This module lists all changes made to this project, including data exports, data changes, and the creation or deletion of users.

Filter by event:

Filter by user name:

Filter by record:

Displaying events (by most recent):

Time / Date	HawkID	Action	List of Data Changes OR Fields Exported
5:55pm 04/04/2011	hdavis	Page View	Page accessed: http://redcap.its.umwa.edu/redcap/redcap_v4.0.3/logging/index.php?pid=8&user=&record=&logtype=page_view
5:55pm 04/04/2011	hdavis	Page View	Page accessed: http://redcap.its.umwa.edu/redcap/redcap_v4.0.3/logging/index.php?pid=8
5:54pm 04/04/2011	hdavis	Page View	Page accessed: http://redcap.its.umwa.edu/redcap/redcap_v4.0.3/edit_field_ajax.php?pid=8&field_name=first_name
5:54pm 04/04/2011	hdavis	Page View	Page accessed: http://redcap.its.umwa.edu/redcap/redcap_v4.0.3/design.php?pid=8&page=demographics



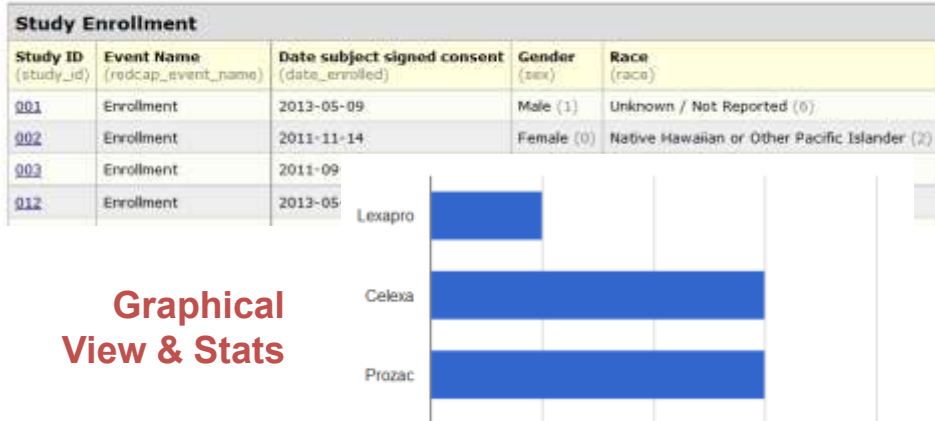
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Reporting Tools

Number of results returned: **6**

Total number of records queried: 29 (records = total available data across designated Events)



Graphical View & Stats



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Data Quality

Data Quality Rules			Processing Complete!	Execute All Rules	Clear
Rule #	Rule Name	Rule Logic (Show discrepancy only if...)	Total Discrepancies		
a	Missing values*	-	Execute		
b	Missing values* (required fields only)	-	Execute		
c	Field validation errors (incorrect data type)	-	Execute		
d	Field validation errors (out of range)	-	0	view	
e	Outliers for numerical fields (numbers, integers, sliders, calc fields)	-	115	view	
f	Hidden fields that contain values**	-	Execute		
g	Multiple choice fields with invalid values	-	Execute		



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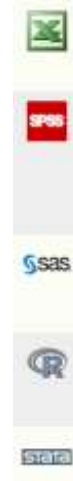
17



Export

REDCap Data Export

- **Export to Excel, SPSS, SAS, STATA, R**
- **Numerous de-identification options**
 - Removal of fields that contain PHI
 - Automatic removal of date fields; date shifting
- **Exports include corresponding syntax files**
- **Maintain record of entire export history**



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Benefits

- **Easy to Comply with Good Clinical Practices (GCP)**
- **Validation, Branching and Locking Features**
- **Allow for lower rate of data collection errors**
 - *Compared to Access/Excel*
- **Statistician can have access to data export tool**
 - *Eliminate need for PI to 'deliver' data to statistician*
- **Central secure access point**
 - *Eliminates need for multiple copies of dataset*



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REDCap Demonstration



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Contact

Lynn Simpson, MPH
Research Data & Analytics Services Manager

**Harvard Catalyst | The Harvard Clinical and
Translational Science Center**
Partners HealthCare | Research Computing, ERIS

<http://rc.partners.org/edcREDCap>
edcsupport@partners.org



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Workshop P 10: Using Media Tools For Clinical Trials: Reference Guide

FDA Electronic source draft guidance (Nov 2012-does not cover SNS or internet trials):

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf>

FDA (Devices): (July 2011, covers mobile medical applications):

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm>

FDA Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (Nov 2011, labeling):

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf>

Some Relevant Articles

1. Andrews, Social Media Recruitment, Applied Clinical Trials, Nov 1, 2012 (corresponding author: **Christine Andrews**, MS-CRA, MBA is Senior Manager, Proposals at PAREXEL International, 195 West Street, Waltham, MA, e-mail: Christine_D_Andrews [christine_d_andrews@yahoo.com])
2. Free, et al, The Effectiveness of Mobile-Health Technologies to Improve Health Care Service Delivery Processes: A Systematic Review and Meta-Analysis, PLOS Medicine, January 2013 | Volume 10 | Issue 1 | e1001363
3. Qureshi A, Connelly B, Abbott E, Maland E, Kim J, Blake J., J Vasc Interv Neurol. 2012 Aug;5(supp):26-9. Mobile applications for handheld devices to screen and randomize acute stroke patients in clinical trials. Source. Zeenat Qureshi Stroke Research Center, University of Minnesota, Minneapolis, MN, USA.
4. Palmier-Claus JE, Ainsworth J, Machin M, Barrowclough C, Dunn G, Barkus E, Rogers A, Wykes T, Kapur S, Buchan I, Salter E, Lewis SW., BMC Psychiatry. 2012 Oct 17;12:172. doi: 10.1186/1471-244X-12-172. The feasibility and validity of ambulatory self-report of psychotic symptoms using a smartphone software application. School of Community Based Medicine, University of Manchester, Oxford Road, Manchester, UK. Jasper.Palmier-Claus@manchester.ac.uk
5. Kerr DA, Pollard CM, Howat P, Delp EJ, Pickering M, Kerr KR, Dhaliwal SS, Pratt IS, Wright J, Boushey CJ. BMC Public Health. 2012 Jun 22;12:477. Connecting Health and Technology (CHAT): protocol of a randomized controlled trial to improve nutrition behaviours using mobile devices and tailored text messaging in young adults. Curtin Health Innovation Research Institute and the School of Public Health, Curtin University, Perth, WA, Australia. d.kerr@curtin.edu.au
6. Spring B, Schneider K, McFadden HG, Vaughn J, Kozak AT, Smith M, Moller AC, Epstein LH, Demott A, Hedeker D, Siddique J, Lloyd-Jones DM., Arch Intern Med. 2012 May 28;172(10):789-96. Multiple behavior changes in diet and activity: a randomized controlled trial using mobile technology. Department of Preventive Medicine, Northwestern University, 680 N Lake Shore Drive, Chicago, IL 60611, USA. bspring@northwestern.edu

7. Cavallo DN, Tate DF, Ries AV, Brown JD, DeVellis RF, Ammerman AS.; Am J Prev Med. 2012 Nov;43(5):527-32. A social media-based physical activity intervention: a randomized controlled trial. Department of Nutrition, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA. dncavallo@ucla.edu
8. Bull SS, Levine DK, Black SR, Schmiede SJ, Santelli J. Am J Prev Med. 2012 Nov;43(5):467-74. Social media-delivered sexual health intervention: a cluster randomized controlled trial. Department of Community and Behavioral Health, Colorado School of Public Health, Denver, Colorado, USA. sheana.bull@ucdenver.edu
9. Baldwin M, Spong A, Doward L, Gnanasakthy A. Patient 2011;4(1):11-7.. Patient-reported outcomes, patient-reported information: from randomized controlled trials to the social web and beyond. Novartis Horsham Research Centre, Horsham, West Sussex, UK. mike.baldwin@novartis.com
10. Mary Foulkes (2011): Social Contexts, Social Media, and Human Subjects Research, The American Journal of Bioethics, 11:5, 35-36