**FORMULARIO Nº 09**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | 1. **IDENTIFICACIÓN DEL ENSAYO CLÍNICO Y CENTRO DE INVESTIGACIÓN** | | | | | | | | | | | | | Título del Ensayo Clínico: | | | | |  | | | | | | | | Patrocinador: | | | | |  | | | | | | | | Fase Clínica del Estudio  **€** I **€** II **€** III **€** IV **€** No aplica | | | | | Código del Protocolo: | | | | | | | | Centro de Investigación | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Nº RCI: \_\_\_\_\_\_\_ | | | | | | | | Investigador Principal | | | | |  | | | | | | | |  | | | | | | | | | | | | | 1. **IDENTIFICACIÓN DE LA NOTIFICACIÓN** | | | | | | | | | | | | | Tipo de Desviación | | | * Crítica o muy grave * Mayor o grave * Menor o leve | | | | | | | | | | Fecha de ocurrencia de la desviación | | | \_\_\_/\_\_\_\_/\_\_\_ | | | Fecha de notificación comité de Ética | | | \_\_\_\_/\_\_\_\_/\_\_\_ | | | |  | | | | | | | | | | | | | 1. **INFORMACIÓN SOBRE LA DESVIACIÓN AL PROTOCOLO** | | | | | | | | | | | | | Tiene impacto o puede tenerlo en:  (marque todas las que apliquen) | | | | * Seguridad de los sujetos en investigación * Producto de investigación * Valor Científico/ Integridad de datos * Confidencialidad /consentimiento informado * Otros, especificar \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | ¿La desviación resultó en un evento adverso serio? | | | | * Sí * No | | | Si marca Sí, escriba: | | | | | | Fecha notificación al CEIB: | | | | \_\_\_/\_\_\_/\_\_\_\_ | | Nº | Código del  participante | Descripción de la desviación | | | | | Acción correctiva | continúa en el estudio | | | Acción preventiva | | SÍ | | NO | |  |  |  | | | | |  |  | |  |  | |  |  |  | | | | |  |  | |  |  | |  | | | | | | | | | | | | | 1. **FIRMA DEL INVESTIGADOR PRINCIPAL** | | | | | | | | | | | | | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  ***Firma del Investigador***  *(Apellidos y Nombres)*  **Fecha:** \_\_\_/\_\_\_\_/\_\_\_ | | | | | | | | | | | |   **NOTIFICACIÓN DE DESVIACIONES AL PROTOCOLO** |