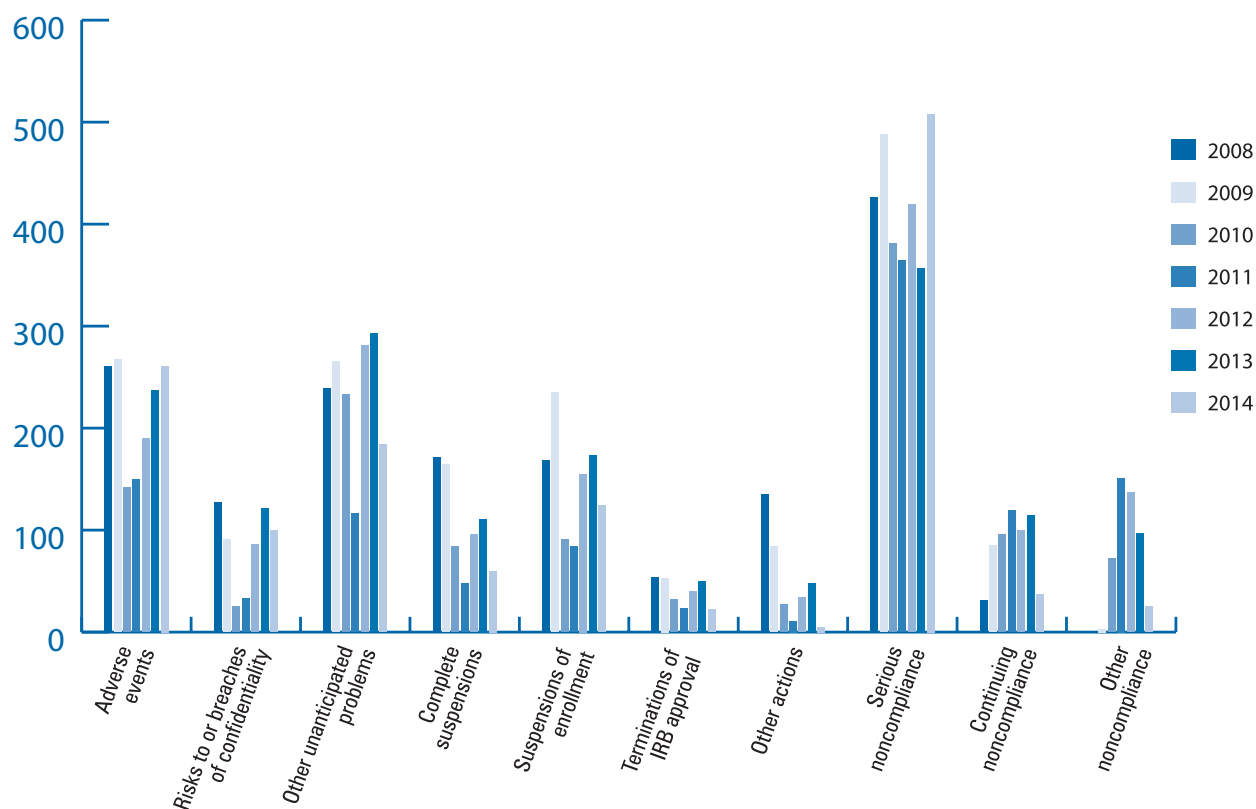


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## Incident Reports and Corrective Actions Received by OHRP

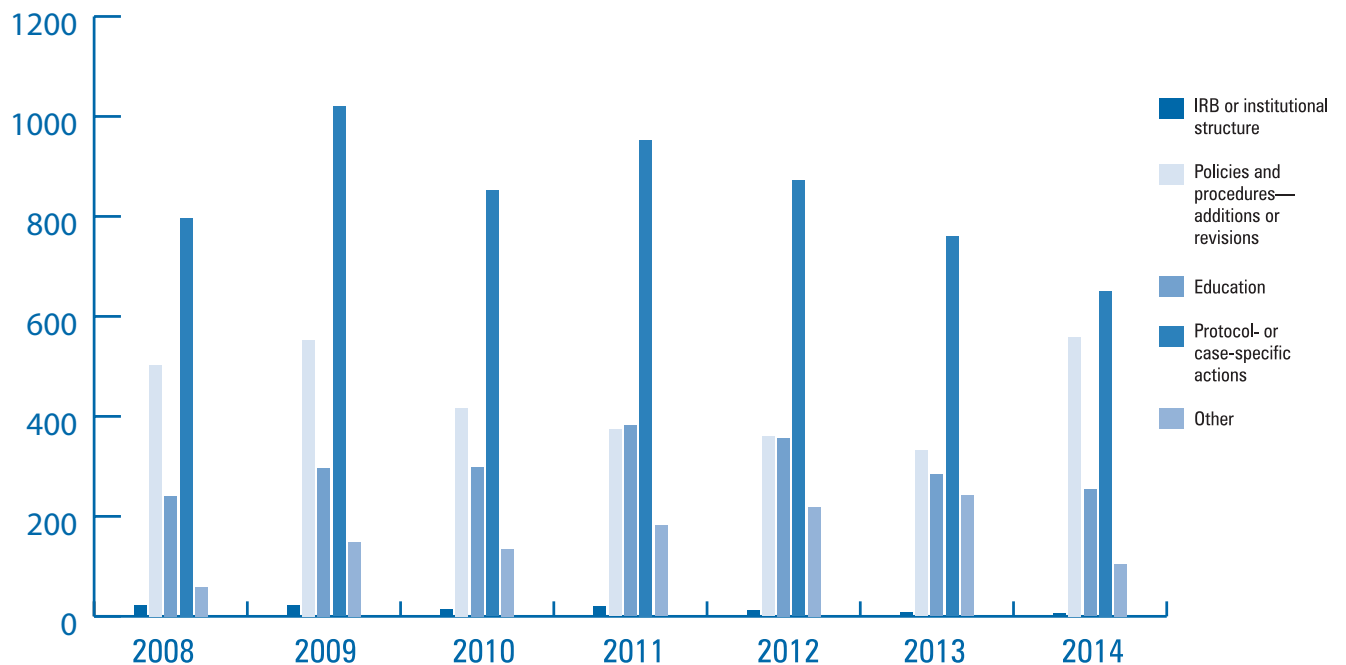
**Figure 1.**  
Types of Incidents Reported to OHRP



**Figure 2.**  
**Top 10 Categories of Serious and Continuing Noncompliance**  
**Reported from 2008 to 2014**

Serious noncompliance—protocol changes	1,515
Serious noncompliance—informed consent	970
Serious noncompliance—initial and continuing review	684
Continuing noncompliance—changes	292
Serious noncompliance—failure to report	231
Continuing noncompliance—informed consent	204
Continuing noncompliance—initial and continuing review	135
Serious noncompliance—IRB documentation	48
Continuing noncompliance—failure to report	42
Serious noncompliance—expedited review	32

**Figure 3.**  
**Total Number of Corrective Actions Reported to OHRP**



**Figure 4.**  
**Top 15 Subcategories of Corrective Actions Reported to OHRP from 2008 to 2014**

<i>Corrective action</i>	<i>Total number</i>	<i>% of total (12,326 )</i>
Adding or revising research standard operating procedures	2,551	21
Education of investigators or research staff	1,779	14
Reconsenting or notifying subjects	1,206	10
Monitoring or auditing of principal investigator (PI)	1,189	10
Requiring PI to submit amendment or amend protocol	1,071	9
Other corrective action (see summary)	867	7
Requiring PI to revise consent forms for specific studies or amend consent	760	6
Use of data disallowed or conditions attached	439	4
Training of PI on specific issues	289	2
Re-review of protocol(s) or grants by IRB	242	2
PI to obtain additional research staff	227	2
Implementation of auditing program(s)	196	2
Educating all investigators at institution	188	2
Use of data disallowed	150	1
Education of IRB members or staff members	131	1