CASE REPORT FORM

Page 2 and 3:	To be completed by first study recruiter
Page 4.	To be completed by patient
Page 5.	To be completed by second study recruiter *
Page 6:	To be completed by Principal Investigator / Co-Investigator

- **10% of all study forms must be completed by a second study recruiter.**
- The second study recruiter must fulfill the following criteria:

    1. Be independent and blinded to the first recruiter's case report form.
    2. Be blinded to the final decision to prescribe oral or IV antibiotics for the patient.

First Study Recruiter

Please complete the following in addition to your ED clinical records and assist the patient with the questionnaire as needed.

Date: __/___/_____

Time: _____

Consent obtained? **Yes☐ No ☐**

If no, what is the reason for not enrolling the patient?
Refused consent?
No telephone?
Social reasons (e.g. homeless)?

_____
_____

Patient enrolment ID number: _____

Was the patient taking oral antibiotics prior to ED attendance? _____**Yes ☐No ☐**

If yes, Name _____ Dose _____ Duration _____ *in days*

Temp __ __. __ °C	Capillary blood glucose (if done)_____mmol/L
HR _____ / min	CRP (if done) _____mmol/L
BP __ __ __ / __ __ __ mmHg	WCC (if done)_____mmol/L
RR __ __ / min	
SpO_2 __ __ %	
Level of awareness: Alert☐ Voice☐ Pain☐ Unresponsive☐	

First Study Recruiter

Patient enrolment ID number: _____

Location of infection _____

Lesion size:

Length ("aligned head to toe") _____cm Width ("maximum diameter")_____

	Yes	No
Purulent discharge	☐	☐
Fluctuance from abscess	☐	☐
Lymphangitis	☐	☐
Ulcer	☐	☐
Wound (surgical or traumatic) Please specify _____	☐	☐
Athletes' Foot (Interdigital skin breakdown/exudate in >1 web space)	☐	☐
Fungal nail infection in affected leg (if applicable)	☐	☐
Skin breakdown due to underlying skin condition	☐	☐
Chronic limb oedema (including lymphoedema)	☐	☐
Medical History		
Chronic underlying co-morbidity (chronic kidney/liver/cardiac disease)	☐	☐
Peripheral Vascular Disease	☐	☐
Venous Insufficiency (1 of leg ulcer, venous eczema, phlebitis)	☐	☐
Diabetes mellitus (either Type 1 or 2)	☐	☐
Intravenous Drug Use	☐	☐

Patient Questionnaire:

Please complete the following questionnaire to the best of your ability. Details about this study will have been given to you in the information leaflet. If you have any queries regarding the questions asked, please ask for help from the doctor or nurse treating you.

Your phone no.: Mobile _____Landline_____

Next-of-kin phone no.: Mobile _____ Landline_____

GP name: _____

Age: _____ years	Gender: Female ☐Male ☐	Are you a smoker: **Yes ☐No ☐**
Your weight: _____ (circle: kg or stones or lb)	Your height: _____ (circle: ft or cm)	

What part of your body is affected by this infection?_____

In the past year, have you had a similar infection in the same part of your body as now? _____ **Yes ☐ No ☐**

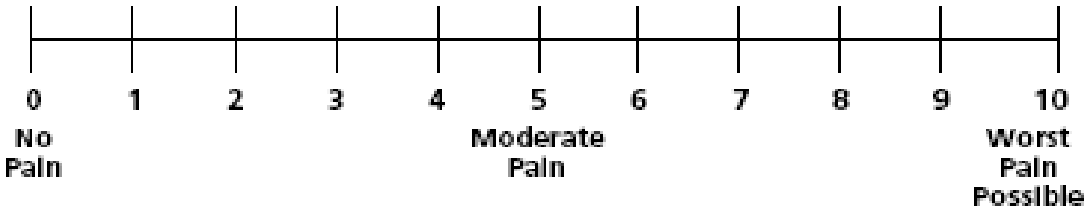
Have you ever had surgery, of any kind, to the same part of your body that is now infected?_____ **Yes ☐No ☐**

Were you referred by your GP? _____ **Yes ☐No ☐**

Did you notice any uncontrolled shivering of your body? _____**Yes ☐No ☐**

Did you have a fever at home prior to coming to hospital?_____ **Yes ☐No ☐**

Choose a number from 0 to 10 that best describes your current pain.
"0" would mean 'No pain' and 10 would mean 'Worst possible pain'.
Mark the chart below at the number that best describes your current pain.



Second Study Recruiter

Please examine the patient and complete the following variables

Patient enrolment ID number: _____

Location of infection _____

Length ("aligned head to toe") _____cm Width ("max diameter")_____

	Yes	No
Purulent discharge	☐	☐
Fluctuance from abscess	☐	☐
Lymphangitis	☐	☐
Ulcer	☐	☐
Wound (surgical or traumatic) Please specify _____	☐	☐
Athletes' Foot (Interdigital skin breakdown/exudate in >1 web space)	☐	☐
Fungal nail infection in affected leg (if applicable)	☐	☐
Skin breakdown due to underlying skin condition	☐	☐
Chronic limb oedema (including lymphoedema)	☐	☐

Medical History

Chronic underlying co-morbidity (chronic kidney/liver/cardiac disease)	☐	☐
Peripheral Vascular Disease	☐	☐
Venous Insufficiency (1 of leg ulcer, venous eczema, phlebitis)	☐	☐
Diabetes mellitus (either Type 1 or 2)	☐	☐
Intravenous Drug Use	☐	☐

In your opinion, what is the most likely diagnosis?_____

In your opinion, will cure be achieved with oral antibiotics? **Yes** ☐ **No** ☐

Telephone follow-up

Day post enrolment: Day_____

Regarding the infection for which you were treated with antibiotics, has there been a decrease in the size of the area of infection by at least 50% from when you were first treated?

Increase ☐ **Decrease** ☐

Do you believe your infection has been cured?

Yes ☐ **No** ☐

Have you received antibiotic injections directly into a vein (intravenously) for your infection since your first assessment?

Yes ☐ **No** ☐

Have you required a second course of antibiotic tablets from your GP or from another doctor since you were first treated in the Emergency Department with this infection?

Yes ☐ **No** ☐

How have you felt since your first visit?

Well ☐ ***Unwell*** ☐

(Any adverse events should be recorded at this point in time. Describe in detail any untoward (unexpected or inappropriate) medical event regardless of its causal relationship to study treatment.)

Adverse event description _____
*Date of onset*_____
Duration _____
Resolution _____
*Severity*_____
*Outcome (Recovery, continuing, worsening, death)*_____
Relationship to treatment for cellulitis?
*Unrelated/Possible/Probable/Definite*_____

Did you require a change in your antibiotic prescription due to a skin rash or other side effect (such as diarrhoea, nausea, vomiting, thrush)?
*Please specify*_____
_____
_____

Does the patient wish to receive the final study results?
Yes ☐ **No** ☐

If yes, specify lay summary, full manuscript or both _____