**GUIDE 630 – Research Advertisements that Require vs. Don’t Require IRB Review and Approval**

Per FDA regulations, the follow **DO NOT** require IRB review:

* Communications intended to be seen or heard by health professionals (e.g. doctor-to-doctor letters)
* News stories
* Publicity intended for other audiences (e.g. financial page advertisements directed toward prospective investors)

Per FDA regulations, the follow **DO** require IRB review:

* Direct advertising for research subjects, i.e. advertising that is intended to be seen or heard by prospective subjects to solicit their participation in a study. Includes, but is not limited to, newspaper, radio, TV, bulletin boards, posters, and flyers

IRB review generally **is not required** for:

* Information about relevant research conducted outside the study:
  + Includes information on websites, blogs, Facebook, or Twitter
* General tips and/or resources containing information that is generally accessible on the internet:
  + Copied information from or links to: blogs, news articles or new sources, websites, or other social media pages
* Signs and symptoms of the underlying disease or condition
* Information, pictures, videos, links or other information posted by a research participant
* Websites that contain only the following information: Study title, purpose of study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the study site for more information (OHRP – Guidance on IRB Review of Clinical Trial Websites)
  + Ex. Clinicaltrials.gov

IRB review generally **is required** for:

* Direct Advertising – This information is presentable in many different forms and can be found on search engines, websites, Facebook, blogs, etc.:
  + Display or Banner Ads – Usually placed along the top or right hand side of a web page
  + Rich Media Ads – Similar to display or banner ads, but have an element of interactivity, such as a rollover, scroll bar or click for more information
* Paid Search Ads – Purchased keywords relevant to the research study, ad appears on the search engine near the search results
  + Likely the information contained on the link page requires review, but not any paid search term
* In-Text Ads – Relevant keywords are selected for intext ads, keywords are highlighted in relevant content throughout a network of sites and, as users roll over keyword, an ad pops up
  + It is the ad that pops up that likely requires review
* Social Network Ads (Ads on Social Network Pages) – Similar to paid search ads, these ads appear on social networks (Facebook, MySpace, LinkedIn) based on keyword searches by users, demographics from their profiles, geographic information from their computers, and more
  + Social networks are very targetable given the amount of information users share on their accounts
  + The ad or linked ad likely require review
* Social Network Pages – Not only ads on social network pages, but also those pages themselves setup for a specific study
  + Access or privacy settings of page?
  + Is any Protected Health Information (PHI) being recorded? Partial HIPAA Waiver required? Prescreening form?
  + Confidentiality of collected information?
* Blogs – Blogs for a specific study containing direct advertising
* Blog Posts – Posts on any blog containing direct advertising
* Tweets containing direct advertising
* Texts containing direct advertising