BSRBR-RA Event of Special Interest (ESI)
SERIOUS INFECTION

Study ID: **HRN:** **Patient Initials:**	**Gender:** **Date of Birth:** **NHS Number:**
Event Date: **Event ID:**	**Biologic/biosimilar at time of event:** **Product Batch Number:**

Event

Site of infection:

Were microbiological/serological tests carried out? YES / NO / DON'T KNOW (Circle)

If yes, specify micro-organism / serological result:

(Please state if nil grown)

Medication at time of infection**:**

At the **TIME OF INFECTION** did the patient have?

Indwelling catheter	☐ YES	☐ NO	☐ DON'T KNOW
Intravenous access *(e.g., Hickman's Line)*	☐ YES	☐ NO	☐ DON'T KNOW
Any wounds or ulcers	☐ YES	☐ NO	☐ DON'T KNOW

At the TIME OF INFECTION what was the patient's:

White cell count: _____

Neutrophil count: _____

Lymphocyte count: _____

PRIOR TO THE INFECTION what was the patient's: (TAKEN ON: ____/_____/_____)

White cell count: _____

Neutrophil count: _____

Lymphocyte count: _____

Has the patient ever had Felty's?	☐ YES	☐ NO	☐ DON'T KNOW
Has the patient ever had a splenectomy?	☐ YES	☐ NO	☐ DON'T KNOW

Do you believe there is a possibility that this adverse event was related to the biologic/biosimilar drug used to treat RA? Yes ☐ No ☐ Unknown ☐

If **Yes** please confirm which drug: _____

What was the outcome of the event?

Resolved ☐ Not Resolved ☐ Resolved with sequelae ☐ Fatal ☐

Form completed
By: _____
On: _____/_____/_____

Return ESI/s to: BSRBR-RA. The University of Manchester,
Unit 4 Rutherford House, 40 Pencroft Way, Manchester Science Park
Manchester, M15 6SZ. You can also fax these to: 0161 2751640