

## **TEN RULES FOR RESEARCHERS TO SURVIVE AN AGENCY VISIT/INSPECTION**

1. DO be honest. Do NOT speculate and Do NOT speak outside your area of responsibility, authority or expertise. A guess may turn out to be wrong and may be viewed as an intentional misrepresentation even if not intended that way.
2. DO make sure you understand each question asked before answering. If you do not understand the question, ask for clarification first.
3. DO answer each question asked, but only that question. Do NOT volunteer information that is not requested. DO speak with the understanding that anything you say may be documented in the agency's records. There are no "off the record" remarks.
4. DO take your time to answer questions to assure your answers are accurate and complete and are not misinterpreted by the inspector (a glass of water or coffee can help by giving you time to gather your thoughts).
5. DO be prepared, display confidence and look relaxed. Do NOT be or act nervous.
6. DO be respectful of the agency representative and the role he/she plays on the agency's behalf (even if he/she becomes confrontational or discourteous). Do NOT be dismissive or display a feeling of superiority. If documentation is being reviewed, Do NOT minimize the importance of data completeness, accuracy, or integrity.
7. DO admit errors or weaknesses that are clear and obvious, but make sure you have a solution prepared. Do NOT admit errors or weaknesses that you are not clear about, there may be a legitimate regulatory defense, which can be examined during or after the visit/inspection and addressed in the response to the agency.
8. DO make yourself available on reasonable terms during the agency visit/inspection to answer questions the agency representative needs to ask you. If you are presented with an affidavit or a search warrant, immediately contact UCSD legal counsel or the Research Compliance and Integrity Office. You are not authorized to sign any document on behalf of "The Regents."
9. If you are the Principal Investigator of the project, DO understand that you are ultimately responsible to comply with applicable regulations and the protocol. Do NOT assign blame to others, even if it is clear to you that identified problems were not your fault. Agencies may hold the Principal Investigator accountable for the conduct of the study at the site, even if other individuals (co-investigators, study coordinators, project managers and administrative staff) are delegated supportive roles on the study and are functionally more directly responsible.

10. Do NOT promise any preventative action plans until you have had the opportunity to think them through and are confident they are realistic and achievable. You may be held to any preventative action plan that is expressed either in writing or verbally.

For information on who to contact for visits by a governmental or regulatory agency, please see [Unannounced Visits by Federal and State Agencies](#).

For additional information or assistance, please contact the Research Compliance and Integrity Office at (858) 822-4939, [rci@ucsd.edu](mailto:rci@ucsd.edu).