EMAILs and Clinical Research
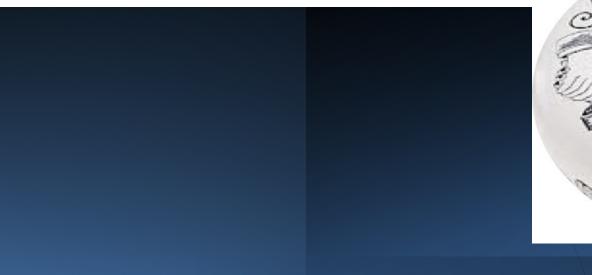
The avalanche ....

Email is the primary form of communication between all the players in clinical research.

As a PI you shall receive hundreds of emails each day.

Learning to whom to respond, how to respond, when to respond, and how to file your emails is a matter of survival.

There will be many times that you will only know meet your colleagues, sponsor and CRO team members by email.

Because we work internationally a certain level of formality is expected until you are known to whom you are writing.

YOU NEVER GET A SECOND CHANCE TO MAKE A FIRST IMPRESSION

The Golden Rules of Research Emails

❖ EVERY email sent and received by anyone in the research team is a legal document, they are discoverable.

❖ EVERY email sent and received by anyone in the research team will be filed in the Trial Master File [TMF].

❖ ALL emails are considered confidential and proprietary by the sponsor.

Subject Line

There is an industry default standard nomenclature for heading emails:

Sponsor/Study Number Site Number/PI Name "title of what is in the email"

Example:

Company A_XXXX_ABO site 100 Unable to access ACM Lab Portal

It is important to limit each email to ONE topic. Frequently you may be writing the email to address multiple concerns. From the sponsor or CRO side each of the concerns is important but will be addressed by different study staff. Having one topic per email allows each issue to be efficiently addressed.

Why the rigidity?

This may seem pedantically rigid, but it will allow the reader to immediately know which trial and site the email belongs. Everyone works on multiple trials and being able to readily visually sift through emails is critical.

Using the standard will ensure that your email is taken seriously and read.

Using this system, you will be able to easily locate your sent email, a year or more when someone requests. Remember ALL research emails are legal documents.

The orphan subject Line

Email chains have a tendency to move from one topic to the next, without the subject line changing.

This creates several problems such as you have now misplaced an email because the subject line is no longer relevant.

Your original request has not been addressed, and you "still can't get into that lab portal/EDC/ECG portal/etc"

There is a simple solution, change the subject line or write a new email.

If you have the time to write the email, you have the time to do it correctly.

Setting the "tone" ...

Tone in an email, or online course, is more difficult than in a conversation or classroom. In emails and other online communication there are no verbal or visual cues.

What is the difference in the tone in these two statements?

"The floors are being done tomorrow. All chairs, rugs, everything must be moved before you leave today."

"Our floors are being waxed over the weekend. Please help with moving all items off the floors. Thank you."

Clearly the second request is collegial and warm. If they both spoken by a smiling person in a warm voice there would be little difference, but the written tone in each statement is quite different.

Tips for "tone" ...

1. READ your email before hitting the send button.

1. This industry is staffed by individuals who have advance degrees, are multilingual, and professionals. They will expect grammatically correct language.

1. Avoid humor, as humor is culturally based, and you may well be communicating in someone in a far different culture.

1. Be conversational, but emails are not novels or dissertations, be concise.   Avoid a cold, remote, superior tone.

Tips for "tone" ...

5. We have become a less formal culture; however, the world of clinical research tends to be hierarchal, driven by privacy and secrecy, all emails are legal documents, and we work across cultures. The upshot is if there is the slightest doubt, and until if and when you are communicating with someone who you are on a first name basis and equal rank, be formal.

Tips for "tone" …

6. This brings us to salutations. The lack of a greeting appears brusque, unfriendly, or uneducated. Salutations are the norm for clinical research.

- Hey, dude, Yo, You, etc are not appropriate

- Clinical Research tends to be a formal setting, the use of first names is to be avoided under most circumstances.

- Know the title of the person you are addressing.
  - Dear Dr. XXX
  - Hello Ms. CCC

Tips for "tone" ...

7. Just as with a salutation, emails need to a have a closing line and signature.

- Informal:
    - Thank you,
    - Have a good day,

- Formal:
    - Sincerely,
    - Respectfully,
    - Cordially,

    Sign your name after the closing statement. If you have signed your first name, then below or using a "/" use your full name and degree. If you are an MD use MD, likewise for a PhD.

Items to avoid ....

1. Poor grammar.
2. Inappropriate punctuation, exclamation points are to be avoided.
3. Multiple ink colours.
4. Highlighting except on a specific occasions, such as when responding to a list of questions. You may highlight OR change font colour not both your responses.
5. Use of imoges, sets a juvenile tone.
6. Disconnected sentences, that are simply strung together to make a point.

Any and all of the above will not stand you or your staff in the best stead with sponsor or CRO staff. Remember you are the leader of the team at your site, how staff write their emails reflects on you and the site.

Technologic and other curses …

Blind CC …

Think several times before using a blind cc. It may create grief and mistrust. Trust in clinical research is like coral it grows slowly and is easily destroyed. An inadvertent BCC recipient or an email passed along to the wrong person can be disastrous.

If in doubt, do not BCC. If you need to send the email confidentially to an internal ERG staff, then using a forward may be appropriate. Using a forward allow you to add an explanation as to why you are sending the email, need for confidentiality, or any other necessary notations.

Technologic and other curses ...

Spell-check ...

Yes, by all means use spell-check.

The following are missed by spell-check:
- for and four
- to, too, and two
- a dress, address
- ass and add
- bowel and bowl
- ballet and ballot
- blows and glows
- damn and dam
- dick and deck

Technologic and other curses ...

And the list goes on and on:

❑ fat and fast and fart

❑ flee and feel

❑ rape and reap

❑ stalking and talking

❑ their and there

This list can go and on. So a word to the wise, use spell-check and read your email for spelling, grammar, and typographical errors.

Technologic and other curses ...

There will be a time when you will disparately desire to vent, we are human.

Simply do not send an angry email. You may write one leaving the address lines blank. Then delete.

Technologic and other curses ...

The address line[s]. The first address line must include those who must take action/respond to your email, the cc line is for those who you wish to know or acknowledge that you have sent the information.

Email address may change, be confusing or written incorrectly. Double and triple check your addresses.

To sound like a broken record, all emails are confidential and are legal documents.

If and when you use the wrong address, you may unsend the email by recalling it or if you know the person, pick up the telephone and call them. Apologize, and request that they delete the email, and would they please send you an email stating that it has been deleted, unread.

Technologic and other curses ...

Replying All, before you hit that button, ask yourself: does everyone on this list of 150 people need to see your response?

An example would be a request from the study lead for the site to acknowledge receipt of an email. The study lead and your monitor would need to be informed of your reply, not the other 149 sites in the study.

The sponsor and CRO will expect you to reply to emails.

The rule of thumb is 24 hours to reply to emails.

If the medical monitor has sent you, the PI, an email, then unless you are physically unable to reply it is discourteous to have your coordinator or site director reply.

The above is applicable for Global Project Managers, Global Study Leads, National Study Leads, etc. These are the professionals who are running the trial, they deserve your personal attention and respect.

If your coordinator has sent an email that is not suitable then you as the PI or if appropriate the site director may politely correct this error. Then speak with the coordinator. Do NOT ignore this oversight.

Technologic and other curses ...

If you have time to write an email, you have time to write it well.

Read it at least twice before sending. If there is the slightest doubt about content, facts, appropriateness or "tone," please take a breath, have your site director or a trusted colleague review your thoughts on a telephone call.

Don't send the email.

The Golden Rules of Emails You Send

"Never write anything in an email that you would not want to see, attributed to you, on the front page of the morning paper."

Corollary: *Emails are forever*

Housekeeping …

Housekeeping ...

Filing your emails is essential to not being buried in the avalanche.

Typically, we file emails by the sponsor, then underneath by the study number, then beneath an individual study number IWRS, MM communication, IRB information, etc.

For example:

SPONSOR

ACP_222

IWRS

MM correspondence

IRB

This is only an example of a filing system. If you prefer you may file in your own style. The point of filing is to keep your inbox clean and neat.

The final word, file do not erase that email. You may never know when you need to locate it again.

Now that you have completed the lecture, please schedule your review call.

After the call you will receive a series of mock emails from several individuals. Please respond to the emails.

You will be assessed on the following:

1. Timeliness of response
2. To whom you choose to send, cc and forward the email
3. Subject line
4. Content of email, does it address the issue at hand

One final quiz, and you are nearly done!

You will receive access to the quiz after the email exchange and follow up discussions.

You will have TWO chances to take the quiz.

90% is the pass score